Appendix G: CRF Tabulations by Patient

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	29JUL94	1	03AUG94	6	6
00061	Oral	2	100 MG	04AUG94	7	10AUG94	13	7
00061	Oral	3	150 MG	11AUG94	14	17AUG94	20	7
00061	Oral	4	200 MG	18AUG94	21	24AUG94	27	7
00061	Oral	4	200 MG	25AUG94	28	31AUG94	34	7
	Oral	4	200 MG	01SEP94	35	14SEP94	48	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	48	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
REPEATED SINUS INFECTIONS ABOUT ONE TIME PER MONTH	SINUSITIS, OTHER	RESPIRATORY SYST DIS	CUR	1989
FOOT CASTED	THERAPY, REHAB	PROCEDURES	PRV	1977
FOOT TURNED AT BIRTH	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1977
REPEATED STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	PRV	1978
RESPIRATORY DIFFICULTIES AT BIRTH	CONDITIONS, PERINATAL	PERINATAL COND	PRV	1977
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Diphenhydramine Citrate	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
	Paracetamol	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
DERMATOLOGICALS	Diphenhydramine Citrate	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
	Paracetamol	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-15, .	14JUL94	14JUL94#	200MG	HEADACHE
RESPIRATORY	Diphenhydramine Citrate	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
	Paracetamol	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Qt Interval Prolonged	WIDENED CORRECTED QT {INTERVAL} QRS	35, .	Not Stated	200	CON	MIL	STP	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	14, .	Not Stated	150	CON	MIL	NO	REL	No	No
	Dysphagia	DIFFICULTY SWALLOWING 1 HOUR DURATION AFTER AWAKENING	31, .	Not Stated	200	3	MIL	NO	PSR	No	No
Nervous System	Concentration Impaired	DECREASE CONCENTRATION	2, .	27 Days	50	CON	MOD	NO	REL	No	No
			35, .	Not Stated	200	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS UPON GETTING UP SUDDENLY	9, .	20 Days	100	CON	MIL	NO	REL	No	No
	Insomnia	INSOMNIA MIDDLE	21, .	Not Stated	200	7	MIL	NO	REL	No	No
	Tremor	HAND TREMORS	28, .	Not Stated	200	4	MIL	NO	REL	No	No
Respiratory System	Pharyngitis	SORE THROAT 1 HOUR DURATION AFTER AWAKENING	31, .	Not Stated	200	3	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19JUL94	-10, .	0	104	60	76	106	64	76	145.00	61.0
BL	29JUL94	1, .	0	102	58	72	108	64	72	146.00	
1	04AUG94	7, .	100	94	62	92	100	70	104	143.00	
2	11AUG94	14, .	150	104	64	102	96	64	124 H	145.80	
3	18AUG94	21, .	200	100	62	102	102	64	108	147.80	
4	25AUG94	28, .	200	108	74	96	102	70	102	147.80	
5	01SEP94	35, .	200	100	68	100	98	62	112	149.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.7		.	.	12 - 15.6	G/DL
				Hematocrit	41.2		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47		.	.	30 - 70	%
				Lymphocytes	37.2		.	.	21 - 51	%
				Monocytes	9.8		.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	240000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	90		.	.	22 - 130	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	73		.	.	70 - 115	MG/DL
				Globulin	3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	20OCT94	1	26OCT94	7	7
00062	Oral	2	0 MG	27OCT94	8	02NOV94	14	7
00062	Oral	3	0 MG	03NOV94	15	09NOV94	21	7
00062	Oral	4	0 MG	10NOV94	22	15NOV94	27	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	27	0	Protocol violation, including non-compliance	PATIENT REFUSED FURTHER MEDICATION.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1979
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1988

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Mylanta	-2240, .	01SEP88	01SEP93#	2TSP	STOMACH ACHE
	Dimeticone, Activated	Mylanta	-2240, .	01SEP88	01SEP93#	2TSP	STOMACH ACHE
	Magnesium Hydroxide	Mylanta	-2240, .	01SEP88	01SEP93#	2TSP	STOMACH ACHE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-5437, .	01DEC79	.	1000MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK AND NECK ACHES	12, .	19 Days	0		MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	16, .	Not Stated	0	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	4, .	Not Stated	0	CON	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS WHEN RIDING IN ELEVATOR OR ESCALATOR	22, .	9 Days	0		MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06OCT94	-14, .	0	88	50	80	84	60	88	98.00	60.5
BL	20OCT94	1, .	0	90	60	68	100	56	84	98.00	
1	27OCT94	8, .	0	98	60	80	90	68	100	99.75	
2	03NOV94	15, .	0	92	56	80	86	60	96	99.75	
3	10NOV94	22, .	0	92	58	80	100	60	96	101.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66	.	.	.	30 - 70	%
				Lymphocytes	25.4	.	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	2.7	H	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08NOV94	1	14NOV94	7	7
00063	Oral	2	20 MG	15NOV94	8	21NOV94	14	7
00063	Oral	3	20 MG	22NOV94	15	28NOV94	21	7
00063	Oral	4	20 MG	29NOV94	22	05DEC94	28	7
00063	Oral	4	20 MG	06DEC94	29	12DEC94	35	7
	Oral	4	20 MG	13DEC94	36	25DEC94	48	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	48	20	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
ALLERGY POLLEN	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
PAIN LEFT WRIST(POSSIBLE SPRAIN)	SPRAINS/STRAINS	INJURY/POISONING	CUR	1994
SLIGHTLY OBESE	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	29, .	06DEC94	16DEC94	750MG	EAR ACHE SORE THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-1529, .	01SEP90	.	500MG PRN	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-4086, .	01SEP83	.	25MG PRN	ALLERGY
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-4086, .	01SEP83	.	25MG PRN	ALLERGY
	Pseudoephedrine Hydrochloride	Actifed	-4086, .	01SEP83	.	1TAB PRN	ALLERGY
	Triprolidine Hydrochloride	Actifed	-4086, .	01SEP83	.	1TAB PRN	ALLERGY

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	2, .	8 Days	20	5	MIL	NO	PSR	No	No
			23, .	Not Stated	20	CON	MIL	NO	PSR	No	No
	Trauma	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENED) [SPRAIN]	-3, .	12 Days	0	CON	MIL	NO	UNR	No	No
Digestive System	Decreased Appetite	ANOREXIA	3, .	Not Stated	20	CON	MIL	NO	PSR	No	No
	Diarrhea	DIARRHEA	2, .	14 Days	20	3	MIL	NO	PSR	No	No
	Nausea	NAUSEA	23, .	Not Stated	20	CON	MIL	NO	PSR	No	No
Musculoskeletal System	Tendinous Disorder	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENED) [TENDONITIS]	-3, .	12 Days	0	CON	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZINESS	3, .	5 Mins	20	1	MIL	NO	PSR	No	No
	Manic Reaction	MANIA SYMPTOMS	34, .	Not Stated	20	CON	MOD	STP	PSR	No	No
	Paresthesia	TINGLING LEG AND FEET	3, .	7 Days	20	2	MIL	NO	PSR	No	No
	Tremor	TREMBLING JAW	3, .	7 Days	20	3	MIL	NO	PSR	No	No
		TREMORS	34, .	Not Stated	20	3	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	28, .	9 Days	20	CON	MOD	NO	UNR	Yes	No
Special Senses	Ear Pain	RIGHT EARACHE	28, .	9 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	02NOV94	-6, .	0	110	80	72	126	84	88	177.50	70.0
BL	08NOV94	1, .	0	96	60	66	100	70	80	181.00	
1	15NOV94	8, .	20	120	60	86	120	60	68	178.00	
2	22NOV94	15, .	20	124	80	80	122	76	88	180.00	
3	29NOV94	22, .	20	122	64	80	120	70	104	179.20	
4	06DEC94	29, .	20	120	70	84	120	76	98	179.70	
5	13DEC94	36, .	20	100	58	68	108	78	88	183.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.7		.	.	12 - 15.6	G/DL
				Hematocrit	40.4		.	.	35 - 46	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.6		.	.	30 - 70	%
				Lymphocytes	42.3		.	.	21 - 51	%
				Monocytes	5.9		.	.	0 - 10	%
				Eosinophils	9.7	H	.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	294000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	83		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	216		.	.	44 - 280	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	14		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	96		.	.	70 - 115	MG/DL
				Globulin	3.8		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	10NOV94	1	15NOV94	6	6
00064	Oral	2	0 MG	16NOV94	7	21NOV94	12	6
00064	Oral	3	0 MG	22NOV94	13	28NOV94	19	7
00064	Oral	4	0 MG	29NOV94	20	05DEC94	26	7
00064	Oral	4	0 MG	06DEC94	27	12DEC94	33	7
00064	Oral	4	0 MG	13DEC94	34	19DEC94	40	7
00064	Oral	4	0 MG	20DEC94	41	26DEC94	47	7
00064	Oral	4	0 MG	27DEC94	48	02JAN95	54	7
00050	Oral	4	0 MG	03JAN95	55	30JAN95	82	28
00050	Oral	4	0 MG	31JAN95	83	27FEB95	110	28
00050	Oral	4	0 MG	28FEB95	111	27MAR95	138	28
00064	Oral	4	0 MG	28MAR95	139	10APR95	152	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	152	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1994
BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
BROKEN RIGHT WRIST	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
COLD(HEAD)	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1994
EAR INFECTION	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1983
MYRINGOTOMY	OPERATION, EAR	OPERATIONS	PRV	1983
PNEUMONIA	PNEUMONIA, OTHER	RESPIRATORY SYST DIS	PRV	1981

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-4013,-4067	15NOV83	.	1000MG	EAR INFECTIONS, HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	14, -41	03:00 Hrs	0	1	MIL	NO	PSR	No	No
			22, -33	8 Days	0	2	MIL	NO	PSR	No	No
	Headache	HEADACHE	78, 24	6 Days	0	2	MIL	NO	PBU	No	No
	Trauma	FRACTURED LEFT INDEX FINGER	77, 23	35 Days	0	CON	MOD	NO	UNR	No	No
		SPRAINED ANKLE	56, 2	18 Days	0	CON	MOD	NO	UNR	No	No
Digestive System	Diarrhea	DIARRHEA	14, -41	03:00 Hrs	0	2	MIL	NO	PSR	No	No
			83, 29	2 Days	0	CON	MIL	NO	UNR	No	No
	Nausea	NAUSEA	83, 29	2 Days	0	CON	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZY UPON POSITION CHANGE	3, -52	6 Days	0	5	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	CONGESTED COUGH	45, -10	18 Days	0	CON	MIL	NO	UNR	No	No
	Rhinitis	NASAL CONGESTION	45, -10	18 Days	0	CON	MIL	NO	UNR	No	No
Urogenital System	Albuminuria	URINE 1+PROTEIN	139, 85	Not Stated	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04NOV94	-6, -60	0	120	60	80	130	70	84	165.00	71.5
BL	10NOV94	1, -54	0	110	60	72	106	70	88	165.00	
1	16NOV94	7, -48	0	104	68	68	122	70	80	165.00	
2	22NOV94	13, -42	0	114	72	68	104	60	88	166.00	
3	29NOV94	20, -35	0	110	70	68	128	70	80	166.00	
4	06DEC94	27, -28	0	100	70	64	120	78	74	165.00	
5	13DEC94	34, -21	0	108	70	70	106	66	84	165.00	
6	20DEC94	41, -14	0	104	68	60	110	70	88	165.50	
7	27DEC94	48, -7	0	114	70	66	120	72	72	167.00	
8	03JAN95	55, 1	0	112	60	76	118	64	92	167.00	
12	31JAN95	83, 29	0	116	80	68	110	74	84	169.80	
16	28FEB95	111, 57	0	116	70	66	110	80	84	169.00	
20	28MAR95	139, 85	0	100	70	64	112	78	82	169.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.5	.	.	.	30 - 70	%
				Lymphocytes	44.1	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	7.6	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	195000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	265	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	15.9		.	.	13.8 - 17.2	G/DL
				Hematocrit	46.7		.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.8		.	.	30 - 70	%
				Lymphocytes	32.4		.	.	21 - 51	%
				Monocytes	6.9		.	.	0 - 10	%
				Eosinophils	4.6		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	195000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	83		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	200		.	.	44 - 400	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	14		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	139	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	2.4	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	197000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	189	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	139	Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
			145	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	17NOV94	1	22NOV94	6	6
00065	Oral	2	20 MG	23NOV94	7	30NOV94	14	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	14	20	Adverse event, including intercurrent illness	NEEDED PSYCHIATRIC HOSPITALIZATION FOR INCREASED AGGRESSION AGAINST SELF.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DIZZINESS UPON CHANGING POSITIONS	DIZZINESS, POSTURAL	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HAND TREMORS	TREMOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1989
STOMACH UPSET(NAUSEA)	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
OSGOOD SCHLATTER DISEASE	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1991

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Codeine Phosphate	Tylenol #1	-2115, .	01FEB89	.	1000MG	HEADACHE
	Paracetamol	Tylenol #1	-2115, .	01FEB89	.	1000MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	5, .	Not Stated	20	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	2, .	Not Stated	20	4	MOD	NO	REL	No	No
	Vomiting	VOMITING	5, .	1 Mins	20	1	MIL	NO	REL	No	No
Nervous System	Depression	WORSENING OF DEPRESSION HOSPITALIZED	14, .	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Dizziness	DIZZINESS	2, .	Not Stated	20	4	MIL	NO	REL	No	No
		LIGHTHEADED	2, .	Not Stated	20	4	MIL	NO	REL	No	No
	Hostility	NEEDED 6 STITCHES TO HAND AFTER BREAKING PICTURES (DUE TO ANGER) RESULTED IN HOSPITALIZATION TO PREVENT AGGRESSION AGAINST SELF	14, .	1 Days	20	CON	MOD	STP	PBU	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	07NOV94	-10, .	0	114	70	60	110	64	74	131.00	65.0
BL	17NOV94	1, .	0	120	68	60	92	64	80	128.00	
1	21NOV94	5, .	20	110	70	60	118	80	72	126.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.4	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	209	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22NOV94	1	27NOV94	6	6
00066	Oral	2	100 MG	28NOV94	7	04DEC94	13	7
	Oral	2	100 MG	05DEC94	14	13DEC94	22	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	22	100	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
MILD ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
MOLE LEFT KNEE-RAISED	NEOPLASMS BENIGN	NEOPLASMS	CUR	1994
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
MOLE EXCISED BELOW UMBILICUS/BENIGN	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1984
SUTURES IN CHIN	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1980

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Alka-Seltzer	-731, .	21NOV92	.	2	STOMACH ACHE
	Citric Acid	Alka-Seltzer	-731, .	21NOV92	.	2	STOMACH ACHE
	Paracetamol	Tylenol	-731, .	21NOV92	.	650MG	HEADACHE
	Sodium Bicarbonate	Alka-Seltzer	-731, .	21NOV92	.	2	STOMACH ACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, .	5 Days	50	2	MIL	NO	PSR	No	No
Carciovascular System	Tachycardia	INCREASED HEART RATE	14, .	Not Stated	100	CON	MOD	STP	REL	No	No
Digestive System	Decreased Appetite	DECREASE APPETITE	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	2, .	13 Days	50	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZY	11, .	5 Mins	100	1	MIL	NO	PSR	No	No
Special Senses	Abnormal Vision	BLURRED VISION WHEN READING LONG TIME	11, .	Not Stated	100	3	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14NOV94	-8,	.	0	104	60	62	110	68	100	142.00	68.0
BL	21NOV94	-1,	.	0	98	60	68	92	70	80	142.00	
1	28NOV94	7,	.	100	114	74	100	100	70	120	135.00	
2	05DEC94	14,	.	100	120	68	96	118	78	124 H	140.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14		.	.	12 - 15.6	G/DL
				Hematocrit	41.6		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39		.	.	30 - 70	%
				Lymphocytes	48.2		.	.	21 - 51	%
				Monocytes	5.9		.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	311000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52		.	.	22 - 130	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	7		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	81		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00067 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22NOV94	1	28NOV94	7	7
00067	Oral	2	100 MG	29NOV94	8	05DEC94	14	7
	Oral	2	100 MG	06DEC94	15	13DEC94	22	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	22	100	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00067 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Postural Hypotension	POSTURAL HYPOTENSION	9, .	Not Stated	100	CON	MOD	STP	PSR	No	No
Nervous System	Dizziness	FAINTNESS	9, .	Not Stated	100	CON	MOD	STP	PSR	No	No
	Somnolence	HYPERSOMNIA	9, .	Not Stated	100	5	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15NOV94	-7, .	0	108	60	78	110	60	96	105.50	64.5
BL	22NOV94	1, .	0	100	64	64	88	60	88	106.00	
1	29NOV94	8, .	100	112	76	88	118	84	92	105.00	
2	06DEC94	15, .	100	96	70	92	92	68	118	105.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00067 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.7	L	.	-	41 - 50	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	229	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	+		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00067 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08FEB95	1	14FEB95	7	7
00068	Oral	2	20 MG	15FEB95	8	21FEB95	14	7
00068	Oral	3	20 MG	22FEB95	15	28FEB95	21	7
00068	Oral	4	20 MG	01MAR95	22	07MAR95	28	7
00068	Oral	5	30 MG	08MAR95	29	14MAR95	35	7
00068	Oral	6	40 MG	15MAR95	36	22MAR95	43	8
00068	Oral	6	40 MG	23MAR95	44	28MAR95	49	6
00068	Oral	6	40 MG	29MAR95	50	04APR95	56	7
	Oral	6	40 MG	05APR95	57	20APR95	72	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	72	40	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1993
FEVER BLISTERS	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	CUR	1990
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
NAUSEA STOMACH UPSET	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
INFECTED {BIOPSY MARK RIGHT SUPRACLAVICULAR ARM}	COMPLIC OF MED CARE	INJURY/POISONING	PRV	1991
LYMPH NODE BIOPSY (ENLARGED NODES)	OPERATION, LYMPH	OPERATIONS	PRV	1991

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Dihydroxyaluminum Sodium Carbonate	Rolaids	-982, .	01JUN92	08FEB95	2TABLET	UPSET STOMACH
	Vitamins Nos	Multiple Vitamin	-69, .	01DEC94	08FEB95	1TABLET	DIETARY SUPPLEMENT
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-617, .	01JUN93	08FEB95	2TABS PRN	HEADACHE
	Paracetamol	Tylenol	20, .	27FEB95	28MAR95	1300MG	VIRAL SORE THROAT UPPER RESPIRATORY INFE
VARIOUS	Lysine	Lysine	-366, .	07FEB94	08FEB95	1TABLET	FEVER BLISTER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	3, .	Not Stated	20	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	22, .	29 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Insomnia	MIDDLE INSOMNIA	8, .	Not Stated	20	CON	MOD	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	48, .	2 Days	40	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	VIRAL UPPER RESPIRATORY INFECTION	20, .	7 Days	20	CON	MOD	NO	UNR	Yes	No
Urogenital System	Urine Abnormality	CLOUDY URINE ON URINALYSIS	57, .	Not Stated	40	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01FEB95	-7,	.	0	108	74	68	112	84	80	129.00	62.0
BL	08FEB95	1,	.	0	112	80	84	120	86	80	127.00	
1	15FEB95	8,	.	20	116	72	72	122	80	80	128.00	
2	22FEB95	15,	.	20	108	70	82	112	84	88	128.00	
3	01MAR95	22,	.	20	116	78	104	118	80	108	125.50	
4	08MAR95	29,	.	30	110	78	80	120	80	100	127.70	
5	15MAR95	36,	.	40	116	70	84	110	74	98	128.00	
6	22MAR95	43,	.	40	124	80	80	118	84	88	131.00	
7	29MAR95	50,	.	40	110	80	110	116	84	124 H	131.00	
8	05APR95	57,	.	40	120	80	104	114	82	120	131.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.6	.	.	.	30 - 70	%
				Lymphocytes	39	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Platelets	291000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick		6	.	.		
				Urine Red Blood Cells/HPF		5	.	+		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria		4	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	43	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEC		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7		.	.	12 - 15.6	G/DL
				Hematocrit	39.1		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9		.	.	30 - 70	%
				Lymphocytes	31.2		.	.	21 - 51	%
				Monocytes	3.3		.	.	0 - 10	%
				Eosinophils	4.3		.	.	0 - 5	%
				Basophils	1.3		.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Platelets	329000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	. . .	25 - 35	PG
				Mean Corpuscle Volume	86	. . .	80 - 100	FL
				Blood Urea Nitrogen	11	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5.5	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	. . .	44 - 280	U/L
				Aspartate Aminotransferase	20	. . .	0 - 41	U/L
				Alanine Aminotransferase	14	. . .	0 - 48	U/L
				Total Bilirubin	0.5	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.7	. . .	3.1 - 5.3	G/DL
				Glucose - Random	86	. . .	70 - 115	MG/DL
				Globulin	3.1	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	NEG	. . .		
				Urine Bacteria	5	. . .		
				Urine Protein - Dipstick	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16FEB95	1	22FEB95	7	7
00069	Oral	2	0 MG	23FEB95	8	01MAR95	14	7
00069	Oral	3	0 MG	02MAR95	15	08MAR95	21	7
00069	Oral	4	0 MG	09MAR95	22	15MAR95	28	7
00069	Oral	4	0 MG	16MAR95	29	22MAR95	35	7
00069	Oral	4	0 MG	23MAR95	36	29MAR95	42	7
00069	Oral	5	0 MG	30MAR95	43	05APR95	49	7
00069	Oral	6	0 MG	06APR95	50	12APR95	56	7
	Oral	5	0 MG	13APR95	57	18APR95	62	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	62	0	Lack of Efficacy	NON RESPONDER

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
PHARYNGITIS	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1995
RIGHT OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1985
FEVER	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994
PNEUMONIA	PNEUMONIA, OTHER	RESPIRATORY SYST DIS	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-51, .	27DEC94	27JAN95#		PNEUMONIA
	Sulfamethoxazole	Septra Double Strength	1, .	16FEB95	24FEB95	1TAB	PHARYNGITIS RIGHT OTITIS MEDIA
	Trimethoprim	Septra Double Strength	1, .	16FEB95	24FEB95	1TAB	PHARYNGITIS RIGHT OTITIS MEDIA
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-51, .	27DEC94	27JAN95#	650MG	FEVER PLUS HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Syncope	FAINT UPON STANDING	30, .	22 Days	0	CON	MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	ANOREXIA	31, .	21 Days	0	CON	MIL	NO	PSR	No	No
	Dyspepsia	STOMACH UPSET	35, .	17 Days	0	2	MIL	NO	PSR	No	No
	Nausea	NAUSEA	6, .	02:30 Hrs	0	1	MIL	NO	PSR	No	No
		NAUSEA AM	35, .	17 Days	0	2	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	22, .	8 Days	0	CON	MIL	NO	UNR	No	No
	Respiratory Disorder	UPPER RESPIRATORY CONGESTION	22, .	12 Days	0	CON	MIL	NO	UNR	No	No
Urogenital System	Albuminuria	URINE 1+PROTEIN	57, .	Not Stated	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	07FEB95	-9,	.	0	110	60	64	104	60	80	125.00	70.5
BL	16FEB95	1,	.	0	112	72	60	106	68	72	127.00	
1	23FEB95	8,	.	0	100	70	80	104	70	100	125.00	
2	02MAR95	15,	.	0	112	70	68	118	78	80	127.00	
3	09MAR95	22,	.	0	110	74	66	110	80	100	123.00	
4	16MAR95	29,	.	0	110	70	66	116	80	84	127.00	
5	23MAR95	36,	.	0	106	66	64	98	60	88	123.00	
6	30MAR95	43,	.	0	110	72	72	108	80	100	126.50	
7	06APR95	50,	.	0	122	84	72	128	88	76	127.00	
8	13APR95	57,	.	0	110	70	72	116	80	88	132.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.9	.	.	.	30 - 70	%
				Lymphocytes	21.3	.	.	.	21 - 51	%
				Monocytes	2.7	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	104	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.7	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	2	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22FEB95	1	27FEB95	6	6
00070	Oral	2	100 MG	28FEB95	7	07MAR95	14	8
00070	Oral	3	150 MG	08MAR95	15	14MAR95	21	7
00070	Oral	3	150 MG	15MAR95	22	24MAR95	31	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	No	No	31	150	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIC TO CAFFEINE	ADVERSE EFF/PSYCHOTROPICS	EXT CAUSES OF INJURY/POISONING	CUR	1992
ALLERGIC TO CHOCOLATE	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1992
ALLERGIC TO MOLD	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1992
ENLARGED LYMPH NODES	LYMPHADENOPATHY	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991
BRUISED FOOT	CONTUSION	INJURY/POISONING	PRV	1990
BRUISED HAND	CONTUSION	INJURY/POISONING	PRV	1993
EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1983
SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1991
SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1992
SPRAINED FOOT	SPRAINS/STRAINS	INJURY/POISONING	PRV	1990

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-8, .	14FEB95	20FEB95#		ENLARGED LYMPH NODES
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-2, .	20FEB95	20FEB95#	325MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Syncope	FAINTNESS UPON STANDING	17, .	Not Stated	150	3	MIL	NO	PSR	No	No
	Tachycardia	PULSE {INCREASED} 2 CONSECUTIVE WEEKS	15, .	Not Stated	150	CON	SEV	STP	REL	No	No
	Vasodilatation	HOT FLASHES	8, .	Not Stated	100	2	MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	15, .	Not Stated	150	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
Nervous System	Agitation	INCREASE AGITATION	7, .	Not Stated	100	CON	MIL	NO	PBU	No	No
	Insomnia	MIDDLE INSOMNIA	1, .	16 Days	50	CON	MIL	NO	PBU	No	No
		TERMINAL INSOMNIA	18, .	Not Stated	150	CON	MIL	NO	PBU	No	No
	Tremor	HAND TREMORS	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14FEB95	-8, .	0	108	70	76	112	74	88	76.00	58.0
BL	22FEB95	1, .	0	104	70	82	110	70	92	76.00	
1	28FEB95	7, .	100	100	60	100	98	60	120	76.00	
2	08MAR95	15, .	150	98	60	100	100	70	108	74.00	
3	15MAR95	22, .	150	100	60	102	92	62	118	74.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.5	L	.	-	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3	.	.	.	30 - 70	%
				Lymphocytes	48.2	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	331000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	245	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	23FEB95	1	01MAR95	7	7
00071	Oral	2	0 MG	02MAR95	8	08MAR95	14	7
00071	Oral	3	0 MG	09MAR95	15	15MAR95	21	7
00071	Oral	4	0 MG	16MAR95	22	22MAR95	28	7
00071	Oral	5	0 MG	23MAR95	29	29MAR95	35	7
00071	Oral	6	0 MG	30MAR95	36	05APR95	42	7
00071	Oral	6	0 MG	06APR95	43	12APR95	49	7
00071	Oral	6	0 MG	13APR95	50	19APR95	56	7
	Oral	6	0 MG	20APR95	57	04MAY95	71	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	71	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
FLU	INFLUENZA	RESPIRATORY SYST DIS	PRV	1995
PRESSURE EQUALIZATION TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1983
SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-20, .	03FEB95	13FEB95#	750MG	FLU/SINUSITIS
CENTRAL NERVOUS SYSTEM	Chlorphenamine Maleate	Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
	Dextromethorphan Hydrobromide	Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
	Paracetamol	Tylenol	-17, .	06FEB95	12FEB95#	650MG	HEADACHE
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
	Pseudoephedrine Hydrochloride	Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
			-17, .	06FEB95	12FEB95#	2TABS	FLU
	Dextromethorphan Hydrobromide	Nyquil	-17, .	06FEB95	10FEB95#		FLU
		Robitussin Cf	-21, .	02FEB95	08FEB95#		FLU
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
			-17, .	06FEB95	12FEB95#	2TABS	FLU
	Doxylamine Succinate	Nyquil	-17, .	06FEB95	10FEB95#		FLU
	Guaifenesin	Robitussin Cf	-21, .	02FEB95	08FEB95#		FLU
	Paracetamol	Nyquil	-17, .	06FEB95	10FEB95#		FLU
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
			-17, .	06FEB95	12FEB95#	2TABS	FLU
	Phenylpropanolamine Hydrochloride	Robitussin Cf	-21, .	02FEB95	08FEB95#		FLU
	Pseudoephedrine Hydrochloride	Nyquil	-17, .	06FEB95	10FEB95#		FLU
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
			-17, .	06FEB95	12FEB95#	2TABS	FLU

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	41, .	23 Days	0	CON	MIL	NO	PSR	No	No
Hemic and Lymphatic System	Lymphadenopathy	SWOLLEN LYMPH NODES IN NECK	19, .	4 Days	0	CON	MIL	NO	UNR	No	No
Musculoskeletal System	Myalgia	ARM AND LEG MUSCLE ACHES	27, .	5 Days	0	CON	MIL	NO	PBU	No	No
Respiratory System	Pharyngitis	SORE THROAT	19, .	15 Days	0	CON	MOD	NO	UNR	No	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION	19, .	15 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	02FEB95	-21,	.	0	100	60	80	104	66	100	97.00	61.8
BL	23FEB95	1,	.	0	90	58	72	100	60	92	99.00	
1	02MAR95	8,	.	0	110	60	84	106	60	100	95.00	
2	09MAR95	15,	.	0	100	54	82	102	60	88	96.50	
3	16MAR95	22,	.	0	104	60	76	110	70	84	95.70	
4	23MAR95	29,	.	0	106	64	74	100	60	88	96.50	
5	30MAR95	36,	.	0	110	70	76	100	60	78	96.00	
6	06APR95	43,	.	0	104	64	96	100	80	100	98.00	
7	13APR95	50,	.	0	100	60	82	100	70	96	97.50	
8	20APR95	57,	.	0	100	60	72	106	68	76	97.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.4	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	181	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9		.	.	12 - 15.6	G/DL
				Hematocrit	37.3		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5		.	.	30 - 70	%
				Lymphocytes	37.4		.	.	21 - 51	%
				Monocytes	4.6		.	.	0 - 10	%
				Eosinophils	3.3		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	305000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	184		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	20MAR95	1	26MAR95	7	7
00072	Oral	2	20 MG	27MAR95	8	02APR95	14	7
00072	Oral	3	20 MG	03APR95	15	09APR95	21	7
00072	Oral	4	20 MG	10APR95	22	12APR95	24	3
	Oral	3	20 MG	13APR95	25	20APR95	32	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	32	20	Other reason	FAMILY WITHDREW CONSENT.SEE MISCELLANEOUS NOTES.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
STRESS FRACTURE BACK	BONE/CARTIL DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1993

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	2, .	3 Days	20	2	MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	APPETITE DECREASED	9, .	Not Stated	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	07MAR95	-13,	.	0	104	70	72	100	70	88	152.00	73.5
BL	20MAR95	1,	.	0	108	68	72	98	60	88	153.50	
1	27MAR95	8,	.	20	90	60	66	88	60	84	151.00	
2	03APR95	15,	.	20	100	60	76	90	60	114	150.00	
3	10APR95	22,	.	20	104	60	72	94	62	88	150.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.1	.	.	.	30 - 70	%
				Lymphocytes	48.1	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	252	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	04APR95	1	10APR95	7	7
00121	Oral	2	20 MG	11APR95	8	17APR95	14	7
00121	Oral	3	20 MG	18APR95	15	25APR95	22	8
00121	Oral	4	20 MG	26APR95	23	01MAY95	28	6
00121	Oral	5	30 MG	02MAY95	29	08MAY95	35	7
00121	Oral	5	30 MG	09MAY95	36	15MAY95	42	7
00121	Oral	5	30 MG	16MAY95	43	22MAY95	49	7
00121	Oral	5	30 MG	23MAY95	50	29MAY95	56	7
00051	Oral	5	30 MG	30MAY95	57	26JUN95	84	28
00051	Oral	5	30 MG	27JUN95	85	23JUL95	111	27
00051	Oral	5	30 MG	24JUL95	112	20AUG95	139	28
00121	Oral	5	30 MG	21AUG95	140	04SEP95	154	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	154	30	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DECREASED WHITE BLOOD CELL	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1995
BIRTHMARK REMOVED	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1989
CHICKEN POX	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	PRV	1987
CYST REMOVED FROM CHEST	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1981

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	3, -54	27 Days	20	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS	8, -49	22 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZY	50, -7	20 Mins	30	1	MIL	NO	PBU	No	No
Skin and Appendages	Acne	ACNE WORSE	9, -48	21 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22MAR95	-13, -69	0	102	62	60	98	60	86	143.50	74.0
BL	04APR95	1, -56	0	106	60	68	100	60	100	143.50	
1	11APR95	8, -49	20	104	60	60	106	64	70	141.00	
2	18APR95	15, -42	20	100	66	64	98	70	80	139.75	
3	26APR95	23, -34	20	100	68	64	104	62	88	135.50	
4	02MAY95	29, -28	30	100	60	64	100	64	80	139.00	
5	09MAY95	36, -21	30	110	70	60	100	70	88	138.70	
6	16MAY95	43, -14	30	98	70	64	104	72	84	139.50	
7	23MAY95	50, -7	30	100	60	66	108	64	68	138.00	
8	30MAY95	57, 1	30	98	66	60	100	70	80	138.00	
12	27JUN95	85, 29	30	108	62	80	110	60	112	143.70	
16	24JUL95	112, 56	30	100	60	68	96	62	80	142.70	
20	21AUG95	140, 84	30	108	66	72	100	62	92	144.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	180000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	187	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.9		.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3		.	.	30 - 70	%
				Lymphocytes	36.5		.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	2.6		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	183000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	29	White Blood Cell Count	4.6		.	.	4.5 - 13	THOU/MCL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.2	L	.	-	41 - 50	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2		.	.	30 - 70	%
				Lymphocytes	40.4		.	.	21 - 51	%
				Monocytes	4.6		.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	147000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	170	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	140	White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.9	.	.	.	30 - 70	%
				Lymphocytes	42.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	170000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	157	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 17/DOWN TITRATION	155 (1)	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 17/DOWN TITRATION	155	(1)	Hematocrit	37.5	L	.	.	41 - 50	%
					Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	50.5	.	.	.	30 - 70	%
					Lymphocytes	41.3	.	.	.	21 - 51	%
					Monocytes	4.6	.	.	.	0 - 10	%
					Eosinophils	2	.	.	.	0 - 5	%
					Basophils	1.5	.	.	.	0 - 2	%
					Platelets	195000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.8	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	93	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	20JUN95	1	26JUN95	7	7
00122	Oral	2	100 MG	27JUN95	8	04JUL95	15	8
00122	Oral	3	150 MG	05JUL95	16	10JUL95	21	6
00122	Oral	4	200 MG	11JUL95	22	17JUL95	28	7
00122	Oral	4	200 MG	18JUL95	29	24JUL95	35	7
00122	Oral	4	200 MG	25JUL95	36	31JUL95	42	7
00122	Oral	4	200 MG	01AUG95	43	08AUG95	50	8
00122	Oral	4	200 MG	09AUG95	51	15AUG95	57	7
00052	Oral	4	200 MG	16AUG95	58	11SEP95	84	27
00052	Oral	4	200 MG	12SEP95	85	09OCT95	112	28
00052	Oral	4	200 MG	10OCT95	113	06NOV95	140	28
00052	Oral	4	200 MG	07NOV95	141	04DEC95	168	28
	Oral	4	200 MG	05DEC95	169	18DEC95	182	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	182	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
HEAVY PERSPIRATION	HYPERHIDROSIS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HERNIA REPAIR	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1988
RIGHT FOOT INFECTION {TOENAILS}	CELLULITIS/ABSCESS	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	1985

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Minerals Nos	Centrum	-80, -137	01APR95	20JUN95	ONE DAILY	HEALTH MAINTENANCE
	Vitamins Nos	Centrum	-80, -137	01APR95	20JUN95	ONE DAILY	HEALTH MAINTENANCE
ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole	Bactrim Ds	-139, -196	01FEB95	.	2TWICE DAILY	ACNE
	Trimethoprim	Bactrim Ds	-139, -196	01FEB95	.	2TWICE DAILY	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Extrasystoles	PVC'S ON EKG [PREMATURE VENTRICULAR CONTRACTIONS]	8, -50	9 Days	100	CON	MIL	NO	PBU	No	No
	Tachycardia	HEART RACING (BEATS HARD)	85, 28	30 Days	200	2	MIL	NO	REL	No	No
Digestive System	Constipation	CONSTIPATION	16, -42	4 Days	150	CON	MIL	NO	PSR	No	No
			25, -33	19 Days	200	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	114, 57	Not Stated	200	CON	MOD	NO	REL	No	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN	114, 57	Not Stated	200	CON	MOD	NO	REL	No	No
Nervous System	Amnesia	MORE FORGETFUL	22, -36	15 Days	200	CON	MIL	NO	PSR	No	No
	Hypesthesia	NUMBNESS IN HANDS AND ARMS WHEN AWAKES	29, -29	30 Days	200	CON	MIL	NO	PBU	No	No
	Myoclonus	MUSCLE TWITCH RIGHT EYE	25, -33	19 Days	200	CON	MIL	NO	PSR	No	No
		RIGHT KNEE TWITCH	25, -33	62 Days	200	CON	MIL	NO	REL	No	No
	Tremor	HAND TREMORS	50, -8	120 Days	200	CON	MOD	NO	REL	No	No
		RIGHT KNEE TREMOR	25, -33	62 Days	200	CON	MIL	NO	REL	No	No
Respiratory System	Rhinitis	CONGESTION BACK OF THROAT	110, 53	8 Days	200	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	13JUN95	-7, -64	0	120	72	68	112	70	78	166.00	68.5
BL	20JUN95	1, -57	0	110	60	64	102	70	74	166.00	
1	27JUN95	8, -50	100	110	78	76	110	60	80	163.50	
2	05JUL95	16, -42	150	102	70	80	110	70	104	164.00	
3	11JUL95	22, -36	200	114	80	90	106	84	98	165.00	
4	18JUL95	29, -29	200	110	74	88	120	80	108	164.00	
5	25JUL95	36, -22	200	110	74	90	114	80	102	164.00	
6	01AUG95	43, -15	200	120	80	78	112	86	96	166.00	
7	08AUG95	50, -8	200	116	80	84	110	82	92	168.20	
8	16AUG95	58, 1	200	120	76	96	120	80	98	171.00	
12	12SEP95	85, 28	200	118	70	96	116	80	104	171.00	
16	10OCT95	113, 56	200	110	80	82	108	76	84	171.00	
20	07NOV95	141, 84	200	120	70	88	112	80	112	179.00 H	
24	05DEC95	169, 112	200	120	80	94	114	80	106	180.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.1	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.8		.	.	30 - 70	%
				Lymphocytes	43.2		.	.	21 - 51	%
				Monocytes	8		.	.	0 - 10	%
				Eosinophils	4.4		.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	188000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106		.	.	44 - 400	U/L
				Aspartate Aminotransferase	23		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	1.6	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.9		.	.	3.1 - 5.3	G/DL
				Glucose - Random	79		.	.	70 - 115	MG/DL
				Globulin	2.8		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.4		.	.	30 - 70	%
				Lymphocytes	46.8		.	.	21 - 51	%
				Monocytes	6.6		.	.	0 - 10	%
				Eosinophils	4		.	.	0 - 5	%
				Basophils	0.2		.	.	0 - 2	%
				Platelets	207000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	16		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106		.	.	44 - 400	U/L
				Aspartate Aminotransferase	22		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	45	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	200000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	104	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	141	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.1	L	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	04JAN96	1	11JAN96	8	8
00123	Oral	2	0 MG	12JAN96	9	17JAN96	14	6
00123	Oral	3	0 MG	18JAN96	15	24JAN96	21	7
00123	Oral	4	0 MG	25JAN96	22	31JAN96	28	7
00123	Oral	4	0 MG	01FEB96	29	07FEB96	35	7
00123	Oral	4	0 MG	08FEB96	36	14FEB96	42	7
00123	Oral	4	0 MG	15FEB96	43	21FEB96	49	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	49	0	Lack of Efficacy	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACTERIAL VAGINAL RASH	VAGINITIS	GENITOURINARY SYST DIS	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1992
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1993
BROKEN ANKLE	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
BROKEN WRIST	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1988
FEMORAL EPIPHYSIS RIGHT HIP{JOINT DISORDER}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1989
HIP LEFT FEMORAL EPIPHYSIS{JOINT DISORDER}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1990
SURGERY PINNING LEFT HIP	OPERATION, BONE/JOINT	OPERATIONS	PRV	1990
SURGERY REMOVAL OF PINS IN RIGHT,LEFT HIPS	OPERATION, BONE/JOINT	OPERATIONS	PRV	1991
SURGERY-PLACEMENT OF CANNULATED LOG SCREW RIGHT HIP	OPERATION, BONE/JOINT	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Azithromycin	Zithromax	10, .	13JAN96	18JAN96	1000MGX1	BRONCHITIS
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	12, .	15JAN96	.	650MG	MENSTRUAL CRAMPS
	Mepyramine Maleate	Pamprin	-20, .	15DEC95	17DEC95#	2TABS	MENSTRUAL CRAMPS
	Pamabrom	Pamprin	-20, .	15DEC95	17DEC95#	2TABS	MENSTRUAL CRAMPS
	Paracetamol	Pamprin	-20, .	15DEC95	17DEC95#	2TABS	MENSTRUAL CRAMPS
		Tylenol	49, .	21FEB96	.	650MG	HEADACHE
DERMATOLOGICALS	Methylprednisolone	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS
GU SYSTEM/SEX HORMONES	Desogestrel	Ortho-Cept 28	18, .	21JAN96	.	1TAB 1XDAY	MENSTRUAL CRAMPS
	Ethinylestradiol	Ortho-Cept 28	18, .	21JAN96	.	1TAB 1XDAY	MENSTRUAL CRAMPS
SENSORY ORGANS	Methylprednisolone	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS
SYSTEMIC HORMONAL	Methylprednisolone	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	49, .	Not Stated	0	CON	MOD	NO	PSR	Yes	No
		HEADACHES	18, .	8 Days	0	CON	MIL	NO	UNR	No	No
	Pain	BODY ACHES	19, .	7 Days	0	CON	MIL	NO	UNR	No	No
Digestive System	Nausea	NAUSEA	19, .	7 Days	0	CON	MIL	NO	UNR	No	No
			49, .	Not Stated	0	CON	MIL	NO	PSR	No	No
		NAUSEA (POST TAKING MEDS)	2, .	04:30 Hrs	0	2	MIL	NO	PSR	No	No
			26, .	5 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Depression	WORSENING OF DEPRESSION	46, .	Not Stated	0	CON	SEV	STP	REL	No	Yes
	Emotional Lability	SUICIDAL THOUGHTS	46, .	Not Stated	0	CON	SEV	STP	REL	No	Yes
	Tremor	HAND TREMORS	32, .	Not Stated	0	3	MIL	NO	PSR	No	No
Respiratory System	Bronchitis	BRONCHITIS WITH BRONCHOSPASMS	10, .	13 Days	0	CON	MOD	NO	UNR	Yes	No
	Cough Increased	DRY COUGH	4, .	19 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14DEC95	-21,	.	0	122	68	64	120	70	84	183.00	69.3
BL	04JAN96	1,	.	0	108	72	64	110	70	78	185.00	
1	12JAN96	9,	.	0	112	70	80	110	70	100	185.50	
2	18JAN96	15,	.	0	104	64	82	108	70	68	184.00	
3	25JAN96	22,	.	0	100	60	78	102	70	80	182.75	
4	01FEB96	29,	.	0	120	70	66	116	70	80	186.50	
5	08FEB96	36,	.	0	106	62	68	114	72	70	187.00	
6	15FEB96	43,	.	0	120	70	62	110	68	92	187.50	
7	22FEB96	50,	.	0	102	68	66	90	60	96	184.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	30.7	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	297000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07FEB96	1	14FEB96	8	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	No	No	8	20	Adverse event, including intercurrent illness	MANIA/HYPOMANIA SYMPTOMS

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1984
FACIAL LACERATIONS{DOG BITE}	OPEN WOUND	INJURY/POISONING	PRV	1986
PLASTIC SURGERY FOR FACIAL SCARS	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1994

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Chlorphenamine Maleate	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Paracetamol	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
			-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
			-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Paracetamol	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
			-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
			-27, .	11JAN96	11JAN96#	5TSP.	SINUS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Decreased Appetite	SLIGHT DECREASE APPETITE	3, .	Not Stated	20	CON	MIL	NO	PSR	No	No
Nervous System	Manic Reaction	MANIA AND HYPOMANIA SYMPTOMS	4, .	Not Stated	20	CON	SEV	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	29JAN96	-9, .	0	100	70	68	98	68	88	132.30	60.3
BL	07FEB96	1, .	0	100	66	82	96	70	90	131.00	
1	14FEB96	8, .	20	100	70	80	100	70	92	132.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	33.6	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	349	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	60 - 110	MG/DL
				Globulin	2.5	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	21FEB96	1	27FEB96	7	7
00206	Oral	2	20 MG	28FEB96	8	05MAR96	14	7
00206	Oral	3	20 MG	06MAR96	15	12MAR96	21	7
00206	Oral	4	20 MG	13MAR96	22	19MAR96	28	7
00206	Oral	5	30 MG	20MAR96	29	25MAR96	34	6
00206	Oral	6	40 MG	26MAR96	35	02APR96	42	8
00206	Oral	6	40 MG	03APR96	43	09APR96	49	7
00206	Oral	6	40 MG	10APR96	50	16APR96	56	7
	Oral	5	30 MG	17APR96	57	18APR96	58	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	58	30	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	

CUR = Current, PRV = Past

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	19, .	2 Days	20	CON	MIL	NO	PBU	No	No
Digestive System	Dyspepsia	STOMACH UPSET	19, .	2 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12FEB96	-9,	.	0	122	80	68	124	86	76	158.00	70.5
BL	21FEB96	1,	.	0	118	76	72	122	86	80	157.50	
1	28FEB96	8,	.	20	112	70	68	118	78	84	155.00	
2	06MAR96	15,	.	20	118	74	66	120	80	72	157.00	
3	13MAR96	22,	.	20	104	70	68	100	68	74	155.50	
4	20MAR96	29,	.	30	108	70	68	112	74	76	160.00	
5	26MAR96	35,	.	40	110	70	80	110	68	96	156.50	
6	03APR96	43,	.	40	110	70	72	106	68	84	156.00	
7	10APR96	50,	.	40	114	68	76	120	70	84	161.00	
8	17APR96	57,	.	30	106	70	78	112	70	92	160.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.1	.	.	.	30 - 70	%
				Lymphocytes	33.7	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	187000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	129	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	116	H	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	33.4	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	130	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	35	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28FEB96	1	05MAR96	7	7
00207	Oral	2	0 MG	06MAR96	8	12MAR96	14	7
00207	Oral	3	0 MG	13MAR96	15	19MAR96	21	7
00207	Oral	4	0 MG	20MAR96	22	25MAR96	27	6
00207	Oral	4	0 MG	26MAR96	28	02APR96	35	8
00207	Oral	4	0 MG	03APR96	36	09APR96	42	7
00207	Oral	4	0 MG	10APR96	43	16APR96	49	7
00207	Oral	4	0 MG	17APR96	50	23APR96	56	7
	Oral	3	0 MG	24APR96	57	25APR96	58	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	No	58	0	Lack of Efficacy	NON RESPONDER

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
MUSCLE STRAIN	SPRAINS/STRAINS	INJURY/POISONING	PRV	1996
SORE THROAT WITH COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Clarithromycin	Biaxin	56,	.	23APR96	02MAY96	1000MG	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	53,	.	20APR96	25APR96	650MG	HEADACHE SORE THROAT
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	-7,	.	21FEB96	28FEB96	1TAB	STRAINED MUSCLE
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	-21,	.	07FEB96	28FEB96	60MG	COLD SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH CRAMPS	5, .	23:00 Hrs	0	CON	MIL	NO	UNR	No	No
		STOMACH CRAMPS (SINCE STARTING BIAXIN)	57, .	3 Days	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	51, .	8 Days	0	CON	MOD	NO	PBU	Yes	No
	Pain	BODY ACHES	51, .	7 Days	0	CON	MIL	NO	UNR	No	No
Digestive System	Decreased Appetite	DECREASED APPETITE	23, .	15 Days	0	CON	MIL	NO	PBU	No	No
	Diarrhea	DIARRHEA	5, .	15:00 Hrs	0	3	MOD	NO	UNR	No	No
			39, .	13:00 Hrs	0	4	MIL	NO	PBU	No	No
			57, .	3 Days	0	CON	MIL	NO	UNR	No	No
Respiratory System	Cough Increased	COUGH	38, .	7 Days	0	CON	MIL	NO	UNR	No	No
	Pharyngitis	SORE THROAT	43, .	2 Days	0	CON	MIL	NO	UNR	No	No
	Rhinitis	STUFFY NOSE	38, .	7 Days	0	CON	MIL	NO	UNR	No	No
	Sinusitis	HEAD CONGESTION	24, .	4 Days	0	CON	MIL	NO	UNR	No	No
			38, .	7 Days	0	CON	MIL	NO	UNR	No	No
		SINUS INFECTION	51, .	15 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19FEB96	-9,	.	0	120	76	76	116	72	80	217.00	70.5
BL	28FEB96	1,	.	0	118	70	72	120	78	80	215.00	
1	06MAR96	8,	.	0	120	78	84	120	76	98	220.00	
2	13MAR96	15,	.	0	116	70	92	124	80	100	220.00	
3	20MAR96	22,	.	0	122	76	84	118	82	92	217.50	
4	26MAR96	28,	.	0	112	62	80	116	70	90	217.50	
5	03APR96	36,	.	0	122	74	88	118	78	96	214.00	
6	10APR96	43,	.	0	122	80	88	116	82	96	217.50	
7	17APR96	50,	.	0	116	70	88	114	80	94	220.00	
8	24APR96	57,	.	0	114	72	84	118	78	94	213.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	238	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	42	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37.3		.	.	30 - 70	%
				Lymphocytes	50.7		.	.	21 - 51	%
				Monocytes	9.2		.	.	0 - 10	%
				Eosinophils	2.2		.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	285000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	83		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	225		.	.	44 - 400	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	122	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	09MAR95	1	15MAR95	7	7
00049	Oral	2	0 MG	16MAR95	8	22MAR95	14	7
00049	Oral	3	0 MG	23MAR95	15	29MAR95	21	7
00049	Oral	4	0 MG	30MAR95	22	05APR95	28	7
00049	Oral	5	0 MG	06APR95	29	12APR95	35	7
00049	Oral	6	0 MG	13APR95	36	19APR95	42	7
00049	Oral	6	0 MG	20APR95	43	27APR95	50	8
00049	Oral	6	0 MG	28APR95	51	05MAY95	58	8
	Oral	6	0 MG	06MAY95	59	21MAY95	74	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	74	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BILATERAL HERNIORRHAPHY	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	19, .	27MAR95	27MAR95	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	17, .	3 Days	0	3	MIL	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03MAR95	-6,	.	0	110	65	64	110	80	96	210.00	75.0
BL	08MAR95	-1,	.	0	110	60	80	110	75	104	211.00	
1	15MAR95	7,	.	0	130	65	88	125	70	100	211.50	
2	22MAR95	14,	.	0	115	60	84	115	70	96	211.00	
3	29MAR95	21,	.	0	100	65	68	100	70	92	210.00	
4	05APR95	28,	.	0	100	70	72	100	70	84	211.00	
5	12APR95	35,	.	0	110	65	76	100	75	96	210.50	
6	19APR95	42,	.	0	100	68	82	112	68	105	212.56	
7	27APR95	50,	.	0	110	60	80	100	70	104	208.00	
8	05MAY95	58,	.	0	115	61	81	115	65	106	210.36	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	1000.PRE	-13	Hemoglobin	16.3		.	.	13.8 - 17.2	G/DL
				Hematocrit	49.4		.	.	41 - 50	%
				Red Blood Cell Count	5.7	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4		.	.	30 - 70	%
				Lymphocytes	27.5		.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	1.7		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	229000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	123		.	.	44 - 400	U/L
				Aspartate Aminotransferase	13		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	1		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	68	L	.	.	70 - 115	MG/DL
				Globulin	2.7		.	.	2.3 - 4.1	G/DL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	1000.PRE	-13	Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 1/SCREENING (WEEK -1)	-6	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEC		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	45.6		.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3		.	.	30 - 70	%
				Lymphocytes	33		.	.	21 - 51	%
				Monocytes	9.1		.	.	0 - 10	%
				Eosinophils	1.1		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	58		Platelets	246000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	117	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
					Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	25	L	.	.	70 - 115	MG/DL
					Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	91	(17)	Glucose - Random	96	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	23MAR95	1	29MAR95	7	7
00050	Oral	2	100 MG	30MAR95	8	05APR95	14	7
00050	Oral	3	150 MG	06APR95	15	12APR95	21	7
	Oral	3	150 MG	14APR95	23	26APR95	35	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	No	No	35	150	Adverse event, including intercurrent illness	MULTIPLE SIDE EFFECTS-INCREASED HEART RATE URINARY HESITANCY DIZZINESS

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1991
INTERMITTENT GLUCOSE{DECREASED}	HYPOGLYCEMIA	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
HYPOSPADIAS {MALE}	CONG ANOM, GU	ANOMALIES	PRV	1978
LEFT URETERAL DUPLICATION	CONG ANOM, GU	ANOMALIES	PRV	1978
RIGHT VESICOURETERAL REFLUX	KIDNEY DISORD	GENITOURINARY SYST DIS	PRV	1978

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	5, .	27MAR95	28MAR95	250MG	SORE THROAT
			6, .	28MAR95	08APR95	1500MG	SORE THROAT
	Clindamycin Hydrochloride	Cleocin	-1177, .	01JAN92	.	1%LOTION	ACNE
	Minocycline	Minocycline	-1177, .	01JAN92	.	100MG	ACNE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	4, .	26MAR95	26MAR95	650MG	FEVER
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	5, .	27MAR95	28MAR95	1-2TABS	FEVER/SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Fever	FEVER	1, .	6 Days	50	CON	MOD	NO	PBU	Yes	No
	Headache	HEADACHE	1, .	5 Days	50	CON	MIL	NO	PBU	Yes	No
Carciovascular System	Postural Hypotension	DIZZINESS WITH ORTHOSTATIC HYPOTENSION	8, .	6 Days	100	CON	MIL	STP	PSR	No	No
	Tachycardia	HEART RATE INCREASE	1, .	22 Days	50	CON	MOD	STP	PSR	No	No
Respiratory System	Cough Increased	COUGHING	1, .	12 Days	50	CON	MIL	NO	PBU	Yes	No
	Pharyngitis	SORE THROAT	1, .	6 Days	50	CON	MOD	NO	PBU	Yes	No
Urogenital System	Urination Impaired	URINARY HESITANCY	8, .	6 Days	100	CON	MIL	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	10MAR95	-13,	.	0	140	74	70	149	82	76	152.15	67.5
BL	22MAR95	-1,	.	0	135	75	88	135	75	96	154.00	
1	29MAR95	7,	.	50	115	70	92	115	70	104	154.00	
2	05APR95	14,	.	100	139	69	94	123	73	111	154.00	
3	12APR95	21,	.	150	120	80	104	120	85	112	153.00	
5	28APR95	37,	.	150	139	68	95	122	76	102	155.67	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.1		.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4		.	.	30 - 70	%
				Lymphocytes	25.3		.	.	21 - 51	%
				Monocytes	6.9		.	.	0 - 10	%
				Eosinophils	3.4		.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	275000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	80		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	186	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.7		.	.	3.1 - 5.3	G/DL
				Glucose - Random	46	L	.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.	.	.
				Urine Blood - Dipstick	NEG			.	.	.
				Urine Red Blood Cells/HPF	NEG			.	.	.
				Urine White Blood Cells/HPF	NEG			.	.	.
				Urine Protein - Dipstick	NEG			.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13		Urine Squamous Epithelial Cells	3		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-6		Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
					Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.6		.	.	4 - 8	MG/DL
					Alkaline Phosphatase	203	H	.	.	22 - 180	U/L
					Aspartate Aminotransferase	16		.	.	0 - 41	U/L
					Alanine Aminotransferase	8		.	.	0 - 48	U/L
					Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
					Total Protein	8		.	.	6.2 - 8.8	G/DL
					Albumin	4.7		.	.	3.1 - 5.3	G/DL
					Glucose - Random	80		.	.	70 - 115	MG/DL
					Globulin	3.3		.	.	2.3 - 4.1	G/DL
		VISIT 6/ACUTE PHASE-WEEK 4	37	(2)	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	39	L	.	.	41 - 50	%
					Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.3		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	56.8		.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 6/ACUTE PHASE-WEEK 4	37	(2)	Lymphocytes	35.3	.	.	.	21 - 51	%
					Monocytes	5.9	.	.	.	0 - 10	%
					Eosinophils	2	.	.	.	0 - 5	%
					Basophils	0	.	.	.	0 - 2	%
					Platelets	244000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	199	H	.	.	22 - 180	U/L
					Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	41	L	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	24JUN94	1	29JUN94	6	6
00055	Oral	2	20 MG	30JUN94	7	06JUL94	13	7
00055	Oral	3	20 MG	07JUL94	14	13JUL94	20	7
00055	Oral	4	20 MG	14JUL94	21	20JUL94	27	7
00055	Oral	5	30 MG	21JUL94	28	27JUL94	34	7
00055	Oral	6	40 MG	28JUL94	35	03AUG94	41	7
00055	Oral	6	40 MG	04AUG94	42	10AUG94	48	7
00055	Oral	6	40 MG	11AUG94	49	17AUG94	55	7
00068	Oral	6	40 MG	18AUG94	56	14SEP94	83	28
00068	Oral	6	40 MG	15SEP94	84	13OCT94	112	29
00068	Oral	6	40 MG	14OCT94	113	10NOV94	140	28
00055	Oral	5	30 MG	11NOV94	141	12NOV94	142	2
00055	Oral	4	20 MG	13NOV94	143	14NOV94	144	2
00055	Oral	3	20 MG	15NOV94	145	16NOV94	146	2
00055	Oral	2	20 MG	17NOV94	147	19NOV94	149	3
00055	Oral	1	20 MG	20NOV94	150	26NOV94	156	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	156	20	Lack of Efficacy	RELAPSE IN CONTINUATION PHASE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES-BEE STING	TOXIC EFFECTS, VENOM	INJURY/POISONING	CUR	1987
ALLERGY-CAT FUR(MILD)	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1987
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	123, 68	24OCT94	.	ESTIMATE 650MG PM	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	123, 68	24OCT94	.	800-1200MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Hostility	ALLEGATIONS OF SEXUAL AGGRESSION	32, -24	1 Days	30		MIL	NO	UNR	No	No
Skin and Appendages	Photosensitivity	SUNBURN,APPROPRIATE TO DEGREE OF EXPOSURE(BEACH)	20, -36	3 Days	20	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	09JUN94	-15, -70	0	110	70	85	110	75	88	175.00	65.0
BL	23JUN94	-1, -56	0	115	75	80	120	70	85	174.00	
1	30JUN94	7, -49	20	104	68	64	110	70	75	174.50	
2	07JUL94	14, -42	20	105	68	86	90	75	92	175.00	
3	14JUL94	21, -35	20	100	66	72	100	72	96	173.00	
4	21JUL94	28, -28	30	102	50	92	98	68	112	171.00	
5	28JUL94	35, -21	40	102	60	72	100	62	102	168.00	
6	04AUG94	42, -14	40	98	68	80	94	60	102	169.50	
7	11AUG94	49, -7	40	92	58	72	94	60	100	169.00	
8	18AUG94	56, 1	40	90	60	54	90	68	72	166.00	
12	15SEP94	84, 29	40	94	60	68	92	64	98	170.00	
16	13OCT94	112, 57	40	100	60	60	104	54	80	171.50	
20	10NOV94	140, 85	40	112	70	72	104	68	84	173.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.6	.	.	.	12 - 16	G/DL
				Hematocrit	39.4	.	.	.	36 - 49	%
				Red Blood Cell Count	4.87	.	.	.	4 - 5.2	10^12/L
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	10^9/L
				Neutrophil Bands	56	.	.	+	30 - 70	%
				Segmented Neutrophils	56	.	.	.	30 - 70	%
				Lymphocytes	31	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	3640000	H	.	+	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 33	PG
				Mean Corpuscle Volume	81	.	.	.	77 - 95	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	12	H	.	+	0.7 - 1.4	MG/DL
				Uric Acid	6.6	.	.	.	4 - 8.5	MG/DL
				Alkaline Phosphatase	328	.	.	.	60 - 500	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 42	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 45	U/L
				Total Bilirubin	1	.	.	.	0 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6 - 8.5	GM/DL
				Albumin	4.2	.	.	.	3.2 - 5	GM/DL
				Glucose - Random	108	.	.	.	70 - 113	MG/DL
				Globulin	2.3	.	.	.	2.2 - 4.2	GM/DL
				Urine Blood - Random	NEG		.	.		
				Urine Bilirubin	NEG		.	.		
				Urine Ketones (Acetone)	NEG		.	.		
				Urine PH	5.0		.	.		
				Total Protein in Urine	TRACE		.	.		
				Urine Specific Gravity	1.030		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Appearance	CLEAR	.	.	.		
				Urine Color	YELLOW	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	33.3	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	6.6	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	295	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	27	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	284	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	140	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19JUL94	1	25JUL94	7	7
00056	Oral	2	100 MG	26JUL94	8	01AUG94	14	7
00056	Oral	3	150 MG	02AUG94	15	08AUG94	21	7
00056	Oral	4	200 MG	09AUG94	22	16AUG94	29	8
	Oral	3	150 MG	17AUG94	30	23AUG94	36	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	36	150	Adverse event, including intercurrent illness	INCREASED HEART RATE

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MISCARRIAGE	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994
PREGNANCY	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1994

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Tachycardia	INCREASED HEART RATE	15, .	22 Days	150	CON	MIL	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JUN94	-25,	.	0	90	52	84	80	50	108	111.00	59.4
BL	19JUL94	1,	.	0	82	40	100	84	44	102	113.00	
1	26JUL94	8,	.	100	84	58	100	84	56	120	110.00	
2	02AUG94	15,	.	150	90	50	108	72	40	112	109.00	
3	09AUG94	22,	.	200	92	60	132 H	90	60	104	110.00	
4	16AUG94	29,	.	200	84	52	120	78	42	140 H	112.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	11.8	L	.	.	12 - 15.6	G/DL
				Hematocrit	35.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	62	.	.	.	40 - 75	%
				Lymphocytes	27.9	.	.	.	16 - 46	%
				Monocytes	7.2	.	.	.	0 - 12	%
				Eosinophils	2.2	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	406000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	25.6	L	.	.	27 - 33	PG
				Mean Corpuscle Volume	77	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	08SEP94	1	14SEP94	7	7
00057	Oral	2	100 MG	15SEP94	8	21SEP94	14	7
00057	Oral	3	150 MG	22SEP94	15	28SEP94	21	7
00057	Oral	4	200 MG	29SEP94	22	05OCT94	28	7
00057	Oral	5	250 MG	06OCT94	29	12OCT94	35	7
00057	Oral	6	300 MG	13OCT94	36	19OCT94	42	7
00057	Oral	6	300 MG	20OCT94	43	26OCT94	49	7
00057	Oral	6	300 MG	27OCT94	50	03NOV94	57	8
00067	Oral	6	300 MG	04NOV94	58	30NOV94	84	27
00067	Oral	6	300 MG	01DEC94	85	29DEC94	113	29
00057	Oral	5	250 MG	30DEC94	114	31DEC94	115	2
00057	Oral	4	200 MG	01JAN95	116	02JAN95	117	2
00057	Oral	3	150 MG	03JAN95	118	04JAN95	119	2
00057	Oral	2	100 MG	05JAN95	120	07JAN95	122	3
00057	Oral	1	50 MG	08JAN95	123	14JAN95	129	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	129	50	Adverse event, including intercurrent illness	PT. BECAME PREGNANT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEARTBURN	HEARTBURN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SCHEUERMANN'S KYPHOSIS	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
STOMACH PROBLEMS	STOMACH/DUODENUM DISORD	DIGESTIVE SYST	CUR	1994
CHILDHOOD MIGRAINES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	PRV	1984
CONCUSSION	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1985
HERNIA OPERATION	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1985
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1983
TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1983

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Bayer Aspirin	83, 26	29NOV94	29NOV94	1500MG	HEADACHE
	Cannabis	Cannabis	., .		.	UNKNOWN	
			53, -5	30OCT94	30OCT94	UNKNOWN	
	Paracetamol	Acetaminophen	-38, -95	01AUG94	.	650MG PRN	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Motrin	22, -36	29SEP94	29SEP94	800MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Vomiting	NAUSEA, VOMITING	29, -29	20 Mins	250	CON	MIL	NO	UNR	No	No
Nervous System	Hyperkinesia	SENSATION OF RESTLESSNESS IN LEGS NO OBSERVABLE TREMORS	20, -38	45 Mins	150	CON	MIL	NO	PBU	No	No
Urogenital System	Unintended Pregnancy	PREGNANCY NAUSEA VOMITING	94, 37	Not Stated	300	CON	MOD	STP	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11AUG94	-28, -85	0	98	62	72	88	60	88	162.50	66.5
BL	08SEP94	1, -57	0	99	62	73	92	61	89	163.00	
1	15SEP94	8, -50	100	90	60	88	84	60	84	160.50	
2	22SEP94	15, -43	150	102	70	102	94	60	140 H	158.00	
3	29SEP94	22, -36	200	90	60	100	94	60	100	158.00	
4	06OCT94	29, -29	250	112	68	96	110	66	100	157.00	
5	13OCT94	36, -22	300	104	60	100	88	50	102	159.50	
6	20OCT94	43, -15	300	100	62	100	98	60	104	159.00	
7	27OCT94	50, -8	300	102	64	100	94	62	102	160.00	
8	03NOV94	57, -1	300	90	60	120	80	58	140 H	160.00	
12	01DEC94	85, 28	300	110	60	100	90	60	128 H	163.00	
16	29DEC94	113, 56	300	104	64	100	102	60	120	157.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-28	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	28.8	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	321000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-28	Serum BHCG pregnancy test	NEGATIVE					
				Urine Amphetamines	NEG					
				Urine Barbiturates	NEG					
				Urine Benzodiazepines	NEG					
				Urine Cannabinoids	POS					
				Urine Cocaine	NEG					
				Urine Methadone	NEG					
				Urine Methaqualone	NEG					
				Urine Opiates	NEG					
				Urine Phencyclidine	NEG					
				Urine Propoxyphene	NEG					
		VISIT 1/UNSCHEDULED LAB 1	-21	Urine Amphetamines	NEG					
				Urine Barbiturates	NEG					
				Urine Benzodiazepines	NEG					
				Urine Cannabinoids	NEG					
				Urine Cocaine	NEG					
				Urine Methadone	NEG					
				Urine Methaqualone	NEG					
				Urine Opiates	NEG					
				Urine Phencyclidine	NEC					
				Urine Propoxyphene	NEG					
		1010.ZZ2	-14	Urine Amphetamines	NEG					
				Urine Barbiturates	NEG					
				Urine Benzodiazepines	NEG					
				Urine Cannabinoids	NEG					
				Urine Cocaine	NEG					
				Urine Methadone	NEG					
				Urine Methaqualone	NEG					
				Urine Opiates	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	1010.ZZ2	-14	Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEC	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 8/ACUTE PHASE-WEEK 6	48	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 8/ACUTE PHASE-WEEK 6	48	Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15		.	.	12 - 15.6	G/DL
				Hematocrit	44.4		.	.	35 - 46	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8		.	.	30 - 70	%
				Lymphocytes	23.6		.	.	21 - 51	%
				Monocytes	7		.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.2		.	.	0 - 2	%
				Platelets	347000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	100		.	.	44 - 280	U/L
				Aspartate Aminotransferase	28		.	.	0 - 41	U/L
				Alanine Aminotransferase	28		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	90		.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	85	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEC	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	113	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 12/CONTINUATION-WEEK 16	113	Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	29.2	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	375000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	75	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 12/CONTINUATION-WEEK 16	113	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	20SEP94	1	28SEP94	9	9
00058	Oral	2	20 MG	29SEP94	10	06OCT94	17	8
00058	Oral	3	20 MG	07OCT94	18	12OCT94	23	6
00058	Oral	4	20 MG	13OCT94	24	19OCT94	30	7
00058	Oral	5	30 MG	20OCT94	31	26OCT94	37	7
00058	Oral	6	40 MG	27OCT94	38	02NOV94	44	7
00058	Oral	6	40 MG	03NOV94	45	09NOV94	51	7
00058	Oral	6	40 MG	10NOV94	52	16NOV94	58	7
00070	Oral	6	40 MG	17NOV94	59	14DEC94	86	28
00070	Oral	6	40 MG	15DEC94	87	12JAN95	115	29
00070	Oral	6	40 MG	13JAN95	116	16JAN95	119	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	119	40	Adverse event, including intercurrent illness	INTENTIONAL OVERDOSE OF TYLENOL ON 1/19/95.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
ATTENTION DEFICIT DISORDER	MENTAL STATUS, IMPAIRED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1983

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	60, 2	18NOV94	28NOV94	500MG	STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	122, 64	19JAN95	19JAN95	26,650MG	INTENTIONAL OVERDOSE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	REPORT OF SORE THROAT.POSITIVE CULTURE,THROAT.BETA HEMOLYTIC STREP,GROUP A.	58, -1	3 Days	40	CON	MIL	NO	UNR	Yes	No
Nervous System	Emotional Lability	INTENTIONAL OVERDOSE {TYLENOL OVERDOSE TOOK 80 PILLS}	122, 64	1 Days	40	CON	MOD	STP	PBU	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08SEP94	-12, -70	0	102	70	88	104	70	92	203.50	62.6
BL	20SEP94	1, -58	0	102	70	88	104	70	92	203.50	
1	29SEP94	10, -49	20	100	74	88	94	66	94	198.50	
2	07OCT94	18, -41	20	110	80	100	102	60	84	195.50	
3	13OCT94	24, -35	20	102	84	88	100	82	80	196.00	
4	20OCT94	31, -28	30	100	60	72	98	54	84	197.00	
5	27OCT94	38, -21	40	104	86	88	100	84	80	199.00	
6	03NOV94	45, -14	40	102	80	84	100	78	86	195.00	
7	10NOV94	52, -7	40	100	60	92	102	78	102	194.50	
8	17NOV94	59, 1	40	110	80	80	112	82	100	194.50	
12	15DEC94	87, 29	40	100	70	84	100	70	88	194.00	
16	13JAN95	116, 58	40	120	72	80	122	74	82	190.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	25.7	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	197000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.2		.	.	12 - 15.6	G/DL
				Hematocrit	38.9		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.4		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	4		.	.	4 - 12	%
				Segmented Neutrophils	85	H	.	.	30 - 70	%
				Lymphocytes	5	L	.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	1		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	183000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	82		.	.	80 - 100	FL
				Blood Urea Nitrogen	7		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68		.	.	22 - 130	U/L
				Aspartate Aminotransferase	10		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59		Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
					Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	86	.	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	5	.	.	+		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	130	(11)	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
					Hematocrit	40.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	62.4	.	.	.	30 - 70	%
					Lymphocytes	26.4	.	.	.	21 - 51	%
					Monocytes	8.4	.	.	.	0 - 10	%
					Eosinophils	2.2	.	.	.	0 - 5	%
					Basophils	0.6	.	.	.	0 - 2	%
					Platelets	193000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16 20	F	VISIT 13/CONTINUATION-WEEK	130	(11)	Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	89	.	.	.	70 - 115	MG/DL
					Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	10NOV94	1	16NOV94	7	7
00059	Oral	2	0 MG	17NOV94	8	22NOV94	13	6
00059	Oral	3	0 MG	23NOV94	14	30NOV94	21	8
00059	Oral	4	0 MG	01DEC94	22	07DEC94	28	7
00059	Oral	5	0 MG	08DEC94	29	14DEC94	35	7
00059	Oral	6	0 MG	15DEC94	36	21DEC94	42	7
00059	Oral	6	0 MG	22DEC94	43	28DEC94	49	7
00059	Oral	6	0 MG	29DEC94	50	05JAN95	57	8
	Oral	6	0 MG	06JAN95	58	21JAN95	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	73	0	Lack of Efficacy	NON-RESPONSE TO TREATMENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HISTORY OF MITRAL VALVE PROLAPSE-NO FUNCTIONAL IMPAIRMENT	MITRAL VALVE DISORD	CIRCULATORY SYST	CUR	1987

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03NOV94	-7,	.	0	90	60	72	100	70	88	124.00	71.0
BL	10NOV94	1,	.	0	102	64	80	94	60	88	123.50	
1	17NOV94	8,	.	0	100	72	88	98	68	112	125.00	
2	23NOV94	14,	.	0	102	60	72	90	60	96	126.00	
3	01DEC94	22,	.	0	90	60	80	110	60	100	126.00	
4	08DEC94	29,	.	0	92	52	80	98	60	96	124.00	
5	15DEC94	36,	.	0	100	68	86	98	60	92	125.00	
6	22DEC94	43,	.	0	106	66	88	108	70	80	126.00	
7	29DEC94	50,	.	0	90	60	84	102	78	92	125.00	
8	05JAN95	57,	.	0	104	60	88	100	60	92	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.7	.	.	.	30 - 70	%
				Lymphocytes	40.9	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	121	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	16.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	50.1	H	.	.	41 - 50	%
				Red Blood Cell Count	5.8	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.7		.	.	30 - 70	%
				Lymphocytes	32.7		.	.	21 - 51	%
				Monocytes	7.7		.	.	0 - 10	%
				Eosinophils	3.5		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	162000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1.3		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	112		.	.	22 - 180	U/L
				Aspartate Aminotransferase	22		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	31JAN95	1	06FEB95	7	7
00060	Oral	2	0 MG	07FEB95	8	13FEB95	14	7
00060	Oral	3	0 MG	14FEB95	15	20FEB95	21	7
00060	Oral	4	0 MG	21FEB95	22	27FEB95	28	7
00060	Oral	5	0 MG	28FEB95	29	06MAR95	35	7
00060	Oral	6	0 MG	07MAR95	36	13MAR95	42	7
00060	Oral	6	0 MG	14MAR95	43	20MAR95	49	7
00060	Oral	6	0 MG	21MAR95	50	27MAR95	56	7
00065	Oral	6	0 MG	28MAR95	57	25APR95	85	29

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	85	0	Lack of Efficacy	PT.FELT MEDICATION WASN'T WORKING

* Relative to Start of Study Medication

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	31JAN95	1, -56	0	108	74	88	112	76	88	117.00	64.0
1	07FEB95	8, -49	0	92	50	88	92	54	84	120.00	
2	14FEB95	15, -42	0	90	60	80	90	62	80	119.00	
3	21FEB95	22, -35	0	90	68	80	90	68	80	117.50	
4	28FEB95	29, -28	0	96	64	84	92	64	84	118.00	
5	07MAR95	36, -21	0	88	56	80	70 L	58	84	117.70	
6	14MAR95	43, -14	0	110	64	84	106	64	82	120.00	
7	21MAR95	50, -7	0	110	70	100	102	70	100	120.50	
8	28MAR95	57, 1	0	104	64	74	94	60	74	120.20	
12	25APR95	85, 29	0	100	62	90	100	60	90	117.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	32.7	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	141	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	127	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03JAN95	1	09JAN95	7	7
00097	Oral	2	0 MG	10JAN95	8	17JAN95	15	8
00097	Oral	3	0 MG	18JAN95	16	24JAN95	22	7
00097	Oral	4	0 MG	25JAN95	23	31JAN95	29	7
00097	Oral	5	0 MG	01FEB95	30	06FEB95	35	6
00097	Oral	6	0 MG	07FEB95	36	13FEB95	42	7
00097	Oral	6	0 MG	14FEB95	43	20FEB95	49	7
00097	Oral	6	0 MG	21FEB95	50	01MAR95	58	9
00026	Oral	6	0 MG	02MAR95	59	29MAR95	86	28
00026	Oral	6	0 MG	30MAR95	87	26APR95	114	28
00026	Oral	6	0 MG	27APR95	115	22MAY95	140	26
00026	Oral	6	0 MG	23MAY95	141	28JUN95	177	37
00026	Oral	6	0 MG	29JUN95	178	01AUG95	211	34
00026	Oral	6	0 MG	02AUG95	212	04SEP95	245	34
00097	Oral	5	0 MG	05SEP95	246	06SEP95	247	2
00097	Oral	4	0 MG	07SEP95	248	08SEP95	249	2
00097	Oral	3	0 MG	09SEP95	250	10SEP95	251	2
00097	Oral	2	0 MG	11SEP95	252	13SEP95	254	3
00097	Oral	1	0 MG	14SEP95	255	20SEP95	261	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	261	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES,DAILY 2-3 TIMES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
UPPER RESPIRATORY INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1994

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-15, -73	19DEC94	26DEC94#	200MG PRN	UPPER RESPIRATORY INFECTION
			14, -45	16JAN95	17JAN95	325MG	FLU SYMPTOMS
			29, -30	31JAN95	07FEB95	650MG	HEADACHE
			87, 29	30MAR95	.	650PRN	HEADACHES
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-15, -73	19DEC94	26DEC94#	25MG PRN	UPPER RESPIRATORY INFECTION
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-15, -73	19DEC94	26DEC94#	25MG PRN	UPPER RESPIRATORY INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	80, 22	20 Mins	0	3	MIL	NO	PSR	No	No
	Infection	FLU SYMPTOMS	14, -45	3 Days	0	CON	MIL	NO	UNR	Yes	No
Carciovascular System	Vasodilatation	HOT FLASHES	23, -36	5 Mins	0	4	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS (WHEN STANDS QUICKLY)	80, 22	1 Mins	0	3	MIL	NO	PSR	No	No
Skin and Appendages	Sweating	SWEATY HANDS	15, -44	127 Days	0		MIL	NO	PBU	No	No
Special Senses	Abnormal Vision	BLURRING VISION	16, -43	126 Days	0	99	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20DEC94	-14, -72	0	104	64	83	100	64	89	122.00	60.0
1	10JAN95	8, -51	0	110	65	80	108	55	88	123.00	
2	18JAN95	16, -43	0	100	64	100	106	68	106	123.00	
3	24JAN95	22, -37	0	102	62	84	106	64	86	121.30	
4	31JAN95	29, -30	0	104	60	84	100	60	90	122.75	
5	07FEB95	36, -23	0	118	72	64	116	70	66	124.50	
6	14FEB95	43, -16	0	118	80	72	115	78	84	123.50	
7	21FEB95	50, -9	0	118	80	72	114	77	83	122.00	
8	02MAR95	59, 1	0	104	70	70	100	70	70	124.00	
12	30MAR95	87, 29	0	114	72	80	112	70	72	124.75	
16	27APR95	115, 57	0	104	66	67	106	66	76	126.50	
20	23MAY95	141, 83	0	114	70	78	114	70	98	126.25	
24	29JUN95	178, 120	0	110	68	76	106	64	78	128.00	
28	01AUG95	211, 153	0	110	70	90	108	66	96	133.00 H	
32	05SEP95	246, 188	0	100	68	74	92	66	70	131.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.7	.	.	.	30 - 70	%
				Lymphocytes	32.9	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	277000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	11.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5		.	.	30 - 70	%
				Lymphocytes	33.6		.	.	21 - 51	%
				Monocytes	3.7		.	.	0 - 10	%
				Eosinophils	3.3		.	.	0 - 5	%
				Basophils	1.8		.	.	0 - 2	%
				Platelets	294000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	80		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	178	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.7	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	304000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 14/CONTINUATION-WEEK 24	178	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	109	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	246	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	34.6	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	250000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	246	Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	107	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	03JAN95	1	09JAN95	7	7
00098	Oral	2	100 MG	10JAN95	8	17JAN95	15	8
00098	Oral	3	150 MG	18JAN95	16	23JAN95	21	6
00098	Oral	4	200 MG	24JAN95	22	30JAN95	28	7
00098	Oral	5	250 MG	31JAN95	29	06FEB95	35	7
00098	Oral	6	300 MG	07FEB95	36	13FEB95	42	7
00098	Oral	5	250 MG	14FEB95	43	20FEB95	49	7
00098	Oral	5	250 MG	21FEB95	50	22FEB95	51	2
00098	Oral	4	200 MG	23FEB95	52	01MAR95	58	7
	Oral	5	250 MG	02MAR95	59	16MAR95	73	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	73	250	Lack of Efficacy	NOT RESPONDING TO TREATMENT AND DISCOMFORT DUE TO POSSIBLE SIDE EFFECTS.

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	50,	.	9 Days	250	CON	MOD	DCR	PSR	No	No
Digestive System	Constipation	CONSTIPATION	59,	.	Not Stated	250	CON	MIL	DCR	PSR	No	No
	Dry Mouth	DRY MOUTH	8,	.	Not Stated	100	CON	MOD	DCR	PSR	No	No
Nervous System	Tremor	SHAKING	43,	.	Not Stated	250	CON	MOD	DCR	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20DEC94	-14,	.	0	98	58	88	96	58	92	127.50	61.0
BL	03JAN95	1,	.	0	98	58	88	96	58	92	127.50	
1	10JAN95	8,	.	100	100	58	84	95	60	104	127.00	
2	18JAN95	16,	.	150	118	68	84	110	68	88	126.00	
3	24JAN95	22,	.	200	108	66	84	100	64	86	126.00	
4	31JAN95	29,	.	250	110	72	100	106	72	104	127.50	
5	07FEB95	36,	.	300	116	78	74	106	74	80	128.00	
6	14FEB95	43,	.	250	118	78	108	116	78	112	127.00	
7	21FEB95	50,	.	250	118	70	70	120	72	76	127.00	
8	02MAR95	59,	.	250	102	64	100	102	68	100	127.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	27.9	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.2	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	02MAR95	1	06MAR95	5	5
00099	Oral	2	20 MG	07MAR95	6	13MAR95	12	7
00099	Oral	3	20 MG	14MAR95	13	20MAR95	19	7
00099	Oral	4	20 MG	21MAR95	20	27MAR95	26	7
00099	Oral	4	20 MG	28MAR95	27	03APR95	33	7
00099	Oral	5	30 MG	04APR95	34	11APR95	41	8
00099	Oral	6	40 MG	12APR95	42	18APR95	48	7
00099	Oral	6	40 MG	19APR95	49	25APR95	55	7
00025	Oral	6	40 MG	26APR95	56	22MAY95	82	27
00025	Oral	6	40 MG	23MAY95	83	26JUN95	117	35
00025	Oral	6	40 MG	27JUN95	118	31JUL95	152	35
00025	Oral	6	40 MG	01AUG95	153	30AUG95	182	30
00025	Oral	6	40 MG	31AUG95	183	27SEP95	210	28
00025	Oral	6	40 MG	28SEP95	211	26OCT95	239	29
00099	Oral	5	30 MG	27OCT95	240	28OCT95	241	2
00099	Oral	4	20 MG	29OCT95	242	30OCT95	243	2
00099	Oral	3	20 MG	31OCT95	244	01NOV95	245	2
00099	Oral	2	20 MG	02NOV95	246	04NOV95	248	3
00099	Oral	1	20 MG	05NOV95	249	11NOV95	255	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	Yes	255	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	33, -23	03APR95	03APR95	325MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	34, -22	04APR95	11APR95	100 MG	SEASONAL ALLERGIES
RESPIRATORY	Aminoacetic Acid	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
	Benzalkonium Chloride	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
	Dextromethorphan Hydrobromide	Nyquil	18, -38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
	Diphenhydramine Hydrochloride	Benadryl	34, -22	04APR95	11APR95	100 MG	SEASONAL ALLERGIES
	Doxylamine Succinate	Nyquil	18, -38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
	Oxymetazoline Hydrochloride	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
	Paracetamol	Nyquil	18, -38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
	Phenylmercuric Acetate	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
	Pseudoephedrine Hydrochloride	Nyquil	18, -38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
		Sudafed	28, -28	29MAR95	29MAR95	60MG	STUFFY NOSE
	Sorbitol	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	33, -23	02:00 Hrs	20	CON	MIL	NO	PSR	Yes	No
Carciovascular System	Palpitation	HEART PALPITATIONS	121, 66	63 Days	40	3	MOD	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	48, -8	7 Days	40	21	MIL	NO	PSR	No	No
		NAUSEA (FOR 10 MINUTES DAILY BEFORE BREAKFAST)	121, 66	63 Days	40	25	MIL	NO	PSR	No	No
		NAUSEATED	3, -53	11 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Amnesia	"FORGETFUL"	121, 66	63 Days	40	3	MIL	NO	PBU	No	No
	Dizziness	CONSTANT DIZZINESS (DAILY)	119, 64	93 Days	40	CON	MOD	NO	PSR	No	No
		DIZZINESS ARISING FROM LAYING SITTING OR SOMETIMES WHEN SITTING	27, -29	28 Days	20	78	MOD	NO	PSR	No	No
		DIZZINESS WHEN ARISING SUDDENLY	13, -43	11 Days	20	33	MOD	NO	PSR	No	No
		DIZZY	3, -53	30 Mins	20	CON	MIL	NO	PSR	No	No
	Insomnia	INITIAL INSOMNIA (INCREASE 2 HOURS)	84, 29	02:00 Hrs	40	39	SEV	NO	PBU	No	No
		INITIAL INSOMNIA MOST NIGHTS INCREASE 2 HOURS	104, 49	33 Days	40	10	MOD	NO	PSR	No	No
		RESTLESS AT NIGHT	4, -52	10 Days	20	2	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	HEAD COLD	15, -41	6 Days	20	CON	MIL	NO	UNR	Yes	No
	Rhinitis	STUFFY NOSE	28, -28	16:00 Hrs	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	23FEB95	-7, -62	0	110	68	70	108	68	80	192.25	67.0
1	07MAR95	6, -50	20	122	70	70	118	70	90	190.50	
2	14MAR95	13, -43	20	102	64	64	106	64	60	189.00	
3	21MAR95	20, -36	20	110	70	80	106	70	80	189.25	
4	28MAR95	27, -29	20	110	70	64	108	70	64	189.50	
5	04APR95	34, -22	30	94	66	76	90	68	80	190.00	
6	11APR95	41, -15	30	108	70	66	104	70	64	188.50	
7	18APR95	48, -8	40	90	60	90	90	60	95	188.25	
8	25APR95	55, -1	40	98	60	80	92	60	80	188.75	
12	23MAY95	83, 28	40	96	60	88	96	60	82	192.00	
16	27JUN95	118, 63	40	108	60	100	102	56	100	196.00	
20	01AUG95	153, 98	40	102	68	87	104	70	80	200.00	
24	31AUG95	183, 128	40	90	58	68	94	62	92	203.00	
28	28SEP95	211, 156	40	112	70	66	110	72	68	208.00 H	
32	26OCT95	239, 184	40	108	70	79	110	72	78	207.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.8	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	30.5	.	.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	80	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1.4	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	15.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	46.3		.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1		.	.	30 - 70	%
				Lymphocytes	33.9		.	.	21 - 51	%
				Monocytes	9.9		.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	295000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	83		.	.	80 - 100	FL
				Blood Urea Nitrogen	17		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.6		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	76		.	.	44 - 400	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	16	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6	.	.	.	30 - 70	%
				Lymphocytes	32.1	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	153	Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	239	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	1	L	.	.	4 - 12	%
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	22	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 16/CONTINUATION-WEEK 32	239	Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	07MAR95	1	13MAR95	7	7
00100	Oral	2	100 MG	14MAR95	8	20MAR95	14	7
00100	Oral	3	150 MG	21MAR95	15	27MAR95	21	7
00100	Oral	4	200 MG	28MAR95	22	03APR95	28	7
00100	Oral	4	200 MG	04APR95	29	10APR95	35	7
00100	Oral	5	250 MG	11APR95	36	17APR95	42	7
00100	Oral	5	250 MG	18APR95	43	24APR95	49	7
00100	Oral	5	250 MG	25APR95	50	03MAY95	58	9
00069	Oral	5	250 MG	04MAY95	59	29MAY95	84	26
00069	Oral	5	250 MG	30MAY95	85	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	85	250	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DEPRESSION	DEPRESSION	MENTAL DISORD	CUR	1995
HAND TREMOR	TREMOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
SWEATING AT BROW	HYPERHIDROSIS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-34, -92	01FEB95	01MAR95#	PRN 650MG	HEADACHE
			41, -18	16APR95	30MAY95	325MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	-34, -92	01FEB95	01MAR95#	400MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	39, -20	10 Mins	250	12	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS"OFF AND ON"	39, -20	15 Mins	250	15	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	07MAR95	1, -58	0	130	70	96	132	70	98	144.00	
1	14MAR95	8, -51	100	116	70	78	112	70	90	145.00	
2	21MAR95	15, -44	150	120	80	90	118	80	96	148.00	
3	28MAR95	22, -37	200	120	80	80	114	80	80	146.25	
4	04APR95	29, -30	200	116	78	110	120	78	112	147.25	
5	11APR95	36, -23	250	110	80	84	114	80	86	145.25	
6	18APR95	43, -16	250	118	80	100	112	80	114	147.75	
7	25APR95	50, -9	250	110	62	98	108	62	100	147.50	
8	04MAY95	59, 1	250	108	78	90	100	76	98	148.75	
12	30MAY95	85, 27	250	126	80	100	108	80	112	146.50	
16	27JUN95	113, 55#	0	112	80	100	118	80	116	145.25	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.5	.	.	.	30 - 70	%
				Lymphocytes	23.3	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	156000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	115	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	16.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.1	.	.	.	30 - 70	%
				Lymphocytes	23.9	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	175000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28MAR95	1	03APR95	7	7
00101	Oral	2	0 MG	04APR95	8	12APR95	16	9
00101	Oral	3	0 MG	13APR95	17	19APR95	23	7
00101	Oral	4	0 MG	20APR95	24	26APR95	30	7
00101	Oral	5	0 MG	27APR95	31	03MAY95	37	7
00101	Oral	6	0 MG	04MAY95	38	10MAY95	44	7
00101	Oral	6	0 MG	11MAY95	45	17MAY95	51	7
00101	Oral	6	0 MG	18MAY95	52	24MAY95	58	7
00066	Oral	6	0 MG	25MAY95	59	21JUN95	86	28
	Oral	6	0 MG	22JUN95	87	26JUN95	91	5
00101	Oral	5	0 MG	27JUN95	92	27JUN95	92	1
00101	Oral	4	0 MG	28JUN95	93	29JUN95	94	2
00101	Oral	3	0 MG	30JUN95	95	01JUL95	96	2
00101	Oral	2	0 MG	02JUL95	97	04JUL95	99	3
00101	Oral	1	0 MG	05JUL95	100	11JUL95	106	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	106	0	Protocol violation, including non-compliance	MARIJUANA USE WITH POSITIVE URINE SCREEN, SEE LAB PG. ON WEEK 12 AND SEE A.E. PG. 408.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HISTORY OF APNEA AND RESUSCITATION IN FIRST YEAR OF LIFE(SIDS)	SUDDEN INFANT DEATH SYNDROME	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1979

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Drug Dependence	POSITIVE MARIJUANA URINE SCREEN (PROTOCOL DEVIATION)	87, 29	1 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	20MAR95	-8, -66	0	.	.	.	.	.	.		68.0
BL	28MAR95	1, -58	0	116	78	84	114	78	80	147.00	
1	04APR95	8, -51	0	124	76	100	122	72	88	149.00	
2	13APR95	17, -42	0	122	78	84	124	80	96	147.00	
3	20APR95	24, -35	0	122	70	68	120	72	66	150.20	
4	27APR95	31, -28	0	110	80	64	102	80	68	150.50	
5	04MAY95	38, -21	0	122	70	86	110	70	100	152.70	
6	11MAY95	45, -14	0	122	68	60	118	66	88	149.00	
7	18MAY95	52, -7	0	102	64	60	100	60	68	150.00	
8	25MAY95	59, 1	0	98	72	64	90	68	61	150.00	
12	22JUN95	87, 29	0	108	60	88	102	60	88	145.20	
12	27JUN95	92, 34	0	108	66	88	102	60	88	145.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.4	.	.	.	30 - 70	%
				Lymphocytes	44.7	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	258000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	108	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	31	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.9		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.9		.	.	30 - 70	%
				Lymphocytes	41.3		.	.	21 - 51	%
				Monocytes	7.6		.	.	0 - 10	%
				Eosinophils	2.7		.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Basophils	0.5	.	.	.	0 - 2	%
				Platelets	203000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	96	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Amphetamines	NEG			.		
				Urine Barbiturates	NEG			.		
				Urine Benzodiazepines	NEG			.		
				Urine Cannabinoids	NEG			.		
				Urine Cocaine	NEG			.		
				Urine Methadone	NEG			.		
				Urine Methaqualone	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	87	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 12/CONTINUATION-WEEK 16	92	Hemoglobin	14.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	43		.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H	.	.	30 - 70	%
				Lymphocytes	15.5	L	.	.	21 - 51	%
				Monocytes	7.7		.	.	0 - 10	%
				Eosinophils	3.1		.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	188000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5		.	.	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 12/CONTINUATION-WEEK 16	92	Alkaline Phosphatase	91	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	13APR95	1	17APR95	5	5
00102	Oral	2	20 MG	18APR95	6	24APR95	12	7
00102	Oral	3	20 MG	25APR95	13	01MAY95	19	7
00102	Oral	4	20 MG	02MAY95	20	08MAY95	26	7
00102	Oral	5	30 MG	09MAY95	27	15MAY95	33	7
00102	Oral	6	40 MG	16MAY95	34	22MAY95	40	7
00102	Oral	6	40 MG	23MAY95	41	29MAY95	47	7
00102	Oral	6	40 MG	30MAY95	48	05JUN95	54	7
00071	Oral	6	40 MG	06JUN95	55	12JUL95	91	37
00071	Oral	6	40 MG	13JUL95	92	09AUG95	119	28
00071	Oral	6	40 MG	10AUG95	120	11SEP95	152	33
00071	Oral	6	40 MG	12SEP95	153	09OCT95	180	28
00071	Oral	6	40 MG	10OCT95	181	08NOV95	210	30
00071	Oral	6	40 MG	09NOV95	211	04DEC95	236	26
00102	Oral	5	30 MG	05DEC95	237	06DEC95	238	2
00102	Oral	4	20 MG	07DEC95	239	08DEC95	240	2
00102	Oral	3	20 MG	09DEC95	241	12DEC95	244	4
00102	Oral	2	20 MG	13DEC95	245	16DEC95	248	4
00102	Oral	1	20 MG	17DEC95	249	20DEC95	252	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	252	20		

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES	146, 92	36 Days	40	1	MOD	NO	REL	No	No
	Trauma	MOTOR VEHICLE ACCIDENT	112, 58	1 Days	40	1	MIL	NO	UNR	No	No
Digestive System	Dyspepsia	HEARTBURN ON AN EMPTY STOMACH WHEN TAKING MEDS.	27, -28	7 Days	30	7	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	146, 92	36 Days	40	1	MOD	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	13APR95	1, -54	0	88	70	80	92	70	84	102.50	60.0
1	18APR95	6, -49	20	90	50	92	98	58	95	100.50	
2	25APR95	13, -42	20	88	60	62	92	60	70	101.00	
3	02MAY95	20, -35	20	102	70	88	98	68	86	100.00	
4	09MAY95	27, -28	30	98	60	88	92	60	84	103.50	
5	16MAY95	34, -21	40	94	60	92	98	60	80	102.50	
6	23MAY95	41, -14	40	92	60	110	96	60	120	101.70	
7	30MAY95	48, -7	40	90	58	86	88	56	90	103.00	
8	06JUN95	55, 1	40	90	60	100	92	60	90	104.20	
12	13JUL95	92, 38	40	110	60	86	106	64	100	103.50	
16	10AUG95	120, 66	40	90	64	84	84	60	88	104.00	
20	12SEP95	153, 99	40	84	60	80	86	62	74	105.50	
24	10OCT95	181, 127	40	80	64	80	84	64	80	107.50	
28	09NOV95	211, 157	40	92	60	100	88	60	92	109.50	
32	05DEC95	237, 183	30	84	62	80	80	60	86	108.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	389000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.9		.	.	12 - 15.6	G/DL
				Hematocrit	36.6		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37.9		.	.	30 - 70	%
				Lymphocytes	44.1		.	.	21 - 51	%
				Monocytes	10.7	H	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	323000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73		.	.	22 - 130	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.3	.	.	.	30 - 70	%
				Lymphocytes	31.7	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	7.1	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	380000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	153	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF NEG			.	.		
				Urine Protein - Dipstick NEG			.	.		
		VISIT 16/CONTINUATION-WEEK 32	237	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5	.	.	.	30 - 70	%
				Lymphocytes	32.9	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	361000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	237	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	20APR95	1	26APR95	7	7
00103	Oral	2	100 MG	27APR95	8	01MAY95	12	5
00103	Oral	3	150 MG	02MAY95	13	08MAY95	19	7
00103	Oral	4	200 MG	09MAY95	20	15MAY95	26	7
00103	Oral	4	200 MG	16MAY95	27	24MAY95	35	9
00103	Oral	4	200 MG	25MAY95	36	29MAY95	40	5
00103	Oral	5	250 MG	30MAY95	41	05JUN95	47	7
00103	Oral	5	250 MG	06JUN95	48	14JUN95	56	9
00072	Oral	5	250 MG	15JUN95	57	12JUL95	84	28
00072	Oral	5	250 MG	13JUL95	85	09AUG95	112	28
00103	Oral	5	250 MG	10AUG95	113	11AUG95	114	2
00103	Oral	4	200 MG	12AUG95	115	13AUG95	116	2
00103	Oral	3	150 MG	14AUG95	117	15AUG95	118	2
00103	Oral	2	100 MG	16AUG95	119	18AUG95	121	3
00103	Oral	1	50 MG	19AUG95	122	25AUG95	128	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	128	50	Lack of Efficacy	RELAPSE OF DEPRESSED SYMPTOMS AND SUICIDAL IDEATION.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES(DAILY)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	4, -53	23APR95	23APR95	200MG	HEADACHE
			7, -50	26APR95	26APR95	200MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
		STOMACH ACHE FOLLOWING INGESTION OF MEDS	2, -55	21 Days	50	14	MIL	NO	PSR	No	No
		STOMACH ACHE FOLLOWING INGESTION OF STUDY MEDS	62, 6	52 Days	250	2	MIL	NO	PSR	No	No
	Chills	CHILLS / GOOSE BUMPS WHILE EXERCISING (1X)	19, -38	2 Mins	150	CON	MIL	NO	PSR	No	No
		FEELING HOT/COLD	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
		DIZZINESS (WHEN GOING FROM SIT TO STAND)	113, 57	16 Days	250		MIL	NO	PSR	No	No
Skin and Appendages	Rash	RED SPOTS / BLOTCHES ON SKIN ARMS, THROAT, CHEST	22, -35	35 Days	200		MIL	NO	PSR	No	No
Special Senses	Abnormal Vision	BLURRED VISION WHEN STANDS QUICKLY	50, -7	36 Days	250	10	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	11APR95	-9, -65	0	110	64	65	110	64	66	116.50	60.0
BL	20APR95	1, -56	0	94	62	68	90	62	68	115.00	
1	27APR95	8, -49	100	92	62	70	90	60	68	114.00	
2	02MAY95	13, -44	150	100	70	70	100	70	72	117.25	
3	09MAY95	20, -37	200	102	70	100	102	70	92	114.25	
4	16MAY95	27, -30	200	112	80	80	112	76	80	116.50	
5	25MAY95	36, -21	200	98	68	60	90	64	74	115.00	
6	30MAY95	41, -16	250	102	70	80	98	70	100	115.00	
7	06JUN95	48, -9	250	100	66	88	96	60	84	111.25	
8	15JUN95	57, 1	250	94	68	72	80	64	70	110.50	
12	13JUL95	85, 29	250	102	70	88	96	68	80	112.00	
16	10AUG95	113, 57	250	100	68	90	100	64	84	114.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.6	.	.	.	30 - 70	%
				Lymphocytes	22.2	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	319000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9		.	.	12 - 15.6	G/DL
				Hematocrit	37.4		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	82	H	.	.	30 - 70	%
				Lymphocytes	15	L	.	.	21 - 51	%
				Monocytes	3		.	.	0 - 10	%
				Eosinophils	0		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	331000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93		.	.	44 - 280	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	12		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	04MAY95	1	10MAY95	7	7
00104	Oral	2	100 MG	11MAY95	8	17MAY95	14	7
00104	Oral	3	150 MG	18MAY95	15	24MAY95	21	7
00104	Oral	4	200 MG	25MAY95	22	31MAY95	28	7
00104	Oral	5	250 MG	01JUN95	29	08JUN95	36	8
00104	Oral	6	300 MG	09JUN95	37	15JUN95	43	7
00104	Oral	6	300 MG	16JUN95	44	21JUN95	49	6
00104	Oral	6	300 MG	22JUN95	50	28JUN95	56	7
00027	Oral	6	300 MG	29JUN95	57	24JUL95	82	26
00027	Oral	6	300 MG	25JUL95	83	28AUG95	117	35
00027	Oral	6	300 MG	29AUG95	118	02OCT95	152	35
00027	Oral	6	300 MG	03OCT95	153	05NOV95	186	34
00027	Oral	6	300 MC	06NOV95	187	05DEC95	216	30
00027	Oral	6	300 MG	06DEC95	217	01JAN96	243	27
00104	Oral	5	250 MG	02JAN96	244	03JAN96	245	2
00104	Oral	4	200 MG	04JAN96	246	05JAN96	247	2
00104	Oral	3	150 MG	06JAN96	248	07JAN96	249	2
00104	Oral	2	100 MG	08JAN96	250	10JAN96	252	3
00104	Oral	1	50 MG	11JAN96	253	17JAN96	259	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	Yes	259	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	232, 176	21DEC95	31DEC95	1500 MG	STREP THROAT
	Minocycline	Monocycline	-123, -179	01JAN95	.	150 MGS	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT	232, 176	11 Days	300	1	MOD	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	8, -49	76 Days	100	CON	MOD	NO	REL	No	No
	Vomiting	NAUSEA AND VOMITING DURING DOWN TITRATION	252, 196	6 Days	100	1	MOD	NO	PSR	No	No
		VOMITING WHEN FORGOT DOSE	83, 27	1 Days	300	1	MOD	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	21, -36	133 Days	150	CON	MIL	NO	REL	No	No
Urogenital System	Urination Impaired	DIFFICULTY INITIATING URINATION	1, -56	8 Days	50	2	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	28APR95	-6, -62	0	100	60	94	98	58	90	128.50	67.0
1	11MAY95	8, -49	100	120	68	80	118	66	84	127.70	
2	18MAY95	15, -42	150	106	74	76	100	70	80	130.50	
3	25MAY95	22, -35	200	110	76	81	100	70	74	130.00	
4	01JUN95	29, -28	250	122	80	92	120	72	100	126.00	
5	09JUN95	37, -20	300	90	60	88	102	64	80	128.00	
6	16JUN95	44, -13	300	90	66	80	82	64	74	129.00	
7	22JUN95	50, -7	300	88	60	90	80	60	100	128.20	
8	29JUN95	57, 1	300	122	76	100	100	70	68	130.00	
12	25JUL95	83, 27	300	110	70	109	90	64	94	130.00	
16	29AUG95	118, 62	300	102	76	90	96	60	130 H	128.00	
20	03OCT95	153, 97	300	94	68	84	80	68	78	131.00	
28	06NOV95	187, 131	300	108	70	106	112	72	80	129.50	
32	06DEC95	217, 161	300	120	72	100	110	74	84	130.50	
32	02JAN96	244, 188	250	110	60	100	108	60	92	127.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8		.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58		.	.	30 - 70	%
				Lymphocytes	29.4		.	.	21 - 51	%
				Monocytes	9.4		.	.	0 - 10	%
				Eosinophils	2.7		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	329000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	401	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	101		.	.	70 - 115	MG/DL
				Globulin	2.8		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.3		.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.6		.	.	30 - 70	%
				Lymphocytes	35.1		.	.	21 - 51	%
				Monocytes	9.7		.	.	0 - 10	%
				Eosinophils	2.6		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	302000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	348		.	.	44 - 400	U/L
				Aspartate Aminotransferase	24		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.5	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	334000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	272	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	153	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	244	Hemoglobin	14		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3		.	.	41 - 50	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	15.1	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	82.2	H	.	.	30 - 70	%
				Lymphocytes	10.8	L	.	.	21 - 51	%
				Monocytes	3.6		.	.	0 - 10	%
				Eosinophils	3		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	476000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	92		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153		.	.	44 - 400	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	24		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	101		.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 16/CONTINUATION-WEEK 32	244	Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	WHITE/HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	27JUL95	1	02AUG95	7	7
00105	Oral	2	20 MG	03AUG95	8	09AUG95	14	7
00105	Oral	3	20 MG	10AUG95	15	16AUG95	21	7
00105	Oral	4	20 MG	17AUG95	22	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	No	No	22	20	Protocol violation, including non-compliance	PATIENT RAN AWAY FROM HOME WITHOUT MEDS. WAS OFF MEDS SEVERAL DAYS BEFORE HE RETURNED HOME. UNABLE TO REACH FAMILY TO RETRIEVE MED PAK/DO WK. 32 VISIT. SEE PROGRESS NOTE FROM WEEK 4

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES{CATS,POLLEN}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1990
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
HEARTBURN	HEARTBURN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	16, .	11AUG95	24AUG95	650 MG	HEADACHE
	Paracetamol	Tylenol	1, .	27JUL95	03AUG95	1950 MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-329, .	01SEP94	.	2 TBSP PRN	ALLERGIES
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-329, .	01SEP94	.	2 TBSP PRN	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Diarrhea	DIARRHEA	8, .	8 Days	20	4	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	27JUL95	1, .	0	110	78	62	112	80	84	162.00	69.3
1	03AUG95	8, .	20	132	70	100	138	78	108	162.50	
2	10AUG95	15, .	20	122	74	88	112	70	80	161.00	
3	17AUG95	22, .	20	120	74	80	130	80	82	158.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.4		.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3		.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9		.	.	30 - 70	%
				Lymphocytes	27.8		.	.	21 - 51	%
				Monocytes	8.3		.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	189000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	92		.	.	80 - 100	FL
				Blood Urea Nitrogen	19		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	93		.	.	22 - 180	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	15		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.7		.	.	3.1 - 5.3	G/DL
				Glucose - Random	97		.	.	70 - 115	MG/DL
				Globulin	3.1		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	27JUL95	1	02AUG95	7	7
00106	Oral	2	20 MG	03AUG95	8	07AUG95	12	5
00106	Oral	3	20 MG	08AUG95	13	16AUG95	21	9
00106	Oral	4	20 MG	17AUG95	22	23AUG95	28	7
00106	Oral	4	20 MG	24AUG95	29	30AUG95	35	7
	Oral	5	30 MG	31AUG95	36	04SEP95	40	5
00106	Oral	6	40 MG	05SEP95	41	11SEP95	47	7
00106	Oral	6	40 MG	12SEP95	48	12SEP95	48	1

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	48	40	Other reason	PT D/C ON OWN -- OPPOSITIONAL DEFIANT DISORDER

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Action	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES	8, .	10 Mins	20	10	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	8, .	03:00 Hrs	20	CON	MIL	NO	REL	No	No
Nervous System	Hostility	OPPOSITIONAL DEFIANT DISORDER	51, .	16 Days	40	CON	SEV	NO	PBU	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	27JUL95	1, .	0	86	68	72	84	62	90	148.00	68.0
1	03AUG95	8, .	20	110	60	80	106	60	84	149.50	
2	08AUG95	13, .	20	102	60	96	102	68	100	154.00	
3	17AUG95	22, .	20	80	60	68	78	58	75	152.00	
4	24AUG95	29, .	20	100	64	70	100	60	68	152.00	
5	31AUG95	36, .	30	98	70	66	100	64	74	153.00	
6	05SEP95	41, .	40	98	68	64	96	70	78	153.00	
7	12SEP95	48, .	40	90	64	80	86	64	72	153.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.4	.	.	.	30 - 70	%
				Lymphocytes	26.9	.	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	25JAN96	1	31JAN96	7	7
00107	Oral	2	0 MG	01FEB96	8	07FEB96	14	7
00107	Oral	3	0 MG	08FEB96	15	12FEB96	19	5
00107	Oral	4	0 MG	13FEB96	20	19FEB96	26	7
00107	Oral	4	0 MG	20FEB96	27	26FEB96	33	7
00107	Oral	4	0 MG	27FEB96	34	04MAR96	40	7
00107	Oral	5	0 MG	05MAR96	41	14MAR96	50	10
00107	Oral	6	0 MG	15MAR96	51	20MAR96	56	6
00176	Oral	6	0 MG	21MAR96	57	22APR96	89	33
00176	Oral	6	0 MG	23APR96	90	20MAY96	117	28
00176	Oral	6	0 MG	21MAY96	118	19JUN96	147	30
00176	Oral	6	0 MG	20JUN96	148	24JUL96	182	35
00176	Oral	6	0 MG	25JUL96	183	28AUG96	217	35
00176	Oral	6	0 MG	29AUG96	218	25SEP96	245	28
00176	Oral	5	0 MG	26SEP96	246	08OCT96	258	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	Yes	258	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EPIGASTRIC DISTRESS	DYSPEPSIA	DIGESTIVE SYST	CUR	1995
FAINTING{OCCASIONAL}	SYNCOPE AND COLLAPSE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MISSED MENSES	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	236, 180	16SEP96	26SEP96	1500 MG	STREP THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT	236, 180	46 Days	0	CON	MOD	NO	UNR	Yes	No
Hemic and Lymphatic System	Wbc Abnormality	ELEVATED ATYPICAL LYMPHS	236, 180	46 Days	0	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS (WHEN STANDING)	214, 158	Not Stated	0	CON	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	TONSILLITIS	236, 180	46 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JAN96	-7, -63	0	112	74	70	110	72	68	167.00	65.0
1	01FEB96	8, -49	0	108	78	66	106	76	60	172.00	
2	08FEB96	15, -42	0	110	76	64	106	72	62	174.00	
3	13FEB96	20, -37	0	108	74	64	110	76	80	173.00	
4	20FEB96	27, -30	0	110	68	68	104	70	62	174.50	
5	27FEB96	34, -23	0	106	70	66	100	66	62	174.00	
6	05MAR96	41, -16	0	114	74	70	110	72	68	179.00 H	
7	15MAR96	51, -6	0	106	72	64	104	70	64	179.50 H	
8	21MAR96	57, 1	0	94	72	70	92	68	92	178.00	
12	23APR96	90, 34	0	104	68	60	110	76	64	178.00	
16	21MAY96	118, 62	0	106	64	64	100	68	78	177.00	
20	20JUN96	148, 92	0	110	62	48	104	64	70	167.00	
24	18JUL96	176, 120	0	110	62	60	100	60	62	162.00	
32	29AUG96	218, 162	0	108	64	62	104	64	70	157.00	
32	26SEP96	246, 190	0	100	62	60	94	60	78	156.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67	.	.	.	30 - 70	%
				Lymphocytes	24.9	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.6	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.6	.	.	.	30 - 70	%
				Lymphocytes	35.6	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	148	Uric Acid	5.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		
		VISIT 16/CONTINUATION-WEEK 32	246	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/CONTINUATION-WEEK 32	246	Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	167	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	58	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	101	H	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	PORTUGUESE

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	06FEB96	1	12FEB96	7	7
00241	Oral	2	0 MG	13FEB96	8	21FEB96	16	9
00241	Oral	3	0 MG	22FEB96	17	26FEB96	21	5
00241	Oral	4	0 MG	27FEB96	22	04MAR96	28	7
00241	Oral	4	0 MG	05MAR96	29	11MAR96	35	7
00241	Oral	5	0 MG	12MAR96	36	18MAR96	42	7
00241	Oral	5	0 MG	19MAR96	43	25MAR96	49	7
00241	Oral	6	0 MG	26MAR96	50	01APR96	56	7
00145	Oral	6	0 MG	02APR96	57	30APR96	85	29
00145	Oral	6	0 MG	01MAY96	86	23MAY96	108	23

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	108	0	Adverse event, including intercurrent illness	PT HOSPITALIZED DUE TO HOMICIDAL / SUICIDAL IDEATION

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES {TO PENICILLIN}	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	1991
ALLERGIES {TO POLLEN, POULTRY DUST}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1991
NASAL CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1996
SINUS RHYTHM ALTERNATING WITH ECTOPIC ATRIAL RHYTHM	EXTRASYSTOLES, ATRIAL	CIRCULATORY SYST	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Fluoxetine	Prozac	108, 52	23MAY96	.	10 MG	DEPRESSION
RESPIRATORY	Chlorphenamine Maleate	Dristan	-36, -92	01JAN96	25JAN96#	2 SPRAYS	NASAL CONGESTION
	Cough Syrup/Med	Cough Medicine	64, 8	09APR96	30APR96	18 TBSP	COUGH
	Paracetamol	Dristan	-36, -92	01JAN96	25JAN96#	2 SPRAYS	NASAL CONGESTION
	Phenylephrine Hydrochloride	Dristan	-36, -92	01JAN96	25JAN96#	2 SPRAYS	NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Vomiting	NAUSEA AND VOMITING	27, -30	3 Days	0	2	MIL	NO	PBU	No	No
Nervous System	Emotional Lability	PT. HOSPITALIZED FOR SUICIDAL IDEATION	108, 52	Not Stated	0	CON	SEV	STP	PBU	Yes	Yes
	Hostility	PT. HOSPITALIZED FOR HOMICIDAL IDEATION	108, 52	Not Stated	0	CON	SEV	STP	PBU	No	Yes
Respiratory System	Cough Increased	COUGH	64, 8	22 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25JAN96	-12, -68	0	110	70	66	106	70	80	202.00	69.0
BL	06FEB96	1, -56	0	110	72	64	110	70	80	202.00	
1	13FEB96	8, -49	0	108	60	60	110	70	70	205.00	
2	22FEB96	17, -40	0	110	60	62	108	60	66	205.00	
3	27FEB96	22, -35	0	112	78	64	106	74	72	202.00	
4	05MAR96	29, -28	0	110	70	62	104	68	60	205.00	
5	12MAR96	36, -21	0	120	68	60	114	70	58	205.00	
6	19MAR96	43, -14	0	120	64	64	112	60	68	205.00	
7	26MAR96	50, -7	0	122	70	70	120	72	62	204.00	
8	02APR96	57, 1	0	110	64	64	108	68	72	199.00	
12	30APR96	85, 29	0	106	60	60	100	62	61	207.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	15.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	45.6		.	.	41 - 50	%
				Red Blood Cell Count	5.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7		.	.	30 - 70	%
				Lymphocytes	27.1		.	.	21 - 51	%
				Monocytes	8.4		.	.	0 - 10	%
				Eosinophils	6.6	H	.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	285000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1.2		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117		.	.	44 - 400	U/L
				Aspartate Aminotransferase	25		.	.	0 - 41	U/L
				Alanine Aminotransferase	26		.	.	0 - 48	U/L
				Total Bilirubin	1.1		.	.	0.3 - 1.3	MG/DL
				Total Protein	8		.	.	6.2 - 8.8	G/DL
				Albumin	5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	74		.	.	70 - 115	MG/DL
				Globulin	3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	44.3		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.5		.	.	30 - 70	%
				Lymphocytes	27.6		.	.	21 - 51	%
				Monocytes	7.6		.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Basophils	0.8	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	115	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	30	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07FEB96	1	14FEB96	8	8
00242	Oral	2	20 MG	15FEB96	9	21FEB96	15	7
00242	Oral	3	20 MG	22FEB96	16	28FEB96	22	7
00242	Oral	4	20 MG	29FEB96	23	05MAR96	28	6
00242	Oral	5	30 MG	06MAR96	29	13MAR96	36	8
00242	Oral	5	30 MG	14MAR96	37	20MAR96	43	7
00242	Oral	6	40 MG	21MAR96	44	28MAR96	51	8
00242	Oral	6	40 MG	29MAR96	52	04APR96	58	7
	Oral	6	40 MG	05APR96	59	07MAY96	91	33
00136	Oral	6	40 MG	08MAY96	92	05JUN96	120	29
00242	Oral	.		06JUN96	121	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	120	40	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {RECURRENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-6, -64	01FEB96	01FEB96#	650 MC	HEADACHE
	Paracetamol	Tylenol	42, -17	19MAR96	19MAR96	650 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Somnolence	MILD SEDATION	30, -29	8 Days	30	1	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26JAN96	-12, -70	0	130	80	92	120	70	88	166.48	65.0
1	14FEB96	8, -51	20	100	70	88	105	65	92	162.07	
2	21FEB96	15, -44	20	110	70	92	115	75	100	158.76	
3	29FEB96	23, -36	20	110	70	96	115	75	100	161.41	
4	06MAR96	29, -30	30	110	70	96	115	75	100	159.86	
5	14MAR96	37, -22	30	105	70	76	110	80	80	156.56	
6	20MAR96	43, -16	30	110	75	84	110	80	108	158.76	
7	28MAR96	51, -8	40	110	70	88	120	80	100	159.86	
8	05APR96	59, 1	40	110	70	88	120	80	100	159.86	
12	08MAY96	92, 34	40	125	80	80	125	85	96	161.41	
16	05JUN96	120, 62	40	125	80	80	125	85	92	161.63	
20	10JUL96	155, 97#	0	116	62	77	108	58	79	159.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	389000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.2		.	.	12 - 15.6	G/DL
				Hematocrit	40.2		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.8		.	.	30 - 70	%
				Lymphocytes	29.6		.	.	21 - 51	%
				Monocytes	7		.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	1.2		.	.	0 - 2	%
				Platelets	391000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	59		Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	84	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
		VISIT 17/DOWN TITRATION	155	(35)	Hemoglobin	14.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	42.8	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	60	.	.	.	30 - 70	%
					Lymphocytes	26.6	.	.	.	21 - 51	%
					Monocytes	8.1	.	.	.	0 - 10	%
					Eosinophils	4.7	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	316000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	113	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	57	L	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 17/DOWN TITRATION	155	(35)	Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	14MAR96	1	20MAR96	7	7
00243	Oral	2	100 MG	21MAR96	8	27MAR96	14	7
00243	Oral	3	150 MG	28MAR96	15	04APR96	22	8
00243	Oral	3	150 MG	05APR96	23	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	23	150	Adverse event, including intercurrent illness	HIT HEAD DURING A FALL

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SHAKINESS	NERVOUSNESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SORE THROAT-TONSILLITIS	TONSILLITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Phenoxymethylpenicillin	Pen-Vee-K	1, .	14MAR96	21MAR96	250 4XDAY	TONSILLITIS
			1, .	14MAR96	21MAR96	1000 MG	PROBABLE STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	22, .	04APR96	04APR96	650 MG PRN	HEADACHES
DERMATOLOGICALS	Calamine	Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
	Camphor	Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
	Diphenhydramine Hydrochloride	Benadryl	4, .	17MAR96	24MAR96	25 MG	RASH
		Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
	Glycerol	Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	4, .	17MAR96	24MAR96	25 MG	RASH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES	8, .	Not Stated	100	CON	MIL	NO	REL	No	No
	Asthenia	TIREDNESS AND DROWSINESS	1, .	Not Stated	50	CON	MOD	NO	PSR	No	No
	Trauma	DIZZINESS - (HIT HEAD DURING FALL)	4, .	Not Stated	50	CON	MOD	STP	PSR	No	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	15, .	Not Stated	150	CON	MIL	NO	PSR	No	No
Digestive System	Constipation	CONSTIPATION	22, .	Not Stated	150	CON	SEV	NO	PSR	No	No
	Nausea	NAUSEA	8, .	Not Stated	100	CON	MIL	NO	REL	No	No
Nervous System	Tremor	(WORSENING) ENTIRE BODY SHAKES AND SHAKY HAND	9, .	Not Stated	100	CON	MOD	NO	PSR	No	No
Skin and Appendages	Rash	ITCHING AND RASH TO RIGHT FOREARM AND BOTH CALVES	4, .	6 Days	50	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	27FEB96	-16, .	0	94	64	68	92	60	64	112.50	62.0
1	21MAR96	8, .	100	98	66	66	98	64	68	111.00	
2	28MAR96	15, .	150	90	60	78	88	60	64	111.00	
3	04APR96	22, .	150	90	62	74	88	64	76	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5	.	.	.	30 - 70	%
				Lymphocytes	36.1	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	21MAR96	1	27MAR96	7	7
00244	Oral	2	100 MG	28MAR96	8	03APR96	14	7
00244	Oral	3	150 MG	04APR96	15	10APR96	21	7
00244	Oral	4	200 MG	11APR96	22	17APR96	28	7
00244	Oral	5	250 MG	18APR96	29	24APR96	35	7
00244	Oral	4	200 MG	25APR96	36	01MAY96	42	7
00244	Oral	5	250 MG	02MAY96	43	08MAY96	49	7
00244	Oral	6	300 MG	09MAY96	50	16MAY96	57	8
00138	Oral	6	300 MG	17MAY96	58	23MAY96	64	7
00138	Oral	5	250 MG	24MAY96	65	28MAY96	69	5
00244	Oral	4	200 MG	29MAY96	70	31MAY96	72	3
00244	Oral	3	150 MG	01JUN96	73	02JUN96	74	2
00244	Oral	2	100 MG	03JUN96	75	05JUN96	77	3
00244	Oral	1	50 MG	06JUN96	78	12JUN96	84	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	84	50	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEAVY CRAMPS DUE TO MENSES	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	P&C	1990
NAUSEA DUE TO MENSES	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	P&C	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FEELS MORE TIRED AFTER TAKING MEDS	2, -56	14 Days	50	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY THROAT, MOUTH	9, -49	61 Days	100	CON	MOD	NO	PSR	No	No
Metabolic and Nutritional Disorders	Thirst	INCREASED THIRST	9, -49	61 Days	100	CON	MOD	NO	PBU	No	No
Nervous System	Depersonalization	"SPACEY" 1X	3, -55	02:00 Hrs	50	7	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS UPON STANDING {1-2X/DAILY}	9, -49	24 Days	100	48	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14MAR96	-7, -64	0	122	72	84	120	70	80	141.00	63.0
BL	21MAR96	1, -57	0	110	66	80	112	70	98	143.00	
1	28MAR96	8, -50	100	120	78	78	118	70	70	142.00	
2	04APR96	15, -43	150	122	74	89	120	76	82	143.00	
3	11APR96	22, -36	200	112	70	99	110	72	110	143.00	
4	18APR96	29, -29	250	106	74	106	100	72	100	144.00	
5	25APR96	36, -22	200	110	64	75	108	68	80	145.00	
6	02MAY96	43, -15	250	120	70	84	116	70	86	144.00	
7	09MAY96	50, -8	300	110	70	94	112	70	88	144.50	
8	16MAY96	57, -1	300	104	68	106	92	70	104	144.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7		.	.	12 - 15.6	G/DL
				Hematocrit	41.2		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.2		.	.	30 - 70	%
				Lymphocytes	32.8		.	.	21 - 51	%
				Monocytes	6.7		.	.	0 - 10	%
				Eosinophils	2		.	.	0 - 5	%
				Basophils	1.2		.	.	0 - 2	%
				Platelets	268000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71		.	.	22 - 130	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	84		.	.	70 - 115	MG/DL
				Globulin	2.9		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.8	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	70	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28MAR96	1	04APR96	8	8
00245	Oral	1	20 MG	05APR96	9	09APR96	13	5
	Oral	1	20 MG	10APR96	14	14APR96	18	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	18	20	Adverse event, including intercurrent illness	DOWN TITRATED (PER S. FRITSH, M.D.) 3.A.M. DOSES, LEVEL 1.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MIGRAINE HEADACHES {ACCORDING TO PATIENT}	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-452, .	01JAN95	.	PRN	HEADACHE
	Sertraline Hydrochloride	Zoloft	-27, .	01MAR96	14MAR96#	25 MG	DEPRESSION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Emotional Lability	TYLENOL OVERDOSE {INTENTIONAL}	14, .	1 Days	20	1	SEV	STP	UNR	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21MAR96	-7, .	0	100	60	66	96	64	70	131.00	66.0
BL	28MAR96	1, .	0	98	60	60	90	62	70	127.00	
1	04APR96	8, .	20	98	62	62	96	60	68	126.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	220000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	159	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	118	H	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	18APR96	1	24APR96	7	7
00246	Oral	2	0 MG	25APR96	8	01MAY96	14	7
00246	Oral	3	0 MG	02MAY96	15	08MAY96	21	7
00246	Oral	4	0 MG	09MAY96	22	15MAY96	28	7
00246	Oral	5	0 MG	16MAY96	29	22MAY96	35	7
00246	Oral	5	0 MG	23MAY96	36	29MAY96	42	7
00246	Oral	5	0 MG	30MAY96	43	03JUN96	47	5
00246	Oral	6	0 MG	04JUN96	48	17JUN96	61	14
	Oral	6	0 MG	18JUN96	62	28JUN96	72	11

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	72	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
GASTROINTESTINAL DISTRESS	GASTROINTEST PROB, NEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
{PAST} ALCOHOL USE	ALCOHOL INGESTION, OTHER	FAMILY/PERSONAL HISTORY	PRV	1994
{PAST} MARIJUANA USE	DRUG ABUSE	MENTAL DISORD	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid	-838, .	01JAN94	.	PRN-10MGS	GASTROINTESTINAL DISTRESS
MUSCULO-SKELETAL	Ibuprofen	Advil	48, .	04JUN96	04JUN96		HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES (IF TAKES MEDS WITHOUT FOOD)	33, .	Not Stated	0		MIL	NO	PSR	No	No
	Asthenia	FATIGUE	8, .	Not Stated	0	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES (WORSENING)	23, .	Not Stated	0		MIL	NO	PSR	Yes	No
	Trauma	CAR ACCIDENT (NO INJURIES)	28, .	1 Days	0	CON	MIL	NO	UNR	No	No
		FALL FROM ROPE RESULTING IN DIZZINESS,HEADACHES, AND FATIGUE	39, .	5 Days	0		MOD	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	8, .	Not Stated	0	CON	MIL	NO	REL	No	No
	Vomiting	VOMITING	15, .	2 Days	0	2	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	36, .	7 Days	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Herpes Zoster	VARICELLA	56, .	5 Days	0		MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01APR96	-17,	.	0	126	74	62	120	70	66	190.00	61.0
1	25APR96	8,	.	0	122	68	72	120	64	66	191.00	
2	02MAY96	15,	.	0	122	66	72	120	68	80	187.00	
3	09MAY96	22,	.	0	104	64	76	100	60	72	189.00	
4	16MAY96	29,	.	0	108	85	88	115	88	95	189.50	
5	23MAY96	36,	.	0	110	80	70	118	78	88	189.00	
6	30MAY96	43,	.	0	108	62	88	110	66	88	194.00	
7	04JUN96	48,	.	0	102	64	88	98	62	90	191.00	
8	18JUN96	62,	.	0	130	70	74	124	72	86	194.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-17	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	25.4	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-17	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	30 - 70	%
				Lymphocytes	30.6	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	90	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	45	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	114	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	30APR96	1	06MAY96	7	7
00319	Oral	2	20 MG	07MAY96	8	13MAY96	14	7
00319	Oral	3	20 MG	14MAY96	15	20MAY96	21	7
00319	Oral	4	20 MG	21MAY96	22	27MAY96	28	7
00319	Oral	5	30 MG	28MAY96	29	03JUN96	35	7
00319	Oral	5	30 MG	04JUN96	36	10JUN96	42	7
00319	Oral	5	30 MG	11JUN96	43	17JUN96	49	7
00319	Oral	5	30 MG	18JUN96	50	24JUN96	56	7
00162	Oral	5	30 MG	25JUN96	57	22JUL96	84	28
00162	Oral	5	30 MG	23JUL96	85	14AUG96	107	23
00162	Oral	5	30 MG	15AUG96	108	23SEP96	147	40
00162	Oral	5	30 MG	24SEP96	148	21OCT96	175	28
00162	Oral	5	30 MG	22OCT96	176	18NOV96	203	28
00162	Oral	5	30 MG	19NOV96	204	16DEC96	231	28
00319	Oral	5	30 MG	17DEC96	232	17DEC96	232	1
00319	Oral	4	20 MG	18DEC96	233	19DEC96	234	2
00319	Oral	3	20 MG	20DEC96	235	21DEC96	236	2
00319	Oral	2	20 MG	22DEC96	237	24DEC96	239	3
00319	Oral	1	20 MG	25DEC96	240	30DEC96	245	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	245	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {FRONTAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	203, 147	18NOV96	18NOV96	1 TABLET	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH PAIN	71, 15	16:00 Hrs	30	1	MIL	NO	UNR	No	No
	Asthenia	FATIGUE	2, -55	202 Days	20	CON	MIL	NO	REL	No	No
	Chest Pain	CHEST PAIN	71, 15	16:00 Hrs	30	1	MIL	NO	UNR	No	No
	Headache	HEADACHE	203, 147	04:00 Hrs	30	1	MOD	NO	PBU	Yes	No
	Infection	FLU SYMPTOMS - FEVER, HEADACHES, MUSCLE ACHES	221, 165	6 Days	30	1	MOD	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	2, -55	202 Days	20	CON	MIL	NO	REL	No	No
Respiratory System	Pharyngitis	THROAT PAIN	71, 15	16:00 Hrs	30	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	23APR96	-7, -63	0	110	60	100	108	66	94	109.00	61.0
1	07MAY96	8, -49	20	112	70	78	110	66	84	109.00	
2	14MAY96	15, -42	20	128	68	70	120	70	64	111.50	
3	21MAY96	22, -35	20	110	62	64	106	64	80	109.00	
4	28MAY96	29, -28	30	110	70	66	106	72	68	111.00	
5	04JUN96	36, -21	30	102	64	80	98	64	76	112.50	
6	11JUN96	43, -14	30	100	68	64	98	68	72	115.00	
7	18JUN96	50, -7	30	108	68	80	112	76	64	113.50	
8	25JUN96	57, 1	30	112	70	72	100	74	80	114.00	
12	23JUL96	85, 29	30	102	70	66	108	68	68	116.00	
16	15AUG96	108, 52	30	98	60	80	98	62	88	115.00	
20	24SEP96	148, 92	30	108	68	66	110	66	68	117.00 H	
24	22OCT96	176, 120	30	104	66	64	106	64	68	113.50	
28	19NOV96	204, 148	30	92	64	80	94	68	80	117.00 H	
32	17DEC96	232, 176	30	100	70	76	98	70	72	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.8		.	.	12 - 15.6	G/DL
				Hematocrit	43.2		.	.	35 - 46	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.8	H	.	.	30 - 70	%
				Lymphocytes	19.5	L	.	.	21 - 51	%
				Monocytes	2.7		.	.	0 - 10	%
				Eosinophils	1.4		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	251000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54		.	.	22 - 130	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	6		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	8		.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	95		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.4		.	.	12 - 15.6	G/DL
				Hematocrit	39		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.4		.	.	30 - 70	%
				Lymphocytes	27.5		.	.	21 - 51	%
				Monocytes	5.2		.	.	0 - 10	%
				Eosinophils	1.8		.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	184000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65		.	.	22 - 130	U/L
				Aspartate Aminotransferase	13		.	.	0 - 41	U/L
				Alanine Aminotransferase	7		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.5	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	3.4	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	148	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	232	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	171000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	232	Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16MAY96	1	22MAY96	7	7
00320	Oral	2	0 MG	23MAY96	8	29MAY96	14	7
00320	Oral	3	0 MG	30MAY96	15	03JUN96	19	5
00320	Oral	4	0 MG	04JUN96	20	17JUN96	33	14
00320	Oral	5	0 MG	18JUN96	34	24JUN96	40	7
00320	Oral	5	0 MG	25JUN96	41	01JUL96	47	7
00320	Oral	6	0 MG	02JUL96	48	08JUL96	54	7
00320	Oral	6	0 MG	09JUL96	55	15JUL96	61	7
00182	Oral	6	0 MG	16JUL96	62	12AUG96	89	28
00182	Oral	6	0 MG	13AUG96	90	16SEP96	124	35
00182	Oral	6	0 MG	17SEP96	125	25SEP96	133	9
00320	Oral	5	0 MG	26SEP96	134	08OCT96	146	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	146	0	Lack of Efficacy	ESCALATING DEPRESSIVE SYMPTOMS

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BILATERAL KNEE PAIN	PAIN, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
CHRONIC BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
DIZZINESS	DIZZINESS AND GIDDINESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
FRACTURED LEFT FEMUR	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
FRACTURED RIGHT TIBIA	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
FRACTURED SKULL	FRACTURE, SKULL	INJURY/POISONING	PRV	1990
LYME DISEASE	ARTHROPOD-BORNE DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995
SPRAINED WRIST	SPRAINS/STRAINS	INJURY/POISONING	PRV	1990
SUBDURAL HEMATOMA	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1990

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTE MIC	Amoxicillin Trihydrate	Augmentin	117, 56	09SEP96	19SEP96		EAR INFECTION
	Clavulanic Acid	Augmentin	117, 56	09SEP96	19SEP96		EAR INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	32, -30	16JUN96	22JUN96	PRN	PAIN IN (EST) SHOULDER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK PAIN	125, 64	Not Stated	0	CON	MOD	NO	UNR	No	No
	Trauma	SHOULDER TRAUMA	32, -30	1 Days	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	30, -32	11 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	FAINTING	111, 50	Not Stated	0	CON	MOD	NO	UNR	No	No
Special Senses	Otitis Media	EAR INFECTION	117, 56	11 Days	0	1	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	16MAY96	1, -61	0	94	62	96	78	60	115	154.00	
1	23MAY96	8, -54	0	96	60	84	90	58	92	154.50	
2	30MAY96	15, -47	0	106	62	68	90	60	72	155.50	
3	04JUN96	20, -42	0	98	64	64	100	68	70	154.50	
5	18JUN96	34, -28	0	122	70	68	120	74	64	155.00	
6	25JUN96	41, -21	0	98	62	100	96	64	116	156.25	
7	02JUL96	48, -14	0	120	64	80	116	66	102	158.00	
8	09JUL96	55, -7	0	108	70	75	106	72	86	160.00	
8	16JUL96	62, 1	0	108	70	84	110	74	100	160.00	
12	13AUG96	90, 29	0	110	70	66	108	68	88	160.00	
16	17SEP96	125, 64	0	92	70	80	90	68	86	159.40	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9		.	.	12 - 15.6	G/DL
				Hematocrit	39.5		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.6		.	.	30 - 70	%
				Lymphocytes	35.1		.	.	21 - 51	%
				Monocytes	10		.	.	0 - 10	%
				Eosinophils	7.5	H	.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	285000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	198		.	.	44 - 280	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	88		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	12.1		.	.	12 - 15.6	G/DL
				Hematocrit	36.7		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7		.	.	30 - 70	%
				Lymphocytes	30.1		.	.	21 - 51	%
				Monocytes	11.2	H	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	279000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	175		.	.	44 - 280	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	23MAY96	1	03JUN96	12	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	12	50	Adverse event, including intercurrent illness	PT WAS HOSPITALIZED ON 6-2-96 AT BRADLEY HOSPITAL FOLLOWING ASSAULTIVE BEHAVIOR NO DOWN TITRATION SINCE PT WAS ONLY ON LEVEL 1.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-508, .	01JAN95	.	PRN	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Hostility	PSYCHIATRIC HOSPITALIZATION FOLLOWING ASSAULTIVE BEHAVIOR	11, .	Not Stated	50	1	SEV	STP	UNR	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	23MAY96	1, .	0	96	64	64	100	70	66	112.00	65.0
1	30MAY96	8, .	50	88	64	66	88	64	80	114.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.2	.	.	.	30 - 70	%
				Lymphocytes	39.6	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	249000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	100	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	09JAN97	1	15JAN97	7	7
00322	Oral	2	100 MG	16JAN97	8	22JAN97	14	7
00322	Oral	3	150 MG	23JAN97	15	29JAN97	21	7
00322	Oral	4	200 MG	30JAN97	22	03FEB97	26	5
00322	Oral	4	200 MG	04FEB97	27	13FEB97	36	10
	Oral	4	200 MG	14FEB97	37	23FEB97	46	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	46	200	Adverse event, including intercurrent illness	ORTHOSTATIC SIDE EFFECTS

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	13, .	02:00 Hrs	100	1	MOD	NO	PBU	No	No
		STOMACH ACHE, RE-OCCURRING	29, .	Not Stated	200		MIL	NO	PSR	No	No
Cardiovascular System	Arrhythmia	ORTHOSTATIC CHANGES [IRREGULAR PULSE]	36, .	Not Stated	200	CON	MOD	STP	PSR	No	No
Nervous System	Dizziness	DIZZINESS	3, .	Not Stated	50	CON	MOD	STP	PBU	No	No
		ORTHOSTATIC CHANGES [DIZZINESS]	36, .	Not Stated	200	CON	MOD	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06JAN97	-3,	.	0	120	84	80	120	80	86	136.00	68.5
1	16JAN97	8,	.	100	120	68	108	114	68	130 H	136.00	
2	23JAN97	15,	.	150	120	76	80	110	70	84	135.00	
3	30JAN97	22,	.	200	90	70	86	88 L	70	82	132.00	
4	04FEB97	27,	.	200	112	68	80	108	70	74	134.00	
5	13FEB97	36,	.	200	125	70	110	100	90	132 H	132.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	14.6		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4		.	.	30 - 70	%
				Lymphocytes	36.7		.	.	21 - 51	%
				Monocytes	9.2		.	.	0 - 10	%
				Eosinophils	1.7		.	.	0 - 5	%
				Basophils	0.9		.	.	0 - 2	%
				Platelets	225000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	7		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	294		.	.	44 - 400	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	95		.	.	70 - 115	MG/DL
				Globulin	2.6		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-3	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	12NOV96	1	18NOV96	7	7
00323	Oral	2	0 MG	19NOV96	8	25NOV96	14	7
00323	Oral	3	0 MG	26NOV96	15	04DEC96	23	9
00323	Oral	4	0 MG	05DEC96	24	09DEC96	28	5
00323	Oral	4	0 MG	10DEC96	29	16DEC96	35	7
00323	Oral	4	0 MG	17DEC96	36	25DEC96	44	9
00323	Oral	4	0 MG	26DEC96	45	01JAN97	51	7
00323	Oral	4	0 MG	02JAN97	52	08JAN97	58	7
00175	Oral	4	0 MG	09JAN97	59	03FEB97	84	26
00175	Oral	4	0 MG	04FEB97	85	03MAR97	112	28
00175	Oral	5	0 MG	04MAR97	113	02APR97	142	30
00175	Oral	5	0 MG	03APR97	143	29APR97	169	27
00175	Oral	5	0 MG	30APR97	170	26MAY97	196	27
00175	Oral	5	0 MG	27MAY97	197	11JUN97	212	16
00323	Oral	5	0 MG	12JUN97	213	14JUN97	215	3
00323	Oral	4	0 MG	15JUN97	216	16JUN97	217	2
00323	Oral	3	0 MG	17JUN97	218	18JUN97	219	2
00323	Oral	2	0 MG	19JUN97	220	20JUN97	221	2
00323	Oral	1	0 MG	21JUN97	222	26JUN97	227	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	Yes	227	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
ELEVATED CHOLESTEROL	CHOLEST/TRIGLYCERIDE, ELEVATED	ENDOCR/METAB/IMMUNITY DISORD	PRV	
HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	151, 93	11APR97	18APR97	250 MG	PHARYNGITIS
CENTRAL NERVOUS SYSTEM	Analgesics	Unknown {Analgesic Nos}	-1, -59	11NOV96	01DEC96		BACK PAIN
		Unknown {Analgesic}	49, -10	30DEC96	.	UNKNOWN	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	113, 55	Not Stated	0	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	82, 24	4 Days	0	1	MIL	NO	PSR	No	No
		HEADACHES	49, -10	11 Days	0	CON	MIL	NO	PSR	Yes	No
Metabolic and Nutritional Disorders	Thirst	INCREASED THIRST	15, -44	10 Days	0	CON	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS (ESPECIALLY DURING AEROBICS AND HEAVY LIFTING)	8, -51	37 Days	0	CON	MOD	NO	PSR	No	No
	Somnolence	FALLING ASLEEP IN THE AFTERNOON	4, -55	42 Days	0	CON	MOD	NO	PSR	No	No
Respiratory System	Pharyngitis	PHARYNGITIS	151, 93	8 Days	0	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	04NOV96	-8, -66	0	92	68	84	90	64	90	118.00	63.0
BL	12NOV96	1, -58	0	92	68	84	90	64	90	118.00	
1	19NOV96	8, -51	0	94	66	88	98	64	80	117.00	
2	26NOV96	15, -44	0	102	78	84	100	78	78	109.00 L	
3	05DEC96	24, -35	0	96	70	80	94	66	82	112.00	
4	10DEC96	29, -30	0	100	68	66	96	66	64	112.00	
5	17DEC96	36, -23	0	98	60	90	94	62	84	114.00	
6	26DEC96	45, -14	0	88	66	74	88	64	76	112.00	
7	02JAN97	52, -7	0	102	72	80	104	60	84	112.00	
8	09JAN97	59, 1	0	100	68	74	100	66	80	114.50	
12	04FEB97	85, 27	0	102	64	74	102	60	84	116.00	
16	04MAR97	113, 55	0	108	68	84	104	66	88	118.00	
20	03APR97	143, 85	0	108	62	100	112	70	106	120.00	
24	30APR97	170, 112	0	116	58	82	116	58	92	119.00	
28	27MAY97	197, 139	0	110	70	72	110	80	100	118.50	
32	12JUN97	213, 155	0	110	80	76	105	75	76	114.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.5				12 - 15.6	G/DL
				Hematocrit	39				35 - 46	%
				Red Blood Cell Count	4.4				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1				4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.7				30 - 70	%
				Lymphocytes	23				21 - 51	%
				Monocytes	6.9				0 - 10	%
				Eosinophils	2.4				0 - 5	%
				Basophils	1				0 - 2	%
				Platelets	198000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1				25 - 35	PG
				Mean Corpuscle Volume	89				80 - 100	FL
				Blood Urea Nitrogen	13				7 - 25	MG/DL
				Creatinine	0.9				0.8 - 1.5	MG/DL
				Uric Acid	1.9	L			2.3 - 7	MG/DL
				Alkaline Phosphatase	56				22 - 130	U/L
				Aspartate Aminotransferase	14				0 - 41	U/L
				Alanine Aminotransferase	17				0 - 48	U/L
				Total Bilirubin	0.6				0.3 - 1.3	MG/DL
				Total Protein	7.4				6.2 - 8.8	G/DL
				Albumin	4.2				3.1 - 5.3	G/DL
				Glucose - Random	109				70 - 115	MG/DL
				Globulin	3.2				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.9		.	.	12 - 15.6	G/DL
				Hematocrit	40.8		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.6		.	.	30 - 70	%
				Lymphocytes	26.8		.	.	21 - 51	%
				Monocytes	8.4		.	.	0 - 10	%
				Eosinophils	3.2		.	.	0 - 5	%
				Basophils	0.9		.	.	0 - 2	%
				Platelets	204000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	143	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	30 - 70	%
				Lymphocytes	27.2	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	143	Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	53	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	213	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 16/CONTINUATION-WEEK 32	213	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19JAN95	1	24JAN95	6	6
00073	Oral	2	100 MG	25JAN95	7	02FEB95	15	9
00073	Oral	3	150 MG	03FEB95	16	06FEB95	19	4
00073	Oral	4	200 MG	07FEB95	20	13FEB95	26	7
00073	Oral	4	200 MG	14FEB95	27	21FEB95	34	8
00073	Oral	5	250 MG	22FEB95	35	28FEB95	41	7
00073	Oral	5	250 MG	01MAR95	42	04MAR95	45	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	45	250	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Caffeine	Dexatrim	13, .	31JAN95	03FEB95	UNKNOWN	DIETING
	Dicycloverine Hydrochloride	Bentyl	45, .	04MAR95	06MAR95	UNKNOWN	NAUSEA
	Phenylpropanolamine Hydrochloride	Dexatrim	13, .	31JAN95	03FEB95	UNKNOWN	DIETING
CENTRAL NERVOUS SYSTEM	Analgesics	Pain Medication {Nos}	-11, .	08JAN95	.	4 TABLETS	SPRAINED ANKLE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Postural Hypotension	ORTHOSTATIC SYMPTOMS {ORTHOSTATIC HYPOTENSION}	16, .	Not Stated	150	CON	MOD	NO	PSR	No	No
Digestive System	Gastrointestinal Disorder	NAUSEA,VOMITING HEADACHES,DIARRHEA{GASTROINTESTINAL ILLNESS}	36, .	Not Stated	250	CON	MOD	NO	UNR	No	No
	Vomiting	VOMITING	45, .	Not Stated	250	CON	SEV	STP	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	11JAN95	-8,	.	0	110	72	86	112	72	88	138.92	63.8
BL	18JAN95	-1,	.	0	100	70	82	90	68	87	140.00	
1	25JAN95	7,	.	100	110	68	100	100	70	120	136.70	
2	03FEB95	16,	.	150	114	74	92	96	70	120	135.61	
3	07FEB95	20,	.	200	114	72	120	96	78	132 H	136.27	
4	14FEB95	27,	.	200	112	78	92	102	66	120	134.73	
5	22FEB95	35,	.	250	116	82	116	114	90	130 H	135.61	
6	01MAR95	42,	.	250	128	72	114	116	68	128 H	134.73	
7	08MAR95	49,	.	250	100	76	120	104	80	140 H	128.11 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.2	.	.	.	30 - 70	%
				Lymphocytes	31.6	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	COLUMBIAN YUGOSLAVIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	25JAN95	1	31JAN95	7	7
00074	Oral	2	0 MG	01FEB95	8	07FEB95	14	7
00074	Oral	3	0 MG	08FEB95	15	14FEB95	21	7
00074	Oral	4	0 MG	15FEB95	22	20FEB95	27	6
00074	Oral	5	0 MG	21FEB95	28	28FEB95	35	8
00074	Oral	6	0 MG	01MAR95	36	14MAR95	49	14
00074	Oral	6	0 MG	15MAR95	50	21MAR95	56	7
00043	Oral	6	0 MG	22MAR95	57	18APR95	84	28
00043	Oral	6	0 MG	19APR95	85	16MAY95	112	28
00043	Oral	6	0 MG	17MAY95	113	18JUN95	145	33
00043	Oral	6	0 MG	19JUN95	146	23JUL95	180	35
00043	Oral	6	0 MG	24JUL95	181	29AUG95	217	37
00043	Oral	6	0 MG	30AUG95	218	11OCT95	260	43
00074	Oral	5	0 MG	25OCT95	274	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	Yes	274	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
STATUS POST ACUTE APPENDICITIS	APPENDICITIS	DIGESTIVE SYST	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	16, -41	01:30 Hrs	0	2	MIL	NO	PSR	No	No
Digestive System	Constipation	CONSTIPATION	25, -32	12 Days	0	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JAN95	-7, -63	0	110	66	76	106	58	76	91.07	61.4
BL	25JAN95	1, -56	0	104	86	75	98	78	90	94.20	
1	01FEB95	8, -49	0	110	76	72	108	80	82	95.48	
2	08FEB95	15, -42	0	110	84	84	110	70	96	94.82	
3	15FEB95	22, -35	0	100	70	76	100	78	88	95.70	
4	21FEB95	28, -29	0	102	78	88	102	80	117	95.48	
5	01MAR95	36, -21	0	100	72	76	110	66	84	96.36	
7	15MAR95	50, -7	0	110	86	76	104	88	98	97.02	
8	22MAR95	57, 1	0	104	74	68	100	78	92	96.80	
12	19APR95	85, 29	0	106	76	72	92	70	104	98.34	
16	17MAY95	113, 57	0	94	66	80	98	72	78	98.34	
20	19JUN95	146, 90	0	100	72	60	94	76	80	97.46	
24	24JUL95	181, 125	0	104	74	85	100	76	104	101.65 H	
32	30AUG95	218, 162	0	108	74	68	96	70	88	103.19 H	
32	11OCT95	260, 204	0	90	70	96	100	76	100	102.53 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.6		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9		.	.	41 - 50	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	2	L	.	.	4 - 12	%
				Segmented Neutrophils	50		.	.	30 - 70	%
				Lymphocytes	37		.	.	21 - 51	%
				Monocytes	9		.	.	0 - 10	%
				Eosinophils	2		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	152000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	96		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	344		.	.	44 - 400	U/L
				Aspartate Aminotransferase	23		.	.	0 - 41	U/L
				Alanine Aminotransferase	12		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2		.	.	6.2 - 8.8	G/DL
				Albumin	4.8		.	.	3.1 - 5.3	G/DL
				Glucose - Random	106		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14		.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1		.	.	30 - 70	%
				Lymphocytes	25.4		.	.	21 - 51	%
				Monocytes	6.6		.	.	0 - 10	%
				Eosinophils	1.1		.	.	0 - 5	%
				Basophils	2.9	H	.	.	0 - 2	%
				Platelets	185000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	96		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	406	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	146	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.2	.	.	.	30 - 70	%
				Lymphocytes	45.1	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	148000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	359	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	146	Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	260	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.4	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	34	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	99	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 16/CONTINUATION-WEEK 32	260	Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	316	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	25JAN95	1	31JAN95	7	7
00075	Oral	2	20 MG	01FEB95	8	07FEB95	14	7
00075	Oral	3	20 MG	08FEB95	15	14FEB95	21	7
00075	Oral	4	20 MG	15FEB95	22	20FEB95	27	6
00075	Oral	5	30 MG	21FEB95	28	28FEB95	35	8
00075	Oral	3	20 MG	01MAR95	36	07MAR95	42	7
00075	Oral	2	20 MG	08MAR95	43	14MAR95	49	7
00075	Oral	4	20 MG	15MAR95	50	21MAR95	56	7
00041	Oral	4	20 MG	22MAR95	57	18APR95	84	28
00041	Oral	4	20 MG	19APR95	85	16MAY95	112	28
00041	Oral	4	20 MG	17MAY95	113	13JUN95	140	28
00041	Oral	4	20 MG	14JUN95	141	11JUL95	168	28
00041	Oral	4	20 MG	12JUL95	169	09AUG95	197	29
00041	Oral	4	20 MG	10AUG95	198	12SEP95	231	34
00075	Oral	3	20 MG	13SEP95	232	14SEP95	233	2
00075	Oral	2	20 MG	15SEP95	234	17SEP95	236	3
00075	Oral	1	20 MG	18SEP95	237	21SEP95	240	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	Yes	240	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-7, -63	18JAN95	.	PRN	HEADACHE
			16, -41	09FEB95	14FEB95	PRN	HEADACHES
MUSCULO-SKELETAL	Ibuprofen	Motrin	-7, -63	18JAN95	.	PRN	HEADACHE
			16, -41	09FEB95	14FEB95	PRN 200-400	HEADACHE
RESPIRATORY	Salbutamol	Proventil	., .		.	PRN	ASTHMA
			., .		.	PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	TIRED	141, 85	2 Days	20		MIL	NO	UNR	No	No
	Headache	HEADACHES	15, -42	Not Stated	20	CON	MIL	NO	PBU	No	No
Carciovascular System	Tachycardia	HEART RACING	102, 46	12 Days	20	CON	MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	APPETITE SUPPRESSION	71, 15	98 Days	20	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	1, -56	4 Days	20	CON	MIL	NO	PSR	No	No
	Gastrointestinal Disorder	NAUSEA AND REFLUX {ESOPHAGEAL}	22, -35	24:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	43, -14	128 Days	20	CON	MIL	INC	PSR	No	No
			234, 178	6 Days	20		MOD	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	43, -14	15 Days	20	CON	MOD	INC	PSR	No	No
			158, 102	10 Days	20	CON	MIL	NO	PBU	No	No
			234, 178	6 Days	20		MOD	NO	PBU	No	No
	Hyperkinesia	HYPERACTIVITY	170, 114	70 Days	20	CON	MIL	NO	PBU	No	No
	Insomnia	TROUBLE SLEEPING	234, 178	6 Days	20		MOD	NO	PBU	No	No
	Nervousness	NERVOUS JITTERY	1, -56	8 Days	20	CON	MIL	NO	PSR	No	No
		TREMULOUS TEETH CHATTERING(JITTERINESS)	51, -6	13 Days	20	CON	MIL	NO	REL	No	No
	Somnolence	DROWSINESS	37, -20	5 Days	20	CON	MIL	DCR	PSR	No	No
Urogenital System	Amenorrhea	AMENORRHEA	8, -49	161 Days	20	CON	MOD	NO	PSR	No	No
	Female Genital Disorders	ANORGASMIA {FEMALE}	1, -56	57 Days	20	CON	SEV	DCR	REL	No	No
			58, 2	56 Days	20	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JAN95	-7, -63	0	124	66	82	124	70	82	145.75	60.6
BL	25JAN95	1, -56	0	120	76	88	118	80	85		
1	01FEB95	8, -49	20	130	78	78	132	88	82	143.55	
2	08FEB95	15, -42	20	130	88	72	126	86	76	142.22	
3	15FEB95	22, -35	20	120	66	78	126	64	90	141.34	
4	21FEB95	28, -29	30	116	88	80	112	90	70	142.44	
5	01MAR95	36, -21	20	130	76	88	138	80	92	142.22	
6	08MAR95	43, -14	20	120	82	72	126	80	82	143.10	
7	15MAR95	50, -7	20	120	82	74	130	84	76	142.22	
8	22MAR95	57, 1	20	130	76	72	118	84	78	143.33	
12	19APR95	85, 29	20	112	78	72	128	88	84	141.56	
16	17MAY95	113, 57	20	114	70	72	118	68	76	142.00	
20	14JUN95	141, 85	20	124	70	72	110	72	72	141.12	
24	12JUL95	169, 113	20	130	62	80	120	64	86	142.22	
28	09AUG95	197, 141	20	120	80	72	110	70	76	140.68	
32	13SEP95	232, 176	20	120	78	64	130	86	72	140.24	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Segmented Neutrophils	50		.	.	30 - 70	%
				Lymphocytes	37		.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	1		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87		.	.	22 - 130	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	12		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	91		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEC		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8		.	.	12 - 15.6	G/DL
				Hematocrit	40.4		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35.8		.	.	30 - 70	%
				Lymphocytes	54.7	H	.	.	21 - 51	%
				Monocytes	7.9		.	.	0 - 10	%
				Eosinophils	1.3		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	304000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92		.	.	22 - 130	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	14		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	75		.	.	70 - 115	MG/DL
				Globulin	3.3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	13.5		.	.	12 - 15.6	G/DL
				Hematocrit	40.2		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.8		.	.	30 - 70	%
				Lymphocytes	40.4		.	.	21 - 51	%
				Monocytes	5.8		.	.	0 - 10	%
				Eosinophils	3.9		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	306000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94		.	.	22 - 130	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	90		.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	141	Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	232	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	41.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	0.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	335000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 16/CONTINUATION-WEEK 32	232	Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	140	H	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	31JAN95	1	06FEB95	7	7
00076	Oral	2	100 MG	07FEB95	8	13FEB95	14	7
00076	Oral	3	150 MG	14FEB95	15	20FEB95	21	7
00076	Oral	4	200 MG	21FEB95	22	26FEB95	27	6
00076	Oral	4	200 MG	27FEB95	28	05MAR95	34	7
00076	Oral	4	200 MG	06MAR95	35	12MAR95	41	7
00076	Oral	4	200 MG	13MAR95	42	19MAR95	48	7
00076	Oral	4	200 MG	20MAR95	49	26MAR95	55	7
00045	Oral	4	200 MG	27MAR95	56	02MAY95	92	37
00045	Oral	4	200 MG	03MAY95	93	30MAY95	120	28
00045	Oral	4	200 MG	31MAY95	121	27JUN95	148	28
00045	Oral	4	200 MG	28JUN95	149	01AUG95	183	35
00045	Oral	4	200 MG	02AUG95	184	05SEP95	218	35
00045	Oral	4	200 MG	06SEP95	219	27SEP95	240	22

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	240	200		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	
GLASSES FOR DISTANCE SINCE GRADE 4	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	PRV	1988
HISTORY FUNCTIONAL HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	
SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1994

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	.,	.	.		CRAMPS
	Caffeine	Midol	.,	.	.		CRAMPS
	Cinnamedrine Hydrochloride	Midol	.,	.	.		CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	2, -54	48 Days	50	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	188, 133	66 Days	200	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JAN95	-7, -62	0	126	66	80	132	66	86	200.66	65.4
BL	31JAN95	1, -55	0	114	76	76	110	72	80	197.70	
1	07FEB95	8, -48	100	118	82	100	120	78	118	201.76	
2	14FEB95	15, -41	150	126	80	88	130	78	112	198.01	
3	21FEB95	22, -34	200	110	78	117	104	70	112	200.66	
4	27FEB95	28, -28	200	128	68	112	120	80	118	201.76	
5	06MAR95	35, -21	200	128	76	102	124	80	112	202.20	
6	13MAR95	42, -14	200	130	66	96	132	82	108	203.52	
7	20MAR95	49, -7	200	112	84	96	110	80	112	206.17	
8	27MAR95	56, 1	200	124	80	112	130	82	120	206.17	
12	03MAY95	93, 38	200	116	60	86	114	66	100	205.07	
16	31MAY95	121, 66	200	114	60	92	104	68	112	205.07	
20	28JUN95	149, 94	200	102	60	110	104	68	122 H	209.92	
28	02AUG95	184, 129	200	124	70	100	120	76	104	206.39	
32	06SEP95	219, 164	200	122	68	120	120	74	120	209.25	
32	11OCT95	254, 199	0	120	52	100	130	64	108	218.30 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	317000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.9		.	.	12 - 15.6	G/DL
				Hematocrit	44		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54		.	.	30 - 70	%
				Lymphocytes	37.2		.	.	21 - 51	%
				Monocytes	7.4		.	.	0 - 10	%
				Eosinophils	0.5		.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	309000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	92		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93		.	.	22 - 130	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	26		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	15.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	38	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	286000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	149		Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	51	H	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	19	L	.	.	70 - 115	MG/DL
					Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	254	(14)	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	42.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54.5	.	.	.	30 - 70	%
					Lymphocytes	37.3	.	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	1.8	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	300000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	254	(14)	Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	67	H	.	.	0 - 48	U/L
					Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	119	H	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00077 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	06MAR95	1	12MAR95	7	7
00077	Oral	2	20 MG	13MAR95	8	19MAR95	14	7
00077	Oral	3	20 MG	20MAR95	15	26MAR95	21	7
00077	Oral	4	20 MG	27MAR95	22	04APR95	30	9
00077	Oral	5	30 MG	05APR95	31	11APR95	37	7
00077	Oral	5	30 MG	12APR95	38	18APR95	44	7
00077	Oral	5	30 MG	19APR95	45	26APR95	52	8
00077	Oral	5	30 MG	27APR95	53	03MAY95	59	7
00042	Oral	5	30 MG	04MAY95	60	06JUN95	93	34
00042	Oral	5	30 MG	07JUN95	94	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00077 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	94	30	Lost to follow-up	[redacted] DID NOT ARRIVE FOR MONTH 2VISIT,FAMILY DID NOT RESPOND TO ATTEMPTS TO CONTACT THEM.

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Tachycardia	HEART RACING	46, -14	3 Days	30	3	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	42, -18	10 Days	30		MIL	NO	PSR	No	No
	Dyspepsia	UPSET STOMACH AND HEARTBURN	7, -53	08:30 Hrs	20	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	47, -13	3 Days	30	3	MIL	NO	PSR	No	No
			58, -2	35 Days	30	2	MIL	NO	PSR	No	No
Nervous System	Insomnia	INSOMNIA	80, 21	Not Stated	30	CON	SEV	DCR	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00077 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01MAR95	-5, -64	0	138	70	76	138	72	72	132.30	68.9
BL	06MAR95	1, -59	0	138	70	76	138	72	72	132.30	
1	13MAR95	8, -52	20	134	86	76	148	78	90	134.51	
2	20MAR95	15, -45	20	118	88	76	116	86	88	134.51	
3	27MAR95	22, -38	20	124	82	82	126	76	88	137.37	
4	05APR95	31, -29	30	128	84	78	126	88	78	136.27	
5	12APR95	38, -22	30	128	66	80	134	78	86	138.47	
6	19APR95	45, -15	30	130	76	80	138	84	84	138.03	
7	26APR95	52, -8	30	120	82	84	130	80	90	139.58	
8	03MAY95	59, -1	30	114	78	78	130	86	78	140.68	
12	07JUN95	94, 35	30	126	76	78	122	80	80	136.71	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	26APR95	1	01MAY95	6	6
00078	Oral	2	0 MG	02MAY95	7	09MAY95	14	8
00078	Oral	3	0 MG	10MAY95	15	16MAY95	21	7
00078	Oral	4	0 MG	17MAY95	22	23MAY95	28	7
00078	Oral	5	0 MG	24MAY95	29	29MAY95	34	6
00078	Oral	6	0 MG	30MAY95	35	06JUN95	42	8
00078	Oral	6	0 MG	07JUN95	43	14JUN95	50	8
00078	Oral	6	0 MG	15JUN95	51	21JUN95	57	7
	Oral	6	0 MG	22JUN95	58	28JUN95	64	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	64	0	Lack of Efficacy	

* Relative to Start of Study Medication

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	11APR95	-15, .	0	110	65	72	110	65	72	195.00	68.5
BL	26APR95	1, .	0	120	75	80	.	.	.	198.00	
1	02MAY95	7, .	0	110	78	80	105	75	90	198.00	
2	10MAY95	15, .	0	110	70	80	120	80	84	200.00	
3	17MAY95	22, .	0	118	70	80	110	80	88	195.50	
4	24MAY95	29, .	0	122	76	80	114	80	88	194.00	
5	30MAY95	35, .	0	120	80	82	110	78	88	196.00	
6	07JUN95	43, .	0	118	68	82	110	76	84	192.00	
7	15JUN95	51, .	0	110	80	90	112	80	78	192.00	
8	21JUN95	57, .	0	112	80	80	110	84	84	196.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2		.	.	12 - 15.6	G/DL
				Hematocrit	41.5		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.4	H	.	.	30 - 70	%
				Lymphocytes	19.9	L	.	.	21 - 51	%
				Monocytes	5.8		.	.	0 - 10	%
				Eosinophils	1.3		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	193000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94		.	.	22 - 130	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	91		.	.	70 - 115	MG/DL
				Globulin	3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83		.	.	22 - 130	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	93		.	.	70 - 115	MG/DL
				Globulin	2.8		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/UNSCHEDULED LAB 1	78	(14)	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	66.7	.	.	.	30 - 70	%
					Lymphocytes	23.8	.	.	.	21 - 51	%
					Monocytes	7.3	.	.	.	0 - 10	%
					Eosinophils	1.5	.	.	.	0 - 5	%
					Basophils	0.7	.	.	.	0 - 2	%
					Platelets	198000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	87	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	03MAY95	1	09MAY95	7	7
00079	Oral	2	100 MG	10MAY95	8	18MAY95	16	9
00079	Oral	3	150 MG	19MAY95	17	19MAY95	17	1

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	17	150	Other reason	PATIENT WITHDREW BY OWN VOLITION

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	15, .	17MAY95	17MAY95		SORE THROAT
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	15, .	17MAY95	17MAY95		SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Insomnia	INSOMNIA (FREQUENT AWAKENING)	9, .	Not Stated	100	CON	MOD	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	15, .	Not Stated	100	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	03MAY95	1, .	0	112	78	64	100	70	84	152.15	68.1
1	10MAY95	8, .	100	110	74	78	100	80	86	150.38	
2	19MAY95	17, .	150	124	74	90	112	80	112	149.28	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	38.2	.	.	.	30 - 70	%
				Lymphocytes	49	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	27NOV95	1	03DEC95	7	7
00080	Oral	2	0 MG	04DEC95	8	10DEC95	14	7
00080	Oral	3	0 MG	11DEC95	15	17DEC95	21	7
00080	Oral	4	0 MG	18DEC95	22	28DEC95	32	11
	Oral	4	0 MG	29DEC95	33	03JAN96	38	6
00080	Oral	5	0 MG	04JAN96	39	09JAN96	44	6
00080	Oral	6	0 MG	10JAN96	45	16JAN96	51	7
00080	Oral	6	0 MG	17JAN96	52	23JAN96	58	7
00080	Oral	5	0 MG	24JAN96	59	09FEB96	75	17

* DAYS RELATIVE TO START OF STUDY MEDICATION

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	75	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FATIGUE	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
GU SYSTEM/SEX HORMONES	Injectable Contraceptive, Nos	Injectable Contraceptive {Nos}	-51, .	07OCT95	.		BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	39, .	Not Stated	0	CON	SEV	NO	PBU	No	No
	Headache	HEADACHES	38, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	39, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	39, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS	27, .	12 Days	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22NOV95	-5,	.	0	110	70	68	124	62	84	177.94	62.6
1	04DEC95	8,	.	0	122	72	80	110	80	96	178.61	
1	07DEC95	11,	.	0	124	64	94	120	62	100	179.27	
3	18DEC95	22,	.	0	114	58	88	110	66	100	177.50	
5	29DEC95	33,	.	0	134	48 L	98	112	60	106	181.03	
5	04JAN96	39,	.	0	128	58	86	126	74	90	179.05	
6	10JAN96	45,	.	0	122	58	82	110	48	88	179.71	
7	17JAN96	52,	.	0	122	68	82	120	74	100	181.47	
8	24JAN96	59,	.	0	120	64	102	110	60	112	179.27	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	205000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	RESULT IS AN	U	.	U	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	34.5	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	106	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11DEC95	1	17DEC95	7	7
00081	Oral	2	20 MG	18DEC95	8	27DEC95	17	10
00081	Oral	3	20 MG	28DEC95	18	02JAN96	23	6
00081	Oral	4	20 MG	03JAN96	24	09JAN96	30	7
00081	Oral	5	30 MG	10JAN96	31	16JAN96	37	7
00081	Oral	5	30 MG	17JAN96	38	23JAN96	44	7
00081	Oral	5	30 MG	24JAN96	45	30JAN96	51	7
00081	Oral	6	40 MG	31JAN96	52	06FEB96	58	7
	Oral	6	40 MG	07FEB96	59	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	59	40	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{DAILY}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-193, .	01JUN95	.	500MGS	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Increased Appetite	INCREASED APPETITE	9, .	16 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	18, .	14 Days	20	CON	MIL	NO	PBU	No	No
	Somnolence	SOMNOLENCE	9, .	23 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	11DEC95	1,	.	0	110	70	92	110	80	92	110.00	63.5
1	18DEC95	8,	.	20	92	50	100	110	60	102	111.79	
2	28DEC95	18,	.	20	104	64	86	106	70	96	109.15	
3	03JAN96	24,	.	20	104	58	92	104	66	102	111.35	
4	10JAN96	31,	.	30	104	70	102	106	80	114	110.25	
5	17JAN96	38,	.	30	104	58	104	110	70	108	113.56	
6	24JAN96	45,	.	30	104	60	96	110	62	108	113.34	
7	31JAN96	52,	.	40	100	58	100	94	56	112	110.69	
8	07FEB96	59,	.	40	110	66	84	102	74	82	111.79	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
				Hematocrit	35.8	.	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	188	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7		Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	(1)	Hemoglobin	12.1		.	.	12 - 15.6	G/DL
					Hematocrit	35.2		.	.	35 - 46	%
					Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.1		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	53.6		.	.	30 - 70	%
					Lymphocytes	33.8		.	.	21 - 51	%
					Monocytes	7.9		.	.	0 - 10	%
					Eosinophils	3.4		.	.	0 - 5	%
					Basophils	1.3		.	.	0 - 2	%
					Platelets	229000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.3		.	.	25 - 35	PG
					Mean Corpuscle Volume	91		.	.	80 - 100	FL
					Blood Urea Nitrogen	11		.	.	8 - 21	MG/DL
					Creatinine	0.6		.	.	0.4 - 1.1	MG/DL
					Uric Acid	2.6		.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	156		.	.	44 - 280	U/L
					Aspartate Aminotransferase	17		.	.	0 - 41	U/L
					Alanine Aminotransferase	10		.	.	0 - 39	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	59 (1)	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	H	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11DEC95	1	27DEC95	17	17
00082	Oral	2	100 MG	28DEC95	18	02JAN96	23	6
00082	Oral	3	150 MG	03JAN96	24	10JAN96	31	8
00082	Oral	4	200 MG	11JAN96	32	16JAN96	37	6
00082	Oral	5	250 MG	17JAN96	38	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	38	250	Lost to follow-up	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
GU SYSTEM/SEX HORMONES	Desogestrel	Desogen-28	-344, .	01JAN95	.	X 1	BIRTH CONTROL
	Ethinylestradiol	Desogen-28	-344, .	01JAN95	.	X 1	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	23, .	04:00 Hrs	100	1	MOD	NO	PSR	No	No
			38, .	Not Stated	250	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	38, .	Not Stated	250	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZY	24, .	Not Stated	150	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	11DEC95	1,	.	0	108	66	56	110	67	93	120.00	63.5
2	28DEC95	18,	.	100	100	65	70	110	70	90	118.50	
3	03JAN96	24,	.	150	116	60	88	104	58	118	119.07	
4	11JAN96	32,	.	200	132	63	93	121	55	89	120.25	
5	17JAN96	38,	.	250	124	80	92	114	74	116	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	10.5	H	.	+	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	08NOV94	1	14NOV94	7	7
00085	Oral	2	0 MG	15NOV94	8	20NOV94	13	6
00085	Oral	3	0 MG	21NOV94	14	27NOV94	20	7
00085	Oral	4	0 MG	28NOV94	21	05DEC94	28	8
00085	Oral	5	0 MG	06DEC94	29	12DEC94	35	7
00085	Oral	6	0 MG	13DEC94	36	19DEC94	42	7
00085	Oral	6	0 MG	20DEC94	43	27DEC94	50	8
00085	Oral	6	0 MG	28DEC94	51	03JAN95	57	7
	Oral	5	0 MG	04JAN95	58	17JAN95	71	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	71	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EKG SHOWS RAPID HEART RATE DUE TO PREVIOUS BLOOD DRAWING-NORMAL	TACHYCARDIA, UNSPEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1988

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	45, .	4 Days	0	1	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26OCT94	-13,	.	0	110	70	110	100	80	120	199.00	63.8
BL	07NOV94	-1,	.	0	90	60	96	90	60	96	207.50	
1	14NOV94	7,	.	0	98	58	104	.	.	104	204.50	
2	21NOV94	14,	.	0	110	70	100	110	70	100	203.00	
3	28NOV94	21,	.	0	110	80	100	106	80	100	206.00	
4	05DEC94	28,	.	0	110	70	104	110	70	104	208.00	
5	12DEC94	35,	.	0	108	74	96	108	74	96	209.00	
6	19DEC94	42,	.	0	110	70	96	110	72	96	203.00	
7	27DEC94	50,	.	0	110	76	92	112	76	92	205.00	
8	03JAN95	57,	.	0	130	86	100	120	86	100	207.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	25.7	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-13	Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	3	L	.	.	4 - 12	%
				Segmented Neutrophils	70		.	.	30 - 70	%
				Lymphocytes	13	L	.	.	21 - 51	%
				Monocytes	9		.	.	0 - 10	%
				Eosinophils	3		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84		.	.	22 - 130	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	20		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	4.6	H	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	63	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	.	.	.	30 - 70	%
				Lymphocytes	23.6	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	276000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28NOV94	1	04DEC94	7	7
00086	Oral	2	0 MG	05DEC94	8	12DEC94	15	8
00086	Oral	3	0 MG	13DEC94	16	19DEC94	22	7
00086	Oral	4	0 MG	20DEC94	23	27DEC94	30	8
00086	Oral	5	0 MG	28DEC94	31	03JAN95	37	7
00086	Oral	6	0 MG	04JAN95	38	09JAN95	43	6
00086	Oral	6	0 MG	10JAN95	44	17JAN95	51	8
00086	Oral	6	0 MG	18JAN95	52	23JAN95	57	6
00038	Oral	6	0 MG	24JAN95	58	19FEB95	84	27
00038	Oral	6	0 MG	20FEB95	85	28MAR95	121	37
00038	Oral	6	0 MG	29MAR95	122	25APR95	149	28
00038	Oral	6	0 MG	26APR95	150	30MAY95	184	35
00038	Oral	6	0 MG	31MAY95	185	11JUL95	226	42
00038	Oral	6	0 MG	12JUL95	227	16AUG95	262	36
00086	Oral	5	0 MG	17AUG95	263	18AUG95	264	2
00086	Oral	4	0 MG	19AUG95	265	20AUG95	266	2
00086	Oral	3	0 MG	21AUG95	267	22AUG95	268	2
00086	Oral	2	0 MG	23AUG95	269	25AUG95	271	3
00086	Oral	1	0 MG	26AUG95	272	02SEP95	279	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	Yes	279	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ABDOMINAL PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
RHINORRHEA	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-58, -115	01OCT94	08OCT94#	500MG	ABD.PAIN
			36, -22	02JAN95	03JAN95	500MG	FEVER
DERMATOLOGICALS	Calamine	Caladryl Lotion	78, 21	13FEB95	25APR95	LOCAL TOPICAL	RASH
	Camphor	Caladryl Lotion	78, 21	13FEB95	25APR95	LOCAL TOPICAL	RASH
	Diphenhydramine Hydrochloride	Caladryl Lotion	78, 21	13FEB95	25APR95	LOCAL TOPICAL	RASH
	Glycerol	Caladryl Lotion	78, 21	13FEB95	25APR95	LOCAL TOPICAL	RASH
RESPIRATORY	Aminoacetic Acid	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
	Benzalkonium Chloride	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
	Clemastine Fumarate	Tavist D	15, -43	12DEC94	14DEC94		COLD
		Tavist-D	169, 112	15MAY95	19MAY95	2 TSP	COLD
	Oxymetazoline Hydrochloride	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
	Phenylmercuric Acetate	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
	Phenylpropanolamine Hydrochloride	Tavist D	15, -43	12DEC94	14DEC94		COLD
		Tavist-D	169, 112	15MAY95	19MAY95	2 TSP	COLD
	Sorbitol	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Fever	FEVER	36, -22	02:00 Hrs	0		MIL	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	4, -54	Not Stated	0	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	15, -43	Not Stated	0	CON	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	15, -43	3 Days	0	CON	MIL	NO	UNR	Yes	No
			169, 112	5 Days	0	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Rash	RASH ON BACK	78, 21	72 Days	0	CON	MOD	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	09NOV94	-19, -76	0	127	70	71	123	76	78	93.70	58.0
BL	21NOV94	-7, -64	0	78	54	64	78	54	64	100.00	
1	05DEC94	8, -50	0	92	60	72	90	60	72	96.00	
2	12DEC94	15, -43	0	88	62	72	88	62	76	96.00	
3	19DEC94	22, -36	0	84	56	80	84	56	84	97.50	
4	27DEC94	30, -28	0	76	48	72	76	48	72	97.00	
5	03JAN95	37, -21	0	86	50	88	86	50	84	97.00	
6	09JAN95	43, -15	0	86	56	70	86	56	70	96.50	
7	17JAN95	51, -7	0	90	58	84	90	58	84	98.50	
8	23JAN95	57, -1	0	84	56	72	84	56	76	98.00	
12	13FEB95	78, 21	0	84	56	80	84	56	80	98.00	
16	28MAR95	121, 64	0	86	54	72	86	54	72	100.00	
20	25APR95	149, 92	0	84	54	80	84	54	80	100.00	
28	30MAY95	184, 127	0	80	50	84	80	50	84	100.50	
32	11JUL95	226, 169	0	82	52	84	80	50	84	100.00	
32	17AUG95	263, 206	0	84	52	84	80	52	84	95.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-19	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	20000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	178	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-19	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	17.1	H	.	.	12 - 15.6	G/DL
				Hematocrit	52.3	H	.	.	35 - 46	%
				Red Blood Cell Count	5.9	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4		.	.	30 - 70	%
				Lymphocytes	31.2		.	.	21 - 51	%
				Monocytes	6.4		.	.	0 - 10	%
				Eosinophils	2.8		.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	215000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	173		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	144	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	149	Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	263	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.9	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	199000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	124	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	263	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00087 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	31JAN95	1	03FEB95	4	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	4	20	Other reason	VOLUNTARY WITHDRAWAL

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00087 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1994

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23JAN95	-8, .	0	110	70	84	110	70	84	135.00	67.0
BL	30JAN95	-1, .	0	110	70	84	110	70	84	135.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00087 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	24.9	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	10.8	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00087 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-4	Serum BHCG pregnancy test	NEGATIVE	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28FEB95	1	08MAR95	9	9
00088	Oral	2	100 MG	09MAR95	10	14MAR95	15	6
00088	Oral	3	150 MG	15MAR95	16	20MAR95	21	6
00088	Oral	4	200 MG	21MAR95	22	29MAR95	30	9
	Oral	4	200 MG	30MAR95	31	03APR95	35	5
00088	Oral	4	200 MG	04APR95	36	09APR95	41	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	41	200	Adverse event, including intercurrent illness	URINARY RETENTION

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	13, .	1 Days	100	1	MIL	NO	PSR	No	No
Digestive System	Constipation	CONSTIPATION	15, .	Not Stated	100	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	22, .	Not Stated	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	15, .	764 Days	100	CON	MIL	NO	PBU	No	No
Special Senses	Abnormal Vision	BLURRED VISION	15, .	Not Stated	100	CON	MIL	NO	PSR	No	No
	Taste Perversion	BAD TASTE	11, .	21 Days	100	CON	MIL	NO	PSR	No	No
Urogenital System	Urinary Retention	URINARY RETENTION	15, .	Not Stated	100	CON	SEV	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06FEB95	-22, .	0	.	.	.	110	62	84	109.00	52.3
BL	28FEB95	1, .	0	90	60	80	90	60	80	113.00	
1	09MAR95	10, .	100	90	60	96	90	60	96	111.00	
2	14MAR95	15, .	100	96	56	100	96	56	100	111.00	
3	21MAR95	22, .	200	90	60	96	90	60	96	112.00	
4	30MAR95	31, .	200	80	50	96	80	50	96	111.00	
5	04APR95	36, .	200	82	50	96	82	50	96	110.00	
6	11APR95	43, .	200	84	58	96	84	58	96	109.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-22	Hemoglobin	14.7				12 - 15.6	G/DL
				Hematocrit	42.3				35 - 46	%
				Red Blood Cell Count	4.9				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5				4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L			4 - 12	%
				Segmented Neutrophils	58.5				30 - 70	%
				Lymphocytes	29.2				21 - 51	%
				Monocytes	11.2	H			0 - 10	%
				Eosinophils	0.4				0 - 5	%
				Basophils	0.7				0 - 2	%
				Platelets	45000	L		-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8				25 - 35	PG
				Mean Corpuscle Volume	86				80 - 100	FL
				Blood Urea Nitrogen	11				7 - 25	MG/DL
				Creatinine	0.8				0.8 - 1.5	MG/DL
				Uric Acid	2.9				2.3 - 7	MG/DL
				Alkaline Phosphatase	106				44 - 280	U/L
				Aspartate Aminotransferase	16				0 - 41	U/L
				Alanine Aminotransferase	9				0 - 48	U/L
				Total Bilirubin	0.7				0.3 - 1.3	MG/DL
				Total Protein	7.3				6.2 - 8.8	G/DL
				Albumin	4.6				3.1 - 5.3	G/DL
				Glucose - Random	91				70 - 115	MG/DL
				Globulin	2.7				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	5			+		
				Urine Bacteria	5					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-22	Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07MAR95	1	13MAR95	7	7
00089	Oral	2	20 MG	14MAR95	8	21MAR95	15	8
00089	Oral	3	20 MG	22MAR95	16	27MAR95	21	6
00089	Oral	4	20 MG	28MAR95	22	04APR95	29	8
00089	Oral	4	20 MG	05APR95	30	11APR95	36	7
00089	Oral	4	20 MG	12APR95	37	18APR95	43	7
00089	Oral	4	20 MG	19APR95	44	25APR95	50	7
00089	Oral	4	20 MG	26APR95	51	01MAY95	56	6
	Oral	3	20 MG	02MAY95	57	05MAY95	60	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	60	20	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	8, .	14MAR95	.	500MG	HEADACHE
			42, .	17APR95	18APR95	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	TIRED	4,	.	Not Stated	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	8,	.	8 Days	20	CON	MIL	NO	PSR	Yes	No
			42,	.	24:00 Hrs	20		MOD	NO	UNR	Yes	No
Digestive System	Constipation	CONSTIPATION	15,	.	7 Days	20		MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	15,	.	Not Stated	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	4,	.	Not Stated	20	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS WHEN STANDING	8,	.	24:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Euphoria	ELATION AND EXPANSIVE MOOD	29,	.	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Insomnia	SLEEP PROBLEMS-EXAMPLE WAKES UP TOO EARLY	8,	.	Not Stated	20	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	27,	.	Not Stated	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	24FEB95	-11,	.	0	110	70	72	.	.	.	115.00	67.5
BL	07MAR95	1,	.	0	96	66	84	96	66	84	115.00	
1	14MAR95	8,	.	20	90	62	92	90	62	92	115.50	
2	21MAR95	15,	.	20	90	60	84	90	60	84	116.00	
3	28MAR95	22,	.	20	90	62	88	90	62	88	117.00	
4	04APR95	29,	.	20	90	60	84	90	60	84	117.00	
5	11APR95	36,	.	20	100	62	96	100	62	96	118.00	
6	18APR95	43,	.	20	100	60	92	100	60	92	116.50	
7	25APR95	50,	.	20	96	60	88	96	60	88	119.00	
8	02MAY95	57,	.	20	100	60	100	100	60	100	120.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-63	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	42	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	188	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	NEC		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-63	Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.2		.	.	12 - 15.6	G/DL
				Hematocrit	38.7		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3		.	.	30 - 70	%
				Lymphocytes	23.9		.	.	21 - 51	%
				Monocytes	5.5		.	.	0 - 10	%
				Eosinophils	2.2		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	319000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153		.	.	44 - 280	U/L
				Aspartate Aminotransferase	26		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG					
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	14MAR95	1	18MAR95	5	5
00090	Oral	1	50 MG	19MAR95	6	23MAR95	10	5
00090	Oral	1	50 MG	24MAR95	11	27MAR95	14	4
00090	Oral	2	100 MG	28MAR95	15	03APR95	21	7
00090	Oral	3	150 MG	04APR95	22	10APR95	28	7
00090	Oral	4	200 MG	11APR95	29	17APR95	35	7
00090	Oral	4	200 MG	18APR95	36	25APR95	43	8
00090	Oral	5	250 MG	26APR95	44	01MAY95	49	6
00090	Oral	4	200 MG	02MAY95	50	08MAY95	56	7
00090	Oral	4	200 MG	09MAY95	57	15MAY95	63	7
	Oral	3	150 MG	16MAY95	64	21MAY95	69	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	69	150	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
IRRITABLE BOWEL SYNDROME	DIGESTIVE DISORD, OTHER	DIGESTIVE SYST	CUR	1987

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Mylanta	50, .	02MAY95	.	UNKNOWN	INDIGESTION
	Dimeticone, Activated	Mylanta	50, .	02MAY95	.	UNKNOWN	INDIGESTION
	Enema, Nos	Enema Nos	49, .	01MAY95	01MAY95		CONSTIPATION
	Magnesium Hydroxide	Mylanta	50, .	02MAY95	.	UNKNOWN	INDIGESTION
	Senna Fruit	Senokot	50, .	02MAY95	.	UNKNOWN	CONSTIPATION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	., .		.		HEADACHE
			50, .	02MAY95	02MAY95	650MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	3, .	16MAR95	.	400MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	3, .	13 Days	50	CON	SEV	DCR	PSR	Yes	No
		HEADACHES	29, .	15 Days	200	CON	MIL	NO	PSR	Yes	No
			44, .	9 Days	250	CON	MOD	DCR	PSR	Yes	No
			53, .	1 Days	200	3	MIL	NO	PSR	Yes	No
Digestive System	Constipation	CONSTIPATION	44, .	6 Days	250	CON	SEV	DCR	PSR	Yes	No
			50, .	Not Stated	200	CON	MOD	NO	PSR	Yes	No
	Dry Mouth	DRY MOUTH	15, .	15 Days	100	CON	MIL	NO	PSR	No	No
	Dyspepsia	HEARTBURN	50, .	Not Stated	200	CON	MIL	NO	PSR	Yes	No
		INDIGESTION	44, .	6 Days	250	CON	MOD	DCR	PSR	No	No
			50, .	Not Stated	200	CON	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	15, .	29 Days	100	CON	MIL	NO	PSR	No	No
			57, .	Not Stated	200	CON	MIL	NO	PSR	No	No
Special Senses	Taste Perversion	BAD TASTE	3, .	5 Days	50	CON	MIL	DCR	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	08MAR95	-6,	.	0	100	60	70	100	60	72	137.00	64.0
BL	14MAR95	1,	.	0	70	44	80	70	44	80	140.00	
2	28MAR95	15,	.	100	96	60	84	96	60	84	139.00	
3	04APR95	22,	.	150	100	60	80	100	60	80	138.00	
4	11APR95	29,	.	200	96	60	84	90	60	84	140.00	
5	18APR95	36,	.	200	96	60	84	80	60	84	137.50	
6	25APR95	43,	.	200	90	60	84	90	60	84	139.50	
7	02MAY95	50,	.	200	100	60	88	100	60	88	138.00	
8	09MAY95	57,	.	200	96	56	84	96	56	84	139.00	
8	16MAY95	64,	.	150	92	58	96	92	58	96	140.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.9	.	.	.	30 - 70	%
				Lymphocytes	42.3	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	275000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	128	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	45		.	.	30 - 70	%
				Lymphocytes	40		.	.	21 - 51	%
				Monocytes	8		.	.	0 - 10	%
				Eosinophils	2		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131		.	.	44 - 280	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	20		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.7		.	.	3.1 - 5.3	G/DL
				Glucose - Random	86		.	.	70 - 115	MG/DL
				Globulin	3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	64		Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3		.	.		
					Urine Bacteria	4		.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4		.	.		
		VISIT 10/UNSCHEDULED LAB 1	78	(9)	Hemoglobin	13.7		.	.	12 - 15.6	G/DL
					Hematocrit	40.1		.	.	35 - 46	%
					Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.7		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.9		.	.	30 - 70	%
					Lymphocytes	39.7		.	.	21 - 51	%
					Monocytes	6		.	.	0 - 10	%
					Eosinophils	0.8		.	.	0 - 5	%
					Basophils	0.6		.	.	0 - 2	%
					Platelets	310000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.4		.	.	25 - 35	PG
					Mean Corpuscle Volume	86		.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	24MAR95	1	28MAR95	5	5
00091	Oral	2	20 MG	29MAR95	6	04APR95	12	7
00091	Oral	3	20 MG	05APR95	13	11APR95	19	7
00091	Oral	4	20 MG	12APR95	20	18APR95	26	7
00091	Oral	5	30 MG	19APR95	27	25APR95	33	7
00091	Oral	6	40 MG	26APR95	34	01MAY95	39	6
00091	Oral	6	40 MG	02MAY95	40	09MAY95	47	8
00091	Oral	6	40 MG	10MAY95	48	16MAY95	54	7
00033	Oral	6	40 MG	17MAY95	55	16JUN95	85	31
00033	Oral	6	40 MG	17JUN95	86	14JUL95	113	28
00033	Oral	6	40 MG	15JUL95	114	10AUG95	140	27
00033	Oral	6	40 MG	11AUG95	141	05SEP95	166	26
00033	Oral	6	40 MG	06SEP95	167	02OCT95	193	27
00033	Oral	6	40 MG	03OCT95	194	07NOV95	229	36
00091	Oral	5	30 MG	08NOV95	230	09NOV95	231	2
00091	Oral	4	20 MG	10NOV95	232	11NOV95	233	2
00091	Oral	3	20 MG	12NOV95	234	13NOV95	235	2
00091	Oral	2	20 MG	14NOV95	236	16NOV95	238	3
00091	Oral	1	20 MG	17NOV95	239	23NOV95	245	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	245	20		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	211, 157	20OCT95	30OCT95	1000 MG	COLD AND SORE THROAT
	Penicillin Nos	Penicillin	182, 128	21SEP95	01OCT95	1000 MG	SORE THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	9, -46	01APR95	01APR95	650MG	HEADACHE
			36, -19	28APR95	02MAY95	650MG	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, -53	15 Mins	20		MIL	NO	PBU	No	No
Digestive System	Nausea	NAUSEA	3, -52	10 Mins	20		MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS"FELT LIKE FAINTING"	9, -46	01:30 Hrs	20		MOD	NO	PSR	Yes	No
Respiratory System	Pharyngitis	SORE THROAT	182, 128	11 Days	40	1	MOD	NO	UNR	Yes	No
	Respiratory Disorder	COLD {SYMPTOMS}	36, -19	5 Days	40	1	MIL	NO	UNR	Yes	No
			211, 157	11 Days	40	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14MAR95	-10, -64	0	108	64	72	110	70	72	126.00	67.0
BL	24MAR95	1, -54	0	90	60	72	90	60	72	131.00	
1	28MAR95	5, -50	20	90	56	72	90	56	72	131.00	
2	04APR95	12, -43	20	100	60	84	100	60	84	130.00	
3	11APR95	19, -36	20	100	60	84	100	60	84	131.50	
4	18APR95	26, -29	20	90	60	84	90	60	84	132.00	
5	25APR95	33, -22	30	110	60	80	100	60	80	133.00	
6	02MAY95	40, -15	40	120	66	80	120	66	80	132.00	
7	09MAY95	47, -8	40	116	64	84	116	64	84	132.00	
8	16MAY95	54, -1	40	110	60	80	110	60	80	132.00	
12	16JUN95	85, 31	40	110	60	76	110	60	76	131.50	
16	14JUL95	113, 59	40	110	70	84	100	60	84	128.00	
20	10AUG95	140, 86	40	106	66	72	100	66	72	132.00	
24	05SEP95	166, 112	40	98	58	72	98	58	72	127.00	
28	03OCT95	194, 140	40	96	54	80	96	54	80	128.00	
32	07NOV95	229, 175	40	86	54	84	86	54	84	129.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.1		.	.	12 - 15.6	G/DL
				Hematocrit	39		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2		.	.	30 - 70	%
				Lymphocytes	32.6		.	.	21 - 51	%
				Monocytes	6.6		.	.	0 - 10	%
				Eosinophils	7.8	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	225000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	103		.	.	22 - 130	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	90		.	.	70 - 115	MG/DL
				Globulin	3.7		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Segmented Neutrophils	50		.	.	30 - 70	%
				Lymphocytes	35		.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79		.	.	22 - 130	U/L
				Aspartate Aminotransferase	26		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	0.4		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	87		.	.	70 - 115	MG/DL
				Globulin	3.3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13		.	.	12 - 15.6	G/DL
				Hematocrit	37.8		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.5		.	.	30 - 70	%
				Lymphocytes	32		.	.	21 - 51	%
				Monocytes	10		.	.	0 - 10	%
				Eosinophils	9.9	H	.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	196000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76		.	.	22 - 130	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.4		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8		.	.	6.2 - 8.8	G/DL
				Albumin	4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	88		.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	140	Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	229	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.5	.	.	.	30 - 70	%
				Lymphocytes	20	L	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	250000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	229	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	03MAY95	1	11MAY95	9	9
00092	Oral	2	100 MG	12MAY95	10	16MAY95	14	5
00092	Oral	3	150 MG	17MAY95	15	25MAY95	23	9
00092	Oral	4	200 MG	26MAY95	24	02JUN95	31	8
00092	Oral	4	200 MG	03JUN95	32	05JUN95	34	3
00092	Oral	4	200 MG	06JUN95	35	13JUN95	42	8
00092	Oral	4	200 MG	14JUN95	43	20JUN95	49	7
00092	Oral	4	200 MG	21JUN95	50	29JUN95	58	9
00035	Oral	4	200 MG	30JUN95	59	08AUG95	98	40
00035	Oral	4	200 MG	09AUG95	99	05SEP95	126	28
00035	Oral	4	200 MG	06SEP95	127	26SEP95	147	21
00035	Oral	4	200 MG	27SEP95	148	21OCT95	172	25
00035	Oral	0	0 MG	22OCT95	173	23OCT95	174	2
00035	Oral	4	200 MG	24OCT95	175	07NOV95	189	15
00035	Oral	4	200 MG	08NOV95	190	05DEC95	217	28
00035	Oral	4	200 MG	06DEC95	218	02JAN96	245	28
00092	Oral	5	250 MG	03JAN96	246	04JAN96	247	2
00092	Oral	4	200 MG	05JAN96	248	06JAN96	249	2
00092	Oral	3	150 MG	07JAN96	250	08JAN96	251	2
00092	Oral	2	100 MG	09JAN96	252	11JAN96	254	3
00092	Oral	1	50 MG	12JAN96	255	18JAN96	261	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	Yes	261	50		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Mylanta	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Bismuth Subsalicylate	Pepto Bismol	39, -20	10JUN95	10JUN95	2TBP	CRAMPS
	Caffeine	Coke Syrup	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Corn Syrup	Coke Syrup	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Dimeticone, Activated	Mylanta	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Magnesium Hydroxide	Milk Of Magnesia	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
		Mylanta	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Natural Flavors	Coke Syrup	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	234, 176	02:00 Hrs	200	1	MIL	NO	PBU	No	No
		STOMACH CRAMPS	19, -40	30 Mins	150	2	MIL	NO	PBU	No	No
			39, -20	1 Days	200	1	MOD	NO	PBU	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	2, -57	146 Days	50	CON	MIL	NO	PSR	No	No
	Gastrointestinal Disorder	STOMACH PROBLEMS	173, 115	2 Days	0		MOD	DCR	PBU	Yes	No
Nervous System	Somnolence	DROWSINESS	15, -44	16 Days	150	CON	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	-2, -60	16 Days	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	13APR95	-20, -78	0	104	60	68	104	62	72	99.00	60.5
BL	02MAY95	-1, -59	0	94	56	72	94	56	72	102.00	
1	11MAY95	9, -50	50	88	56	76	88	56	76	101.00	
2	16MAY95	14, -45	100	90	60	96	90	60	96	101.50	
3	26MAY95	24, -35	200	90	60	88	90	60	88	99.50	
4	02JUN95	31, -28	200	90	64	96	90	64	96	99.50	
5	06JUN95	35, -24	200	100	60	88	.	.	.	100.00	
6	13JUN95	42, -17	200	106	66	88	106	66	88	98.50	
7	20JUN95	49, -10	200	100	60	84	100	60	84	99.00	
8	30JUN95	59, 1	200	100	60	84	100	60	84	99.50	
12	08AUG95	98, 40	200	96	62	84	90	62	84	97.00	
16	05SEP95	126, 68	200	92	66	84	90	66	84	98.00	
20	26SEP95	147, 89	200	96	62	96	90	60	96	101.00	
28	07NOV95	189, 131	200	90	58	88	90	58	88	98.00	
32	05DEC95	217, 159	200	90	60	84	90	60	84	103.00	
32	02JAN96	245, 187	200	100	60	84	100	60	84	102.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-20	Hemoglobin	13.9		.	.	12 - 15.6	G/DL
				Hematocrit	39.3		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.2	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.3		.	.	30 - 70	%
				Lymphocytes	46.2		.	.	21 - 51	%
				Monocytes	8		.	.	0 - 10	%
				Eosinophils	1.1		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	192000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	83		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	8 - 21	MG/DL
				Creatinine	0.8		.	.	0.4 - 1.1	MG/DL
				Uric Acid	4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	320	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	28		.	.	0 - 41	U/L
				Alanine Aminotransferase	14		.	.	0 - 39	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2		.	.	5.7 - 8.2	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	90		.	.	60 - 110	MG/DL
				Globulin	2.8		.	.	2.1 - 3.8	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-5	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/UNSCHEDULED LAB 1	-5	Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	40		.	.	30 - 70	%
				Lymphocytes	52	H	.	.	21 - 51	%
				Monocytes	7		.	.	0 - 10	%
				Eosinophils	1		.	.	0 - 5	%
				Blood Urea Nitrogen	11		.	.	8 - 21	MG/DL
				Creatinine	0.9		.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	245		.	.	44 - 280	U/L
				Aspartate Aminotransferase	31		.	.	0 - 41	U/L
				Alanine Aminotransferase	15		.	.	0 - 39	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	5.7 - 8.2	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	65	Glucose - Random	101	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	42.4	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	223	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	60	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.9	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 16/CONTINUATION-WEEK 32	245	Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	7000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	225	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	2.8	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 16/CONTINUATION-WEEK 32	245	Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/UNSCHEDULED LAB 1	259	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	27.6	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	187000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	21JUN95	1	26JUN95	6	6
00093	Oral	2	100 MG	27JUN95	7	06JUL95	16	10
00093	Oral	3	150 MG	07JUL95	17	21JUL95	31	15
00093	Oral	4	200 MG	22JUL95	32	25JUL95	35	4
00093	Oral	5	250 MG	26JUL95	36	01AUG95	42	7
00093	Oral	6	300 MG	02AUG95	43	10AUG95	51	9
00093	Oral	6	300 MG	11AUG95	52	16AUG95	57	6
00093	Oral	6	300 MG	17AUG95	58	22AUG95	63	6
00053	Oral	6	300 MG	23AUG95	64	08SEP95	80	17

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	80	300	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1989
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Butalbital	Butalbital	-171, -234	01JAN95	.	1 DAILY PRN	HEADACHES
RESPIRATORY	Salbutamol	Albuterol	-1997,-2060	01JAN90	.	8 PUFFS DAILY PRN	ASTHMA
			-1997,-2060	01JAN90	.	8 PUFFS DAILY PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	-1, -64	106 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	49, -15	20 Mins	300	1	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	08JUN95	-13, -76	0	106	70	64	110	70	70	127.00	61.5
BL	20JUN95	-1, -64	0	90	60	84	90	60	84	125.00	
1	27JUN95	7, -57	100	90	60	84	90	60	84	122.50	
2	06JUL95	16, -48	100	90	60	84	90	60	84	125.00	
4	21JUL95	31, -33	150	86	60	84	80	60	84	125.00	
5	25JUL95	35, -29	200	92	56	88	90	56	88	125.00	
6	01AUG95	42, -22	250	84	54	100	86	54	100	126.00	
7	10AUG95	51, -13	300	86	54	96	80	54	96	126.00	
8	22AUG95	63, -1	300	90	60	88	86	60	88	126.00	
16	03OCT95	105, 42#	0	90	60	80	90	60	80	128.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	27	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-8	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.5	.	.	.	30 - 70	%
				Lymphocytes	36.2	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	361000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/UNSCHEDULED LAB 1	-8	Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	30	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	108	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	63		Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	77	.	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/UNSCHEDULED LAB 1	72		Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.7	.	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
					Platelets	344000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
		VISIT 11/CONTINUATION-WEEK 12	105	(25)	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	59.6	.	.	.	30 - 70	%
					Lymphocytes	29.7	.	.	.	21 - 51	%
					Monocytes	5	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/CONTINUATION-WEEK 12	105	(25)	Eosinophils	5.3	H	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	370000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	109	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	102	.	.	.	70 - 115	MG/DL
					Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	+		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	2	.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	24OCT95	1	30OCT95	7	7
00094	Oral	2	0 MG	31OCT95	8	06NOV95	14	7
00094	Oral	3	0 MG	07NOV95	15	13NOV95	21	7
00094	Oral	4	0 MG	14NOV95	22	20NOV95	28	7
00094	Oral	5	0 MG	21NOV95	29	27NOV95	35	7
00094	Oral	6	0 MG	28NOV95	36	04DEC95	42	7
00094	Oral	6	0 MG	05DEC95	43	11DEC95	49	7
00094	Oral	6	0 MG	12DEC95	50	19DEC95	57	8
	Oral	5	0 MG	20DEC95	58	04JAN96	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	73	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGY TO PENICILLIN {PATIENT GETS A RASH}	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	
SKIN CUTS MULTIPLE {SUPERFICIAL ON LEFT FOREARM}	OPEN WOUND	INJURY/POISONING	CUR	1995
SKIN CUTS MULTIPLE {SUPERFICIAL ON RIGHT THIGH}	OPEN WOUND	INJURY/POISONING	CUR	1995
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Omeprazole	Prilosec	32, .	24NOV95	.	PRN	ACIDITY
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	49, .	11DEC95	11DEC95	500MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	WEAKNESS	49, .	02:00 Hrs	0	1	MOD	NO	PSR	No	No
			50, .	Not Stated	0	CON	MIL	NO	PBU	No	No
	Headache	HEADACHE	49, .	02:00 Hrs	0	1	MOD	NO	PSR	No	No
			50, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Digestive System	Dyspepsia	STOMACH ACIDITY	32, .	Not Stated	0	CON	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	49, .	02:00 Hrs	0	1	MOD	NO	PSR	No	No
Skin and Appendages	Rash	RASH {MINOR OF UNKNOWN CAUSES}	5, .	24:00 Hrs	0	1	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20OCT95	-4,	.	0	108	62	.	100	70	70	112.00	64.5
BL	24OCT95	1,	.	0	110	20	84	110	70	84	118.00	
1	31OCT95	8,	.	0	116	74	108	116	74	108	113.00	
2	07NOV95	15,	.	0	110	70	88	110	70	84	111.00	
3	14NOV95	22,	.	0	114	78	84	114	78	84	111.50	
4	21NOV95	29,	.	0	110	70	84	110	70	84	112.00	
5	28NOV95	36,	.	0	112	74	104	112	74	104	113.00	
6	05DEC95	43,	.	0	114	74	84	114	74	84	111.00	
7	12DEC95	50,	.	0	100	64	96	100	64	96	110.50	
8	19DEC95	57,	.	0	100	66	96	100	66	96	111.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.8		.	.	12 - 15.6	G/DL
				Hematocrit	39.3		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73	H	.	.	30 - 70	%
				Lymphocytes	19.4	L	.	.	21 - 51	%
				Monocytes	4.7		.	.	0 - 10	%
				Eosinophils	1.9		.	.	0 - 5	%
				Basophils	1.1		.	.	0 - 2	%
				Platelets	263000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120		.	.	44 - 280	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2		.	.	6.2 - 8.8	G/DL
				Albumin	5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	89		.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick	2		.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	71	Hemoglobin	13		.	.	12 - 15.6	G/DL
				Hematocrit	37.2		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H	.	.	30 - 70	%
				Lymphocytes	19.3	L	.	.	21 - 51	%
				Monocytes	3		.	.	0 - 10	%
				Eosinophils	3.3		.	.	0 - 5	%
				Basophils	0.9		.	.	0 - 2	%
				Platelets	206000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	115		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	71	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	01FEB96	1	06FEB96	6	6
00247	Oral	2	100 MG	07FEB96	7	12FEB96	12	6
00247	Oral	3	150 MG	13FEB96	13	20FEB96	20	8
00247	Oral	4	200 MG	21FEB96	21	27FEB96	27	7
00247	Oral	4	200 MG	28FEB96	28	07MAR96	36	9
00247	Oral	4	200 MG	08MAR96	37	11MAR96	40	4
00247	Oral	4	200 MG	12MAR96	41	21MAR96	50	10
00247	Oral	4	200 MG	22MAR96	51	25MAR96	54	4
00128	Oral	4	200 MG	26MAR96	55	29APR96	89	35
00128	Oral	4	200 MG	30APR96	90	20MAY96	110	21
00128	Oral	4	200 MG	21MAY96	111	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	111	200	Protocol violation, including non-compliance	CHOSE TO LEAVE STUDY EARLY

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Phenol	Chloraseptic	34, -21	05MAR96	.		COLD
RESPIRATORY	Dextromethorphan Hydrobromide	Nyquil	34, -21	05MAR96	.		COLD
	Doxylamine Succinate	Nyquil	34, -21	05MAR96	.		COLD
	Paracetamol	Nyquil	34, -21	05MAR96	.		COLD
	Pseudoephedrine Hydrochloride	Nyquil	34, -21	05MAR96	.		COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	TIRED	90, 36	1 Days	200	1	MIL	NO	UNR	No	No
Carciovascular System	Postural Hypotension	DIZZINESS WHEN STANDING UP ORTHOSTATIC HYPOTENSION	9, -46	33 Days	100	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	10, -45	23 Days	100	CON	MIL	NO	PSR	No	No
			36, -19	15 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS WHEN WAKING UP IN AM	10, -45	32 Days	100		MIL	NO	PSR	No	No
	Nervousness	IRRITABLE EDGY BURNT SELF WITH CIGARETTE	45, -10	11 Days	200	1	MIL	DCR	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	34, -21	3 Days	200	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05JAN96	-27, -81	0	90	62	.	.	.	.	132.00	70.5
BL	30JAN96	-2, -56	0	100	60	72	100	60	72	130.00	
1	06FEB96	6, -49	50	100	60	72	100	60	72	130.00	
2	13FEB96	13, -42	150	96	60	84	80	56	84	131.00	
3	20FEB96	20, -35	150	98	56	88	100	56	88	131.00	
4	27FEB96	27, -28	200	96	68	112	90	64	112	130.00	
5	07MAR96	36, -19	200	102	60	96	102	60	96	135.00	
6	12MAR96	41, -14	200	96	62	96	96	60	96	132.00	
7	21MAR96	50, -5	200	94	60	96	94	60	96	132.00	
8	26MAR96	55, 1	200	90	60	84	90	60	84	131.00	
12	30APR96	90, 36	200	100	60	84	96	60	88	135.00	
16	21MAY96	111, 57	200	90	60	96	90	60	96	131.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.2	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	139	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	30.2	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	01MAR96	1	05MAR96	5	5
00248	Oral	2	20 MG	06MAR96	6	11MAR96	11	6
00248	Oral	3	20 MG	12MAR96	12	18MAR96	18	7
00248	Oral	4	20 MG	19MAR96	19	25MAR96	25	7
00248	Oral	5	30 MG	26MAR96	26	01APR96	32	7
00248	Oral	6	40 MG	02APR96	33	10APR96	41	9
00248	Oral	6	40 MG	11APR96	42	15APR96	46	5
00248	Oral	6	40 MG	16APR96	47	22APR96	53	7
	Oral	5	30 MG	23APR96	54	02MAY96	63	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	63	30	Lack of Efficacy	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	60, .	29APR96	.		HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU	33, .	10 Days	40	CON	MIL	NO	UNR	No	No
Carciovascular System	Arrhythmia	IRREGULAR PULSE	-8, .	Not Stated	0	CON	MIL	NO	UNR	No	No
Hemic and Lymphatic System	Anemia	ANEMIA	54, .	Not Stated	30	CON	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	26, .	17 Days	30	CON	MIL	NO	PSR	No	No
	Withdrawal Syndrome	MIGRAINE HEADACHE {WITHDRAWAL SYMPTOM}	60, .	6 Days	30	CON	SEV	NO	REL	Yes	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14FEB96	-16, .	0	100	60	.	.	.	.	121.00	65.5
BL	22FEB96	-8, .	0	80	50	64	80	50	64	129.00	
1	05MAR96	5, .	20	88	54	64	80	50	64	125.00	
2	12MAR96	12, .	20	94	58	68	94	58	68	124.00	
3	19MAR96	19, .	20	90	60	72	90	60	72	125.00	
4	26MAR96	26, .	30	96	56	80	90	56	80	126.00	
5	02APR96	33, .	40	96	62	80	90	60	80	126.00	
6	11APR96	42, .	40	94	60	80	90	60	80	122.00	
7	16APR96	47, .	40	94	62	80	90	60	80	124.00	
8	23APR96	54, .	30	86	62	80	80	60	80	123.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	13.3		.	.	12 - 15.6	G/DL
				Hematocrit	38.5		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.5		.	.	30 - 70	%
				Lymphocytes	37.6		.	.	21 - 51	%
				Monocytes	5.7		.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	1.1		.	.	0 - 2	%
				Platelets	210000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	156		.	.	44 - 280	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	88		.	.	70 - 115	MG/DL
				Globulin	2.9		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Squamous Epithelial Cells	3		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	11.9	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.4	L	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2		.	.	30 - 70	%
				Lymphocytes	39.9		.	.	21 - 51	%
				Monocytes	5.9		.	.	0 - 10	%
				Eosinophils	7.3	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	228000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	137		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	07MAR96	1	11MAR96	5	5
00249	Oral	2	100 MG	12MAR96	6	18MAR96	12	7
00249	Oral	3	150 MG	19MAR96	13	25MAR96	19	7
00249	Oral	4	200 MG	26MAR96	20	01APR96	26	7
00249	Oral	5	250 MG	02APR96	27	08APR96	33	7
00249	Oral	6	300 MG	09APR96	34	15APR96	40	7
00249	Oral	6	300 MG	16APR96	41	22APR96	47	7
00249	Oral	6	300 MG	23APR96	48	29APR96	54	7
	Oral	5	250 MG	30APR96	55	07MAY96	62	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	62	250	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
CIGARETTE SMOKER	TOBACCO USE	MENTAL DISORD	CUR	
DYSMENORRHEA	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1991
NEAR-SIGHTED	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	CUR	
SCARS LEFT AND RIGHT FOREARM	SCARRING	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-1892, .	01JAN91	.		HEADACHE
			3, .	09MAR96	09MAR96	200 MG	HEADACHE
			38, .	13APR96	15APR96	400 MG BID	MENSTRUAL CRAMPS
RESPIRATORY	Chlorphenamine Maleate	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD
	Dextromethorphan Hydrobromide	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD
	Paracetamol	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD
	Phenylpropanolamine Hydrochloride	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	1, .	3 Days	50	2	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	40, .	1 Mins	300	1	MIL	NO	PSR	No	No
		DIZZINESS (ORTHOSTATIC)	41, .	2 Mins	300		MIL	NO	PSR	No	No
		LIGHT HEADEDNESS	14, .	14 Days	150	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	48, .	8 Days	300		MIL	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	38, .	3 Days	300		MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01MAR96	-6,	.	0	90	60	78	90	58	76	176.00	63.3
BL	07MAR96	1,	.	0	86	60	88	86	60	88	176.00	
1	12MAR96	6,	.	100	90	60	84	90	60	84	176.00	
2	19MAR96	13,	.	150	100	70	96	100	70	96	177.00	
3	26MAR96	20,	.	200	92	56	84	90	56	84	175.00	
4	02APR96	27,	.	250	100	60	84	90	60	88	176.00	
5	09APR96	34,	.	300	106	70	84	100	66	84	178.00	
6	16APR96	41,	.	300	106	72	96	100	66	96	180.00	
7	23APR96	48,	.	300	98	78	88	90	74	88	176.00	
8	30APR96	55,	.	250	100	70	96	96	70	96	177.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	320000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.1		.	.	12 - 15.6	G/DL
				Hematocrit	36.8		.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.3		.	.	30 - 70	%
				Lymphocytes	37.5		.	.	21 - 51	%
				Monocytes	5.5		.	.	0 - 10	%
				Eosinophils	2.4		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	376000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	7		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81		.	.	22 - 130	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	14MAR96	1	18MAR96	5	5
00250	Oral	2	20 MG	19MAR96	6	25MAR96	12	7
00250	Oral	3	20 MG	26MAR96	13	01APR96	19	7
00250	Oral	4	20 MG	02APR96	20	11APR96	29	10
00250	Oral	5	30 MG	12APR96	30	18APR96	36	7
00250	Oral	6	40 MG	19APR96	37	22APR96	40	4
00250	Oral	6	40 MG	23APR96	41	29APR96	47	7
00250	Oral	5	30 MG	30APR96	48	09MAY96	57	10
00250	Oral	6	40 MG	10MAY96	58	12MAY96	60	3
00250	Oral	5	30 MG	13MAY96	61	27MAY96	75	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	75	30	Adverse event, including intercurrent illness	PT TOOK OVERDOSE & WAS HOSPITALIZED

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	47, -11	29APR96	29APR96	25 MG	ALLERGY
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	47, -11	29APR96	29APR96	25 MG	ALLERGY

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	ALLERGIES	47, -11	24:00 Hrs	40		MIL	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEOUS	2, -56	12 Days	20	CON	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	2, -56	5 Mins	20	2	MIL	NO	PBU	No	No
	Emotional Lability	OVERDOSE {INTENTIONAL}	37, -21	21 Days	40	CON	MOD	NO	UNR	No	Yes
			75, 18	01:00 Hrs	30	1	SEV	STP	UNR	No	Yes
	Somnolence	SLEEPINESS	37, -21	Not Stated	40	CON	MOD	DCR	PSR	No	No
		SLEEPY	2, -56	12 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	05MAR96	-9, -66	0	110	70	60	100	65	64	180.00	64.0
BL	14MAR96	1, -57	0	100	60	96	100	60	96	186.00	
1	19MAR96	6, -52	20	120	66	88	110	60	88	181.00	
2	26MAR96	13, -45	20	100	60	84	100	60	84	179.00	
3	02APR96	20, -38	20	110	62	96	100	60	96	180.00	
4	12APR96	30, -28	30	118	76	96	110	70	96	181.00	
5	16APR96	34, -24	30	114	72	88	110	70	88	183.00	
6	23APR96	41, -17	40	112	68	96	110	68	96	181.00	
7	30APR96	48, -10	30	110	70	88	110	70	88	182.00	
8	09MAY96	57, -1	30	110	70	96	110	70	96	184.00	
12	28MAY96	76, 19	30	94	58	88	90	60	88	182.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	12.1		.	.	12 - 15.6	G/DL
				Hematocrit	36.8		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.4		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	3	L	.	.	4 - 12	%
				Segmented Neutrophils	58		.	.	30 - 70	%
				Lymphocytes	29		.	.	21 - 51	%
				Monocytes	7		.	.	0 - 10	%
				Eosinophils	2		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	340000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	25.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	77	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99		.	.	44 - 280	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	12		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	8		.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	77		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	6	Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00251 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28MAR96	1	04APR96	8	8
00251	Oral	2	0 MG	05APR96	9	08APR96	12	4
00251	Oral	3	0 MG	09APR96	13	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	13	0	Lost to follow-up	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00251 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MYRINGOTOMY {TUBE PLACEMENT}	OPERATION, EAR	OPERATIONS	.	
DIZZINESS	DIZZINESS AND GIDDINESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SHORTNESS OF BREATH	DYSPNEA, OTHER	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19MAR96	-9, .	0	120	80	60	120	90	61	124.50	61.0
1	04APR96	8, .	0	110	70	96	100	66	96	130.00	
2	09APR96	13, .	0	112	64	96	106	56	96	131.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00251 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.5	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00251 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	10APR96	1	16APR96	7	7
00252	Oral	2	0 MG	17APR96	8	23APR96	14	7
00252	Oral	3	0 MG	24APR96	15	30APR96	21	7
00252	Oral	4	0 MG	01MAY96	22	09MAY96	30	9
00252	Oral	4	0 MG	10MAY96	31	14MAY96	35	5
00252	Oral	5	0 MG	15MAY96	36	20MAY96	41	6
00252	Oral	4	0 MG	21MAY96	42	27MAY96	48	7
00252	Oral	4	0 MG	28MAY96	49	10JUN96	62	14
	Oral	3	0 MG	11JUN96	63	18JUN96	70	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	70	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIC TO SULFA DRUGS	ADVERSE EFF/ANTI-INFECT	EXT CAUSES OF INJURY/POISONING	CUR	
ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	
FACIAL CYSTIC ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	
MURMUR {I/VI SYSTOLIC EJECTION MURMUR}	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	39, .	18MAY96	18MAY96	2 TAB	HEADACHE
	Caffeine	Midol	39, .	18MAY96	18MAY96	2 TAB	HEADACHE
	Cinnamedrine Hydrochloride	Midol	39, .	18MAY96	18MAY96	2 TAB	HEADACHE
	Paracetamol	Tylenol	., .		.	500 MG	HEADACHE
DERMATOLOGICALS	Tretinoin	Retin-A	., .		.		CYSTIC ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	16, .	20 Days	0	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	21, .	30 Mins	0	5	MIL	NO	PSR	No	No
			39, .	02:00 Hrs	0	1	MOD	DCR	PSR	Yes	No
Digestive System	Nausea	NAUSEA	21, .	30 Mins	0	5	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	20, .	1 Mins	0	1	MIL	NO	PSR	No	No
	Nervousness	IRRITABILITY	37, .	13 Days	0	CON	MOD	DCR	PSR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	42, .	30 Mins	0	1	MIL	DCR	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19MAR96	-22,	.	0	100	68	68	100	64	66	106.00	66.5
BL	09APR96	-1,	.	0	100	60	88	100	60	88	109.00	
1	16APR96	7,	.	0	102	58	96	100	58	96	113.00	
2	23APR96	14,	.	0	90	56	.	100	56	104	113.00	
3	30APR96	21,	.	0	102	54	100	100	54	100	113.00	
4	09MAY96	30,	.	0	98	54	96	96	54	96	114.00	
5	14MAY96	35,	.	0	100	56	96	100	56	96	114.00	
6	21MAY96	42,	.	0	102	56	84	102	56	84	113.00	
7	28MAY96	49,	.	0	100	60	84	100	60	84	113.00	
8	04JUN96	56,	.	0	100	60	96	100	60	96	112.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
				Hematocrit	34	L	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.4	H	.	.	30 - 70	%
				Lymphocytes	22	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	103	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	30.7	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28FEB96	1	05MAR96	7	7
00289	Oral	2	100 MG	06MAR96	8	12MAR96	14	7
00289	Oral	3	150 MG	13MAR96	15	19MAR96	21	7
00289	Oral	4	200 MG	20MAR96	22	26MAR96	28	7
00289	Oral	4	200 MG	27MAR96	29	02APR96	35	7
00289	Oral	4	200 MG	03APR96	36	09APR96	42	7
00289	Oral	4	200 MG	10APR96	43	16APR96	49	7
00289	Oral	4	200 MG	17APR96	50	23APR96	56	7
00131	Oral	4	200 MG	24APR96	57	21MAY96	84	28
00131	Oral	4	200 MG	22MAY96	85	19JUN96	113	29
00131	Oral	4	200 MG	20JUN96	114	18JUL96	142	29
00131	Oral	4	200 MG	19JUL96	143	15AUG96	170	28
00131	Oral	4	200 MG	16AUG96	171	12SEP96	198	28
00131	Oral	4	200 MG	13SEP96	199	10OCT96	226	28
00289	Oral	3	150 MG	11OCT96	227	12OCT96	228	2
00289	Oral	2	100 MG	13OCT96	229	15OCT96	231	3
00289	Oral	1	50 MG	16OCT96	232	22OCT96	238	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	238	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES {TO POLLEN, TREES, DUST}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
DYSMENORRHEA	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
ASTHMA {AS YOUNG CHILD}	ASTHMA	RESPIRATORY SYST DIS	PRV	1981

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Mepyramine Maleate	Pamprin	.,	.	.	2 TABS	MENSTRUAL CRAMPS
	Pamabrom	Pamprin	.,	.	.	2 TABS	MENSTRUAL CRAMPS
	Paracetamol	Pamprin	.,	.	.	2 TABS	MENSTRUAL CRAMPS
		Tylenol	.,	.	.	1000MG	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	1, -56	85 Days	50		MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	13, -44	31 Days	100		MIL	NO	PSR	No	No
Hemic and Lymphatic System	Anemia	ANEMIA	227, 171	Not Stated	150	CON	MIL	NO	UNR	No	No
Nervous System	Insomnia	INSOMNIA	15, -42	129 Days	150		MIL	NO	PBU	No	No
Uroçenital System	Dysmenorrhea	MENSTRUAL CRAMPS	57, 1	Not Stated	200	6	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12FEB96	-16, -72	0	110	56	76	104	62	76	118.63	63.0
1	06MAR96	8, -49	100	114	82	84	102	72	84	119.07	
2	13MAR96	15, -42	150	94	70	108	88	68	120	118.41	
3	20MAR96	22, -35	200	102	70	96	98	70	112	117.53	
4	27MAR96	29, -28	200	104	70	94	94	76	112	114.66	
5	03APR96	36, -21	200	94	64	96	84	66	112	113.12	
6	10APR96	43, -14	200	98	70	82	86	66	96	114.66	
7	17APR96	50, -7	200	100	66	98	92	62	112	116.87	
8	24APR96	57, 1	200	106	74	84	98	68	82	118.41	
12	22MAY96	85, 29	200	104	74	102	90	70	108	113.78	
16	20JUN96	114, 58	200	90	62	92	84	64	100	115.10	
20	19JUL96	143, 87	200	99	65	86	93	66	90	105.80 L	
24	16AUG96	171, 115	200	80 L	60	100	84	60	104	102.09 L	
28	13SEP96	199, 143	200	92	58	80	82	64	90	106.06 L	
32	11OCT96	227, 171	150	88	60	68	86	64	70	108.93 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	12.3		.	.	12 - 15.6	G/DL
				Hematocrit	35.3		.	.	35 - 46	%
				Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.9	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	2.6		.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	1.3		.	.	0 - 2	%
				Platelets	281000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60		.	.	22 - 130	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4		.	.	6.2 - 8.8	G/DL
				Albumin	4.8		.	.	3.1 - 5.3	G/DL
				Glucose - Random	82		.	.	70 - 115	MG/DL
				Globulin	3.6		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	6		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	10.3	L	.	.	12 - 15.6	G/DL
				Hematocrit	30.4	L	.	-	35 - 46	%
				Red Blood Cell Count	3.4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.4	.	.	.	30 - 70	%
				Lymphocytes	33.1	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.6	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	143	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	36	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40.6	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	143	Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	227	Hemoglobin	10.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	30.5	L	.	-	35 - 46	%
				Red Blood Cell Count	3.4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.4	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	227	Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	19	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	47	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11MAR96	1	19MAR96	9	9
00290	Oral	2	100 MG	20MAR96	10	22MAR96	12	3

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	No	No	12	100	Adverse event, including intercurrent illness	HIGH BLOOD PRESSURE

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
NEARSIGHTED	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	CUR	
SORE THROATS {FREQUENT}	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1994
TONSILLECTOMY AND ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1994

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Hypertension	HIGH BLOOD PRESSURE	10, .	15 Days	100	CON	MIL	STP	PSR	No	No
	Tachycardia	TACHYCARDIA	10, .	Not Stated	100	CON	MIL	STP	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	2, .	24:00 Hrs	50	1	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06MAR96	-5, .	0	122	70	90	128	72	112	176.18	66.1
1	20MAR96	10, .	100	150	76	112	160	86	124	175.08	
2	22MAR96	12, .	100	136	70	104	160	88	118		

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	38.9	.	.	.	30 - 70	%
				Lymphocytes	44.3	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	68	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03JUL96	1	14JUL96	12	12
00291	Oral	2	0 MG	15JUL96	13	23JUL96	21	9
00291	Oral	3	0 MG	24JUL96	22	30JUL96	28	7
00291	Oral	4	0 MG	31JUL96	29	06AUG96	35	7
00291	Oral	4	0 MG	07AUG96	36	13AUG96	42	7
00291	Oral	4	0 MG	14AUG96	43	20AUG96	49	7
00291	Oral	4	0 MG	21AUG96	50	27AUG96	56	7
00291	Oral	5	0 MG	28AUG96	57	05SEP96	65	9
00135	Oral	5	0 MG	06SEP96	66	01OCT96	91	26
00135	Oral	5	0 MG	02OCT96	92	29OCT96	119	28
00135	Oral	5	0 MG	30OCT96	120	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	120	0	Lost to follow-up	

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH PAINS	7, -59	01:00 Hrs	0	2	MIL	NO	PSR	No	No
	Headache	HEADACHE	12, -54	01:00 Hrs	0	1	MOD	NO	PSR	No	No
Carciovascular System	Arrhythmia	SINUS-ARRHYTHMIA	92, 27	29 Days	0	1	MIL	NO	PBU	No	No
Digestive System	Constipation	CONSTIPATION	50, -16	Not Stated	0	1	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	57, -9	8 Days	0	CON	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZINESS	36, -30	8 Days	0	1	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01JUL96	-2, -67	0	100	58	84	102	60	84	101.65	62.2
BL	03JUL96	1, -65	0	97	75	66	97	64	70		
2	15JUL96	13, -53	0	109	68	84	105	64	96	102.53	
3	24JUL96	22, -44	0	110	62	80	102	64	88	101.43	
4	31JUL96	29, -37	0	108	56	92	104	58	92	103.19	
5	07AUG96	36, -30	0	112	64	78	108	66	86	102.75	
6	14AUG96	43, -23	0	108	60	86	100	62	104	102.09	
7	21AUG96	50, -16	0	110	70	78	110	65	92	102.53	
8	28AUG96	57, -9	0	102	62	84	108	58	90	102.75	
8	04SEP96	64, -2	0	104	58	92	104	62	98	103.19	
12	02OCT96	92, 27	0	104	60	92	108	62	98	100.99	
16	30OCT96	120, 55	0	106	60	90	108	70	90	102.31	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-2	Hemoglobin	12.9		.	.	12 - 15.6	G/DL
				Hematocrit	38.5		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1		.	.	30 - 70	%
				Lymphocytes	23.8		.	.	21 - 51	%
				Monocytes	4.2		.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	290000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	7		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72		.	.	22 - 130	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	8		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	84		.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-2	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	MONGOLOID (KOREAN)

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07AUG96	1	16AUG96	10	10
00292	Oral	2	20 MG	17AUG96	11	21AUG96	15	5
00292	Oral	3	20 MG	22AUG96	16	30AUG96	24	9
00292	Oral	4	20 MG	31AUG96	25	04SEP96	29	5
00292	Oral	4	20 MG	05SEP96	30	17SEP96	42	13
00292	Oral	4	20 MG	18SEP96	43	25SEP96	50	8
00292	Oral	4	20 MG	26SEP96	51	03OCT96	58	8
00179	Oral	4	20 MG	04OCT96	59	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	59	20	Lost to follow-up	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	07AUG96	1, -58	0	126	56	80	130	56	80	143.10	60.6
1	16AUG96	10, -49	20	138	74	86	142	62	88	141.56	
2	21AUG96	15, -44	20	112	80	80	118	76	45 L	139.36	
3	30AUG96	24, -35	20	122	50	80	128	54	82	139.80	
4	04SEP96	29, -30	20	126	50	92	116	46	106	141.12	
7	25SEP96	50, -9	20	128	58	95	132	48	98	142.88	
8	04OCT96	59, 1	20	120	65	100	120	70	96	144.43	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	4.3	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	134	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-5		Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70	(12)	Hemoglobin	15.4		.	.	13.8 - 17.2	G/DL
					Hematocrit	45.2		.	.	41 - 50	%
					Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	9.4		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	76.1	H	.	.	30 - 70	%
					Lymphocytes	18.9	L	.	.	21 - 51	%
					Monocytes	2.4		.	.	0 - 10	%
					Eosinophils	2		.	.	0 - 5	%
					Basophils	0.6		.	.	0 - 2	%
					Platelets	325000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.5		.	.	25 - 35	PG
					Mean Corpuscle Volume	89		.	.	80 - 100	FL
					Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
					Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
					Uric Acid	6.1		.	.	4 - 8	MG/DL
					Alkaline Phosphatase	101		.	.	22 - 180	U/L
					Aspartate Aminotransferase	11		.	.	0 - 41	U/L
					Alanine Aminotransferase	13		.	.	0 - 48	U/L
					Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
					Total Protein	8.1		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	70	(12)	Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	82	.	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG			.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	+		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG			.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	17MAY96	1	20MAY96	4	4
00313	Oral	2	20 MG	21MAY96	5	28MAY96	12	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	No	No	12	20	Adverse event, including intercurrent illness	PT. WAS DROPPED DUE TO HOSPITALIZATION I.E. ADVERSE EXPERIENCE

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OVERWEIGHT	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	
TUBERCULOSIS	TUBERCULOSIS	INFECTIOUS/PARASITIC DIS	PRV	

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	2, .	Not Stated	20	CON	MIL	NO	PSR	No	No
Nervous System	Emotional Lability	SUPERFICIAL CUTS RISK TO SELF	12, .	6 Days	20	CON	SEV	STP	PBU	No	Yes
	Hallucinations	AUDITORY HALLUCINATIONS	12, .	6 Days	20	CON	SEV	STP	PBU	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	08MAY96	-9,	.	0	116	70	60	118	80	60	175.00	63.0
BL	17MAY96	1,	.	0	90	60	72	82	56	72	191.00	
1	21MAY96	5,	.	20	90	60	72	90	60	72	194.00	
2	28MAY96	12,	.	20	112	74	84	112	74	84	182.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6				13.8 - 17.2	G/DL
				Hematocrit	46.5				41 - 50	%
				Red Blood Cell Count	5.1				4.4 - 5.8	MILL/MCL
				White Blood Cell Count	7.7				3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	57.9				40 - 75	%
				Lymphocytes	32.5				16 - 46	%
				Monocytes	6.5				0 - 12	%
				Eosinophils	2.7				0 - 7	%
				Basophils	0.5				0 - 2	%
				Platelets	205000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6				27 - 33	PG
				Mean Corpuscle Volume	91				80 - 100	FL
				Blood Urea Nitrogen	14				7 - 25	MG/DL
				Creatinine	0.9				0.8 - 1.5	MG/DL
				Uric Acid	4.8				4 - 8	MG/DL
				Alkaline Phosphatase	71				22 - 180	U/L
				Aspartate Aminotransferase	34				0 - 41	U/L
				Alanine Aminotransferase	69	H			0 - 48	U/L
				Total Bilirubin	0.6				0.3 - 1.3	MG/DL
				Total Protein	7.9				6.2 - 8.8	G/DL
				Albumin	4.4				3.1 - 5.3	G/DL
				Glucose - Random	108				70 - 115	MG/DL
				Globulin	3.5				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	NEG					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22OCT96	1	28OCT96	7	7
00314	Oral	2	100 MG	29OCT96	8	04NOV96	14	7
00314	Oral	3	150 MG	05NOV96	15	13NOV96	23	9
00314	Oral	4	200 MG	14NOV96	24	25NOV96	35	12
00314	Oral	4	200 MG	26NOV96	36	02DEC96	42	7
00314	Oral	4	200 MG	03DEC96	43	09DEC96	49	7
00314	Oral	4	200 MG	10DEC96	50	17DEC96	57	8
00314	Oral	5	250 MG	18DEC96	58	22DEC96	62	5
00314	Oral	5	250 MG	23DEC96	63	06JAN97	77	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	77	250	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
PHARYNGITIS	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid Ac	44, .	04DEC96	06DEC96	ONE CAP	HEARTBURN
ANTIINFECTIVES,SYSTEMIC	Phenoxymethylpenicillin Potassium	Pen-Vee-K	-111, .	03JUL96	13JUL96#	TABS 2X DAY	PHARYNGITIS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	60, .	20DEC96	20DEC96	500 GRM	EARACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	25, .	15NOV96	17NOV96	200 MG TID	FLU

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU	25, .	3 Days	200	1	MIL	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	24, .	Not Stated	200	1	MIL	NO	PSR	No	No
	Dyspepsia	HEARTBURN	44, .	48:00 Hrs	200	1	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZINESS	57, .	Not Stated	200	CON	MIL	NO	PSR	No	No
		LIGHT HEADED	3, .	13 Days	50	CON	MIL	NO	PSR	No	No
	Insomnia	INSOMNIA	2, .	3 Days	50	3	MOD	NO	PSR	No	No
Special Senses	Ear Pain	EARACHE	60, .	24:00 Hrs	250	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

					Sitting			Standing				
Week	Visit Date	Relative Days *		Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15OCT96	-7,	.	0	100	60	70	.	.	.	145.00	65.5
BL	22OCT96	1,	.	0	106	64	84	106	64	84	148.00	
1	29OCT96	8,	.	100	90	60	96	90	60	96	147.00	
2	05NOV96	15,	.	150	100	60	96	100	60	96	147.00	
3	14NOV96	24,	.	200	104	64	84	104	64	84	151.00	
5	26NOV96	36,	.	200	110	70	84	110	70	84	150.00	
6	03DEC96	43,	.	200	106	70	96	100	70	96	152.00	
7	10DEC96	50,	.	200	112	74	84	112	74	84	152.00	
8	17DEC96	57,	.	200	110	76	84	110	76	84	153.00	
8	23DEC96	63,	.	250	110	60	80	105	60	80	150.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.8	.	.	.	30 - 70	%
				Lymphocytes	23.2	.	.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	301000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	50	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 8/ACUTE PHASE-WEEK 6	50	Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.1		.	.	12 - 15.6	G/DL
				Hematocrit	38.3		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.3		.	.	30 - 70	%
				Lymphocytes	21.1		.	.	21 - 51	%
				Monocytes	11.7	H	.	.	0 - 10	%
				Eosinophils	1.5		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	283000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87		.	.	22 - 130	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	7		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	102		.	.	70 - 115	MG/DL
				Globulin	2.6		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6		.	.		
				Urine Red Blood Cells/HPF	5		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	12NOV96	1	21NOV96	10	10
00315	Oral	2	0 MG	22NOV96	11	25NOV96	14	4
00315	Oral	3	0 MG	26NOV96	15	02DEC96	21	7
00315	Oral	4	0 MG	03DEC96	22	11DEC96	30	9
00315	Oral	4	0 MG	12DEC96	31	17DEC96	36	6
00315	Oral	4	0 MG	18DEC96	37	22DEC96	41	5
00315	Oral	4	0 MG	23DEC96	42	29DEC96	48	7
00315	Oral	4	0 MG	30DEC96	49	06JAN97	56	8
	Oral	4	0 MG	07JAN97	57	10JAN97	60	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	60	0		PT. DID NOT WANT TO CONTINUE

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Sinutab	7, .	18NOV96	20NOV96	2	COLD
	Phenacetin	Sinutab	7, .	18NOV96	20NOV96	2	COLD
	Phenylpropanolamine Hydrochloride	Sinutab	7, .	18NOV96	20NOV96	2	COLD
	Phenyltoloxamine Citrate	Sinutab	7, .	18NOV96	20NOV96	2	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	7, .	3 Days	0	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	05NOV96	-7, .	0	110	70	84	110	70	84	177.00	
SC	12NOV96	1, .	0	112	62	80	110	68	84	173.00	65.0
1	21NOV96	10, .	0	120	80	96	120	80	96	178.00	
2	26NOV96	15, .	0	116	80	96	116	80	96	178.00	
3	03DEC96	22, .	0	130	84	84	130	84	84	181.00	
4	12DEC96	31, .	0	120	84	84	120	84	84	182.00	
5	17DEC96	36, .	0	120	76	84	120	76	84	182.00	
6	23DEC96	42, .	0	126	80	80	120	80	80	185.00	
8	07JAN97	57, .	0	120	80	78	100	80	78	187.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.5		.	.	12 - 15.6	G/DL
				Hematocrit	40.8		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.6		.	.	30 - 70	%
				Lymphocytes	37		.	.	21 - 51	%
				Monocytes	4.5		.	.	0 - 10	%
				Eosinophils	7.1	H	.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	322000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77		.	.	22 - 130	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	8		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	95		.	.	70 - 115	MG/DL
				Globulin	3.7		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1		.	.	12 - 15.6	G/DL
				Hematocrit	38.7		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.8		.	.	30 - 70	%
				Lymphocytes	31.5		.	.	21 - 51	%
				Monocytes	5.6		.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	1.8		.	.	0 - 2	%
				Platelets	320000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	17DEC96	1	23DEC96	7	7
00316	Oral	2	0 MG	24DEC96	8	30DEC96	14	7
00316	Oral	3	0 MG	31DEC96	15	07JAN97	22	8
00316	Oral	4	0 MG	08JAN97	23	14JAN97	29	7
00316	Oral	5	0 MG	15JAN97	30	21JAN97	36	7
00316	Oral	6	0 MG	22JAN97	37	28JAN97	43	7
00316	Oral	6	0 MG	29JAN97	44	03FEB97	49	6
00316	Oral	6	0 MG	04FEB97	50	09FEB97	55	6
	Oral	5	0 MG	10FEB97	56	18FEB97	64	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	64	0	Lack of Efficacy	

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Hemic and Lymphatic System	Thrombocythemia	ELEVATED PLATELETS	57, .	Not Stated	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	05DEC96	-12,	.	0	110	70	.	.	.	.	135.00	65.8
BL	17DEC96	1,	.	0	96	62	96	96	62	96	135.00	
1	23DEC96	7,	.	0	110	70	80	110	70	90	138.00	
3	07JAN97	22,	.	0	100	70	80	100	70	88	136.50	
4	14JAN97	29,	.	0	104	64	96	104	64	96	138.00	
5	21JAN97	36,	.	0	100	66	96	100	66	96	140.00	
6	28JAN97	43,	.	0	96	66	84	96	66	84	140.00	
7	04FEB97	50,	.	0	106	70	84	106	70	84	138.00	
8	11FEB97	57,	.	0	110	70	84	100	70	84	140.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	14.7		.	.	12 - 15.6	G/DL
				Hematocrit	43.6		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.5	H	.	.	30 - 70	%
				Lymphocytes	17.3	L	.	.	21 - 51	%
				Monocytes	5.4		.	.	0 - 10	%
				Eosinophils	4.1		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	606000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	142	H	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	18		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	92		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6		.	.		
				Urine Red Blood Cells/HPF	5		.	+		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.6		.	.	12 - 15.6	G/DL
				Hematocrit	40.6		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.2		.	.	30 - 70	%
				Lymphocytes	21.1		.	.	21 - 51	%
				Monocytes	6.2		.	.	0 - 10	%
				Eosinophils	2.6		.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	771000	H	.	+	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	115		.	.	22 - 130	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19DEC96	1	23DEC96	5	5
00317	Oral	2	100 MG	24DEC96	6	30DEC96	12	7
00317	Oral	3	150 MG	31DEC96	13	07JAN97	20	8
00317	Oral	4	200 MG	08JAN97	21	14JAN97	27	7
00317	Oral	4	200 MG	15JAN97	28	21JAN97	34	7
00317	Oral	5	250 MG	22JAN97	35	28JAN97	41	7
00317	Oral	6	300 MG	29JAN97	42	04FEB97	48	7
00317	Oral	6	300 MG	05FEB97	49	11FEB97	55	7
	Oral	5	250 MG	11FEB97	55	26FEB97	70	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	70	250	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIC RHINITIS	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	1, .	19DEC96	04FEB97	500 MG	HEADACHES
			34, .	21JAN97	21JAN97	500 MG	BACKACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	27, .	14JAN97	14JAN97	25 GM	ALLERGIES
RESPIRATORY	Antiasthmatic, Nos	Over The Counter {Asthma Nos}	., .		.		ASTHMA
	Diphenhydramine Hydrochloride	Benadryl	27, .	14JAN97	14JAN97	25 GM	ALLERGIES
VARIOUS	Allergenic Extract, Nos	Over The Counter {Allergenic Extract Nos}	., .		.		ALLERGIC

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	ALLERGY	27, .	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
	Back Pain	BACKACHE	20, .	27 Days	150	3	MIL	NO	PSR	No	No
	Headache	HEADACHES	1, .	48 Days	50	7	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS ORTHOSTATIC	20, .	29 Days	150	4	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {COMMON}	27, .	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12DEC96	-7,	.	0	110	70	80	108	64	88	120.00	62.3
BL	17DEC96	-2,	.	0	110	70	96	110	70	96	122.00	
1	23DEC96	5,	.	50	90	60	96	90	60	110	119.00	
3	07JAN97	20,	.	150	115	80	88	115	70	96	118.50	
4	14JAN97	27,	.	200	110	80	96	100	80	96	118.00	
5	21JAN97	34,	.	200	110	80	88	100	80	88	118.50	
6	28JAN97	41,	.	250	110	80	92	100	80	92	118.00	
7	04FEB97	48,	.	300	110	74	84	110	74	84	118.00	
8	11FEB97	55,	.	250	120	70	84	120	70	84	116.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.4		.	.	12 - 15.6	G/DL
				Hematocrit	34.6	L	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60		.	.	30 - 70	%
				Lymphocytes	24.3		.	.	21 - 51	%
				Monocytes	10		.	.	0 - 10	%
				Eosinophils	3.1		.	.	0 - 5	%
				Basophils	2.6	H	.	.	0 - 2	%
				Platelets	213000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33		.	.	25 - 35	PG
				Mean Corpuscle Volume	92		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84		.	.	22 - 130	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	6		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	78		.	.	70 - 115	MG/DL
				Globulin	3.6		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF NEG			.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.6		.	.	12 - 15.6	G/DL
				Hematocrit	36.3		.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66		.	.	30 - 70	%
				Lymphocytes	24.3		.	.	21 - 51	%
				Monocytes	6.9		.	.	0 - 10	%
				Eosinophils	1.9		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	292000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	94		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19JUL94	1	25JUL94	7	7
00013	Oral	2	100 MG	26JUL94	8	01AUG94	14	7
00013	Oral	3	150 MG	02AUG94	15	08AUG94	21	7
00013	Oral	4	200 MG	09AUG94	22	14AUG94	27	6
00013	Oral	4	200 MG	15AUG94	28	22AUG94	35	8
00013	Oral	4	200 MG	23AUG94	36	30AUG94	43	8
00013	Oral	4	200 MG	31AUG94	44	07SEP94	51	8
00013	Oral	4	200 MG	08SEP94	52	15SEP94	59	8
00074	Oral	4	200 MG	16SEP94	60	10OCT94	84	25
00074	Oral	4	200 MG	11OCT94	85	26OCT94	100	16
00074	Oral	5	250 MG	27OCT94	101	07NOV94	112	12
00074	Oral	5	250 MG	08NOV94	113	05DEC94	140	28
00074	Oral	5	250 MG	06DEC94	141	09JAN95	175	35
00074	Oral	5	250 MG	10JAN95	176	06FEB95	203	28
00074	Oral	5	250 MG	07FEB95	204	09MAR95	234	31
00013	Oral	4	200 MG	10MAR95	235	11MAR95	236	2
00013	Oral	3	150 MG	12MAR95	237	13MAR95	238	2
00013	Oral	2	100 MG	14MAR95	239	16MAR95	241	3
00013	Oral	1	50 MG	17MAR95	242	23MAR95	248	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	Yes	248	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Minocycline	Minocin	-48, -107	01JUN94	01FEB95	200MG	ACNE
DERMATOLOGICALS	Isotretinoin	Accutane	59, -1	15SEP94	16SEP94	40-80MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	2, -58	5 Days	50	CON	SEV	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	12, -48	Not Stated	100	CON	MOD	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	2, -58	5 Days	50	CON	MOD	NO	REL	No	No
	Somnolence	SLEEPINESS	2, -58	3 Days	50	2	MIL	NO	REL	No	No
	Tremor	TREMBLING OF HANDS	20, -40	4 Days	150	2	MIL	NO	REL	No	No
Skin and Appendages	Sweating	SWEATING	2, -58	3 Days	50	CON	MIL	NO	REL	No	No
Special Senses	Abnormal Vision	VISUAL BRIGHT SPOTS	2, -58	5 Days	50	8	MIL	NO	REL	No	No
	Tinnitus	RINGING IN EARS-5-10 MINUTES IN A.M.	16, -44	8 Days	150	7	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	05JUL94	-14, -73	0	90	60	78	100	60	84	132.30	68.5
BL	19JUL94	1, -59	0	108	70	60	104	70	64	131.86	
1	26JUL94	8, -52	100	104	56	84	104	58	88	133.62	
2	02AUG94	15, -45	150	104	78	74	96	76	88	132.30	
3	09AUG94	22, -38	200	110	84	80	108	80	96	134.06	
4	15AUG94	28, -32	200	115	80	78	100	75	100	136.71	
5	23AUG94	36, -24	200	112	82	88	112	80	116	136.93	
6	31AUG94	44, -16	200	120	82	92	100	72	104	136.71	
7	08SEP94	52, -8	200	100	80	100	98	80	100	136.27	
8	16SEP94	60, 1	200	102	82	92	104	82	108	138.92	
12	11OCT94	85, 26	200	114	82	84	112	80	96	141.12 H	
16	08NOV94	113, 54	250	110	80	90	120	90	100	144.43 H	
20	06DEC94	141, 82	250	110	80	80	110	80	88	148.84 H	
24	10JAN95	176, 117	250	110	70	80	110	70	100	151.04 H	
28	07FEB95	204, 145	250	112	84	88	110	82	96	153.25 H	
32	10MAR95	235, 176	200	112	84	92	116	86	92	153.03 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.5	.	.	.	30 - 70	%
				Lymphocytes	31.1	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	118	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	15.4		.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.3		.	.	30 - 70	%
				Lymphocytes	25.5		.	.	21 - 51	%
				Monocytes	7.6		.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	212000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	96		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103		.	.	22 - 180	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	14		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	60	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	85	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.1	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	172000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106	.	.	.	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	141	Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	176	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	26.9	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	9.8	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	177000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 14/CONTINUATION-WEEK 24	176	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
		VISIT 15/CONTINUATION-WEEK 28	204	Hemoglobin	15.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9		.	.	30 - 70	%
				Lymphocytes	25.9		.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%
				Eosinophils	2		.	.	0 - 5	%
				Basophils	0.9		.	.	0 - 2	%
				Platelets	226000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 15/CONTINUATION-WEEK 28	204	Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	235	Hemoglobin	15.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	45.3		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.7		.	.	30 - 70	%
				Lymphocytes	31.3		.	.	21 - 51	%
				Monocytes	12.1	H	.	.	0 - 10	%
				Eosinophils	2.5		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	231000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1.2		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	86		.	.	22 - 180	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	19		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	64	L	.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.	.	
				Urine Blood - Dipstick	NEG			.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 16/CONTINUATION-WEEK 32	235	Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	29NOV94	1	04DEC94	6	6
00014	Oral	2	100 MG	05DEC94	7	13DEC94	15	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	15	100	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ascorbic Acid	Vitamin C	-5, .	24NOV94	.	UNKNOWN	COMMON COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Constipation	CONSTIPATED	4, .	Not Stated	50	CON	MOD	NO	REL	No	No
	Dysphagia	LUMP IN THE THROAT	1, .	11 Days	50	7	MOD	NO	REL	No	No
	Nausea	NAUSEA	7, .	3 Days	100	1	MOD	NO	PSR	No	No
			9, .	Not Stated	100	18	SEV	NO	PSR	No	No
		RETCHING	7, .	Not Stated	100	21	MOD	STP	PSR	No	No
Respiratory System	Respiratory Disorder	COMMON COLD	-5, .	6 Days	0	1	MIL	NO	UNR	Yes	No
Urogenital System	Polyuria	POLYURIA	7, .	1 Days	100		MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22NOV94	-7,	.	0	100	68	70	110	80	80	145.31	72.8
BL	29NOV94	1,	.	0	100	60	78	100	60	80	147.51	
1	05DEC94	7,	.	100	130	70	84	120	70	88	142.44	
2	13DEC94	15,	.	100	100	60	80	100	70	88	138.03	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49		.	.	30 - 70	%
				Lymphocytes	34.4		.	.	21 - 51	%
				Monocytes	6.8		.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	162000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	174		.	.	44 - 400	U/L
				Aspartate Aminotransferase	22		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	98		.	.	70 - 115	MG/DL
				Globulin	2.7		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.2		.	.	13.8 - 17.2	G/DL
				Hematocrit	42		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.9	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.6		.	.	30 - 70	%
				Lymphocytes	36.4		.	.	21 - 51	%
				Monocytes	7.2		.	.	0 - 10	%
				Eosinophils	8.5	H	.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	163000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	83		.	.	80 - 100	FL
		VISIT 4/ACUTE PHASE-WEEK 2	15	Hemoglobin	14.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	42.9		.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9		.	.	30 - 70	%
				Lymphocytes	32.5		.	.	21 - 51	%
				Monocytes	8.1		.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 4/ACUTE PHASE-WEEK 2	15	Platelets	174000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	179	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.	.	
				Urine Blood - Dipstick	NEG			.	.	
				Urine Red Blood Cells/HPF	NEG			.	.	
				Urine White Blood Cells/HPF	NEG			.	.	
				Urine Bacteria	3	.	.	.	.	
				Urine Protein - Dipstick	NEG			.	.	
				Urine Squamous Epithelial Cells	4	.	.	.	.	
				Urine Amphetamines	NEG			.	.	
				Urine Barbiturates	NEG			.	.	
				Urine Benzodiazepines	NEG			.	.	
				Urine Cannabinoids	NEG			.	.	
				Urine Cocaine	NEG			.	.	
				Urine Methadone	NEG			.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 4/ACUTE PHASE-WEEK 2	15	Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08DEC94	1	13DEC94	6	6
00015	Oral	2	20 MG	14DEC94	7	20DEC94	13	7
00015	Oral	3	20 MG	21DEC94	14	27DEC94	20	7
00015	Oral	4	20 MG	28DEC94	21	03JAN95	27	7
00015	Oral	4	20 MG	04JAN95	28	10JAN95	34	7
00015	Oral	4	20 MG	11JAN95	35	17JAN95	41	7
00015	Oral	4	20 MG	18JAN95	42	24JAN95	48	7
00015	Oral	4	20 MG	25JAN95	49	02FEB95	57	9
00073	Oral	4	20 MG	03FEB95	58	27FEB95	82	25
00073	Oral	4	20 MG	28FEB95	83	21MAR95	104	22
00073	Oral	4	20 MG	22MAR95	105	18APR95	132	28
00073	Oral	4	20 MG	19APR95	133	16MAY95	160	28
00073	Oral	4	20 MG	17MAY95	161	13JUN95	188	28
00015	Oral	4	20 MG	14JUN95	189	14JUN95	189	1
00015	Oral	3	20 MG	15JUN95	190	15JUN95	190	1
00015	Oral	2	20 MG	16JUN95	191	18JUN95	193	3
00015	Oral	1	20 MG	19JUN95	194	28JUN95	203	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	203	20	Other reason	CONFLICT BETWEEN SCHOOL AND STUDY

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ENURESIS	INCONTINENCE, URINARY	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1990
URETERS BILATERALLY REEMBEDDED	OPERATION, OTHER URINARY	OPERATIONS	PRV	1990

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ascorbic Acid	Vitamin C	5, -53	12DEC94	13DEC94	1	COLD,NASAL CONGESTION
	Minerals Nos	Centrum	5, -53	12DEC94	13DEC94	1	COLD-NASAL CONGESTION
	Vitamins Nos	Centrum	5, -53	12DEC94	13DEC94	1	COLD-NASAL CONGESTION
ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole	Septra Double Strength	82, 25	27FEB95	05MAR95	2TABS	COLD
	Trimethoprim	Septra Double Strength	82, 25	27FEB95	05MAR95	2TABS	COLD
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	13, -45	20DEC94	20DEC94	500MG	HEADACHE
			69, 12	14FEB95	14FEB95	2TAB	HEADACHE
			79, 22	24FEB95	24FEB95	2TAB	HEADACHE
		Tylenol Extra Strength	4, -54	11DEC94	11DEC94	2000MG	HEADACHE
			34, -24	10JAN95	10JAN95	500MG	HEADACHE
			41, -17	17JAN95	17JAN95	2000MG	HEADACHE
			53, -5	29JAN95	29JAN95	2000MG	MENSTRUAL CRAMPS
			131, 74	17APR95	17APR95	2TAB	MENSTRUAL CRAMPS
RESPIRATORY	Dexbrompheniramine Maleate	Drixoral Pills	5, -53	12DEC94	13DEC94	1	COLD NASAL CONGESTION
	Pseudoephedrine Sulfate	Drixoral Pills	5, -53	12DEC94	13DEC94	1	COLD NASAL CONGESTION
SENSORY ORGANS	Gramicidin	Polysporin Eye Drops	-1, -58	07DEC94	18DEC94	6DROPS	BILATERAL EYE INFECTION
			27, -31	03JAN95	14JAN95	4DROPS	BILATERAL EYE INFECTION
	Polymyxin B Sulfate	Polysporin Eye Drops	-1, -58	07DEC94	18DEC94	6DROPS	BILATERAL EYE INFECTION
			27, -31	03JAN95	14JAN95	4DROPS	BILATERAL EYE INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES INTERMITTENT AM AND LUNCH	1, -57	12 Days	20	6	MIL	NO	REL	No	No
	Allergic Reaction	CONGESTION-NASAL DUE TO ALLERGIES	184, 127	Not Stated	20	CON	MOD	NO	UNR	No	No
		ITCHY EYES-DUE TO ALLERGIES	184, 127	Not Stated	20	CON	MOD	NO	UNR	No	No
	Asthenia	FATIGUE	1, -57	15 Days	20	CON	MIL	NO	REL	No	No
			15, -43	11 Days	20	CON	MOD	NO	REL	No	No
		FATIGUE NEW	57, -1	43 Days	20	CON	MOD	NO	PBU	No	No
	Headache	HEADACHE	13, -45	03:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			34, -24	01:00 Hrs	20	1	SEV	NO	PBU	Yes	No
			41, -17	02:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			69, 12	01:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			79, 22	01:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			180, 123	2 Days	20	CON	MOD	NO	UNR	No	No
		HEADACHES 1 DAILY	4, -54	7 Days	20	3	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	73, 16	31 Days	20	CON	MIL	NO	PBU	No	No
			180, 123	2 Days	20	CON	MOD	NO	UNR	No	No
	Emotional Lability	SELF-MUTILATION	31, -27	30 Mins	20	1	MIL	NO	UNR	No	No
		SUICIDAL IDEATION	73, 16	03:00 Hrs	20	1	MIL	NO	UNR	No	No
	Tremor	HANDS TREMBLING INTERMITTENT	3, -55	14 Days	20	4	MOD	NO	REL	No	No
Respiratory System	Cough Increased	COUGH	5, -53	5 Days	20	CON	MIL	NO	UNR	Yes	No
			57, -1	34 Days	20	CON	MOD	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	57, -1	34 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	4, -54	10 Days	20	CON	MIL	NO	UNR	Yes	No
			57, -1	34 Days	20	CON	MOD	NO	UNR	Yes	No
Special Senses	Conjunctivitis	CONJUNCTIVITIS BILATERAL	1, -57	11 Days	20	CON	MOD	NO	UNR	Yes	No
			27, -31	12 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	131, 74	30 Mins	20	1	MOD	NO	UNR	Yes	No
		PREMENSTRUAL CRAMPS	53, -5	02:00 Hrs	20	1	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	30NOV94	-8, -65	0	100	68	80	110	70	84	109.37	62.6
BL	07DEC94	-1, -58	0	100	68	60	96	70	80	116.87	
1	14DEC94	7, -51	20	90	60	96	90	64	104	107.16 L	
2	21DEC94	14, -44	20	100	60	88	100	64	100	106.06 L	
3	28DEC94	21, -37	20	100	70	82	100	70	90	104.96 L	
4	04JAN95	28, -30	20	90	60	74	90	60	80	102.53 L	
5	11JAN95	35, -23	20	110	70	76	110	78	100	102.97 L	
6	18JAN95	42, -16	20	98	60	80	90	68	96	105.18 L	
7	25JAN95	49, -9	20	110	78	94	100	66	100	105.18 L	
8	03FEB95	58, 1	20	104	68	80	100	66	84	105.84 L	
12	27FEB95	82, 25	20	102	64	80	98	64	104	99.67 L	
16	22MAR95	105, 48	20	108	76	72	106	72	72	102.97 L	
20	19APR95	133, 76	20	90	60	68	90	60	70	103.64 L	
24	17MAY95	161, 104	20	90	60	64	100	60	64	105.84 L	
28	14JUN95	189, 132	20	100	60	60	100	64	64	106.94 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9		.	.	12 - 15.6	G/DL
				Hematocrit	40.3		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.3		.	.	30 - 70	%
				Lymphocytes	27		.	.	21 - 51	%
				Monocytes	2.6		.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	206000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75		.	.	22 - 130	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	97		.	.	70 - 115	MG/DL
				Globulin	3.3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	6		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.4		.	.	12 - 15.6	G/DL
				Hematocrit	42		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4		.	.	30 - 70	%
				Lymphocytes	28.1		.	.	21 - 51	%
				Monocytes	4.4		.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	1.7		.	.	0 - 2	%
				Platelets	239000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	-1	Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	14.2		.	.	12 - 15.6	G/DL
				Hematocrit	40.8		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.2	H	.	.	30 - 70	%
				Lymphocytes	19.7	L	.	.	21 - 51	%
				Monocytes	3.2		.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	258000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 6/ACUTE PHASE-WEEK 4	28	Urine Red Blood Cells/HPF	5			+		
				Urine White Blood Cells/HPF	NEG					
				Urine Protein - Dipstick	6					
		VISIT 7/ACUTE PHASE-WEEK 5	35	Hemoglobin	14.1				12 - 15.6	G/DL
				Hematocrit	41.1				35 - 46	%
				Red Blood Cell Count	4.6				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9				4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.6				30 - 70	%
				Lymphocytes	23.8				21 - 51	%
				Monocytes	3.2				0 - 10	%
				Eosinophils	9	H			0 - 5	%
				Basophils	0.3				0 - 2	%
				Platelets	247000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5				25 - 35	PG
				Mean Corpuscle Volume	89				80 - 100	FL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	4					
				Urine Protein - Dipstick	NEG					
				Urine Squamous Epithelial Cells	4					
				Serum BHCG pregnancy test	NEGATIVE					
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.1				12 - 15.6	G/DL
				Hematocrit	39.1				35 - 46	%
				Red Blood Cell Count	4.4				4.1 - 5.3	MILL/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	White Blood Cell Count	9.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9		.	.	30 - 70	%
				Lymphocytes	21.8		.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	222000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67		.	.	22 - 130	U/L
				Aspartate Aminotransferase	17		.	.	0 - 41	U/L
				Alanine Aminotransferase	8		.	.	0 - 48	U/L
				Total Bilirubin	0.4		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	6.2 - 8.8	G/DL
				Albumin	4.5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	97		.	.	70 - 115	MG/DL
				Globulin	2.9		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	6		.	.		
				Urine Red Blood Cells/HPF	5		.	.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		
		VISIT 11/CONTINUATION-WEEK 12	82	Hemoglobin	14.1		.	.	12 - 15.6	G/DL
				Hematocrit	41.9		.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 11/CONTINUATION-WEEK 12	82	Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	16.8	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.9	H	.	.	30 - 70	%
				Lymphocytes	15.6	L	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	344000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	133	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	215000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	133	Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEC		.	.		
		VISIT 14/UNSCHEDULED LAB 1	182	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.6	.	.	.	30 - 70	%
				Lymphocytes	21	.	.	.	21 - 51	%
				Monocytes	9.2	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 14/UNSCHEDULED LAB 1	182	Basophils	0.7	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	13MAR95	1	19MAR95	7	7
00016	Oral	2	0 MG	20MAR95	8	28MAR95	16	9
00016	Oral	3	0 MG	29MAR95	17	04APR95	23	7
00016	Oral	4	0 MG	05APR95	24	11APR95	30	7
00016	Oral	4	0 MG	12APR95	31	19APR95	38	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	No	No	38	0	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES-ANIMAL HAIR & POLLENS	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1988

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Hyoscine Butylbromide	Buscopan	16, .	28MAR95	30MAR95	10MG	STOMACH CRAMPS
RESPIRATORY	Cetirizine Hydrochloride	Reactine	13, .	25MAR95	.	10MG	ALLERGIES/HAYFEVER
	Salbutamol Sulfate	Ventodisk	-2628, .	01JAN88	.	1XWK	ALLERGIES
			-2628, .	01JAN88	.	1XWK	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH CRAMPS	16, .	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Allergic Reaction	COUGHING DUE TO ALLERGIES	18, .	Not Stated	0	CON	MIL	NO	UNR	Yes	No
		HEADACHES DUE TO ALLERGIES	12, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No
		SNEEZING DUE TO ALLERGIES	12, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No
		STUFFED SINUSES DUE TO ALLERGIES	12, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01MAR95	-12,	.	0	104	60	64	98	74	68	155.45	68.5
BL	13MAR95	1,	.	0	104	80	72	108	84	80	155.45	
1	20MAR95	8,	.	0	108	72	72	108	76	72	157.66	
2	29MAR95	17,	.	0	110	60	78	120	70	84	158.76	
3	05APR95	24,	.	0	112	72	80	114	84	80	157.66	
4	12APR95	31,	.	0	100	60	70	110	78	78	158.98	
5	19APR95	38,	.	0	110	68	84	110	70	84	159.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	14.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.4		.	.	41 - 50	%
				Red Blood Cell Count	5.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54		.	.	30 - 70	%
				Lymphocytes	33.1		.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	1.6		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	283000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28		.	.	25 - 35	PG
				Mean Corpuscle Volume	80		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1.3		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	131		.	.	22 - 180	U/L
				Aspartate Aminotransferase	11		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	109		.	.	70 - 115	MG/DL
				Globulin	2.6		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	6		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-3	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEC		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	1	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	31	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.6	.	.	.	30 - 70	%
				Lymphocytes	36.1	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
		VISIT 7/ACUTE PHASE-WEEK 5	38	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.9	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.9	.	.	.	0 - 2	%
				Platelets	315000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 7/ACUTE PHASE-WEEK 5	38	Alkaline Phosphatase	117	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	EAST INDIAN

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	22MAR95	1	26MAR95	5	5
00017	Oral	0	0 MG	27MAR95	6	27MAR95	6	1
00017	Oral	1	20 MG	28MAR95	7	29MAR95	8	2
00017	Oral	2	20 MG	30MAR95	9	05APR95	15	7
00017	Oral	3	20 MG	06APR95	16	12APR95	22	7
00017	Oral	4	20 MG	13APR95	23	19APR95	29	7
00017	Oral	4	20 MG	20APR95	30	25APR95	35	6
	Oral	5	30 MG	26APR95	36	02MAY95	42	7
00017	Oral	5	30 MG	03MAY95	43	09MAY95	49	7
00017	Oral	5	30 MG	10MAY95	50	16MAY95	56	7
00075	Oral	5	30 MG	17MAY95	57	13JUN95	84	28
00075	Oral	5	30 MG	14JUN95	85	12JUL95	113	29
00075	Oral	5	30 MG	13JUL95	114	09AUG95	141	28
00075	Oral	5	30 MG	10AUG95	142	05SEP95	168	27
00075	Oral	5	30 MG	06SEP95	169	03OCT95	196	28
00075	Oral	5	30 MG	04OCT95	197	31OCT95	224	28
00017	Oral	4	20 MG	01NOV95	225	02NOV95	226	2
00017	Oral	3	20 MG	03NOV95	227	04NOV95	228	2
00017	Oral	2	20 MG	05NOV95	229	07NOV95	231	3
00017	Oral	1	20 MG	08NOV95	232	14NOV95	238	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	238	20		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Maalox	232, 176	08NOV95	08NOV95	5CC	NAUSEA
	Calcium Pantothenate	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
	Magnesium Hydroxide	Maalox	232, 176	08NOV95	08NOV95	5CC	NAUSEA
	Nicotinamide	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
	Pyridoxine Hydrochloride	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
	Riboflavin	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
	Thiamine Hydrochloride	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	161, 105	29AUG95	30AUG95	650MG	FEVER
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benylin	177, 121	14SEP95	16SEP95	1TSP	COLD
RESPIRATORY	Diphenhydramine Hydrochloride	Benylin	177, 121	14SEP95	16SEP95	1TSP	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH PAIN	235, 179	Not Stated	20	CON	MIL	NO	UNR	No	No
	Chills	SHIVERING AND SHAKING	7, -50	12 Days	20	CON	MIL	NO	PSR	No	No
	Fever	FEVER	161, 105	18:00 Hrs	30		MOD	NO	UNR	Yes	No
Digestive System	Constipation	CONSTIPATION	23, -34	12 Days	20	CON	MOD	NO	REL	No	No
			35, -22	28 Days	20	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	2, -55	4 Days	20	CON	SEV	DCR	REL	No	No
			6, -51	5 Days	0	CON	MIL	NO	REL	No	No
			230, 174	7 Days	20	CON	MOD	NO	UNR	Yes	No
	Vomiting	VOMITING	232, 176	5 Days	20	3	MOD	NO	UNR	No	No
Nervous System	Anxiety	ANXIETY	2, -55	4 Days	20	CON	SEV	DCR	REL	No	No
	Dizziness	DIZZINESS	230, 174	5 Days	20	CON	MIL	NO	UNR	No	No
	Insomnia	INSOMNIA	6, -51	5 Days	0	CON	MIL	NO	PSR	No	No
		INSOMNIA(NO SLEEP)	3, -54	3 Days	20	CON	SEV	DCR	REL	No	No
	Manic Reaction	HOSPITALIZATION RULE-OUT HYPOMANIA	163, 107	3 Days	30	CON	MIL	NO	UNR	No	Yes
	Tremor	TREMORS	31, -26	11 Days	20	CON	MOD	NO	REL	No	No
			42, -15	87 Days	30	CON	SEV	NO	REL	Yes	No
			129, 73	40 Days	30	CON	MOD	NO	REL	No	No
			169, 113	57 Days	30	CON	MIL	NO	REL	No	No
Respiratory System	Cough Increased	COUGHING	63, 7	15 Days	30	CON	MOD	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	233, 177	5 Days	20	CON	MOD	NO	UNR	No	No
	Respiratory Disorder	RHINITIS-COLD	177, 121	3 Days	30	CON	MIL	NO	UNR	Yes	No
	Rhinitis	RHINITIS	233, 177	5 Days	20	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	15MAR95	-7, -63	0	112	70	56	112	74	60	137.15	63.4
BL	22MAR95	1, -56	0	90	60	64	100	68	70	135.17	
1	30MAR95	9, -48	20	80	60	64	90	60	64	135.39	
2	06APR95	16, -41	20	90	60	68	100	70	70	133.84	
3	13APR95	23, -34	20	100	60	70	100	60	74	134.95	
4	20APR95	30, -27	20	100	60	72	110	60	78	137.59	
5	26APR95	36, -21	30	100	60	64	110	70	68	135.39	
6	03MAY95	43, -14	30	90	60	60	90	70	72	133.62	
7	10MAY95	50, -7	30	90	60	64	100	60	68	132.96	
8	17MAY95	57, 1	30	90	60	68	90	60	70	133.40	
12	14JUN95	85, 29	30	100	60	70	110	80	70	131.64	
16	13JUL95	114, 58	30	110	70	72	110	70	80	131.42	
20	10AUG95	142, 86	30	110	70	60	105	70	68	135.61	
24	06SEP95	169, 113	30	90	60	60	100	70	64	135.17	
28	04OCT95	197, 141	30	90	60	64	100	68	68	138.92	
32	01NOV95	225, 169	20	100	70	78	100	68	68	140.02	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	. . .		
				Serum BHCG pregnancy test	NEGATIVE	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.7	. . .	12 - 15.6	G/DL
				Hematocrit	37.1	. . .	35 - 46	%
				Red Blood Cell Count	4.3	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.7	. . .	30 - 70	%
				Lymphocytes	32	. . .	21 - 51	%
				Monocytes	7.5	. . .	0 - 10	%
				Eosinophils	1.4	. . .	0 - 5	%
				Basophils	0.4	. . .	0 - 2	%
				Platelets	262000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	. . .	25 - 35	PG
				Mean Corpuscle Volume	85	. . .	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	30	Hemoglobin	12.5	. . .	12 - 15.6	G/DL
				Hematocrit	36.6	. . .	35 - 46	%
				Red Blood Cell Count	4.3	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	. . .	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 6/ACUTE PHASE-WEEK 4	30	Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	32.3	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	277000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	24	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	42	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	142	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	169	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	313000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
		VISIT 16/CONTINUATION-WEEK 32	225	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	225	Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	28.3	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	290000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	225	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03MAY95	1	10MAY95	8	8
00018	Oral	2	0 MG	11MAY95	9	17MAY95	15	7
00018	Oral	3	0 MG	18MAY95	16	24MAY95	22	7
00018	Oral	4	0 MG	25MAY95	23	31MAY95	29	7
00018	Oral	5	0 MG	01JUN95	30	07JUN95	36	7
00018	Oral	5	0 MG	08JUN95	37	18JUN95	47	11
00018	Oral	6	0 MG	19JUN95	48	21JUN95	50	3
00018	Oral	6	0 MG	22JUN95	51	28JUN95	57	7
00018	Oral	5	0 MG	29JUN95	58	14JUL95	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	73	0	Other reason	PATIENT WANTED TO TERMINATE,DID NOT WISH TO BE ON MEDICATION

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991
UPPER RESPIRATORY TRACT INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	-9, .	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION
ANTINEOPLASTIC & IMMUNOSUP	Diethylstilbestrol Dipropionate	Cyclen	-1583, .	01JAN91	24MAY95	1TAB	BIRTH CONTROL
CENTRAL NERVOUS SYSTEM	Diazepam	Valium	26, .	28MAY95	28MAY95	15MG	TENSION
	Paracetamol	Tylenol	-1583, .	01JAN91	03MAY95	650TO 1300MG	HEADACHES
			22, .	24MAY95	.	325-650	HEADACHE
DERMATOLOGICALS	Erythromycin	Erythromycin	-9, .	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION
GU SYSTEM/SEX HORMONES	Diethylstilbestrol Dipropionate	Cyclen	-1583, .	01JAN91	24MAY95	1TAB	BIRTH CONTROL
	Ethinylestradiol	Ortho Tri-Cyclen	30, .	01JUN95	.	1TAB	BIRTH CONTROL
	Norgestimate	Ortho Tri-Cyclen	30, .	01JUN95	.	1TAB	BIRTH CONTROL
RESPIRATORY	Brompheniramine Maleate	Dimetapp	-12, .	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
		Dimetapp-C	-12, .	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION
	Codeine Phosphate	Dimetapp-C	-12, .	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION
	Loratadine	Claritin	13, .	15MAY95	18MAY95	1TAB	POLLEN ALLERGY
	Paracetamol	Neo Citran	-12, .	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
	Pheniramine Maleate	Neo Citran	-12, .	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
	Phenylephrine Hydrochloride	Dimetapp	-12, .	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
		Dimetapp-C	-12, .	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION
		Neo Citran	-12, .	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
	Phenylpropanolamine Hydrochloride	Dimetapp	-12, .	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
		Dimetapp-C	-12, .	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
SENSORY ORGANS	Erythromycin	Erythromycin	-9, .	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	RHINITIS, SNEEZING, ITCHY EYES (POLLEN ALLERGY)	10, .	7 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	22, .	02:00 Hrs	0	1	SEV	NO	UNR	Yes	No
		HEADACHES	51, .	Not Stated	0	CON	MOD	NO	PSR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	49, .	21 Days	0	CON	SEV	NO	PSR	No	No
	Nausea	NAUSEA	7, .	5 Days	0	CON	MOD	NO	REL	No	No
	Vomiting	NAUSEA-VOMITING	30, .	38 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Anxiety	TENSION (ANXIOUS FEELING POST CONFRONTATION NON-MEDICATION RELATED)	26, .	1 Days	0	1	SEV	NO	UNR	Yes	No
	Insomnia	INSOMNIA(WORSENING)	5, .	20 Days	0	CON	SEV	NO	REL	No	No
Special Senses	Abnormal Vision	BLURRY VISION	49, .	21 Days	0	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19APR95	-14,	.	0	125	75	88	125	75	88	126.79	64.2
BL	03MAY95	1,	.	0	120	70	70	120	70	72	126.79	
1	11MAY95	9,	.	0	100	60	70	100	60	84	127.89	
2	18MAY95	16,	.	0	100	60	80	100	60	84	127.89	
3	25MAY95	23,	.	0	110	70	90	110	70	98	127.23	
4	01JUN95	30,	.	0	120	70	104	118	70	108	126.35	
5	08JUN95	37,	.	0	100	60	72	110	70	84	126.79	
7	19JUN95	48,	.	0	118	70	68	120	70	78	126.13	
7	22JUN95	51,	.	0	100	70	84	120	70	96	124.14	
8	29JUN95	58,	.	0	140	84	90	145	90	100	127.01	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	POS		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-7	Hemoglobin	13.6		.	.	12 - 15.6	G/DL
				Hematocrit	39.2		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2		.	.	30 - 70	%
				Lymphocytes	36.8		.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	1.6		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	278000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	93		.	.	80 - 100	FL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/UNSCHEDULED LAB 1	-7	Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		1010.ZZ2	-2	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	POS	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEC	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.5	. . .	12 - 15.6	G/DL
				Hematocrit	40	. . .	35 - 46	%
				Red Blood Cell Count	4.2	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	. . .	30 - 70	%
				Lymphocytes	28.4	. . .	21 - 51	%
				Monocytes	3	. . .	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	119	H	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		ACUTE PHASE/DOWN TITRATION	72	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	ACUTE PHASE/DOWN TITRATION	72	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	31MAY95	1	06JUN95	7	7
00019	Oral	2	20 MG	07JUN95	8	13JUN95	14	7
00019	Oral	3	20 MG	14JUN95	15	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	15	20	Lost to follow-up	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	7, .	06JUN95	06JUN95	3TABS	HEADACHE
	Caffeine	Excedrin	7, .	06JUN95	06JUN95	3TABS	HEADACHE
	Paracetamol	Excedrin	7, .	06JUN95	06JUN95	3TABS	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	7, .	09:00 Hrs	20	1	MOD	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZY GETTING OUT OF BED OR AFTER LYING DOWN A LONG TIME	4, .	Not Stated	20		MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	24MAY95	-7, .	0	90	60	60	100	70	78	120.17	66.1
BL	31MAY95	1, .	0	100	60	64	110	70	80	117.31	
1	07JUN95	8, .	20	90	60	80	110	70	84	119.51	
2	14JUN95	15, .	20	100	60	70	110	80	90	120.61	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2		.	.	12 - 15.6	G/DL
				Hematocrit	40.7		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.1		.	.	30 - 70	%
				Lymphocytes	29.5		.	.	21 - 51	%
				Monocytes	4.7		.	.	0 - 10	%
				Eosinophils	5.9	H	.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	209000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66		.	.	22 - 130	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.4		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	98		.	.	70 - 115	MG/DL
				Globulin	2.2	L	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	09NOV95	1	15NOV95	7	7
00020	Oral	2	0 MG	16NOV95	8	24NOV95	16	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	16	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANXIETY	ANXIETY	MENTAL DISORD	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Diazepam	Valium	-21, .	19OCT95	19OCT95#	5MG	ANXIETY

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	4, .	3 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02NOV95	-7, .	0	90	60	72	100	60	80	110.47	62.6
BL	09NOV95	1, .	0	90	60	70	90	60	74	110.25	
1	16NOV95	8, .	0	90	64	78	98	70	80	109.15	
2	24NOV95	16, .	0	90	60	60	90	60	78	109.15	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.5	.	.	.	30 - 70	%
				Lymphocytes	35.3	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	199000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	16	Hemoglobin	13		.	.	12 - 15.6	G/DL
				Hematocrit	38.1		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.8		.	.	30 - 70	%
				Lymphocytes	37.9		.	.	21 - 51	%
				Monocytes	2.5		.	.	0 - 10	%
				Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	219000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 4/ACUTE PHASE-WEEK 2	16	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEC		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	02FEB96	1	08FEB96	7	7
00211	Oral	2	100 MG	09FEB96	8	15FEB96	14	7
00211	Oral	3	150 MG	16FEB96	15	22FEB96	21	7
00211	Oral	4	200 MG	23FEB96	22	28FEB96	27	6
00211	Oral	4	200 MG	29FEB96	28	06MAR96	34	7
00211	Oral	4	200 MG	07MAR96	35	13MAR96	41	7
00211	Oral	4	200 MG	14MAR96	42	21MAR96	49	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	No	No	49	200	Adverse event, including intercurrent illness	DEHYDTRATION POST NAUSEA AND VOMITTING/DIARRHEA DUE TO BACTERIA GASTROENTERITIS RESULTED IN SEVERE DEHYDRATION AND MOUTH SORES/CUTS UNABLE TO TOLERATE SIDE EFFECTS OF DRY MOUTH.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Antiemetics & Antinauseants Nos	Antiemetic {Nos}	49, .	21MAR96	22MAR96		NAUSEA&VOMITING
	Ascorbic Acid	Vitamin C	., .		.	500MG	HEALTH MAINTENANCE
	Calcium Pantothenate	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
	Nicotinamide	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
	Pyridoxine Hydrochloride	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
	Riboflavin	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
	Thiamine Hydrochloride	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
BLOOD/BLOOD FORM ORGANS	I.V. Fluids	Intravenous Fluids	49, .	21MAR96	22MAR96		DEHYDRATION
CENTRAL NERVOUS SYSTEM	Analgesics	Analgesic {Nos}	49, .	21MAR96	22MAR96		MOUTH SORES
	Paracetamol	Tylenol	38, .	10MAR96	.	2TABS	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	22, .	Not Stated	200	CON	MOD	NO	PBU	Yes	No
	Trauma	MOUTH CUTS	48, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	11, .	7 Days	100	CON	MIL	NO	PSR	No	No
			18, .	15 Days	150	CON	MOD	NO	REL	No	No
			33, .	Not Stated	200	CON	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	4, .	14 Days	50	CON	MIL	NO	PSR	No	No
			18, .	15 Days	150	CON	SEV	NO	REL	No	No
			33, .	14 Days	200	CON	MOD	NO	REL	No	No
			47, .	Not Stated	200	CON	SEV	STP	REL	No	No
	Gastroenteritis	BACTERIAL GASTROENTERITIS	49, .	3 Days	200	CON	SEV	STP	UNR	Yes	No
	Ulcerative Stomatitis	MOUTH SORES	48, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
Nervous System	Dizziness	DIZZINESS	18, .	18 Days	150	CON	MIL	NO	REL	No	No
	Hypertonia	STIFF NECK	22, .	18 Days	200	CON	MIL	NO	PBU	No	No
	Tremor	TREMORS	18, .	22 Days	150	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JAN96	-9, .	0	80	60	60	90	60	68	102.53	63.0
BL	01FEB96	-1, .	0	100	60	64	100	60	72	102.53	
1	08FEB96	7, .	50	100	60	60	100	60	70	100.33	
2	16FEB96	15, .	150	100	70	78	90	70	80	102.53	
3	23FEB96	22, .	200	100	70	70	100	70	74	101.87	
4	29FEB96	28, .	200	100	72	80	100	70	80	103.64	
5	07MAR96	35, .	200	100	60	78	110	80	88	104.96	
6	14MAR96	42, .	200	90	60	70	100	60	90	104.08	
7	25MAR96	53, .	200	90	60	80	90	60	84	98.12	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.5		.	.	12 - 15.6	G/DL
				Hematocrit	38.6		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6		.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	37.3	L	.	.	40 - 75	%
				Lymphocytes	48.4	H	.	.	16 - 46	%
				Monocytes	10.4		.	.	0 - 12	%
				Eosinophils	3.1		.	.	0 - 7	%
				Basophils	0.9		.	.	0 - 2	%
				Platelets	237000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6		.	.	27 - 33	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	7		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62		.	.	22 - 130	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	18		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	6.2 - 8.8	G/DL
				Albumin	4.9		.	.	3.1 - 5.3	G/DL
				Glucose - Random	108		.	.	70 - 115	MG/DL
				Globulin	2.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-9		Urine Squamous Epithelial Cells	4		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	53	(4)	Hemoglobin	15.6		.	.	12 - 15.6	G/DL
					Hematocrit	44.1		.	.	35 - 46	%
					Red Blood Cell Count	4.9		.	.	3.9 - 5.2	MILL/MCL
					White Blood Cell Count	5.1		.	.	3.8 - 10.8	THOU/MCL
					Segmented Neutrophils	72.4		.	.	40 - 75	%
					Lymphocytes	14.1	L	.	.	16 - 46	%
					Monocytes	9.4		.	.	0 - 12	%
					Eosinophils	2.4		.	.	0 - 7	%
					Basophils	1.8		.	.	0 - 2	%
					Platelets	244000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.1		.	.	27 - 33	PG
					Mean Corpuscle Volume	91		.	.	80 - 100	FL
					Blood Urea Nitrogen	7		.	.	7 - 25	MG/DL
					Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.6		.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	96		.	.	22 - 130	U/L
					Aspartate Aminotransferase	67	H	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 9/ACUTE PHASE-WEEK 7	53	(4)	Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	91	.	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	03JUN96	1	09JUN96	7	7
00212	Oral	2	20 MG	10JUN96	8	20JUN96	18	11
00212	Oral	3	20 MG	21JUN96	19	25JUN96	23	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	23	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES{ENVIRONMENTAL}	ALLERGY, NEC	INJURY/POISONING	CUR	1995
AMENORRHEA	AMENORRHEA	GENITOURINARY SYST DIS	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Sinutabs	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
	Phenacetin	Sinutabs	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
	Phenylpropanolamine Hydrochloride	Sinutabs	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
	Phenyltoloxamine Citrate	Sinutabs	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Ortho 777	-215, .	01NOV95	.	1 TABLET	BIRTH CONTROL
	Norethisterone	Ortho 777	-215, .	01NOV95	.	1 TABLET	BIRTH CONTROL
RESPIRATORY	Loratadine	Claritin	-215, .	01NOV95	09JUN96	0-2 TABS	ENVIRONMENTAL ALLERGIES
	Pseudoephedrine Hydrochloride	Sudafed	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Somnolence	SEDATION	7, .	12:00 Hrs	20	1	SEV	NO	PSR	No	No
			8, .	2 Days	20	CON	MIL	NO	PSR	No	No
			10, .	14 Days	20	CON	SEV	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24MAY96	-10, .	0	100	60	60	90	60	72	143.33	65.7
BL	03JUN96	1, .	0	90	60	72	90	60	78	139.80	
1	10JUN96	8, .	20	110	60	78	110	78	84	137.81	
3	21JUN96	19, .	20	116	78	80	108	80	92	139.58	
4	28JUN96	26, .	20	118	78	90	110	80	98	137.81	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-10		Urine Squamous Epithelial Cells	4	.	.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	26	(3)	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.2	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	46.1	.	.	.	30 - 70	%
					Lymphocytes	43.1	.	.	.	21 - 51	%
					Monocytes	6.6	.	.	.	0 - 10	%
					Eosinophils	3.9	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	211000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
					Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	52	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 5/ACUTE PHASE-WEEK 3	26	(3)	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	19	L	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEC		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	02AUG96	1	07AUG96	6	6
00213	Oral	2	0 MG	08AUG96	7	14AUG96	13	7
00213	Oral	3	0 MG	15AUG96	14	20AUG96	19	6
00213	Oral	4	0 MG	21AUG96	20	28AUG96	27	8
00213	Oral	4	0 MG	29AUG96	28	02SEP96	32	5
00213	Oral	4	0 MG	03SEP96	33	09SEP96	39	7
00213	Oral	4	0 MG	10SEP96	40	16SEP96	46	7
00213	Oral	4	0 MG	17SEP96	47	24SEP96	54	8
00122	Oral	4	0 MG	25SEP96	55	21OCT96	81	27
00122	Oral	4	0 MG	22OCT96	82	18NOV96	109	28
00122	Oral	4	0 MG	19NOV96	110	19DEC96	140	31
00122	Oral	4	0 MG	20DEC96	141	20JAN97	172	32
00122	Oral	4	0 MG	21JAN97	173	17FEB97	200	28
00122	Oral	4	0 MG	18FEB97	201	18MAR97	229	29
00213	Oral	3	0 MG	19MAR97	230	20MAR97	231	2
00213	Oral	2	0 MG	21MAR97	232	23MAR97	234	3
00213	Oral	1	0 MG	24MAR97	235	30MAR97	241	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	Yes	241	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACKACHES	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	222	65, 11	05OCT96	05OCT96	375 MGS	HEADACHE
		Bufferin	3, -52	04AUG96	04AUG96	325 MGS	HEADACHE
	Aluminium Glycinate	Bufferin	3, -52	04AUG96	04AUG96	325 MGS	HEADACHE
	Caffeine Citrate	222	65, 11	05OCT96	05OCT96	375 MGS	HEADACHE
	Codeine Phosphate	222	65, 11	05OCT96	05OCT96	375 MGS	HEADACHE
	Magnesium Carbonate	Bufferin	3, -52	04AUG96	04AUG96	325 MGS	HEADACHE
	Paracetamol	Acetaminophen	65, 11	05OCT96	05OCT96	1000 MG	HEADACHE
			110, 56	19NOV96	19NOV96	1000 MG	HEADACHE
			122, 68	01DEC96	01DEC96	375 MG	HEADACHE
			150, 96	29DEC96	29DEC96	1000 MG	HEADACHE
			224, 170	13MAR97	13MAR97	1000 MG	HEADACHE
		Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD
	Phenacetin	Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD
	Phenylpropanolamine Hydrochloride	Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD
	Phenyltoloxamine Citrate	Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES	2, -53	8 Days	0	CON	MIL	NO	PSR	No	No
			10, -45	192 Days	0	CON	MOD	NO	UNR	Yes	No
	Back Pain	BACKACHE	1, -54	8 Days	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHES	3, -52	227 Days	0	CON	MIL	NO	UNR	Yes	No
	Trauma	HEAD INJURY WITH LACERATION TO SCALP (4 STITCHES) NO LOSS OF CONSCIOUSNESS (PUSHED ONTO SUBWAY TRACK)	65, 11	5 Mins	0	1	MOD	NO	UNR	No	No
Digestive System	Constipation	CONSTIPATION	7, -48	5 Days	0	2	MIL	NO	PSR	No	No
			9, -46	13 Days	0	CON	MIL	NO	UNR	No	No
	Diarrhea	DIARRHEA	6, -49	4 Days	0	4	MIL	NO	PSR	No	No
			192, 138	31 Days	0	CON	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	44, -11	Not Stated	0	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	UPPER RESPIRATORY INFECTION (COLD)	11, -44	19 Days	0	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Rash	RASH	141, 87	8 Days	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JUL96	-15, -69	0	98	78	90	110	98	100	191.17	63.8
BL	01AUG96	-1, -55	0	100	70	74	110	78	80	190.73	
1	08AUG96	7, -48	0	100	70	88	110	78	90	192.94	
2	15AUG96	14, -41	0	100	60	84	110	78	90	194.04	
3	21AUG96	20, -35	0	110	70	64	110	80	88	193.60	
4	29AUG96	28, -27	0	124	64	92	110	68	100	196.25	
5	03SEP96	33, -22	0	110	80	90	120	88	104	197.79	
6	10SEP96	40, -15	0	120	88	80	110	70	90	195.36	
7	17SEP96	47, -8	0	110	70	104	120	80	120	195.80	
8	24SEP96	54, -1	0	120	70	84	120	80	100	196.25	
12	22OCT96	82, 28	0	110	70	120	100	60	120	191.84	
16	19NOV96	110, 56	0	120	70	80	110	70	84	196.25	
20	20DEC96	141, 87	0	130	70	84	120	70	90	193.82	
24	21JAN97	173, 119	0	120	66	84	116	70	88	198.01	
28	18FEB97	201, 147	0	120	58	84	110	60	80	196.69	
32	19MAR97	230, 176	0	115	60	68	114	58	76	195.58	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	12.9		.	.	12 - 15.6	G/DL
				Hematocrit	39.4		.	.	35 - 46	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74.3	H	.	.	30 - 70	%
				Lymphocytes	17.4	L	.	.	21 - 51	%
				Monocytes	5.6		.	.	0 - 10	%
				Eosinophils	2.7		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	308000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	81		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66		.	.	44 - 280	U/L
				Aspartate Aminotransferase	9		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	100		.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	13		.	.	12 - 15.6	G/DL
				Hematocrit	40.6		.	.	35 - 46	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.7	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	4		.	.	0 - 10	%
				Eosinophils	1.5		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	318000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	82		.	.	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	13.7		.	.	12 - 15.6	G/DL
				Hematocrit	43		.	.	35 - 46	%
				Red Blood Cell Count	5.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3		.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 6/ACUTE PHASE-WEEK 4	28	Segmented Neutrophils	70.8	H	.	.	30 - 70	%
				Lymphocytes	21.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.5	.	.	.	30 - 70	%
				Lymphocytes	21.2	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	319000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	8	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE			.		
				Urine Amphetamines	NEG			.		
				Urine Barbiturates	NEG			.		
				Urine Benzodiazepines	NEG			.		
				Urine Cannabinoids	NEG			.		
				Urine Cocaine	NEG			.		
				Urine Methadone	NEG			.		
				Urine Methaqualone	NEG			.		
				Urine Opiates	NEG			.		
				Urine Phencyclidine	NEC			.		
				Urine Propoxyphene	NEG			.		
		VISIT 14/CONTINUATION-WEEK 24	174	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74.9	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 14/CONTINUATION-WEEK 24	174	Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	79	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEC		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	230	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/CONTINUATION-WEEK 32	230	Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.7	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.2	L	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	04OCT96	1	08OCT96	5	5
00214	Oral	2	20 MG	09OCT96	6	14OCT96	11	6
00214	Oral	3	20 MG	15OCT96	12	20OCT96	17	6
00214	Oral	4	20 MG	21OCT96	18	30OCT96	27	10
00214	Oral	5	30 MG	01NOV96	29	10NOV96	38	10
00214	Oral	5	30 MG	11NOV96	39	17NOV96	45	7
00214	Oral	4	20 MG	18NOV96	46	24NOV96	52	7
00214	Oral	4	20 MG	25NOV96	53	02DEC96	60	8
00119	Oral	4	20 MG	03DEC96	61	30DEC96	88	28

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	88	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
JOINT PAIN - FLEXIBLE JOINTS	PAIN, JOINT	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
HEAD LACERATION	OPEN WOUND	INJURY/POISONING	PRV	1987

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Hepatitis B Vaccine	Hepatitis B Shot {Vaccine}	60, -1	02DEC96	02DEC96		PROPHYLAXIS
		Hepatitis B {Vaccine}	-1, -61	03OCT96	03OCT96#		PROPHYLAXIS
	Tetracycline Hydrochloride	Apo-Tetra	-16, -76	18SEP96	18SEP96#		COLD
			10, -51	13OCT96	13OCT96	500 MG	COLD
			14, -47	17OCT96	20OCT96	500 MG	COLD
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	36, -25	08NOV96	09NOV96	700 MG	HEADACHE
			44, -17	16NOV96	16NOV96	700 MG	HEADACHE
			83, 23	25DEC96	25DEC96	1000 MG	DIZZINESS
			84, 24	26DEC96	26DEC96	1000 MG	DIZZINESS
			85, 25	27DEC96	27DEC96	1000 MG	DIZZINESS
			87, 27	29DEC96	29DEC96	1000 MG	DIZZINESS
		Tylenol Extra Strength	-8, -68	26SEP96	26SEP96#	700 MG	KNEE PAIN
DERMATOLOGICALS	Tetracycline Hydrochloride	Apo-Tetra	-16, -76	18SEP96	18SEP96#		COLD
			10, -51	13OCT96	13OCT96	500 MG	COLD
			14, -47	17OCT96	20OCT96	500 MG	COLD
GU SYSTEM/SEX HORMONES	Oral Contraceptive	Birth Control Pill	-32, -92	02SEP96	.	1	TO REGULATE PERIODS
RESPIRATORY	Dimenhydrinate	Gravol	37, -24	09NOV96	10NOV96	100 MG	UPSET STOMACH
			44, -17	16NOV96	17NOV96	50 MG	NAUSEA
SENSORY ORGANS	Tetracycline Hydrochloride	Apo-Tetra	-16, -76	18SEP96	18SEP96#		COLD
			10, -51	13OCT96	13OCT96	500 MG	COLD
			14, -47	17OCT96	20OCT96	500 MG	COLD
			-16, -76	18SEP96	18SEP96#		COLD
			10, -51	13OCT96	13OCT96	500 MG	COLD
			14, -47	17OCT96	20OCT96	500 MG	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	36, -25	2 Days	30	CON	MIL	DCR	REL	Yes	No
			43, -18	1 Days	30	CON	MOD	DCR	PSR	Yes	No
Digestive System	Dyspepsia	UPSET STOMACH	37, -24	2 Days	30	CON	MIL	DCR	REL	Yes	No
	Nausea	NAUSEA	43, -18	1 Days	30	CON	MOD	DCR	PSR	Yes	No
			81, 21	06:00 Hrs	20	3	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	43, -18	1 Days	30	CON	MOD	DCR	PSR	No	No
			81, 21	06:00 Hrs	20	3	MOD	NO	PSR	No	No
	Hyperkinesia	HYPERACTIVE	5, -56	01:00 Hrs	20	5	MIL	NO	PSR	No	No
	Insomnia	AWAKENING (MIDDLE OF NIGHT)	9, -52	15 Mins	20	2	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	14, -47	4 Days	20	CON	MIL	NO	UNR	No	No
Skin and Appendages	Rash	RASH ON ARMS (RED, DRY, ITCHY)	59, -2	10:00 Hrs	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	27SEP96	-7, -67	0	120	90	68	120	90	80	128.99	60.6
BL	04OCT96	1, -60	0	110	70	78	110	70	80	129.43	
1	09OCT96	6, -55	20	125	70	84	120	80	84	128.11	
2	15OCT96	12, -49	20	120	80	84	120	90	88	127.89	
2	21OCT96	18, -43	20	110	70	78	110	90	98	127.89	
4	01NOV96	29, -32	30	100	60	60	100	60	120	128.99	
5	11NOV96	39, -22	30	110	70	98	100	70	120	126.35	
6	18NOV96	46, -15	20	110	60	100	135	85	120	128.11	
7	25NOV96	53, -8	20	110	60	78	110	70	84	126.79	
8	03DEC96	61, 1	20	125	75	84	125	75	95	129.43	
12	30DEC96	88, 28	20	110	60	88	110	76	96	128.99	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.3				12 - 15.6	G/DL
				Hematocrit	39.2				35 - 46	%
				Red Blood Cell Count	4.7				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2				4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2				30 - 70	%
				Lymphocytes	31.2				21 - 51	%
				Monocytes	4.5				0 - 10	%
				Eosinophils	2.3				0 - 5	%
				Basophils	0.8				0 - 2	%
				Platelets	318000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5				25 - 35	PG
				Mean Corpuscle Volume	84				80 - 100	FL
				Blood Urea Nitrogen	11				7 - 25	MG/DL
				Creatinine	1				0.8 - 1.5	MG/DL
				Uric Acid	2.6				2.3 - 7	MG/DL
				Alkaline Phosphatase	75				44 - 280	U/L
				Aspartate Aminotransferase	18				0 - 41	U/L
				Alanine Aminotransferase	12				0 - 48	U/L
				Total Bilirubin	0.6				0.3 - 1.3	MG/DL
				Total Protein	8.8				6.2 - 8.8	G/DL
				Albumin	4.5				3.1 - 5.3	G/DL
				Glucose - Random	97				70 - 115	MG/DL
				Globulin	4.3	H			2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.8	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEC		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	88	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	88	Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	27.4	.	.	.	21 - 51	%
				Monocytes	11.3	H	.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	266000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	88	Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	20MAR97	1	26MAR97	7	7
00215	Oral	2	100 MG	27MAR97	8	02APR97	14	7
00215	Oral	3	150 MG	03APR97	15	09APR97	21	7
00215	Oral	4	200 MG	10APR97	22	14APR97	26	5
00215	Oral	4	200 MG	15APR97	27	23APR97	35	9
00215	Oral	4	200 MG	24APR97	36	28APR97	40	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	40	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
LOW ENERGY	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
VARIOUS	Herbal Medication	Unknown Chinese Herbal Med	-139, .	01NOV96	11MAR97#		LOW ENERGY
	Homeopathic Preparations	Yinchia0 Tablet (Chiehtupien) {Homeopathic}	7, .	26MAR97	26MAR97	ONE TABLET	RHINITIS AND SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	WEAKNESS	42, .	Not Stated	200	CON	MOD	STP	REL	No	No
	Headache	HEADACHE	6, .	2 Days	50	1	MIL	NO	UNR	No	No
			13, .	30 Days	100	CON	MIL	NO	PSR	No	No
		HEADACHES	43, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	13, .	21 Days	100	CON	MOD	NO	REL	No	No
			34, .	11 Days	200	CON	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	9, .	Not Stated	100	CON	MOD	NO	REL	No	No
	Esophagitis	ESOPHAGEAL IRRITATION	21, .	3 Days	150	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	42, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
	Vomiting	VOMITING	42, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
Musculoskeletal System	Arthralgia	JOINT PAINS	42, .	Not Stated	200	CON	MIL	STP	REL	Yes	No
Nervous System	Abnormal Dreams	NIGHTMARES	37, .	7 Days	200	CON	MOD	STP	REL	No	Yes
	Dizziness	DIZZINESS	16, .	2 Days	150	CON	MIL	NO	REL	No	No
			37, .	Not Stated	200	CON	MOD	STP	REL	No	Yes
	Hallucinations	VISUAL HALLUCINATIONS	37, .	7 Days	200	CON	SEV	STP	REL	No	Yes
	Nervousness	IRRITABILITY	37, .	7 Days	200	CON	SEV	STP	REL	No	Yes
Respiratory System	Pharyngitis	SORE THROAT	6, .	5 Days	50	CON	MIL	NO	UNR	Yes	No
	Rhinitis	RHINITIS	7, .	4 Days	50	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12MAR97	-8, .	0	98	64	60	98	70	64	103.19	58.3
BL	20MAR97	1, .	0	98	50	76	98	45	76	102.31	
1	27MAR97	8, .	100	105	60	84	100	60	88	99.23	
2	03APR97	15, .	150	100	65	92	95	50	100	99.23	
3	10APR97	22, .	200	100	60	100	95	50	108	98.78	
4	15APR97	27, .	200	110	70	104	98	65	112	98.12	
5	24APR97	36, .	200	108	70	104	100	68	108	99.89	
6	29APR97	41, .	200	108	65	96	104	70	104	97.68	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	30.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	9.4	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	97	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8		Urine Squamous Epithelial Cells	4	.	.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	41	(1)	Segmented Neutrophils	54	.	.	.	30 - 70	%
					Lymphocytes	39	.	.	.	21 - 51	%
					Monocytes	4	.	.	.	0 - 10	%
					Eosinophils	1	.	.	.	0 - 5	%
					Basophils	2	.	.	.	0 - 2	%
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEC		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	20APR94	1	26APR94	7	7
00001	Oral	2	0 MG	27APR94	8	03MAY94	14	7
00001	Oral	3	0 MG	04MAY94	15	10MAY94	21	7
00001	Oral	4	0 MG	11MAY94	22	17MAY94	28	7
00001	Oral	5	0 MG	18MAY94	29	24MAY94	35	7
00001	Oral	6	0 MG	25MAY94	36	31MAY94	42	7
00001	Oral	6	0 MG	01JUN94	43	07JUN94	49	7
00001	Oral	6	0 MG	08JUN94	50	14JUN94	56	7
	Oral	6	0 MG	15JUN94	57	28JUN94	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	70	0	Lack of Efficacy	-MINIMAL IMPROVEMENT OF DEPRESSION SYMPTOMS

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	11APR94	-9,	.	0	110	70	105	108	72	108	125.00	67.0
BL	20APR94	1,	.	0	114	80	92	110	78	96	125.91	
1	27APR94	8,	.	0	100	60	96	92	60	106	122.82	
2	04MAY94	15,	.	0	108	60	90	108	80	94	123.92	
3	11MAY94	22,	.	0	126	78	92	124	88	96	123.92	
4	18MAY94	29,	.	0	120	80	96	118	80	90	124.80	
5	25MAY94	36,	.	0	124	78	84	124	78	96	124.80	
6	01JUN94	43,	.	0	122	62	98	118	70	92	124.80	
7	08JUN94	50,	.	0	118	68	80	110	68	92	126.35	
8	15JUN94	57,	.	0	102	60	92	118	78	98	125.02	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.6	.	.	.	30 - 70	%
				Lymphocytes	26.2	.	.	.	21 - 51	%
				Monocytes	4.3	.	.	.	0 - 10	%
				Eosinophils	0.4	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-2	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	67		.	.	30 - 70	%
				Lymphocytes	29		.	.	21 - 51	%
				Monocytes	4		.	.	0 - 10	%
				Eosinophils	0		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66		.	.	22 - 130	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		ACUTE PHASE/DOWN TITRATION	70	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	25MAY94	1	31MAY94	7	7
00002	Oral	2	20 MG	01JUN94	8	07JUN94	14	7
00002	Oral	3	20 MG	08JUN94	15	14JUN94	21	7
00002	Oral	4	20 MG	15JUN94	22	22JUN94	29	8
00002	Oral	5	30 MG	23JUN94	30	29JUN94	36	7
00002	Oral	6	40 MG	30JUN94	37	06JUL94	43	7
00002	Oral	6	40 MG	07JUL94	44	12JUL94	49	6
00002	Oral	6	40 MG	13JUL94	50	19JUL94	56	7
00091	Oral	6	40 MG	20JUL94	57	16AUG94	84	28
00091	Oral	6	40 MG	17AUG94	85	14SEP94	113	29
00091	Oral	6	40 MG	15SEP94	114	17OCT94	146	33
00091	Oral	6	40 MG	18OCT94	147	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	147	40	Other reason	PT.STOPPED TAKING MEDICATION BECAUSE SHE DIDN'T WANT TO TAKE PILLS ANYMORE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
CANNABIS USE	DRUG ABUSE	MENTAL DISORD	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-5, -61	20MAY94	20MAY94#	500MG	HEADACHE
			54, -3	17JUL94	20JUL94	500MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN	26, -31	06:30 Hrs	20	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	-5, -61	03:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
			54, -3	4 Days	40	3	MOD	NO	PSR	Yes	No
Cardiovascular System	Palpitation	CHEST PALPITATIONS	26, -31	06:30 Hrs	20	CON	MOD	NO	PSR	No	No
Nervous System	Drug Dependence	POSITIVE CANNABIS	-5, -61	1 Days	0	1	MIL	NO	UNR	No	No
Skin and Appendages	Urticaria	HIVES - BOTH ARMS BOTH LEGS AND STOMACH AREA (QUESTIONABLE)	20, -37	2 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20MAY94	-5, -61	0	80	60	92	80	60	92	115.76	62.0
BL	25MAY94	1, -56	0	100	70	88	90	70	88	112.90	
1	01JUN94	8, -49	20	90	60	92	90	64	92	114.88	
2	08JUN94	15, -42	20	98	60	80	90	60	80	113.78	
3	15JUN94	22, -35	20	90	60	80	88	60	80	111.79	
4	23JUN94	30, -27	30	90	60	72	88	60	60	115.54	
5	30JUN94	37, -20	40	90	60	72	80	60	76	113.12	
6	07JUL94	44, -13	40	90	60	88	88	60	88	115.10	
7	14JUL94	51, -6	40	84	60	80	80	60	80	115.10	
8	20JUL94	57, 1	40	90	60	88	80	60	88	110.47	
12	17AUG94	85, 29	40	94	68	88	94	70	88	115.10	
16	15SEP94	114, 58	40	90	70	92	90	60	92	113.56	
20	18OCT94	147, 91	40	94	70	94	90	70	86	112.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.4	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG			.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE			.	.		
				Urine Amphetamines NEG			.	.		
				Urine Barbiturates NEG			.	.		
				Urine Benzodiazepines NEG			.	.		
				Urine Cannabinoids POS			.	.		
				Urine Cocaine NEG			.	.		
				Urine Methadone NEG			.	.		
				Urine Methaqualone NEG			.	.		
				Urine Opiates NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93		.	.	44 - 280	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	4		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	31	L	.	.	70 - 115	MG/DL
				Globulin	3.3		.	.	2.3 - 4.1	G/DL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEC		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	22	Glucose - Random	87		.	.	70 - 115	MG/DL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1		.	.	12 - 15.6	G/DL
				Hematocrit	39.5		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.9		.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57		Segmented Neutrophils	75.3	H	.	.	30 - 70	%
					Lymphocytes	13.4	L	.	.	21 - 51	%
					Monocytes	5.8	.	.	.	0 - 10	%
					Eosinophils	5.3	H	.	.	0 - 5	%
					Basophils	0.2	.	.	.	0 - 2	%
					Platelets	245000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	88	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	109	.	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	(1)	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.9	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	58.2	.	.	.	30 - 70	%
					Lymphocytes	33.2	.	.	.	21 - 51	%
					Monocytes	6.2	.	.	.	0 - 10	%
					Eosinophils	1.9	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	271000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	147 (1)	Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	96	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	147	(1)	Urine Propoxyphene	NEG		.	.		
					Urine Squamous Epithelial Cells	4		.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	20SEP94	1	26SEP94	7	7
00003	Oral	2	100 MG	27SEP94	8	30SEP94	11	4
00003	Oral	2	100 MG	01OCT94	12	04OCT94	15	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	15	100	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EAR INFECTION	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1994
ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1988
HISTORY OF HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	-19, .	01SEP94	14SEP94#	750MG	EAR INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Acetaminophen	-5, .	15SEP94	15SEP94#	650MG	HEADACHE
DERMATOLOGICALS	Erythromycin	Erythromycin	-19, .	01SEP94	14SEP94#	750MG	EAR INFECTION
RESPIRATORY	Carbinoxamine Maleate	Naldecon	., .		.	20ML	FOR RELIEF OF ALLERGIES
	Codeine Phosphate	Tussi-Organidin	., .		.	120MG	FOR RELIEF OF ALLERGIES
	Iodinated Glycerol	Tussi-Organidin	., .		.	120MG	FOR RELIEF OF ALLERGIES
	Phenylephrine Hydrochloride	Naldecon	., .		.	20ML	FOR RELIEF OF ALLERGIES
	Phenylpropanolamine Hydrochloride	Naldecon	., .		.	20ML	FOR RELIEF OF ALLERGIES
	Phenyltoloxamine Citrate	Naldecon	., .		.	20ML	FOR RELIEF OF ALLERGIES
SENSORY ORGANS	Erythromycin	Erythromycin	-19, .	01SEP94	14SEP94#	750MG	EAR INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	4, .	03:00 Hrs	50	1	MOD	NO	PSR	No	No
Carciovascular System	Tachycardia	"RACING HEART"	4, .	12 Days	50	4	MOD	NO	PBU	No	No
		RACING HEARTBEAT	11, .	5 Days	100	2	MOD	STP	REL	No	No
Nervous System	Dizziness	DIZZINESS	8, .	10 Days	100	CON	MOD	NO	PSR	No	No
	Tremor	SHAKINESS	8, .	10 Days	100	CON	MOD	NO	PSR	No	No
Skin and Appendages	Sweating	SWEATINESS	3, .	6 Days	50	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12SEP94	-8,	.	0	106	70	80	108	70	84	116.50	60.0
BL	20SEP94	1,	.	0	110	78	82	110	80	90	116.70	
1	27SEP94	8,	.	100	112	72	106	102	80	116	114.60	
2	04OCT94	15,	.	100	106	70	106	102	70	110	112.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1				12 - 15.6	G/DL
				Hematocrit	37.1				35 - 46	%
				Red Blood Cell Count	4.4				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6				4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.8				30 - 70	%
				Lymphocytes	37.7				21 - 51	%
				Monocytes	3.6				0 - 10	%
				Eosinophils	4.9				0 - 5	%
				Basophils	1				0 - 2	%
				Platelets	322000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5				25 - 35	PG
				Mean Corpuscle Volume	84				80 - 100	FL
				Blood Urea Nitrogen	13				7 - 25	MG/DL
				Creatinine	1				0.8 - 1.5	MG/DL
				Uric Acid	4				2.3 - 7	MG/DL
				Alkaline Phosphatase	108				44 - 280	U/L
				Aspartate Aminotransferase	17				0 - 41	U/L
				Alanine Aminotransferase	12				0 - 48	U/L
				Total Bilirubin	0.5				0.3 - 1.3	MG/DL
				Total Protein	7.9				6.2 - 8.8	G/DL
				Albumin	4.2				3.1 - 5.3	G/DL
				Glucose - Random	116	H			70 - 115	MG/DL
				Globulin	3.7				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	10OCT94	1	19OCT94	10	10
00004	Oral	2	20 MG	20OCT94	11	26OCT94	17	7
00004	Oral	3	20 MG	27OCT94	18	02NOV94	24	7
00004	Oral	4	20 MG	03NOV94	25	09NOV94	31	7
00004	Oral	5	30 MG	10NOV94	32	16NOV94	38	7
00004	Oral	6	40 MG	17NOV94	39	22NOV94	44	6
00004	Oral	6	40 MG	23NOV94	45	30NOV94	52	8
00004	Oral	6	40 MG	01DEC94	53	07DEC94	59	7
00093	Oral	6	40 MG	08DEC94	60	04JAN95	87	28
00004	Oral	5	30 MG	05JAN95	88	20JAN95	103	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	103	30	Other reason	PT. CHOSE TO WITHDRAW.

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	81, 22	29DEC94	30DEC94	500MG	SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	15, -45	02:30 Hrs	20	CON	MIL	NO	PBU	No	No
			81, 22	2 Days	40	CON	MOD	NO	PBU	No	No
Respiratory System	Pharyngitis	SORE THROAT	81, 22	2 Days	40	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22SEP94	-18, -77	0	130	70	62	124	70	62	143.00	68.0
BL	10OCT94	1, -59	0	134	74	68	130	70	68	141.50	
1	20OCT94	11, -49	20	130	70	62	124	70	62	142.00	
2	27OCT94	18, -42	20	118	74	64	110	70	62	144.80	
3	03NOV94	25, -35	20	120	70	60	90	70	60	145.40	
4	10NOV94	32, -28	30	120	70	68	100	60	64	148.00	
5	17NOV94	39, -21	40	124	80	84	120	80	80	150.50	
6	23NOV94	45, -15	40	124	80	64	120	80	64	148.00	
7	01DEC94	53, -7	40	112	70	60	100	60	64	152.90 H	
8	08DEC94	60, 1	40	110	60	60	118	60	62	149.60	
12	05JAN95	88, 29	30	118	62	76	110	60	90	153.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	15		.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2		.	.	41 - 50	%
				Red Blood Cell Count	5.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.5		.	.	30 - 70	%
				Lymphocytes	24.1		.	.	21 - 51	%
				Monocytes	10.5	H	.	.	0 - 10	%
				Eosinophils	3.4		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	265000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1.2		.	.	0.8 - 1.5	MG/DL
				Uric Acid	6		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153		.	.	22 - 180	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	4		.	.	0 - 48	U/L
				Total Bilirubin	2.1	H	.	+	0.3 - 1.3	MG/DL
				Total Protein	7.5		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-4	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	15.1		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9		.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.2		.	.	30 - 70	%
				Lymphocytes	22.3		.	.	21 - 51	%
				Monocytes	8.8		.	.	0 - 10	%
				Eosinophils	2.3		.	.	0 - 5	%
				Basophils	1.4		.	.	0 - 2	%
				Platelets	262000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	148		.	.	22 - 180	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	4		.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	1	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	37.5	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	264000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	122	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00005 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	01NOV94	1	09NOV94	9	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	9	0	Adverse event, including intercurrent illness	ELEVATED HEART RATE ON LEVEL ONE

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00005 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	SLIGHTLY TIRED	3, .	14 Days	0	5	MIL	NO	PSR	No	No
Carciovascular System	Tachycardia	ELEVATED HEART RATE	8, .	2 Days	0	2	MOD	STP	PSR	No	No
Nervous System	Dizziness	SLIGHTLY DIZZY	3, .	14 Days	0	4	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24OCT94	-8, .	0	100	64	80	100	60	88	111.57	60.5
BL	01NOV94	1, .	0	98	58	88	104	68	88	114.66	
1	08NOV94	8, .	0	104	66	98	108	62	136 H	114.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00005 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.3		.	.	12 - 15.6	G/DL
				Hematocrit	39.9		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4		.	.	30 - 70	%
				Lymphocytes	34.2		.	.	21 - 51	%
				Monocytes	3.3		.	.	0 - 10	%
				Eosinophils	3.1		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	284000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	340	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7		.	.	6.2 - 8.8	G/DL
				Albumin	4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	87		.	.	70 - 115	MG/DL
				Globulin	3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00005 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 2/ELIGIBILITY	1	Serum BHCG pregnancy test	NEGATIVE	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	04NOV94	1	13NOV94	10	10
00006	Oral	2	100 MG	14NOV94	11	20NOV94	17	7
00006	Oral	3	150 MG	21NOV94	18	27NOV94	24	7
00006	Oral	4	200 MG	28NOV94	25	04DEC94	31	7
00006	Oral	5	250 MG	05DEC94	32	11DEC94	38	7
00006	Oral	6	300 MG	12DEC94	39	18DEC94	45	7
00006	Oral	6	300 MG	19DEC94	46	26DEC94	53	8
00006	Oral	6	300 MG	27DEC94	54	02JAN95	60	7
00089	Oral	6	300 MG	03JAN95	61	01FEB95	90	30
00089	Oral	6	300 MG	02FEB95	91	26FEB95	115	25
00089	Oral	6	300 MG	27FEB95	116	04APR95	152	37
00089	Oral	6	300 MG	05APR95	153	11APR95	159	7
00006	Oral	5	250 MG	12APR95	160	13APR95	161	2
00006	Oral	4	200 MG	14APR95	162	15APR95	163	2
00006	Oral	3	150 MG	16APR95	164	17APR95	165	2
00006	Oral	2	100 MG	18APR95	166	20APR95	168	3
00006	Oral	1	50 MG	21APR95	169	27APR95	175	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	175	50	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HISTORY OF ENVIRONMENTAL ALLERGIES-DUST	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	
HISTORY OF ENVIRONMENTAL ALLERGIES-POLLEN	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	
HISTORY OF RECURRENT TONSILLITIS	TONSILS/ADENOIDS DIS	RESPIRATORY SYST DIS	PRV	
STATUS POST MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1994

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Calcium Carbonate	Tums	23, -38	26NOV94	.	2DAILY	UPSET STOMACH
			23, -38	26NOV94	.	2DAILY	UPSET STOMACH
ANTIINFECTIVES,SYSTEMIC	Cefaclor	Ceclor	21, -40	24NOV94	28NOV94	750MG	TONSILLITIS/STREP THROAT
			25, -36	28NOV94	09DEC94	1000MG	TONSILLITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT/FEVER/SORE THROAT	23, -38	5 Days	150	CON	SEV	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	6, -55	Not Stated	50	CON	MOD	NO	REL	No	No
	Dyspepsia	UPSET STOMACH	23, -38	64 Days	150	CON	MOD	NO	UNR	Yes	No
	Increased Appetite	CRAVINGS:CEREALS,PASTAS, CARBOHYDRATES	21, -40	41 Days	150	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	23, -38	64 Days	150	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS WHEN GETTING OUT OF BED IN AM	8, -53	25 Days	50	CON	MIL	NO	REL	No	No
	Neurosis	OBSESSIVE THOUGHTS	116, 56	Not Stated	300	CON	MOD	STP	PBU	No	No
Urogenital System	Pyuria	URINALYSIS - WBC'S {INCREASED}	176, 116	Not Stated	50		MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	27OCT94	-8, -68	0	110	70	72	108	68	72	145.00	68.0
BL	03NOV94	-1, -61	0	100	70	60	90	70	62	141.90	
1	14NOV94	11, -50	100	110	70	76	100	68	78	141.00	
2	21NOV94	18, -43	150	110	70	64	100	70	64	141.00	
3	28NOV94	25, -36	200	118	74	76	110	70	76	140.24	
4	05DEC94	32, -29	250	100	60	70	90	60	72	142.00	
5	12DEC94	39, -22	300	110	60	64	110	70	68	141.50	
6	19DEC94	46, -15	300	100	64	80	90	60	94	139.00	
8	27DEC94	54, -7	300	106	68	92	94	70	104	138.92	
8	03JAN95	61, 1	300	104	70	90	90	60	94	139.14	
12	02FEB95	91, 31	300	108	70	88	110	60	92	140.00	
16	27FEB95	116, 56	300	104	70	84	100	70	88	145.31	
20	05APR95	153, 93	300	120	70	92	104	70	96	147.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	30 - 70	%
				Lymphocytes	33.2	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEC		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55	.	.	.	30 - 70	%
				Lymphocytes	36	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	61		Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	3	.	.	.	0 - 5	%
					Basophils	0	.	.	.	0 - 2	%
					Platelets	114000	L	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.7	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	76	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	93	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
		VISIT 17/DOWN TITRATION	176	(1)	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	48.4	.	.	.	41 - 50	%
					Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.3	.	.	.	30 - 70	%
					Lymphocytes	34	.	.	.	21 - 51	%
					Monocytes	9.3	.	.	.	0 - 10	%
					Eosinophils	4.1	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	292000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 17/DOWN TITRATION	176 (1)	Blood Urea Nitrogen	20	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEC		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	09NOV94	1	09NOV94	1	1
00007	Oral	1	50 MG	10NOV94	2	15NOV94	7	6
00007	Oral	1	50 MG	16NOV94	8	22NOV94	14	7
00007	Oral	2	100 MG	23NOV94	15	29NOV94	21	7
00007	Oral	3	150 MG	30NOV94	22	06DEC94	28	7
00007	Oral	4	200 MG	07DEC94	29	13DEC94	35	7
00007	Oral	5	250 MG	14DEC94	36	20DEC94	42	7
00007	Oral	6	300 MG	21DEC94	43	27DEC94	49	7
00007	Oral	5	250 MG	28DEC94	50	03JAN95	56	7
00007	Oral	5	250 MG	04JAN95	57	10JAN95	63	7
00092	Oral	5	250 MG	11JAN95	64	14FEB95	98	35
00092	Oral	5	250 MG	15FEB95	99	21MAR95	133	35
00092	Oral	5	250 MC	22MAR95	134	18APR95	161	28
00092	Oral	5	250 MG	19APR95	162	16MAY95	189	28
00092	Oral	5	250 MG	17MAY95	190	19MAY95	192	3

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	192	250	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
QUESTIONABLE OVARIAN CYST	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	81, 18	28JAN95	.	500MG(PRN)	LEG CRAMPS
			180, 117	07MAY95	07MAY95	500MG	HEADACHE
	Prochlorperazine	Compazine	195, 132	22MAY95	22MAY95		DEHYDRATION NAUSEA,VOMITING,DIARRHEA
		Compazine Suppositories	196, 133	23MAY95	24MAY95		DEHYDRATION NAUSEA,VOMITING,DIARRHEA
DERMATOLOGICALS	Calamine	Caladryl Lotion	2, -62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
	Camphor	Caladryl Lotion	2, -62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
	Diphenhydramine Hydrochloride	Benadryl	197, 134	24MAY95	24MAY95		SEIZURE
		Caladryl Lotion	2, -62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
	Glycerol	Caladryl Lotion	2, -62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
GU SYSTEM/SEX HORMONES	Oral Contraceptive	Birth Control Pills	-219, -282	04APR94	.	1A DAY	IRREGULAR MENSTRUAL CYCLES
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	197, 134	24MAY95	24MAY95		SEIZURE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	180, 117	03:30 Hrs	250	CON	MOD	NO	UNR	Yes	No
	Infection	GI	32, -32	4 Days	200	CON	SEV	NO	UNR	No	No
		VIRUS-NAUSEA,VOMITING AND DIARRHEA									
		NAUSEA,VOMITING,DIARRHEA,FLU	52, -12	2 Days	250	CON	SEV	NO	UNR	No	No
Carciovascular System	Postural Hypotension	DIZZINESS-POSTURAL HYPOTENSION(ONLY IN GYM CLASSES)	23, -41	14 Days	150	1	MOD	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	42, -22	151 Days	250	CON	MOD	NO	REL	No	No
Metabolic and Nutritional Disorders	Dehydration	DEHYDRATION	191, 128	8 Days	250	CON	SEV	STP	PBU	Yes	No
Musculoskeletal System	Myalgia	LEG CRAMPS AND ACHES	81, 18	Not Stated	250	CON	MOD	NO	PSR	Yes	No
Nervous System	Abnormal Dreams	NIGHTMARES	145, 82	15 Days	250	10	SEV	NO	UNR	No	No
	Convulsion	SEIZURE	197, 134	5 Mins	250	CON	SEV	STP	UNR	Yes	No
	Tremor	HAND TREMORS	42, -22	6 Days	250	CON	MIL	NO	REL	No	No
			48, -16	3 Days	300	CON	MOD	DCR	REL	No	No
			51, -13	142 Days	250	CON	MIL	NO	REL	No	No
Skin and Appendages	Rash	RASH-BILATERAL FOREARMS	2, -62	5 Days	50	CON	MOD	STP	PBU	Yes	No
	Urticaria	HIVES-BILATERAL FOREARMS	2, -62	5 Days	50	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02NOV94	-7, -70	0	110	70	64	104	68	74	135.00	64.0
BL	09NOV94	1, -63	0	110	70	74	100	70	72	132.30	
2	23NOV94	15, -49	100	110	70	72	100	68	72	132.95	
3	30NOV94	22, -42	150	100	70	74	94	68	74	132.52	
4	07DEC94	29, -35	200	100	68	90	90	60	92	129.00	
5	14DEC94	36, -28	250	110	80	80	94	70	80	127.80	
6	21DEC94	43, -21	300	114	70	100	88	64	100	128.20	
7	28DEC94	50, -14	250	110	80	100	100	70	104	129.50	
8	04JAN95	57, -7	250	100	70	104	104	68	108	128.00	
8	11JAN95	64, 1	250	104	74	86	90	70	92	128.10	
12	15FEB95	99, 36	250	120	80	104	110	80	108	126.00	
20	22MAR95	134, 71	250	120	70	80	98	60	88		
24	19APR95	162, 99	250	104	70	100	100	60	104	127.00	
28	17MAY95	190, 127	250	104	70	100	90	60	104	129.00	
32	09AUG95	274, 211#	0	104	74	92	100	70	98	129.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3		.	.	12 - 15.6	G/DL
				Hematocrit	41.4		.	.	35 - 46	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.1		.	.	30 - 70	%
				Lymphocytes	27.4		.	.	21 - 51	%
				Monocytes	6.8		.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	1.2		.	.	0 - 2	%
				Platelets	307000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87		.	.	44 - 280	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.4		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	94		.	.	70 - 115	MG/DL
				Globulin	3.8		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.8		.	.	12 - 15.6	G/DL
				Hematocrit	39.4		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.3		.	.	30 - 70	%
				Lymphocytes	22.7		.	.	21 - 51	%
				Monocytes	6.2		.	.	0 - 10	%
				Eosinophils	0.6		.	.	0 - 5	%
				Basophils	1.2		.	.	0 - 2	%
				Platelets	44000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	7		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	107	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	99	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	17.4	H	.	.	12 - 15.6	G/DL
				Hematocrit	51.5	H	.	.	35 - 46	%
				Red Blood Cell Count	6.1	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	28.4	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	0.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	28000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	162		Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	99	.	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 15/CONTINUATION-WEEK 28	274	(82)	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	63	.	.	.	30 - 70	%
					Lymphocytes	28.3	.	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	1.2	.	.	.	0 - 5	%
					Basophils	1.6	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 15/CONTINUATION-WEEK 28	274	(82)	Platelets	238000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.8	. . .	25 - 35	PG
					Mean Corpuscle Volume	84	. . .	80 - 100	FL
					Blood Urea Nitrogen	8	. . .	7 - 25	MG/DL
					Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
					Uric Acid	4.9	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	71	. . .	22 - 130	U/L
					Aspartate Aminotransferase	16	. . .	0 - 41	U/L
					Alanine Aminotransferase	7	. . .	0 - 48	U/L
					Total Bilirubin	0.5	. . .	0.3 - 1.3	MG/DL
					Total Protein	7	. . .	6.2 - 8.8	G/DL
					Albumin	4.2	. . .	3.1 - 5.3	G/DL
					Glucose - Random	82	. . .	70 - 115	MG/DL
					Globulin	2.8	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	16NOV94	1	22NOV94	7	7
00008	Oral	2	20 MG	23NOV94	8	29NOV94	14	7
00008	Oral	3	20 MG	30NOV94	15	06DEC94	21	7
00008	Oral	4	20 MG	07DEC94	22	13DEC94	28	7
00008	Oral	5	30 MG	14DEC94	29	20DEC94	35	7
00008	Oral	6	40 MG	21DEC94	36	27DEC94	42	7
00008	Oral	6	40 MG	28DEC94	43	03JAN95	49	7
00008	Oral	6	40 MG	04JAN95	50	09JAN95	55	6
00095	Oral	5	30 MG	10JAN95	56	05FEB95	82	27
00095	Oral	5	30 MG	06FEB95	83	07MAR95	112	30
00095	Oral	5	30 MG	08MAR95	113	06APR95	142	30

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	142	30	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	25, -31	3 Days	20	CON	MOD	NO	UNR	No	No
	Asthenia	EXTREME SLEEPINESS/FATIGUE	44, -12	11 Days	40	CON	SEV	DCR	REL	No	No
	Headache	HEADACHE	25, -31	3 Days	20	CON	MOD	NO	UNR	No	No
	Infection	STOMACH FLU WITH NAUSEA,VOMITING AND DIARRHEA	12, -44	3 Days	20	CON	SEV	NO	UNR	No	No
		STOMACH FLU-NAUSEA,VOMITING AND DIARRHEA	31, -25	4 Days	30	CON	SEV	NO	UNR	No	No
Carciovascular System	Postural Hypotension	POSTURAL HYPOTENSION	-4, -59	2 Mins	0	2	MIL	NO	PSR	No	No
Digestive System	Diarrhea	DIARRHEA	25, -31	3 Days	20	CON	MOD	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	5, -51	140 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Personality Disorder	BEHAVIOR PROBLEMS-->STOLE MOM'S CAR AND WRECKED IT.	77, 22	02:00 Hrs	30	1	SEV	NO	PSR	No	No
		SKIPPING SCHOOL TALKING BACK TO MOM {BEHAVIOR PROBLEMS}	37, -19	47 Days	40	CON	SEV	NO	PSR	No	No
	Somnolence	DROWSINESS-SLEEPINESS	1, -55	17 Days	20	7	MIL	NO	PSR	No	No
			17, -39	160 Days	20	CON	MOD	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	10NOV94	-6, -61	0	100	70	70	100	68	70	88.50	60.0
BL	16NOV94	1, -55	0	100	70	80	110	70	80	91.00	
1	23NOV94	8, -48	20	100	70	72	108	70	72	89.00	
2	30NOV94	15, -41	20	98	70	76	110	70	80	89.50	
3	07DEC94	22, -34	20	80	60	84	84	60	88	88.00	
4	14DEC94	29, -27	30	100	60	80	100	60	88	89.00	
5	21DEC94	36, -20	40	104	70	76	110	70	76	90.85	
6	28DEC94	43, -13	40	90	60	84	90	60	88	91.29	
7	03JAN95	49, -7	40	100	60	80	100	64	84	90.00	
8	10JAN95	56, 1	30	90	60	72	94	64	80	92.00	
12	06FEB95	83, 28	30	100	70	80	96	60	80	95.50	
16	08MAR95	113, 58	30	100	60	80	100	60	88	98.20 H	
24	10MAY95	176, 121#	0	94	64	88	90	60	88	101.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	38.6	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	222000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	281	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	32	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.4		.	.	30 - 70	%
				Lymphocytes	41.8		.	.	21 - 51	%
				Monocytes	10.3	H	.	.	0 - 10	%
				Eosinophils	2.8		.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	207000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	16		.	.	8 - 21	MG/DL
				Creatinine	1.1		.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.4		.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	244		.	.	44 - 400	U/L
				Aspartate Aminotransferase	27		.	.	0 - 41	U/L
				Alanine Aminotransferase	23		.	.	0 - 39	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9		.	.	5.7 - 8.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	56		Albumin	4.2		.	.	3.1 - 5.3	G/DL
					Glucose - Random	103		.	.	60 - 110	MG/DL
					Globulin	2.7		.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	176	(34)	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	37.4	L	.	.	41 - 50	%
					Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	44.2		.	.	30 - 70	%
					Lymphocytes	44.4		.	.	21 - 51	%
					Monocytes	7.8		.	.	0 - 10	%
					Eosinophils	3.2		.	.	0 - 5	%
					Basophils	0.5		.	.	0 - 2	%
					Platelets	211000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
					Mean Corpuscle Volume	86		.	.	80 - 100	FL
					Blood Urea Nitrogen	19		.	.	8 - 21	MG/DL
					Creatinine	1		.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.6		.	.	2.6 - 7	MG/DL
					Alkaline Phosphatase	320		.	.	44 - 400	U/L
					Aspartate Aminotransferase	30		.	.	0 - 41	U/L
					Alanine Aminotransferase	16		.	.	0 - 39	U/L
					Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
					Total Protein	6.8		.	.	5.7 - 8.2	G/DL
					Albumin	4.4		.	.	3.1 - 5.3	G/DL
					Glucose - Random	103		.	.	60 - 110	MG/DL
					Globulin	2.4		.	.	2.1 - 3.8	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	176	(34)	Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Bacteria	4		.	.		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	1/2SPANISH 1/2WHITE

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	12DEC94	1	18DEC94	7	7
00009	Oral	2	100 MG	19DEC94	8	26DEC94	15	8
00009	Oral	3	150 MG	27DEC94	16	02JAN95	22	7
00009	Oral	4	200 MG	03JAN95	23	10JAN95	30	8
00009	Oral	5	250 MG	11JAN95	31	17JAN95	37	7
00009	Oral	6	300 MG	18JAN95	38	24JAN95	44	7
00009	Oral	5	250 MG	25JAN95	45	30JAN95	50	6
00009	Oral	5	250 MG	31JAN95	51	06FEB95	57	7
	Oral	5	250 MG	07FEB95	58	22FEB95	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	73	250	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HAY FEVER	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	1984

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-11, .	01DEC94	07DEC94#	500MG	HEADACHE
			5, .	16DEC94	19DEC94	500MG	HEADACHE
			11, .	22DEC94	27DEC94	500MG	HEADACHES
			21, .	01JAN95	01JAN95	500MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	5,	.	4 Days	50	3	MOD	NO	PSR	Yes	No
			21,	.	04:00 Hrs	150	1	SEV	NO	PSR	Yes	No
		HEADACHES	11,	.	6 Days	100	3	SEV	NO	PSR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	5,	.	Not Stated	50	CON	MOD	NO	REL	No	No
			29,	.	Not Stated	200	CON	MOD	NO	REL	No	No
	Dyspepsia	HEARTBURN	29,	.	03:00 Hrs	200	1	MOD	NO	PBU	No	No
		UPSET STOMACH/INDIGESTION	6,	.	Not Stated	50	6	MIL	NO	PSR	No	No
Hemic and Lymphatic System	Leukocytosis	NEUTROPHILS, SEGS {INCREASED}	-5,	.	1 Days	0	1	MIL	NO	UNR	No	No
	Leukopenia	LYMPHOCYTES {DECREASED}	-5,	.	1 Days	0	1	MIL	NO	UNR	No	No
Metabolic and Nutritional Disorders	Hyperglycemia	GLUCOSE ELEVATED	59,	.	1 Days	250	1	SEV	NO	UNR	No	No
Nervous System	Tremor	HAND TREMORS	32,	.	Not Stated	250	CON	MIL	NO	REL	No	No
			35,	.	10 Days	250	CON	MIL	NO	REL	No	No
			44,	.	8 Days	300	CON	SEV	DCR	REL	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	40,	.	5 Days	300	CON	SEV	NO	UNR	No	No
	Haematuria	[URINE OCCULT BLOOD]	-5,	.	1 Days	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	07DEC94	-5,	.	0	110	70	76	104	70	80	146.00	63.0
BL	12DEC94	1,	.	0	100	70	80	100	60	88	145.00	
1	19DEC94	8,	.	100	110	70	84	116	70	96	143.00	
2	27DEC94	16,	.	150	110	70	100	100	70	100	143.00	
3	03JAN95	23,	.	200	110	70	92	104	74	92	143.00	
4	11JAN95	31,	.	250	110	70	90	94	60	94	145.00	
5	18JAN95	38,	.	300	108	62	80	100	62	100	144.65	
6	25JAN95	45,	.	250	100	70	84	94	70	88	144.43	
7	31JAN95	51,	.	250	110	80	80	100	80	80	144.21	
8	07FEB95	58,	.	250	100	88	96	94	70	104	145.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15		.	.	12 - 15.6	G/DL
				Hematocrit	44.5		.	.	35 - 46	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.5	H	.	.	30 - 70	%
				Lymphocytes	20.3	L	.	.	21 - 51	%
				Monocytes	3.2		.	.	0 - 10	%
				Eosinophils	4.9		.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	211000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41		.	.	22 - 130	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL
				Albumin	4.7		.	.	3.1 - 5.3	G/DL
				Glucose - Random	99		.	.	70 - 115	MG/DL
				Globulin	2.9		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick	6		.	.		
				Urine Red Blood Cells/HPF	3		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	45.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.4	H	.	.	30 - 70	%
				Lymphocytes	20.5	L	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	54000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	45	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	49	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	13DEC94	1	19DEC94	7	7
00010	Oral	2	0 MG	20DEC94	8	26DEC94	14	7
00010	Oral	3	0 MG	27DEC94	15	03JAN95	22	8
00010	Oral	4	0 MG	04JAN95	23	10JAN95	29	7
00010	Oral	5	0 MG	11JAN95	30	17JAN95	36	7
00010	Oral	6	0 MG	18JAN95	37	24JAN95	43	7
00010	Oral	6	0 MG	25JAN95	44	01FEB95	51	8
00010	Oral	6	0 MG	02FEB95	52	07FEB95	57	6
00090	Oral	6	0 MG	08FEB95	58	09MAR95	87	30
00090	Oral	6	0 MG	10MAR95	88	12APR95	121	34
00090	Oral	6	0 MG	13APR95	122	09MAY95	148	27
00090	Oral	6	0 MG	10MAY95	149	05JUN95	175	27
00090	Oral	6	0 MC	06JUN95	176	11JUL95	211	36
00090	Oral	6	0 MG	12JUL95	212	08AUG95	239	28
00010	Oral	5	0 MG	09AUG95	240	10AUG95	241	2
00010	Oral	4	0 MG	11AUG95	242	12AUG95	243	2
00010	Oral	3	0 MG	13AUG95	244	14AUG95	245	2
00010	Oral	2	0 MG	15AUG95	246	17AUG95	248	3
00010	Oral	1	0 MG	18AUG95	249	24AUG95	255	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	255	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DISLOCATED RIGHT HIP AT BIRTH	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1978
HERNIA REPAIR AT AGE 7	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1987
RUPTURED RIGHT EAR DRUM AT BIRTH	CONGEN ANOM, HEAD/NECK	ANOMALIES	PRV	1978

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	122, 65	13APR95	15APR95	1GM	FOOT/ANKLE INJURY
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	81, 24	03MAR95	05MAR95		HIVES
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	81, 24	03MAR95	05MAR95		HIVES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU-NAUSEA,CRAMPS DIARRHEA,STOMACH ACHE	37, -21	3 Days	0	CON	SEV	NO	UNR	No	No
	Trauma	FOOT/ANKLE (RUN OVER BY CAR INJURY-PAIN)	488, 431	3 Days	0	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS	10, -48	6 Days	0	4	MIL	NO	PSR	No	No
			39, -19	24:00 Hrs	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Urticaria	HIVES	80, 23	6 Days	0	CON	MOD	NO	UNR	Yes	No
Urogenital System	Menstrual Disorder	2 MENSTRUAL CYCLES IN JULY-2 WEEKS APART	203, 146	6 Days	0	CON	MOD	NO	PBU	No	No
			218, 161	7 Days	0	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	07DEC94	-6, -63	0	100	72	68	94	60	72	121.00	69.0
BL	13DEC94	1, -57	0	100	60	68	110	68	70	121.00	
1	20DEC94	8, -50	0	100	70	78	100	70	78	120.00	
2	27DEC94	15, -43	0	100	68	88	110	70	88	119.00	
3	04JAN95	23, -35	0	100	60	76	90	60	78	122.16	
4	11JAN95	30, -28	0	104	70	76	100	60	80	123.04	
5	18JAN95	37, -21	0	102	70	72	110	70	72	123.70	
6	25JAN95	44, -14	0	90	60	70	100	70	74	120.39	
7	02FEB95	52, -6	0	104	60	74	90	60	76	121.00	
8	08FEB95	58, 1	0	100	70	76	90	60	76	121.50	
12	10MAR95	88, 31	0	90	60	76	94	60	78	123.00	
16	13APR95	122, 65	0	100	70	80	90	64	84	120.70	
20	10MAY95	149, 92	0	90	60	72	88	58	74	123.00	
24	06JUN95	176, 119	0	100	60	70	100	58	76	120.39	
32	12JUL95	212, 155	0	100	60	70	90	60	76	118.63	
32	09AUG95	240, 183	0	80	60	72	80 L	60	78	120.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.8	.	.	.	30 - 70	%
				Lymphocytes	24.4	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	208000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.4		.	.	12 - 15.6	G/DL
				Hematocrit	39.3		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.2	H	.	.	30 - 70	%
				Lymphocytes	15.8	L	.	.	21 - 51	%
				Monocytes	4		.	.	0 - 10	%
				Eosinophils	1.2		.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	236000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81		.	.	22 - 130	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	6		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.9	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	24000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	149	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	240	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	240	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	13DEC94	1	19DEC94	7	7
00011	Oral	2	20 MG	20DEC94	8	26DEC94	14	7
00011	Oral	3	20 MG	27DEC94	15	02JAN95	21	7
00011	Oral	4	20 MG	03JAN95	22	08JAN95	27	6
00011	Oral	5	30 MG	09JAN95	28	16JAN95	35	8
00011	Oral	6	40 MG	17JAN95	36	22JAN95	41	6
00011	Oral	6	40 MG	23JAN95	42	30JAN95	49	8
00011	Oral	6	40 MG	31JAN95	50	06FEB95	56	7
00021	Oral	6	40 MG	07FEB95	57	08MAR95	86	30
00021	Oral	6	40 MG	09MAR95	87	05APR95	114	28
00021	Oral	6	40 MG	06APR95	115	02MAY95	141	27
00021	Oral	5	30 MG	03MAY95	142	17MAY95	156	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	156	30	Adverse event, including intercurrent illness	OVERDOSE WITH BAYER EXTRA STRENGTH {INTENTIONAL}

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Charcoal, Activated	Charcoal	156, 100	17MAY95	17MAY95	UNKNOWN	OVERDOSE WITH BAYER EXTRA STRENGTH
	Sodium Chloride	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
BLOOD/BLOOD FORM ORGANS	Sodium Chloride	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
			156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Bayer Aspirin Extra Strength	156, 100	17MAY95	17MAY95	UNKNOWN	OVERDOSE
	Paracetamol	Tylenol	8, -49	20DEC94	03JAN95	500MG	HEADACHE
RESPIRATORY	Sodium Chloride	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
SENSORY ORGANS	Sodium Chloride	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE WITH DIZZINESS AND DROWSINESS [FATIGUE WITH DROWSINESS]	47, -10	Not Stated	40	CON	MIL	NO	PSR	No	No
		TIREDNESS INCREASED FATIGUE	7, -50	10 Days	20	4	MIL	NO	PSR	No	No
	Headache	HEADACHES	8, -49	15 Days	20	14	MOD	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	21, -36	34 Days	20		MIL	NO	REL	No	No
		FATIGUE WITH DIZZINESS AND DROWSINESS [DIZZINESS]	47, -10	Not Stated	40	CON	MIL	NO	PSR	No	No
	Emotional Lability	[OVERDOSE{WITH BAYER EXTRA STRENGTH}[INTENTIONAL]	156, 100	1 Days	30	1	SEV	STP	UNR	Yes	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06DEC94	-7, -63	0	112	70	84	100	70	88	122.00	69.0
BL	13DEC94	1, -56	0	100	70	80	100	70	84	122.00	
1	20DEC94	8, -49	20	100	70	84	104	70	84	122.00	
2	27DEC94	15, -42	20	90	60	84	90	60	84	119.00	
3	03JAN95	22, -35	20	90	60	76	90	60	76	121.50	
4	09JAN95	28, -29	30	92	60	88	88	60	88	119.50	
5	17JAN95	36, -21	40	90	60	84	100	70	88	120.50	
6	23JAN95	42, -15	40	90	60	100	90	60	100	121.00	
7	31JAN95	50, -7	40	90	60	72	94	60	76	118.10	
8	07FEB95	57, 1	40	104	70	84	100	60	88	118.50	
12	09MAR95	87, 31	40	110	70	96	112	64	114	117.50	
16	06APR95	115, 59	40	110	70	90	100	62	96	118.20	
20	03MAY95	142, 86	30	100	64	88	98	60	92	119.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	24.7	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	235000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.1		.	.	12 - 15.6	G/DL
				Hematocrit	35		.	.	35 - 46	%
				Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	56.6		.	.	30 - 70	%
				Lymphocytes	34.1		.	.	21 - 51	%
				Monocytes	7.2		.	.	0 - 10	%
				Eosinophils	1.3		.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	51000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3		.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alkaline Phosphatase	58	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Segmented Neutrophils	64	.	.	.	30 - 70	%
				Lymphocytes	26	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	142	Alanine Aminotransferase	7	. . .	0 - 48	U/L
				Total Bilirubin	0.5	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.6	. . .	6.2 - 8.8	G/DL
				Albumin	4.5	. . .	3.1 - 5.3	G/DL
				Glucose - Random	85	. . .	70 - 115	MG/DL
				Globulin	3.1	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	19DEC94	1	26DEC94	8	8
00012	Oral	2	0 MG	27DEC94	9	04JAN95	17	9
00012	Oral	3	0 MG	05JAN95	18	11JAN95	24	7
00012	Oral	4	0 MG	12JAN95	25	17JAN95	30	6
00012	Oral	5	0 MG	18JAN95	31	24JAN95	37	7
00012	Oral	6	0 MG	25JAN95	38	30JAN95	43	6
00012	Oral	6	0 MG	31JAN95	44	07FEB95	51	8
00012	Oral	6	0 MG	08FEB95	52	15FEB95	59	8
00096	Oral	6	0 MG	16FEB95	60	26MAR95	98	39
00096	Oral	6	0 MG	27MAR95	99	03MAY95	136	38
00096	Oral	6	0 MG	04MAY95	137	30MAY95	163	27
00096	Oral	6	0 MG	31MAY95	164	01JUN95	165	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	165	0	Adverse event, including intercurrent illness	RECURRENCE OF OCULAR TAXOPLASMOSIS

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
TOXOPLASMOSIS{RIGHT EYE}	INFECT/PARASIT DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	37, -23	24JAN95	24JAN95	500MG	HEADACHE
SENSORY ORGANS	Steroid Eye Drops, Nos	Steroid Eye Drops {Nos}	165, 106	01JUN95	.		OCULAR TOXOPLASMOSIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	37, -23	04:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
	Infection	STOMACH	13, -47	4 Days	0	CON	SEV	NO	UNR	No	No
		FLU-(HEADACHE,NAUSEA/VOMITING AND DIARRHEA)									
		TOXOPLASMOSIS	165, 106	Not Stated	0	CON	MOD	STP	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH (1/2 HOUR AFTER TAKING MEDICATION)	4, -56	13 Days	0	CON	MIL	NO	REL	No	No
	Dyspepsia	UPSET STOMACH (1/2 HOUR AFTER TAKING MEDICATION)	4, -56	13 Days	0	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12DEC94	-7, -66	0	110	74	80	110	70	84	145.50	69.0
BL	19DEC94	1, -59	0	100	70	84	110	70	88	145.00	
1	27DEC94	9, -51	0	110	70	88	112	72	92	144.00	
2	05JAN95	18, -42	0	120	80	92	118	70	94	143.50	
3	12JAN95	25, -35	0	94	68	68	100	70	72	143.50	
4	18JAN95	31, -29	0	118	74	72	100	70	74	144.00	
5	25JAN95	38, -22	0	110	70	60	108	72	64	142.50	
6	31JAN95	44, -16	0	112	70	60	120	82	64	140.10	
7	08FEB95	52, -8	0	112	70	68	112	80	72	140.00	
8	16FEB95	60, 1	0	110	60	78	100	60	80	145.00	
12	27MAR95	99, 40	0	120	80	80	110	78	84	146.00	
20	04MAY95	137, 78	0	110	64	64	100	70	68	149.30	
24	31MAY95	164, 105	0	110	80	60	100	82	64	147.74	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.2	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.6	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	32	L	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	13		.	.	12 - 15.6	G/DL
				Hematocrit	36.8		.	.	35 - 46	%
				Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.7		.	.	30 - 70	%
				Lymphocytes	46.5		.	.	21 - 51	%
				Monocytes	7.3		.	.	0 - 10	%
				Eosinophils	3.4		.	.	0 - 5	%
				Basophils	2.1	H	.	.	0 - 2	%
				Platelets	298000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	36	L	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	60	Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	164	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5	.	.	.	30 - 70	%
				Lymphocytes	43.9	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	36	L	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	164	Aspartate Aminotransferase	8	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	30DEC94	1	04JAN95	6	6
00109	Oral	2	20 MG	05JAN95	7	11JAN95	13	7
00109	Oral	3	20 MG	12JAN95	14	18JAN95	20	7
00109	Oral	4	20 MG	19JAN95	21	25JAN95	27	7
00109	Oral	4	20 MG	26JAN95	28	01FEB95	34	7
00109	Oral	4	20 MG	02FEB95	35	07FEB95	40	6
00109	Oral	4	20 MG	08FEB95	41	15FEB95	48	8
00109	Oral	4	20 MG	16FEB95	49	20FEB95	53	5
00023	Oral	4	20 MG	21FEB95	54	22MAR95	83	30
00023	Oral	4	20 MG	23MAR95	84	23APR95	115	32
00023	Oral	4	20 MG	24APR95	116	16MAY95	138	23

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	138	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
POSTPARTUM - NOT BREAST FEEDING	POSTPARTUM CARE	FAMILY/PERSONAL HISTORY	CUR	1994
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1979
BLEEDING ULCER {NOS}	CONDITIONS, OTHER, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993

CUR = Current, PRV = Past

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PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ranitidine Hydrochloride	Zantac	123, 70	01MAY95	08MAY95		QUESTIONABLE BLEEDING ULCER
	Vitamins Nos	Prenatal Vitamin	-395, -448	30NOV93	.	1 4X DAILY	PREGNANCY/LACTATION
BLOOD/BLOOD FORM ORGANS	Ferrous Sulfate	Ferrous Sulfate	-133, -186	19AUG94	.	320 MG	LOW IRON
	I.V. Fluids	Iv Fluids	129, 76	07MAY95	10MAY95		QUESTIONABLE BLEEDING ULCER
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	81, 28	20MAR95	22MAR95	1 GM	HEADACHE
GU SYSTEM/SEX HORMONES	Desogestrel	Desogen 28	14, -40	12JAN95	.	1 4X DAILY	BIRTH CONTROL
	Ethinylestradiol	Desogen 28	14, -40	12JAN95	.	1 4X DAILY	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	81, 28	3 Days	20	4	MOD	NO	UNR	Yes	No
	Infection	COLD AND FLU STUFFY NOSE/NAUSEA/VOMITING DIARRHEA	42, -12	4 Days	20	CON	MOD	NO	UNR	No	No
Digestive System	Peptic Ulcer Hemorrhage	BLEEDING ULCER {PEPTIC}	129, 76	4 Days	20	CON	SEV	NO	UNR	Yes	Yes
	Vomiting	NAUSEA AND VOMITING	132, 79	2 Days	20	CON	SEV	NO	PSR	No	No
Nervous System	Drug Dependence	POSITIVE URINE DRUG SCREEN CANNABINOIDS	147, 94	1 Days	20	1	SEV	NO	UNR	No	No
	Tremor	HAND TREMORS	22, -32	12 Days	20	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22DEC94	-8, -61	0	112	70	60	100	70	60	137.00	67.0
BL	30DEC94	1, -53	0	98	60	76	90	60	76	137.50	
1	05JAN95	7, -47	20	110	70	72	120	70	72	138.50	
2	12JAN95	14, -40	20	100	60	76	108	60	72	137.50	
3	19JAN95	21, -33	20	112	70	72	112	70	76	136.20	
4	26JAN95	28, -26	20	120	80	80	110	76	84	136.00	
5	02FEB95	35, -19	20	100	70	76	98	68	80	132.10	
6	08FEB95	41, -13	20	90	60	68	100	60	72	135.50	
7	16FEB95	49, -5	20	128	76	72	128	78	76	135.61	
8	21FEB95	54, 1	20	118	74	72	110	72	74	134.00	
12	23MAR95	84, 31	20	90	70	72	104	70	76	134.00	
16	24APR95	116, 63	20	120	88	60	120	78	68	140.00	
20	25MAY95	147, 94	20	120	80	68	120	78	72	137.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14				12 - 15.6	G/DL
				Hematocrit	40.6				35 - 46	%
				Red Blood Cell Count	4.4				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L			4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.5				30 - 70	%
				Lymphocytes	47.5				21 - 51	%
				Monocytes	8.6				0 - 10	%
				Eosinophils	1.2				0 - 5	%
				Basophils	0.2				0 - 2	%
				Platelets	304000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7				25 - 35	PG
				Mean Corpuscle Volume	92				80 - 100	FL
				Blood Urea Nitrogen	9				7 - 25	MG/DL
				Creatinine	0.5	L			0.8 - 1.5	MG/DL
				Uric Acid	2.9				2.3 - 7	MG/DL
				Alkaline Phosphatase	23				22 - 130	U/L
				Aspartate Aminotransferase	16				0 - 41	U/L
				Alanine Aminotransferase	21				0 - 48	U/L
				Total Bilirubin	0.2	L			0.3 - 1.3	MG/DL
				Total Protein	7.7				6.2 - 8.8	G/DL
				Albumin	4.3				3.1 - 5.3	G/DL
				Glucose - Random	76				70 - 115	MG/DL
				Globulin	3.4				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	6					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	NEG					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8		Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54		Neutrophil Bands	0	L	.	.	4 - 12	%
					Segmented Neutrophils	41		.	.	30 - 70	%
					Lymphocytes	48		.	.	21 - 51	%
					Monocytes	7		.	.	0 - 10	%
					Eosinophils	3		.	.	0 - 5	%
					Basophils	1		.	.	0 - 2	%
					Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
					Creatinine	1		.	.	0.8 - 1.5	MG/DL
					Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	39		.	.	22 - 130	U/L
					Aspartate Aminotransferase	16		.	.	0 - 41	U/L
					Alanine Aminotransferase	12		.	.	0 - 48	U/L
					Total Bilirubin	0.4		.	.	0.3 - 1.3	MG/DL
					Total Protein	7.6		.	.	6.2 - 8.8	G/DL
					Albumin	4.2		.	.	3.1 - 5.3	G/DL
					Glucose - Random	100		.	.	70 - 115	MG/DL
					Globulin	3.4		.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	(9)	Hemoglobin	13.4		.	.	12 - 15.6	G/DL
					Hematocrit	38.8		.	.	35 - 46	%
					Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.8		.	.	30 - 70	%
					Lymphocytes	38.3		.	.	21 - 51	%
					Monocytes	7.1		.	.	0 - 10	%
					Eosinophils	1.1		.	.	0 - 5	%
					Basophils	0.8		.	.	0 - 2	%
					Platelets	319000		.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	147 (9)	Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	32	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Amphetamines	NEG			.		
				Urine Barbiturates	NEG			.		
				Urine Benzodiazepines	NEG			.		
				Urine Cannabinoids	POS			.		
				Urine Cocaine	NEG			.		
				Urine Methadone	NEG			.		
				Urine Methaqualone	NEG			.		
				Urine Opiates	NEG			.		
				Urine Phencyclidine	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	147	(9)	Urine Propoxyphene	NEG		.	.		
					Urine Squamous Epithelial Cells	4		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11JAN95	1	17JAN95	7	7
00110	Oral	2	100 MG	18JAN95	8	19JAN95	9	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	9	100	Adverse event, including intercurrent illness	POSITIVE PREGNANCY TEST

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1984

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Dizziness	DIZZINESS	5, .	5 Mins	50	CON	MIL	NO	PSR	No	No
Urogenital System	Unintended Pregnancy	POSITIVE PREGNANCY TEST RESULT	11, .	1 Days	100	CON	SEV	STP	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	04JAN95	-7,	.	0	98	54	80	106	66	88	124.36	67.0
BL	11JAN95	1,	.	0	100	70	72	100	60	80	123.00	
1	18JAN95	8,	.	100	110	72	70	98	64	90	120.00	
2	25JAN95	15,	.	100	110	70	74	100	70	78	122.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	22.5	.	.	.	21 - 51	%
				Monocytes	16.2	H	.	+	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	46	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	42	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1		Urine Squamous Epithelial Cells	4	.	.	.		
					Serum BHCG pregnancy test	BORDERLINE	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	10	(1)	Serum BHCG pregnancy test	POSITIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11JAN95	1	17JAN95	7	7
00111	Oral	2	0 MG	18JAN95	8	24JAN95	14	7
00111	Oral	3	0 MG	25JAN95	15	31JAN95	21	7
00111	Oral	4	0 MG	01FEB95	22	07FEB95	28	7
00111	Oral	4	0 MG	08FEB95	29	14FEB95	35	7
00111	Oral	4	0 MG	15FEB95	36	21FEB95	42	7
00111	Oral	4	0 MG	22FEB95	43	28FEB95	49	7
00111	Oral	4	0 MG	01MAR95	50	07MAR95	56	7
00018	Oral	4	0 MG	08MAR95	57	04APR95	84	28
00018	Oral	4	0 MG	05APR95	85	18APR95	98	14
00111	Oral	3	0 MG	19APR95	99	20APR95	100	2
00111	Oral	2	0 MG	21APR95	101	23APR95	103	3
00111	Oral	1	0 MG	24APR95	104	30APR95	110	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	110	0	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	37, -20	16FEB95	20FEB95	750MG	SORE THROAT-STREP THROAT?
	Amoxicillin Trihydrate	Augmentin	97, 41	17APR95	27APR95	750MG	SINUS INFECTION
	Clavulanic Acid	Augmentin	97, 41	17APR95	27APR95	750MG	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Codeine Phosphate	Tylenol#3	96, 40	16APR95	17APR95	60MG	H/A/SORE THROAT
	Paracetamol	Tylenol	-4, -60	07JAN95	14FEB95	500MG	HEADACHE/BACKACHE
			36, -21	15FEB95	20FEB95	1GM	SORE THROAT/FEVER
			65, 9	16MAR95	17MAR95	1GM	SORE THROAT
			94, 38	14APR95	15APR95	2GM	H/A,PAIN-FACE,NOSE,TEETH
			96, 40	16APR95	17APR95	2GM	H/A/SORE THROAT
		Tylenol#3	96, 40	16APR95	17APR95	60MG	H/A/SORE THROAT
RESPIRATORY	Beclometasone Dipropionate	Beconase Nasal Spray .042%	85, 29	05APR95	.	4 SPRAYS	ALLERGIES/ASTHMA
			85, 29	05APR95	.	4 SPRAYS	ALLERGIES/ASTHMA
		Vancenase	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
			37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
	Cromoglicate Sodium	Nasalcrom	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
			37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
	Salbutamol	Proventil	85, 29	05APR95	07APR95	2PUFFS PRN 4XHOUR	ALLERGIES/ASTHMA
			85, 29	05APR95	07APR95	2PUFFS PRN 4XHOUR	ALLERGIES/ASTHMA
SENSORY ORGANS	Cromoglicate Sodium	Nasalcrom	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
SYSTEMIC HORMONAL	Corticosteroids	Steroidal Nasal Preps. {Nos}	97, 41	17APR95	.		ALLERGIES/SINUS INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	"PUFFY",ITCHY,WATERY EYES {ALLERGIES}	53, -4	9 Days	0	CON	SEV	NO	PBU	No	No
	Asthenia	FATIGUE	21, -36	8 Days	0	CON	MIL	NO	PSR	No	No
	Back Pain	BACKACHE	-4, -60	39 Days	0	12	MOD	NO	PBU	Yes	No
	Fever	FEVER	36, -21	6 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	-4, -60	39 Days	0	12	MOD	NO	PBU	Yes	No
			94, 38	2 Days	0	CON	SEV	NO	UNR	Yes	No
			96, 40	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Pain	FACE PAIN	94, 38	2 Days	0	CON	SEV	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	36, -21	4 Days	0	CON	MIL	NO	PSR	No	No
			65, 9	2 Days	0	CON	MIL	NO	PBU	No	No
	Tooth Disorder	TEETH PAIN	94, 38	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Vomiting	VOMITING DRY HEAVES	97, 41	20:00 Hrs	0	CON	SEV	NO	UNR	No	No
Respiratory System	Pharyngitis	SORE THROAT	36, -21	6 Days	0	CON	MOD	NO	UNR	Yes	No
			65, 9	2 Days	0	CON	SEV	NO	UNR	Yes	No
			96, 40	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Rhinitis	NASAL STUFFINESS	37, -20	49 Days	0	CON	SEV	NO	PBU	Yes	No
		NOSE PAIN	94, 38	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Sinusitis	SINUS INFECTION	97, 41	Not Stated	0	CON	SEV	STP	UNR	Yes	No
		SINUS STUFFINESS	37, -20	49 Days	0	CON	SEV	NO	PBU	Yes	No
Skin and Appendages	Rash	RASH ON BOTH FOREARMS	20, -37	6 Days	0	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05JAN95	-6, -62	0	94	64	84	100	70	88	132.50	65.0
BL	11JAN95	1, -56	0	90	60	88	94	60	92	132.00	
1	18JAN95	8, -49	0	100	68	92	120	70	98	132.00	
2	25JAN95	15, -42	0	98	60	76	110	80	80	134.70	
3	01FEB95	22, -35	0	90	60	72	98	70	74	132.20	
4	08FEB95	29, -28	0	108	70	88	90	68	88	130.50	
5	15FEB95	36, -21	0	90	60	72	84	60	72	133.50	
6	22FEB95	43, -14	0	100	70	76	94	70	76	132.00	
7	01MAR95	50, -7	0	110	70	70	90	60	90	132.50	
8	08MAR95	57, 1	0	110	70	80	100	70	84	129.00	
12	05APR95	85, 29	0	90	60	80	104	64	76	129.87	
12	19APR95	99, 43	0	94	68	80	90	60	80	128.00	
16	03MAY95	113, 57	0	90	68	80	90	60	84	128.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.6	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	323000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 12/CONTINUATION-WEEK 16	99	Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66		.	.	22 - 130	U/L
				Aspartate Aminotransferase	11		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	98		.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 12/CONTINUATION-WEEK 16	99	Urine White Blood Cells/HPF	NEG	. . .		
				Urine Protein - Dipstick	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	26JAN95	1	31JAN95	6	6
00112	Oral	2	20 MG	01FEB95	7	07FEB95	13	7
00112	Oral	3	20 MG	08FEB95	14	14FEB95	20	7
00112	Oral	4	20 MG	15FEB95	21	22FEB95	28	8
00112	Oral	4	20 MG	23FEB95	29	28FEB95	34	6
00112	Oral	4	20 MG	01MAR95	35	07MAR95	41	7
00112	Oral	4	20 MG	08MAR95	42	14MAR95	48	7
00112	Oral	4	20 MG	15MAR95	49	21MAR95	55	7
00024	Oral	4	20 MG	22MAR95	56	18APR95	83	28
00112	Oral	2	20 MG	19APR95	84	21APR95	86	3
00112	Oral	1	20 MG	22APR95	87	28APR95	93	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	93	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BURNING STOMACH	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-2, -57	24JAN95	26JAN95	1000MG	HEADACHE,FEVER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Fever	FEVER	-2, -57	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	-2, -57	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Infection	NAUSEA VOMITING DIARRHEA (FLU)	47, -9	2 Days	20	CON	SEV	NO	UNR	No	No
Digestive System	Tooth Disorder	TOOTHACHE	32, -24	10:30 Hrs	20	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	17JAN95	-9, -64	0	104	70	66	100	70	72	119.00	61.0
BL	26JAN95	1, -55	0	100	70	68	98	70	68	115.00	
1	01FEB95	7, -49	20	100	70	80	90	60	84	119.00	
2	08FEB95	14, -42	20	100	70	76	104	70	76	119.50	
3	15FEB95	21, -35	20	90	60	84	84	56	88	118.00	
4	23FEB95	29, -27	20	98	60	84	100	70	84	118.00	
5	01MAR95	35, -21	20	100	70	80	110	74	80	118.50	
6	08MAR95	42, -14	20	120	78	100	120	82	110	122.00	
7	15MAR95	49, -7	20	90	60	92	90	60	96	122.00	
8	22MAR95	56, 1	20	94	64	76	92	60	80	123.00	
12	19APR95	84, 29	20	110	74	80	104	70	88	124.00 H	
20	21JUN95	147, 92#	0	100	70	80	104	72	84	124.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3		.	.	41 - 50	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32		.	.	30 - 70	%
				Lymphocytes	60	H	.	.	21 - 51	%
				Monocytes	3		.	.	0 - 10	%
				Eosinophils	5		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	245000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	300		.	.	44 - 400	U/L
				Aspartate Aminotransferase	32		.	.	0 - 41	U/L
				Alanine Aminotransferase	31		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	97		.	.	70 - 115	MG/DL
				Globulin	2.9		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3		.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	34.3		.	.	30 - 70	%
				Lymphocytes	55.2	H	.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	3		.	.	0 - 5	%
				Basophils	1.5		.	.	0 - 2	%
				Platelets	10000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	280		.	.	44 - 400	U/L
				Aspartate Aminotransferase	37		.	.	0 - 41	U/L
				Alanine Aminotransferase	40		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	56		Albumin	4.2		.	.	3.1 - 5.3	G/DL
					Glucose - Random	104		.	.	70 - 115	MG/DL
					Globulin	2.9		.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Bacteria	3		.	.		
					Urine Protein - Dipstick	NEG		.	.		
		VISIT 17/DOWN TITRATION	147	(54)	Hemoglobin	14.2		.	.	13.8 - 17.2	G/DL
					Hematocrit	43.2		.	.	41 - 50	%
					Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.6		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	30.5		.	.	30 - 70	%
					Lymphocytes	58.7	H	.	.	21 - 51	%
					Monocytes	6		.	.	0 - 10	%
					Eosinophils	4.3		.	.	0 - 5	%
					Basophils	0.4		.	.	0 - 2	%
					Platelets	270000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31		.	.	25 - 35	PC
					Mean Corpuscle Volume	94		.	.	80 - 100	FL
					Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
					Creatinine	1		.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.7		.	.	4 - 8	MG/DL
					Alkaline Phosphatase	326		.	.	44 - 400	U/L
					Aspartate Aminotransferase	32		.	.	0 - 41	U/L
					Alanine Aminotransferase	27		.	.	0 - 48	U/L
					Total Bilirubin	1		.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 17/DOWN TITRATION	147	(54)	Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	130	H	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	30JAN95	1	07FEB95	9	9
00113	Oral	2	100 MG	08FEB95	10	15FEB95	17	8
00113	Oral	3	150 MG	16FEB95	18	22FEB95	24	7
00113	Oral	4	200 MG	23FEB95	25	02MAR95	32	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	32	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1985
ABORTION	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	2, .	31JAN95	31JAN95	500 MG	H/A
RESPIRATORY	Salbutamol	Ventolin	-3591, .	01APR85	.	2 PUFFS PRN	ASTHMA
			-3591, .	01APR85	.	2 PUFFS PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, .	03:45 Hrs	50	1	SEV	NO	UNR	Yes	No
Carciovascular System	Palpitation	HEART WAS POUNDING	21, .	30 Mins	150	1	MOD	NO	REL	No	No
	Tachycardia	QUESTIONABLE INCREASED HEART RATE QUESTIONABLE TACHYCARDIA	21, .	30 Mins	150	1	MOD	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	7, .	Not Stated	50	CON	MOD	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	8, .	Not Stated	50	9	MIL	NO	REL	No	No
	Emotional Lability	SUICIDAL IDEATION	32, .	1 Days	200	CON	MOD	STP	UNR	No	No
	Tremor	HAND TREMORS	8, .	Not Stated	50	CON	MIL	NO	REL	No	No
Special Senses	Abnormal Vision	BLURRED VISION	8, .	Not Stated	50	10	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20JAN95	-10,	.	0	110	70	68	100	70	72	145.00	67.0
BL	30JAN95	1,	.	0	90	60	80	100	70	84	143.33	
1	08FEB95	10,	.	100	110	70	72	100	60	74	145.20	
2	16FEB95	18,	.	150	104	70	88	104	68	100	141.34	
3	23FEB95	25,	.	200	110	70	72	100	70	80	140.00	
4	02MAR95	32,	.	200	100	70	80	84	60	80	140.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	12.6		.	.	12 - 15.6	G/DL
				Hematocrit	36.1		.	.	35 - 46	%
				Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	33		.	.	30 - 70	%
				Lymphocytes	58	H	.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	4		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	54000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69		.	.	44 - 280	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	8		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	84		.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	5		.	+		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	31JAN95	1	06FEB95	7	7
00114	Oral	2	0 MG	07FEB95	8	13FEB95	14	7
00114	Oral	3	0 MG	14FEB95	15	20FEB95	21	7
00114	Oral	4	0 MG	21FEB95	22	27FEB95	28	7
00114	Oral	4	0 MG	28FEB95	29	08MAR95	37	9
00114	Oral	4	0 MG	09MAR95	38	14MAR95	43	6
00114	Oral	4	0 MG	15MAR95	44	21MAR95	50	7
00114	Oral	4	0 MG	22MAR95	51	28MAR95	57	7
00020	Oral	4	0 MG	29MAR95	58	25APR95	85	28
00114	Oral	4	0 MG	26APR95	86	26APR95	86	1
00114	Oral	3	0 MG	27APR95	87	28APR95	88	2
00114	Oral	2	0 MG	29APR95	89	01MAY95	91	3
00114	Oral	1	0 MG	02MAY95	92	08MAY95	98	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	98	0	Lack of Efficacy	DEPRESSIVE SYMPTOMS RETURNED AFTER GIRLFRIEND BROKE UP WITH HIM.RETURN MAJOR DEPRESSIVE DISORDER SYMPTOMS.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	7, -51	06FEB95	16FEB95	750MG	STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	5, -53	04FEB95	08FEB95	500MG	STREP THROAT-PAIN
RESPIRATORY	Salbutamol	Ventolin Inhaler	-565, -622	15JUL93	18OCT94#	2PUFFS	ASTHMA
			-565, -622	15JUL93	18OCT94#	2PUFFS	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT SORE THROAT AND FEVER	5, -53	11 Days	0	CON	SEV	NO	UNR	Yes	No
Nervous System	Tremor	HAND TREMORS	30, -28	22 Days	0	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	23JAN95	-8, -65	0	112	70	68	108	72	72	145.20	70.0
BL	31JAN95	1, -57	0	80	60	72	70	50	72	145.00	
1	07FEB95	8, -50	0	108	62	80	102	62	88	153.50	
2	14FEB95	15, -43	0	110	80	60	90	70	64	154.50	
3	21FEB95	22, -36	0	100	70	58	104	70	60	155.89 H	
4	28FEB95	29, -29	0	110	70	70	90	60	72	157.00 H	
5	09MAR95	38, -20	0	100	70	80	90	64	80	157.00 H	
6	15MAR95	44, -14	0	104	80	80	100	70	84	155.00	
7	22MAR95	51, -7	0	104	70	60	90	70	64	154.50	
8	29MAR95	58, 1	0	100	70	68	92	70	72	153.00	
12	26APR95	86, 29	0	90	60	70	98	68	74	155.10	
16	17MAY95	107, 50	0	104	70	72	100	70	74	155.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	15.9		.	.	13.8 - 17.2	G/DL
				Hematocrit	47.4		.	.	41 - 50	%
				Red Blood Cell Count	5.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.6		.	.	30 - 70	%
				Lymphocytes	21.1		.	.	21 - 51	%
				Monocytes	5.6		.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	241000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	1.3		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	99		.	.	22 - 180	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	18		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.6	. . .	13.8 - 17.2	G/DL
				Hematocrit	45.6	. . .	41 - 50	%
				Red Blood Cell Count	5.1	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	. . .	30 - 70	%
				Lymphocytes	49	. . .	21 - 51	%
				Monocytes	10	. . .	0 - 10	%
				Eosinophils	2	. . .	0 - 5	%
				Basophils	0	. . .	0 - 2	%
				Platelets	103000	L . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	13	. . .	7 - 25	MG/DL
				Creatinine	1.4	. . .	0.8 - 1.5	MG/DL
				Uric Acid	6.8	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	91	. . .	22 - 180	U/L
				Aspartate Aminotransferase	14	. . .	0 - 41	U/L
				Alanine Aminotransferase	10	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	6.9	. . .	6.2 - 8.8	G/DL
				Albumin	4.2	. . .	3.1 - 5.3	G/DL
				Glucose - Random	101	. . .	70 - 115	MG/DL
				Globulin	2.7	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		. . .		
				Urine Blood - Dipstick NEG		. . .		
				Urine Red Blood Cells/HPF NEG		. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	58		Urine White Blood Cells/HPF	3	. . .		
					Urine Bacteria	4	. . .		
					Urine Protein - Dipstick	NEG	. . .		
					Urine Squamous Epithelial Cells	4	. . .		
		VISIT 17/DOWN TITRATION	107	(9)	Hemoglobin	15.7	. . .	13.8 - 17.2	G/DL
					Hematocrit	46	. . .	41 - 50	%
					Red Blood Cell Count	5.1	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	60	. . .	30 - 70	%
					Lymphocytes	35	. . .	21 - 51	%
					Monocytes	1	. . .	0 - 10	%
					Eosinophils	4	. . .	0 - 5	%
					Basophils	0	. . .	0 - 2	%
					Platelets	225000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31	. . .	25 - 35	PG
					Mean Corpuscle Volume	91	. . .	80 - 100	FL
					Blood Urea Nitrogen	13	. . .	7 - 25	MG/DL
					Creatinine	1.3	. . .	0.8 - 1.5	MG/DL
					Uric Acid	6.3	. . .	4 - 8	MG/DL
					Alkaline Phosphatase	89	. . .	22 - 180	U/L
					Aspartate Aminotransferase	15	. . .	0 - 41	U/L
					Alanine Aminotransferase	14	. . .	0 - 48	U/L
					Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
					Total Protein	7	. . .	6.2 - 8.8	G/DL
					Albumin	4.3	. . .	3.1 - 5.3	G/DL
					Glucose - Random	89	. . .	70 - 115	MG/DL
					Globulin	2.7	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	06FEB95	1	12FEB95	7	7
00115	Oral	2	0 MG	13FEB95	8	19FEB95	14	7
00115	Oral	3	0 MG	20FEB95	15	01MAR95	24	10
00115	Oral	4	0 MG	02MAR95	25	09MAR95	32	8
00115	Oral	4	0 MG	10MAR95	33	16MAR95	39	7
00115	Oral	4	0 MG	17MAR95	40	27MAR95	50	11
00115	Oral	4	0 MG	28MAR95	51	09APR95	63	13
00115	Oral	4	0 MG	10APR95	64	17APR95	71	8
00003	Oral	4	0 MG	18APR95	72	21APR95	75	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	Yes	No	75	0	Other reason	PT. REPORTS FEELING BETTER AND DOES NOT WANT TO TAKE MEDICATION ANY LONGER.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1984

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	19, -53	24FEB95	15MAR95	750 MG	TOOTH ACHE/SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Hydrocodone Bitartrate	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
	Paracetamol	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
GU SYSTEM/SEX HORMONES	Oral Contraceptive	Birth Control Pills	-31, -102	06JAN95	.	1X	PREVENT PREGNANCY
RESPIRATORY	Hydrocodone Bitartrate	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
	Paracetamol	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
	Salbutamol	Ventolin Inhaler	-27, -98	10JAN95	10JAN95#	2 PUFFS PRN	ASTHMA
			-27, -98	10JAN95	10JAN95#	2 PUFFS PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	7, -65	02:30 Hrs	0	CON	MIL	NO	PSR	No	No
		HEADACHES	37, -35	02:00 Hrs	0	7	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	3, -69	6 Days	0	CON	MIL	NO	REL	No	No
Hemic and Lymphatic System	Wbc Abnormality	ATYPICAL LYMPHS	72, 1	1 Days	0	1	MIL	NO	PBU	No	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS (12 POUNDS)	64, -8	9 Days	0	CON	SEV	NO	UNR	No	No
Respiratory System	Sinusitis	TOOTHACHE/QUESTIONABLE SINUS INFECTION	18, -54	26 Days	0	CON	SEV	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	27JAN95	-10, -81	0	118	76	78	110	74	82	144.00	64.0
BL	06FEB95	1, -71	0	120	70	84	118	60	88	143.50	
1	13FEB95	8, -64	0	104	70	80	110	70	84	143.70	
2	20FEB95	15, -57	0	120	70	88	110	68	92	142.22	
3	02MAR95	25, -47	0	124	80	88	118	70	88	146.00	
5	10MAR95	33, -39	0	120	76	80	112	70	84	144.00	
6	17MAR95	40, -32	0	112	70	76	110	64	80	144.70	
7	28MAR95	51, -21	0	106	70	84	118	80	94	145.00	
8	10APR95	64, -8	0	116	78	60	120	70	60	152.00	
8	18APR95	72, 1	0	110	54	76	110	60	82	140.00	
12	27APR95	81, 10	0	114	70	68	110	68	74	141.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	53.7	.	.	.	40 - 75	%
				Lymphocytes	41.6	.	.	.	16 - 46	%
				Monocytes	3.5	.	.	.	0 - 12	%
				Eosinophils	1	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	72	Hemoglobin	13.6		.	.	12 - 15.6	G/DL
				Hematocrit	38.8		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7		.	.	3.8 - 10.8	THOU/MCL
				Neutrophil Bands	0		.	.	0 - 8	%
				Segmented Neutrophils	44		.	.	40 - 75	%
				Lymphocytes	35		.	.	16 - 46	%
				Monocytes	3		.	.	0 - 12	%
				Eosinophils	0		.	.	0 - 7	%
				Basophils	1		.	.	0 - 2	%
				Platelets	221000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8		.	.	27 - 33	PG
				Mean Corpuscle Volume	82		.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	72		Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	118	H	.	.	70 - 115	MG/DL
					Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	5	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	81	(6)	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	3.9 - 5.2	MILL/MCL
					White Blood Cell Count	5.7	.	.	.	3.8 - 10.8	THOU/MCL
					Segmented Neutrophils	51.8	.	.	.	40 - 75	%
					Lymphocytes	40.7	.	.	.	16 - 46	%
					Monocytes	5.8	.	.	.	0 - 12	%
					Eosinophils	1.5	.	.	.	0 - 7	%
					Basophils	0.3	.	.	.	0 - 2	%
					Platelets	215000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.4	.	.	.	27 - 33	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07FEB95	1	12FEB95	6	6
00116	Oral	2	20 MG	13FEB95	7	19FEB95	13	7
00116	Oral	3	20 MG	20FEB95	14	26FEB95	20	7
00116	Oral	4	20 MG	27FEB95	21	08MAR95	30	10
	Oral	4	20 MG	09MAR95	31	15MAR95	37	7
00116	Oral	4	20 MG	16MAR95	38	22MAR95	44	7
00116	Oral	4	20 MG	23MAR95	45	29MAR95	51	7
00116	Oral	4	20 MG	30MAR95	52	05APR95	58	7
00002	Oral	4	20 MG	06APR95	59	03MAY95	86	28
00002	Oral	4	20 MG	04MAY95	87	30MAY95	113	27
00002	Oral	5	30 MG	31MAY95	114	27JUN95	141	28
00116	Oral	4	20 MG	28JUN95	142	29JUN95	143	2
00116	Oral	3	20 MG	30JUN95	144	01JUL95	145	2
00116	Oral	2	20 MG	02JUL95	146	04JUL95	148	3
00116	Oral	1	20 MG	05JUL95	149	11JUL95	155	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	155	20	Adverse event, including intercurrent illness	SEVERE POISON IVY-TAKING PREDNISONE

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	26, -33	04MAR95	14MAR95	750MG	BRONCHITIS
	Amoxicillin Trihydrate	Augmentin	25, -34	03MAR95	13MAR95	UNKNOWN,THRE E TIMES DAILY	EAR INFECTION
	Cefuroxime Axetil	Ceftin	141, 83	27JUN95	07JUL95	UNKNOWN MG(2PILLS)	TONSILLITIS
	Clavulanic Acid	Augmentin	25, -34	03MAR95	13MAR95	UNKNOWN,THRE E TIMES DAILY	EAR INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	25, -34	03MAR95	04APR95	500MG	EARACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	65, 7	12APR95	12APR95	UNKNOWN	HEADACHE
			111, 53	28MAY95	30MAY95	UNKNOWN PRN	MENSTRUAL CRAMPS
RESPIRATORY	Cough Syrup/Med	Smith Brothers Cough Drop	75, 17	22APR95	07MAY95	1DAILY	COUGH
	Guaifenesin	Robitussin	75, 17	22APR95	07MAY95	2TSP	COUGH
	Prednisone	Prednisone	135, 77	21JUN95	28JUN95	30MG	POISON IVY
			143, 85	29JUN95	02JUL95	20MG	POISON IVY
			147, 89	03JUL95	07JUL95	10MG	POISON IVY
			152, 94	08JUL95	12JUL95	10MG EVERY OTHER DAY	POISON IVY
	Salbutamol	Ventolin Inhaler	26, -33	04MAR95	14MAR95	2PUFFS 4TIME A DAY	BRONCHITIS
			26, -33	04MAR95	14MAR95	2PUFFS 4TIME A DAY	BRONCHITIS
SENSORY ORGANS	Ear Medication, Nos	Ear Drops {Nos}	25, -34	03MAR95	04APR95	THREE TIMES DAILY	EARACHE
SYSTEMIC HORMONAL	Prednisone	Prednisone	135, 77	21JUN95	28JUN95	30MG	POISON IVY
			143, 85	29JUN95	02JUL95	20MG	POISON IVY
			147, 89	03JUL95	07JUL95	10MG	POISON IVY
			152, 94	08JUL95	12JUL95	10MG EVERY OTHER DAY	POISON IVY

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	65, 7	1 Days	20	3	MOD	NO	PBU	Yes	No
	Infection	NAUSEA,VOMITING,DIARRHEA {STOMACH FLU}	28, -31	24:00 Hrs	20	CON	SEV	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	4, -55	152 Days	20	CON	MOD	NO	REL	No	No
	Dyspepsia	UPSET STOMACH	2, -57	6 Days	20	10	MOD	NO	PBU	No	No
		UPSET STOMACH {WHEN TAKES MEDICATIONS AT BEDTIME}	57, -2	99 Days	20	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	9, -50	162 Days	20	CON	MOD	NO	PSR	No	No
Musculoskeletal System	Myalgia	CRAMPS IN LEFT LEG	30, -29	2 Days	20	CON	MOD	NO	UNR	No	No
Nervous System	Tremor	HAND TREMORS	26, -33	29 Days	20	CON	MIL	NO	REL	No	No
Respiratory System	Bronchitis	BRONCHITIS WITH COUGH	26, -33	25 Days	20	CON	SEV	NO	UNR	Yes	No
	Cough Increased	COUGH	75, 17	16 Days	20	5	MOD	NO	UNR	Yes	No
	Pharyngitis	TONSILLITIS	138, 80	14 Days	30	CON	SEV	NO	UNR	Yes	No
Skin and Appendages	Contact Dermatitis	POISON IVY	131, 73	26 Days	30	CON	SEV	STP	UNR	Yes	No
Special Senses	Otitis Media	EAR INFECTION/ACHE	26, -33	25 Days	20	CON	SEV	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	111, 53	3 Days	20	CON	SEV	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	30JAN95	-8, -66	0	118	80	54	110	80	56	206.80	71.0
BL	07FEB95	1, -58	0	112	80	68	90	72	64	206.50	
1	13FEB95	7, -52	20	110	80	72	90	60	74	206.70	
2	20FEB95	14, -45	20	110	70	72	104	60	74	204.10	
3	27FEB95	21, -38	20	118	62	70	112	70	74	203.30	
4	09MAR95	31, -28	20	104	78	84	100	74	88	201.00	
5	16MAR95	38, -21	20	120	78	84	110	80	88	201.00	
6	23MAR95	45, -14	20	118	70	76	110	70	80	201.50	
7	30MAR95	52, -7	20	120	84	96	112	80	98	206.00	
8	06APR95	59, 1	20	120	80	88	112	70	92	208.00	
12	04MAY95	87, 29	20	100	74	72	98	70	80	211.00	
16	31MAY95	114, 56	30	104	80	80	98	70	84	214.00	
20	28JUN95	142, 84	20	90	60	68	88	60	64	212.20	
24	26JUL95	170, 112#	0	118	80	80	110	74	84	212.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	34.9	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	52	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEC		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.1		.	.	12 - 15.6	G/DL
				Hematocrit	38.9		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.4		.	.	30 - 70	%
				Lymphocytes	33.7		.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	3.5		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59		Platelets	71000	L	.	-	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.8	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
					Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	78	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	93	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Protein - Dipstick	NEC		.	.		
		VISIT 17/DOWN TITRATION	170	(15)	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.6	.	.	.	35 - 46	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	57.6	.	.	.	30 - 70	%
					Lymphocytes	32.1	.	.	.	21 - 51	%
					Monocytes	6.9	.	.	.	0 - 10	%
					Eosinophils	2.5	.	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 17/DOWN TITRATION	170	(15)	Platelets	218000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.4	. . .	25 - 35	PG
					Mean Corpuscle Volume	83	. . .	80 - 100	FL
					Blood Urea Nitrogen	13	. . .	7 - 25	MG/DL
					Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
					Uric Acid	3.7	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	72	. . .	22 - 130	U/L
					Aspartate Aminotransferase	7	. . .	0 - 41	U/L
					Alanine Aminotransferase	5	. . .	0 - 48	U/L
					Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
					Total Protein	6.9	. . .	6.2 - 8.8	G/DL
					Albumin	4.2	. . .	3.1 - 5.3	G/DL
					Glucose - Random	95	. . .	70 - 115	MG/DL
					Globulin	2.7	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	18MAR95	1	26MAR95	9	9
00117	Oral	2	100 MG	27MAR95	10	02APR95	16	7
00117	Oral	3	150 MG	03APR95	17	09APR95	23	7
00117	Oral	4	200 MG	10APR95	24	16APR95	30	7
00117	Oral	4	200 MG	17APR95	31	23APR95	37	7
00117	Oral	4	200 MG	24APR95	38	30APR95	44	7
00117	Oral	4	200 MG	01MAY95	45	07MAY95	51	7
00117	Oral	4	200 MG	08MAY95	52	14MAY95	58	7
	Oral	4	200 MG	15MAY95	59	26MAY95	70	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	70	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HISTORY OF CHRONIC OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1979
MILD HEARING LOSS	HEARING LOSS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1979
STATUS POST HIP SURGERY	OPERATION, BONE/JOINT	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Cimetidine	Cimetidine	41, .	27APR95	.	1200MG	GASTRITIS
	Cisapride	Propulsid	41, .	27APR95	.	40MG	GASTRITIS
CENTRAL NERVOUS SYSTEM	Oxycodone Hydrochloride	Percocet	52, .	08MAY95	15MAY95	1X DAILY EVERY 4HRS.AS NE	PAIN
	Oxycodone Terephthalate	Percocet	52, .	08MAY95	15MAY95	1X DAILY EVERY 4HRS.AS NE	PAIN
	Paracetamol	Percocet	52, .	08MAY95	15MAY95	1X DAILY EVERY 4HRS.AS NE	PAIN

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chills	CHILLS-INCREASED AND DECREASED BACK AND ARMS-NO FEVER	1, .	31 Days	50	11	MOD	NO	PSR	No	No
	Headache	HEADACHE	39, .	Not Stated	200	CON	SEV	NO	PBU	No	No
Carciovascular System	Tachycardia	INCREASED HEART RATE	24, .	22 Days	200	CON	MOD	NO	PSR	No	No
	Vasodilatation	FLUSHED FACE-NO HIVES	1, .	4 Days	50	3	MIL	NO	PSR	No	No
Digestive System	Diarrhea	DIARRHEA	2, .	3 Days	50	1	MOD	NO	PSR	No	No
	Gastritis	GASTRITIS	41, .	Not Stated	200	CON	MOD	NO	PBU	Yes	No
	Tooth Disorder	PAIN DUE TO WISDOM TOOTH EXTRACTION	52, .	8 Days	200	CON	MOD	NO	UNR	Yes	No
	Vomiting	NAUSEATED AND VOMITING	21, .	Not Stated	150	CON	SEV	NO	PBU	No	No
Nervous System	Nervousness	INCREASED IRRITABILITY	29, .	Not Stated	200	CON	MOD	NO	PBU	No	No
Respiratory System	Epistaxis	NOSEBLEEDS	28, .	15 Mins	200	2	MIL	NO	PBU	No	No
Skin and Appendages	Pruritus	ITCHING-WITHOUT HIVES	2, .	3 Days	50	1	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06MAR95	-12,	.	0	120	84	82	116	80	86	245.64	52.0
BL	16MAR95	-2,	.	0	124	84	84	100	80	88	246.96	
1	27MAR95	10,	.	100	108	80	98	122	90	98	245.86	
2	03APR95	17,	.	150	114	68	98	118	70	108	249.20	
3	10APR95	24,	.	200	120	70	102	110	70	110	248.40	
4	17APR95	31,	.	200	110	70	100	114	70	108	246.50	
5	24APR95	38,	.	200	100	58	96	98	50	104	246.20	
6	01MAY95	45,	.	200	114	68	98	120	76	108	243.87	
7	08MAY95	52,	.	200	100	72	92	90	60	106	239.46	
8	15MAY95	59,	.	200	98	68	90	90	60	96	237.26	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	28.9	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	364000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	119	H	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells		4	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	17MAY95	1	23MAY95	7	7
00118	Oral	2	100 MG	24MAY95	8	29MAY95	13	6
00118	Oral	3	150 MG	30MAY95	14	05JUN95	20	7
00118	Oral	4	200 MG	06JUN95	21	13JUN95	28	8
00118	Oral	5	250 MG	14JUN95	29	19JUN95	34	6
00118	Oral	6	300 MG	20JUN95	35	26JUN95	41	7
	Oral	5	250 MG	27JUN95	42	05JUL95	50	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	50	250	Protocol violation, including non-compliance	POSITIVE DRUG SCREEN

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
GYNECOMASTIA	GYNECOMASTIA	GENITOURINARY SYST DIS	CUR	
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	4, .	20MAY95	23MAY95	500 MG	SORE THROAT
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-20, .	27APR95	27APR95#	400MG	HEADACHE
RESPIRATORY	Guaifenesin	Robitussin	3, .	19MAY95	.	4 TSP.	COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	24, .	02:00 Hrs	200	2	MOD	NO	PBU	No	No
Carciovascular System	Migraine	MIGRAINE HEADACHE	4, .	04:00 Hrs	50	CON	SEV	NO	UNR	No	No
Nervous System	Dizziness	LIGHT-HEADEDNESS	7, .	23 Days	50	5	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	4, .	4 Days	50	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	CHEST CONGESTION AND COUGH	3, .	6 Days	50	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	09MAY95	-8, .	0	116	70	64	112	72	70	151.00	65.0
BL	17MAY95	1, .	0	110	68	60	108	70	66	151.90	
1	24MAY95	8, .	100	100	70	80	98	64	84	152.20	
2	30MAY95	14, .	150	116	70	86	108	70	96	152.59	
3	06JUN95	21, .	200	108	74	98	98	60	98	151.92	
4	14JUN95	29, .	250	114	78	84	116	80	94	153.47	
5	20JUN95	35, .	300	110	70	94	98	64	110	154.00	
6	27JUN95	42, .	250	112	76	98	104	70	108	153.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	35.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	35	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 7/ACUTE PHASE-WEEK 5	35	Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11JUL95	1	17JUL95	7	7
00119	Oral	2	20 MG	18JUL95	8	25JUL95	15	8
00119	Oral	3	20 MG	26JUL95	16	01AUG95	22	7
00119	Oral	4	20 MG	02AUG95	23	07AUG95	28	6
00119	Oral	5	30 MG	08AUG95	29	14AUG95	35	7
00119	Oral	6	40 MG	15AUG95	36	22AUG95	43	8
00119	Oral	6	40 MG	23AUG95	44	28AUG95	49	6
00119	Oral	6	40 MG	29AUG95	50	07SEP95	59	10
00056	Oral	6	40 MG	08SEP95	60	02OCT95	84	25
00056	Oral	6	40 MG	03OCT95	85	29OCT95	111	27
00056	Oral	6	40 MG	30OCT95	112	27NOV95	140	29
00119	Oral	5	30 MG	28NOV95	141	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	141	30	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	7, -53	17JUL95	17JUL95	650MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	47, -13	26AUG95	26AUG95	1TAB DAILY	ORTHODONTIC DISCOMFORT
RESPIRATORY	Dextromethorphan Hydrobromide	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS
	Doxylamine Succinate	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS
	Guaifenesin	Robitussin	80, 21	28SEP95	28SEP95	1 DOSE	COLD SYMPTOMS
	Paracetamol	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS
	Pseudoephedrine Hydrochloride	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	"STOMACH ACHE"	105, 46	5 Days	40	5	MOD	NO	PBU	No	No
		STOMACH ACHE	10, -50	4 Days	20	2	MIL	NO	PBU	No	No
	Asthenia	FATIGUE	1, -59	4 Days	20	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	7, -53	02:00 Hrs	20		MOD	NO	PSR	Yes	No
			41, -19	01:00 Hrs	40	2	MOD	NO	PBU	No	No
Digestive System	Vomiting	NAUSEA AND VOMITING	105, 46	5 Days	40	5	MOD	NO	PBU	No	No
Nervous System	Hostility	PHYSICAL FIGHT {AGGRESSION}	18, -42	10 Mins	20	1	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS	79, 20	4 Days	40	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	27JUN95	-14, -73	0	118	80	70	110	82	70	150.10	65.0
BL	11JUL95	1, -59	0	128	80	70	120	80	88	153.20	
1	18JUL95	8, -52	20	120	80	74	110	72	76	153.50	
2	26JUL95	16, -44	20	120	82	80	118	88	80	152.60	
3	02AUG95	23, -37	20	124	74	70	120	80	80	152.00	
4	08AUG95	29, -31	30	110	64	72	110	64	86	151.00	
5	15AUG95	36, -24	40	100	60	88	104	60	96	155.20	
6	23AUG95	44, -16	40	128	80	94	120	80	106	156.80	
7	29AUG95	50, -10	40	118	78	86	106	74	92	159.00	
8	08SEP95	60, 1	40	122	80	88	120	72	96	158.00	
12	03OCT95	85, 26	40	128	80	84	118	86	98	156.00	
16	30OCT95	112, 53	40	120	80	92	118	68	108	155.00	
20	28NOV95	141, 82	30	90	60	94	90	50	106	159.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9		.	.	12 - 15.6	G/DL
				Hematocrit	37.1		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.5		.	.	30 - 70	%
				Lymphocytes	38.3		.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	1.1		.	.	0 - 2	%
				Platelets	249000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94		.	.	44 - 280	U/L
				Aspartate Aminotransferase	22		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	81		.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 2/ELIGIBILITY	1	Serum BHCG pregnancy test	NEGATIVE	. . .		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEC	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	12.4	. . .	12 - 15.6	G/DL
				Hematocrit	35.1	. . .	35 - 46	%
				Red Blood Cell Count	4.1	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.8	. . .	30 - 70	%
				Lymphocytes	39.7	. . .	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	60		Monocytes	8.5	.	.	.	0 - 10	%
					Eosinophils	4.2	.	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	295000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	80	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEC		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	(1)	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	37.4	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	141 (1)	Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.9	.	.	.	30 - 70	%
				Lymphocytes	38.4	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	300000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		
				Urine Amphetamines	NEG			.		
				Urine Barbiturates	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	141	(1)	Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
					Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	30AUG95	1	06SEP95	8	8
00120	Oral	2	0 MG	07SEP95	9	13SEP95	15	7
00120	Oral	3	0 MG	14SEP95	16	20SEP95	22	7
00120	Oral	4	0 MG	21SEP95	23	27SEP95	29	7
00120	Oral	5	0 MG	28SEP95	30	04OCT95	36	7
00120	Oral	5	0 MG	05OCT95	37	11OCT95	43	7
00120	Oral	6	0 MG	12OCT95	44	18OCT95	50	7
00120	Oral	6	0 MG	19OCT95	51	26OCT95	58	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	58	0	Lack of Efficacy	DIDN'T RETURN TAPER PACK ALTHOUGH MOM REPORTED THAT HE COMPLETED TAPER PACK DURING A PHONE CONVERSATION.THEY THEN MOVED OUT OF STATE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
RASH ON ARMS AND CHEST{FOLLICULITIS}	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Dermatologicals Nos	Topical Cream {Dermatological Nos}	., .		.		RASH (?FOLLICULITIS)
RESPIRATORY	Guaifenesin	Robitussin	19, .	17SEP95	19SEP95		COUGH
			55, .	23OCT95	23OCT95		COUGH
	Pseudoephedrine Hydrochloride	Actifed	15, .	13SEP95	14SEP95		RUNNY NOSE,COUGH
	Triprolidine Hydrochloride	Actifed	15, .	13SEP95	14SEP95		RUNNY NOSE,COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	16, .	30 Mins	0	1	MIL	NO	UNR	No	No
Hemic and Lymphatic System	Eosinophilia	INCREASED EOSINOPHILS	-8, .	Not Stated	0	CON	MIL	NO	UNR	No	No
			58, .	Not Stated	0	CON	MIL	NO	UNR	No	No
Metabolic and Nutritional Disorders	Hyperglycemia	INCREASED GLUCOSE	-8, .	Not Stated	0	CON	MIL	NO	UNR	No	No
			58, .	Not Stated	0	CON	MIL	NO	UNR	No	No
Nervous System	Euphoria	LAUGHING A LOT {EUPHORIA}	21, .	17 Days	0	3	MOD	NO	UNR	No	No
	Nervousness	NERVOUS	21, .	2 Days	0		MIL	NO	UNR	No	No
			23, .	8 Days	0	CON	MIL	NO	UNR	No	No
Respiratory System	Cough Increased	COUGH	14, .	8 Days	0	CON	MOD	NO	UNR	Yes	No
		COUGHING	55, .	Not Stated	0	CON	MIL	NO	UNR	Yes	No
	Rhinitis	RUNNY NOSE	14, .	7 Days	0	CON	MIL	NO	UNR	Yes	No
Urogenital System	Kidney Function Abnormal	DECREASED UREA NITROGEN	-8, .	66 Days	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22AUG95	-8,	.	0	124	60	96	120	60	98	152.00	61.5
BL	30AUG95	1,	.	0	110	72	72	106	66	80	152.15	
1	07SEP95	9,	.	0	104	62	68	108	66	84	155.23	
2	14SEP95	16,	.	0	112	66	80	108	66	84	159.20	
3	21SEP95	23,	.	0	116	72	84	114	70	88	160.52	
4	28SEP95	30,	.	0	116	68	84	110	66	88	159.86	
5	05OCT95	37,	.	0	108	72	68	104	68	68	162.51	
6	12OCT95	44,	.	0	116	66	68	114	68	72	162.51	
7	19OCT95	51,	.	0	122	68	72	116	66	76	164.71 H	
8	26OCT95	58,	.	0	120	64	88	116	68	80	166.04 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.7		.	.	30 - 70	%
				Lymphocytes	39.1		.	.	21 - 51	%
				Monocytes	6.7		.	.	0 - 10	%
				Eosinophils	9.1	H	.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	283000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	340		.	.	44 - 400	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	17		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	2.7		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1		.	.	30 - 70	%
				Lymphocytes	32		.	.	21 - 51	%
				Monocytes	7.5		.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	288000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	270		.	.	44 - 400	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	15		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	145	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	06SEP95	1	13SEP95	8	8
00151	Oral	2	20 MG	14SEP95	9	19SEP95	14	6
00151	Oral	3	20 MG	20SEP95	15	27SEP95	22	8
00151	Oral	4	20 MG	28SEP95	23	02OCT95	27	5
00151	Oral	4	20 MG	03OCT95	28	10OCT95	35	8
00151	Oral	4	20 MG	11OCT95	36	18OCT95	43	8
00151	Oral	4	20 MG	19OCT95	44	25OCT95	50	7
00151	Oral	4	20 MG	26OCT95	51	01NOV95	57	7
00030	Oral	4	20 MG	02NOV95	58	27NOV95	83	26
00030	Oral	4	20 MG	28NOV95	84	03JAN96	120	37
00030	Oral	5	30 MG	04JAN96	121	30JAN96	147	27
00030	Oral	5	30 MG	31JAN96	148	26FEB96	174	27
00192	Oral	5	30 MG	27FEB96	175	26MAR96	203	29
00192	Oral	5	30 MG	27MAR96	204	30APR96	238	35
00350	Oral	4	20 MG	01MAY96	239	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	Yes	239	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1989
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	41, -17	16OCT95	02NOV95	750MG	EAR INFECTION STREP THROAT
	Erythromycin	Erythromycin	48, -10	23OCT95	07NOV95		URI
CENTRAL NERVOUS SYSTEM	Paracetamol	Extra Strength Tylenol	1, -57	06SEP95	06SEP95	2TABS A DAY	BACK PAIN
		Tylenol	-25, -82	12AUG95	12AUG95#	650MG	HEADACHE
			40, -18	15OCT95	17OCT95	2GM	SORE THROAT/STREP
			44, -14	19OCT95	19OCT95	1GM	BACK PAIN
		Tylenol Extra Strength	., .		03SEP95#	650MG	BACK PAIN
DERMATOLOGICALS	Erythromycin	Erythromycin	48, -10	23OCT95	07NOV95		URI
SENSORY ORGANS	Erythromycin	Erythromycin	48, -10	23OCT95	07NOV95		URI
	Polyvidone	Refresh	156, 99	08FEB96	08MAR96		FOREIGN OBJECT IN EYE
	Polyvinyl Alcohol	Refresh	156, 99	08FEB96	08MAR96		FOREIGN OBJECT IN EYE
	Sodium Chloride	Refresh	156, 99	08FEB96	08MAR96		FOREIGN OBJECT IN EYE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK PAIN	1, -57	1 Days	20	1	MOD	NO	UNR	Yes	No
			44, -14	02:00 Hrs	20	1	MIL	NO	UNR	Yes	No
	Infection	SORE THROAT AND EAR INFECTION DIAGNOSIS:STREP THROAT	40, -18	12 Days	20	CON	SEV	NO	UNR	Yes	No
	Trauma	FOREIGN OBJECT IN EYE	154, 97	3 Days	30	CON	MOD	NO	UNR	Yes	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN	84, 27	156 Days	20	CON	MOD	NO	PSR	No	No
Respiratory System	Respiratory Disorder	UPPER RESPIRATORY INFECTION	47, -11	17 Days	20	CON	MOD	NO	UNR	Yes	No
Urogenital System	Albuminuria	PROTEIN IN URINE	148, 91	92 Days	30	CON	MOD	NO	PBU	No	No
	Urinary Casts	COURSE GRANULAR CASTS HYALINE CAST IN URINE	148, 91	92 Days	30	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	29AUG95	-8, -65	0	110	60	82	108	64	86	112.46	63.0
BL	06SEP95	1, -57	0	102	64	76	106	66	88	110.91	
1	14SEP95	9, -49	20	110	60	68	90	60	68	109.00	
2	20SEP95	15, -43	20	100	60	64	110	70	64	107.50	
3	28SEP95	23, -35	20	100	60	70	90	62	70	108.00	
4	03OCT95	28, -30	20	100	60	88	104	60	92	105.20	
5	11OCT95	36, -22	20	90	50	84	96	56	96	107.00	
6	19OCT95	44, -14	20	100	64	80	102	66	88	109.59	
7	26OCT95	51, -7	20	108	70	84	100	60	88	108.50	
8	02NOV95	58, 1	20	106	66	84	104	64	88	109.81	
12	28NOV95	84, 27	20	98	50	88	98	48	92	111.00	
16	02JAN96	119, 62	20	120	80	80	120	70	86	114.00	
20	31JAN96	148, 91	30	104	70	84	98	68	88	114.00	
24	27FEB96	175, 118	30	90	50	72	90	60	88	116.70	
28	27MAR96	204, 147	30	100	60	78	94	60	76	118.41	
32	01MAY96	239, 182	20	98	68	68	92	64	78	119.75 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.9	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	11.5	H	.	+	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	131000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	89	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.3	.	.	.	30 - 70	%
				Lymphocytes	44.3	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	148	Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	175	Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	239 (1)	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.1	.	.	.	30 - 70	%
				Lymphocytes	46.6	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	239	(1)	Urine Protein - Dipstick	6	.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	26OCT95	1	30OCT95	5	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	5	20	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1985

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	5, .	24:00 Hrs	20	CON	SEV	STP	REL	No	No
Digestive System	Diarrhea	DIARRHEA	5, .	24:00 Hrs	20	CON	SEV	STP	REL	No	No
	Nausea	NAUSEA	2, .	4 Days	20	CON	SEV	STP	REL	No	No
	Vomiting	NAUSEA AND VOMITING	2, .	4 Days	20	8	SEV	STP	REL	No	No
		VOMITING	5, .	24:00 Hrs	20	CON	SEV	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12OCT95	-14,	.	0	100	70	78	94	70	84	128.00	66.0
BL	23OCT95	-3,	.	0	104	70	76	100	70	84	128.50	
1	02NOV95	8,	.	20	100	60	72	90	60	76	126.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.8	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	308000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	-3	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-3	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	25JAN96	1	31JAN96	7	7
00153	Oral	2	100 MG	01FEB96	8	07FEB96	14	7
00153	Oral	3	150 MG	08FEB96	15	14FEB96	21	7
00153	Oral	4	200 MG	15FEB96	22	21FEB96	28	7
00153	Oral	5	250 MG	22FEB96	29	28FEB96	35	7
00153	Oral	5	250 MG	29FEB96	36	05MAR96	41	6
00153	Oral	5	250 MG	06MAR96	42	13MAR96	49	8
00153	Oral	5	250 MG	14MAR96	50	20MAR96	56	7
00125	Oral	5	250 MG	21MAR96	57	16APR96	83	27
00125	Oral	6	300 MG	17APR96	84	14MAY96	111	28
00125	Oral	6	300 MG	15MAY96	112	11JUN96	139	28
00125	Oral	6	300 MG	12JUN96	140	09JUL96	167	28
00125	Oral	6	300 MG	10JUL96	168	04AUG96	193	26
00125	Oral	6	300 MG	05AUG96	194	03SEP96	223	30
00153	Oral	5	250 MG	04SEP96	224	05SEP96	225	2
00153	Oral	4	200 MG	06SEP96	226	07SEP96	227	2
00153	Oral	3	150 MG	08SEP96	228	09SEP96	229	2
00153	Oral	2	100 MG	10SEP96	230	13SEP96	233	4
00153	Oral	1	50 MG	14SEP96	234	16SEP96	236	3

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	Yes	Yes	236	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
INCREASED LYMPHOCYTES	LYMPHOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
INCREASED NEUTROPHIL SEGS	LEUCOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
TRACE PROTEIN IN URINE	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Tetracycline	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	7, -50	31JAN96	31JAN96	6 TABS	MENSTRUAL CRAMPS
	Caffeine	Midol	7, -50	31JAN96	31JAN96	6 TABS	MENSTRUAL CRAMPS
	Chlorphenamine Maleate	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
	Cinnamedrine Hydrochloride	Midol	7, -50	31JAN96	31JAN96	6 TABS	MENSTRUAL CRAMPS
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
	Paracetamol	Tylenol	., .		17APR96	2 EXTRA STRENGTH	HEADACHE X3
			28, -29	21FEB96	21FEB96	1000 MG	HEADACHE
			38, -19	02MAR96	02MAR96	1000 MG	HEADACHE
			57, 1	21MAR96	17APR96	1000 MG	HEADACHE X3
			84, 28	17APR96	15MAY96	1000 MG	HEADACHE X2
			112, 56	15MAY96	12JUN96	1000 MG	HEADACHE X6
			140, 84	12JUN96	10JUL96	1000 MG	HEADACHE X2
			168, 112	10JUL96	05AUG96	1000 MG	HEADACHE X1
		Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
		Tylenol Extra Strength	-2, -58	23JAN96	23JAN96#	500 MG	BACK PAIN
			17, -40	10FEB96	10FEB96	1000 MG	HEADACHE
		Tylenol Gelcaps	-9, -65	16JAN96	27JAN96		COLD
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
DERMATOLOGICALS	Tetracycline	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	., .		.	200 MG	HEADACHE
			84, 28	17APR96	15MAY96	400 MG	HEADACHE X1
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
			-9, -65	16JAN96	27JAN96		COLD
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
			-9, -65	16JAN96	27JAN96		COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Paracetamol	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
			-9, -65	16JAN96	27JAN96		COLD
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
			-9, -65	16JAN96	27JAN96		COLD
SENSORY ORGANS	Tetracycline	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
			-389, -445	01JAN95	.	1000MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK PAIN	-2, -58	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	Headache	HEADACHE	17, -40	05:00 Hrs	150	CON	MIL	NO	PBU	Yes	No
			28, -29	03:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
			38, -19	03:30 Hrs	250	CON	MIL	NO	UNR	Yes	No
			57, 1	28 Days	250	3	MOD	NO	UNR	Yes	No
			84, 28	57 Days	300	9	MIL	NO	UNR	Yes	No
			140, 84	55 Days	300	3	MIL	NO	UNR	Yes	No
Carciovascular System	Palpitation	PALPITATIONS	9, -48	9 Days	100		MIL	NO	PSR	No	No
	Tachycardia	INCREASED PULSE ON EXERTION	33, -24	4 Days	250	4	MIL	NO	PSR	No	No
		TACHYCARDIA INCREASED PULSE	10, -47	8 Days	100		MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	DECREASED APPETITE	1, -56	42 Days	50	CON	MOD	NO	PSR	No	No
Nervous System	Dizziness	LIGHTHEADED	1, -56	29 Days	50	7	MIL	NO	PSR	No	No
Skin and Appendages	Sweating	SWEATING	23, -34	13 Days	200	5	MIL	NO	PSR	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	7, -50	12:00 Hrs	50	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	25JAN96	1, -56	0	110	62	72	102	64	80	174.20	
1	01FEB96	8, -49	100	102	64	96	96	60	104	171.99	
2	08FEB96	15, -42	150	98	70	104	90	68	108	172.65	
3	15FEB96	22, -35	200	102	70	108	96	72	112	174.64	
4	22FEB96	29, -28	250	98	74	112	92	74	116	176.40	
5	29FEB96	36, -21	250	110	72	104	100	68	112	179.71	
6	06MAR96	42, -15	250	120	82	96	122	80	116	179.93	
7	14MAR96	50, -7	250	116	70	104	114	70	112	179.93	
8	21MAR96	57, 1	250	108	72	84	100	72	104	180.59	
12	17APR96	84, 28	300	106	66	100	100	68	108	184.12	
16	15MAY96	112, 56	300	116	76	96	108	72	104	188.50 H	
20	12JUN96	140, 84	300	120	80	100	116	74	108	187.20 H	
24	10JUL96	168, 112	300	102	72	108	96	70	112	193.00 H	
28	05AUG96	194, 138	300	106	78	100	96	78	104	191.20 H	
32	04SEP96	224, 168	250	114	72	108	114	70	112		

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	14.8		.	.	12 - 15.6	G/DL
				Hematocrit	42.9		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7.4		.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	32	L	.	.	40 - 75	%
				Lymphocytes	58	H	.	.	16 - 46	%
				Monocytes	9		.	.	0 - 12	%
				Eosinophils	1		.	.	0 - 7	%
				Basophils	0		.	.	0 - 2	%
				Platelets	228000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.9		.	.	27 - 33	PG
				Mean Corpuscle Volume	95		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	53		.	.	22 - 130	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	19		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	93		.	.	70 - 115	MG/DL
				Globulin	2.8		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	2		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-3	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.3		.	.	12 - 15.6	G/DL
				Hematocrit	41.9		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	9.6		.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.4		.	.	40 - 75	%
				Lymphocytes	31.2		.	.	16 - 46	%
				Monocytes	4.1		.	.	0 - 12	%
				Eosinophils	7.6	H	.	.	0 - 7	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	288000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.8		.	.	27 - 33	PG
				Mean Corpuscle Volume	96		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63		.	.	22 - 130	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	15.8	H	.	.	12 - 15.6	G/DL
				Hematocrit	45.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	60.3	.	.	.	40 - 75	%
				Lymphocytes	27.9	.	.	.	16 - 46	%
				Monocytes	6	.	.	.	0 - 12	%
				Eosinophils	4.8	.	.	.	0 - 7	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 13/CONTINUATION-WEEK 20	142	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	224	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	40 - 75	%
				Lymphocytes	31.4	.	.	.	16 - 46	%
				Monocytes	4.3	.	.	.	0 - 12	%
				Eosinophils	6.4	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	282000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 16/CONTINUATION-WEEK 32	224	Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	08FEB96	1	13FEB96	6	6
00253	Oral	2	0 MG	14FEB96	7	20FEB96	13	7
00253	Oral	3	0 MG	21FEB96	14	27FEB96	20	7
00253	Oral	4	0 MG	28FEB96	21	05MAR96	27	7
00253	Oral	5	0 MG	06MAR96	28	13MAR96	35	8
00253	Oral	6	0 MG	14MAR96	36	19MAR96	41	6
00253	Oral	6	0 MG	20MAR96	42	26MAR96	48	7
00253	Oral	6	0 MG	27MAR96	49	02APR96	55	7
	Oral	5	0 MG	03APR96	56	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	56	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	CUR	1996
POSITIVE URINE DRUG SCREEN FOR CODEINE AND MORPHINE.	DRUG DEPEND	MENTAL DISORD	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
	Doxycycline	Doxycycline	26, .	04MAR96	12MAR96	200 MG BID	CHLAMYDIA
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-6, .	02FEB96	14FEB96	650 MG	HEADACHE
	Paracetamol	Tylenol	19, .	26FEB96	26FEB96	650 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	20, .	27FEB96	27FEB96		HEADACHE
	Naproxen Sodium	Aleve	45, .	23MAR96	23MAR96	1 TAB	HEADACHE
RESPIRATORY	Codeine	Promethazine With Codeine	-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
	Promethazine Hydrochloride	Promethazine With Codeine	-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
	Salbutamol	Proventil Inhaler	-10, .	29JAN96	08FEB96	3 PUFFS	BRONCHITIS
			-10, .	29JAN96	08FEB96	3 PUFFS	BRONCHITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	-6, .	04:00 Hrs	0	2	MIL	NO	UNR	Yes	No
			19, .	05:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			20, .	03:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
			45, .	04:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
	Infection	CHLAMYDIA	26, .	9 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	31JAN96	-8,	.	0	106	62	72	102	60	80	133.40	63.0
BL	08FEB96	1,	.	0	96	68	72	94	66	78	133.62	
1	14FEB96	7,	.	0	122	72	76	118	70	88	133.18	
2	21FEB96	14,	.	0	118	64	96	108	62	108	133.84	
3	28FEB96	21,	.	0	120	76	80	110	76	104	132.30	
4	06MAR96	28,	.	0	108	72	72	106	72	80	132.74	
5	14MAR96	36,	.	0	118	72	84	116	70	96	134.51	
6	20MAR96	42,	.	0	104	66	88	102	62	92	133.84	
7	28MAR96	50,	.	0	104	68	80	100	60	100	133.84	
8	03APR96	56,	.	0	112	66	76	106	62	88	129.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.4	.	.	.	30 - 70	%
				Lymphocytes	45.9	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8		Serum BHCG pregnancy test	NEGATIVE	. . .		
					Urine Amphetamines	NEG	. . .		
					Urine Barbiturates	NEG	. . .		
					Urine Benzodiazepines	NEG	. . .		
					Urine Cannabinoids	NEG	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	56	(1)	Hemoglobin	14.6	. . .	12 - 15.6	G/DL
					Hematocrit	42.9	. . .	35 - 46	%
					Red Blood Cell Count	4.8	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	56.1	. . .	30 - 70	%
					Lymphocytes	35.2	. . .	21 - 51	%
					Monocytes	6.1	. . .	0 - 10	%
					Eosinophils	1.9	. . .	0 - 5	%
					Basophils	0.7	. . .	0 - 2	%
					Platelets	249000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.7	. . .	25 - 35	PG
					Mean Corpuscle Volume	90	. . .	80 - 100	FL
					Blood Urea Nitrogen	14	. . .	7 - 25	MG/DL
					Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
					Uric Acid	2.9	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	61	. . .	22 - 130	U/L
					Aspartate Aminotransferase	12	. . .	0 - 41	U/L
					Alanine Aminotransferase	8	. . .	0 - 48	U/L
					Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56 (1)	Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEC		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	15FEB96	1	20FEB96	6	6
00254	Oral	2	0 MG	21FEB96	7	27FEB96	13	7
00254	Oral	3	0 MG	28FEB96	14	05MAR96	20	7
00254	Oral	4	0 MG	06MAR96	21	12MAR96	27	7
00254	Oral	4	0 MG	13MAR96	28	19MAR96	34	7
00254	Oral	4	0 MG	20MAR96	35	26MAR96	41	7
00254	Oral	4	0 MG	27MAR96	42	02APR96	48	7
00254	Oral	4	0 MG	03APR96	49	09APR96	55	7
00146	Oral	4	0 MG	10APR96	56	08MAY96	84	29
00146	Oral	4	0 MG	09MAY96	85	11JUN96	118	34
00146	Oral	4	0 MG	12JUN96	119	09JUL96	146	28
00146	Oral	4	0 MG	10JUL96	147	07AUG96	175	29
00146	Oral	4	0 MG	08AUG96	176	11SEP96	210	35
00146	Oral	4	0 MG	12SEP96	211	15OCT96	244	34
00254	Oral	4	0 MG	16OCT96	245	17OCT96	246	2
00254	Oral	3	0 MG	18OCT96	247	19OCT96	248	2
00254	Oral	2	0 MG	20OCT96	249	22OCT96	251	3
00254	Oral	1	0 MG	23OCT96	252	29OCT96	258	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	258	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Bayer Aspirin	104, 49	28MAY96	28MAY96	UNKNOWN	MENSTRUAL CRAMPS
	Paracetamol	Tylenol	-13, -68	02FEB96	06FEB96#	500MG	HEADACHE
			-4, -59	11FEB96	11FEB96#	500MG	HEADACHE
			23, -33	08MAR96	08MAR96	500MG	HEADACHE
			53, -3	07APR96	07APR96	500MG	HEADACHE
			201, 146	02SEP96	02SEP96	500 MG	HEADACHE
			202, 147	03SEP96	03SEP96	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	24, -32	09MAR96	09MAR96		MENSTRUAL CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	14, -42	03:00 Hrs	0	CON	MOD	NO	UNR	No	No
	Asthenia	TIRED	31, -25	Not Stated	0	CON	MIL	NO	PSR	No	No
	Chest Pain	CHEST PAIN	14, -42	03:00 Hrs	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	2, -54	5 Days	0	3	MIL	NO	PSR	No	No
			-4, -59	03:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			10, -46	1 Days	0	2	MIL	NO	PBU	No	No
			23, -33	02:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			53, -3	02:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			201, 146	02:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
			202, 147	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
Musculoskeletal System	Arthralgia	SHOULDER PAIN IN AM	33, -23	3 Days	0	3	MOD	NO	UNR	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	24, -32	12:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			104, 49	06:30 Hrs	0	CON	SEV	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	08FEB96	-7, -62	0	94	72	76	90	68	84	130.00	67.0
BL	14FEB96	-1, -56	0	82	60	80	80	60	80	126.00	
1	21FEB96	7, -49	0	104	68	80	90	60	76	130.00	
2	28FEB96	14, -42	0	90	60	80	100	70	84	128.50	
3	06MAR96	21, -35	0	80	60	76	78	58	80	130.00	
4	13MAR96	28, -28	0	88	60	76	80	64	76	127.00	
5	20MAR96	35, -21	0	90	60	76	90	60	80	129.50	
6	27MAR96	42, -14	0	90	60	76	94	60	80	129.50	
7	03APR96	49, -7	0	98	70	80	98	68	80	128.00	
8	10APR96	56, 1	0	90	60	80	88	60	80	128.00	
12	22MAY96	98, 43	0	104	70	80	98	60	84	125.00	
16	12JUN96	119, 64	0	102	70	80	90	70	80	122.20	
20	10JUL96	147, 92	0	112	70	76	110	70	80	122.50	
28	12SEP96	211, 156	0	94	70	74	90	60	80	129.00	
32	16OCT96	245, 190	0	90	60	80	90	64	84	128.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.4	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	243000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	209000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	15.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	45	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.2	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	147	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEC		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	04MAR96	1	10MAR96	7	7
00255	Oral	2	100 MG	11MAR96	8	17MAR96	14	7
00255	Oral	3	150 MG	18MAR96	15	24MAR96	21	7
00255	Oral	4	200 MG	25MAR96	22	31MAR96	28	7
00255	Oral	5	250 MG	01APR96	29	07APR96	35	7
00255	Oral	6	300 MG	08APR96	36	14APR96	42	7
00255	Oral	5	250 MG	15APR96	43	22APR96	50	8
00255	Oral	5	250 MG	23APR96	51	28APR96	56	6
	Oral	4	200 MG	29APR96	57	13MAY96	71	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	71	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1986
ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
URINARY TRACT INFECTION	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	CUR	1996
STRABISMUS	EYE DISORD, OTHER	NERVOUS SYST/SENSE ORGAN DIS	PRV	

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole	Sulfamethoxazole/Trimethoprim Ds	36, .	08APR96	15APR96	1 X 2 DAY	UTI (URINARY TRACT INFECTION)
	Trimethoprim	Sulfamethoxazole/Trimethoprim Ds	36, .	08APR96	15APR96	1 X 2 DAY	UTI (URINARY TRACT INFECTION)
DERMATOLOGICALS	Butoconazole Nitrate	Femstat	38, .	10APR96	15APR96		YEAST INFECTION
	Terconazole	Terazol-7	47, .	19APR96	21APR96		YEAST INFECTION
GU SYSTEM/SEX HORMONES	Butoconazole Nitrate	Femstat	38, .	10APR96	15APR96		YEAST INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-3, .	01MAR96	03MAR96#	2 TABS	HA (HEADACHE)
			8, .	11MAR96	11MAR96	2 TABS	HA (HEADACHE)
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	32, .	04APR96	04APR96	1 X DAY	ENVIRONMENTAL ALLERGIES
			45, .	17APR96	18APR96	1 X DAY	ENVIRONMENTAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	2, .	04:00 Hrs	50	1	MOD	NO	PBU	No	No
	Headache	HEADACHE	1, .	22 Days	50	16	MOD	NO	PSR	Yes	No
		HEADACHES	21, .	9 Days	150	4	MOD	NO	PBU	No	No
		SOMATIC COMPLAINT HEADACHE	57, .	Not Stated	200		MOD	NO	PSR	No	No
Carciovascular System	Vasodilatation	FLUSHED FACE	8, .	04:00 Hrs	100	1	MOD	NO	PSR	No	No
Digestive System	Nausea	SOMATIC COMPLAINT NAUSEA	57, .	Not Stated	200		MOD	NO	PSR	No	No
Hemic and Lymphatic System	Eosinophilia	EOSINOPHILS ELEVATED	57, .	Not Stated	200	CON	MOD	NO	PBU	No	No
Nervous System	Tremor	"SHAKINESS"	2, .	4 Days	50	CON	MOD	NO	PSR	No	No
		HAND TREMORS	33, .	19 Days	250	CON	MOD	DCR	REL	No	No
Respiratory System	Pharyngitis	SORE THROAT	42, .	4 Days	300	CON	MIL	NO	PBU	No	No
Special Senses	Abnormal Vision	BLURRED VISION	43, .	8 Days	250	15	SEV	DCR	REL	No	No
Urogenital System	Vaginal Moniliasis	YEAST INFECTION (VAGINAL)	47, .	5 Days	250	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26FEB96	-7,	.	0	120	80	60	120	78	76	150.20	69.0
BL	04MAR96	1,	.	0	100	60	86	90	50	82	149.30	
1	11MAR96	8,	.	100	110	78	86	100	70	96	151.00	
2	18MAR96	15,	.	150	104	80	76	100	70	76	149.00	
3	25MAR96	22,	.	200	102	66	96	100	60	108	149.50	
4	01APR96	29,	.	250	112	80	86	100	70	104	148.50	
5	08APR96	36,	.	300	112	70	106	118	80	110	153.50	
6	15APR96	43,	.	250	110	80	90	110	76	100	145.00	
7	23APR96	51,	.	250	110	80	90	120	84	102	150.50	
8	29APR96	57,	.	200	90	60	96	90	60	100	147.25	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2	.	.	.	30 - 70	%
				Lymphocytes	30.5	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	17.7	H	.	+	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	299000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.1		.	.	12 - 15.6	G/DL
				Hematocrit	41.7		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	53		.	.	30 - 70	%
				Lymphocytes	34		.	.	21 - 51	%
				Monocytes	4		.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	299000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32		.	.	25 - 35	PG
				Mean Corpuscle Volume	95		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8		.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05MAR96	1	11MAR96	7	7
00256	Oral	2	100 MG	12MAR96	8	20MAR96	16	9
00256	Oral	3	150 MG	21MAR96	17	25MAR96	21	5
00256	Oral	4	200 MG	26MAR96	22	01APR96	28	7
00256	Oral	5	250 MG	02APR96	29	10APR96	37	9
00256	Oral	5	250 MG	11APR96	38	15APR96	42	5
00256	Oral	5	250 MG	16APR96	43	22APR96	49	7
00256	Oral	6	300 MG	23APR96	50	29APR96	56	7
00133	Oral	6	300 MG	30APR96	57	27MAY96	84	28
00133	Oral	6	300 MG	28MAY96	85	01JUL96	119	35
00256	Oral	5	250 MG	02JUL96	120	03JUL96	121	2
00256	Oral	4	200 MG	04JUL96	122	05JUL96	123	2
00256	Oral	3	150 MG	06JUL96	124	07JUL96	125	2
00256	Oral	2	100 MG	08JUL96	126	10JUL96	128	3
00256	Oral	1	50 MG	11JUL96	129	17JUL96	135	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	135	50	Other reason	PT CHOSING TO WITHDRAW AS SHE WANTS TO BEGIN KNOWN MED THERAPY

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DECREASED LYMPHOCYTES	LYMPHOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Nizatidine	Axid	129, 73	11JUL96	.		GI UPSET
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	1, -56	05MAR96	07MAR96	650 MG	HA
			13, -44	17MAR96	20MAR96	500 MG	H/A AND BACKACHE
			16, -41	20MAR96	21MAR96		MENSTRUAL CRAMPS
		Tylenol Extra Strength	28, -29	01APR96	01APR96		SORE THROAT
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	1, -56	05MAR96	07MAR96		HA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	13, -44	4 Days	100	CON	MOD	NO	UNR	Yes	No
	Fever	FEVER	1, -56	2 Days	50	1	MOD	NO	PBU	No	No
	Headache	HEADACHE	1, -56	3 Days	50	1	MOD	NO	PBU	Yes	No
			13, -44	4 Days	100	CON	MOD	NO	UNR	Yes	No
Carciovascular System	Vasodilatation	HOT FLASHES	19, -38	3 Days	150	2	MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	26, -31	33 Days	200	CON	MOD	NO	PSR	No	No
	Dyspepsia	GI UPSET	129, 73	Not Stated	50	CON	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	1, -56	3 Days	50	1	MOD	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS UPON STANDING	31, -26	13 Days	250	4	MIL	NO	REL	No	No
Respiratory System	Pharyngitis	SORE THROAT	24, -33	5 Days	200	CON	MOD	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	16, -41	2 Days	100	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20FEB96	-14, -70	0	96	58	86	90	56	94	111.00	64.0
BL	05MAR96	1, -56	0	98	66	88	92	60	98	110.50	
1	12MAR96	8, -49	100	98	70	88	90	60	104	110.50	
2	21MAR96	17, -40	150	90	60	88	90	58	90	111.00	
3	26MAR96	22, -35	200	88	50	82	80	48	104	111.00	
4	02APR96	29, -28	250	100	60	94	94	58	108	111.00	
5	11APR96	38, -19	250	100	60	98	90	58	108	111.50	
6	16APR96	43, -14	250	110	60	96	100	56	108	111.50	
7	23APR96	50, -7	300	110	70	102	100	60	108	111.50	
8	30APR96	57, 1	300	100	60	98	100	60	104	113.00	
12	28MAY96	85, 29	300	80	40 L	96	80	40 L	96	114.50	
16	02JUL96	120, 64	250	90	60	92	80	52	90	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14		.	.	12 - 15.6	G/DL
				Hematocrit	40.7		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.6		.	.	30 - 70	%
				Lymphocytes	20.9	L	.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	3.8		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	196000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	98		.	.	22 - 130	U/L
				Aspartate Aminotransferase	9		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.7		.	.	3.1 - 5.3	G/DL
				Glucose - Random	96		.	.	70 - 115	MG/DL
				Globulin	3.1		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	32.4	.	.	.	21 - 51	%
				Monocytes	8.7	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	23.7	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	218000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
		VISIT 12/CONTINUATION-WEEK 16	120	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	28	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	206000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 12/CONTINUATION-WEEK 16	120	Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11MAR96	1	17MAR96	7	7
00257	Oral	2	20 MG	18MAR96	8	24MAR96	14	7
00257	Oral	3	20 MG	25MAR96	15	31MAR96	21	7
00257	Oral	4	20 MG	01APR96	22	07APR96	28	7
00257	Oral	4	20 MG	08APR96	29	14APR96	35	7
00257	Oral	4	20 MG	15APR96	36	21APR96	42	7
00257	Oral	5	30 MG	22APR96	43	28APR96	49	7
00257	Oral	5	30 MG	29APR96	50	05MAY96	56	7
00144	Oral	5	30 MG	06MAY96	57	02JUN96	84	28
00144	Oral	5	30 MG	03JUN96	85	07JUL96	119	35
00144	Oral	5	30 MG	08JUL96	120	06AUG96	149	30
00144	Oral	5	30 MG	07AUG96	150	26AUG96	169	20
00144	Oral	5	30 MG	27AUG96	170	30SEP96	204	35
00144	Oral	5	30 MG	01OCT96	205	21OCT96	225	21
00257	Oral	4	20 MG	22OCT96	226	23OCT96	227	2
00257	Oral	3	20 MG	24OCT96	228	25OCT96	229	2
00257	Oral	2	20 MG	26OCT96	230	28OCT96	232	3
00257	Oral	1	20 MG	29OCT96	233	04NOV96	239	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	Yes	239	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ascorbic Acid	Vitamin C	3, -54	13MAR96	.		"A COLD"
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	145, 89	02AUG96	09AUG96		SWIMMER'S EAR
	Antibiotic Nos	Antibiotics Ear Drops {Nos}	145, 89	02AUG96	09AUG96		SWIMMER'S EAR
	Cefaclor	Ceclor	15, -42	25MAR96	05APR96		SINUS INFECTION
			43, -14	22APR96	06MAY96		SINUS INFECTION
	Miconazole Nitrate	Monistat 7	242, 186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
CARDIOVASCULAR	Theophylline	Slo-Bid	54, -3	03MAY96	10MAY96	150 MG BID	UPPER RESPIRATORY INFECTION AND SINUS IN
DERMATOLOGICALS	Fluticasone Propionate	Flonase	43, -14	22APR96	28APR96	2 SQUIRTS	SINUS INFECTION
	Isotretinoin	Accutane	-121, -177	11NOV95	.		ACNE
			-121, -177	11NOV95	.		ACNE
	Miconazole Nitrate	Monistat 7	242, 186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
GU SYSTEM/SEX HORMONES	Miconazole Nitrate	Monistat 7	242, 186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
MUSCULO-SKELETAL	Ibuprofen	Advil	157, 101	14AUG96	21AUG96		HEADACHE
RESPIRATORY	Acrivastine	Semprex-D	14, -43	24MAR96	24MAR96		"A COLD"
			14, -43	24MAR96	24MAR96		"A COLD"
			14, -43	24MAR96	24MAR96		"A COLD"
	Chlorphenamine Tannate	Rynatan	15, -42	25MAR96	27MAR96		SINUS INFECTION
	Ephedrine Sulfate	Marax	202, 146	28SEP96	.		EXERCISE INDUCED ASTHMA
	Fluticasone Propionate	Flonase	43, -14	22APR96	28APR96	2 SQUIRTS	SINUS INFECTION
	Hydroxyzine Hydrochloride	Marax	202, 146	28SEP96	.		EXERCISE INDUCED ASTHMA
	Mepyramine Tannate	Rynatan	15, -42	25MAR96	27MAR96		SINUS INFECTION
	Phenylephrine Tannate	Rynatan	15, -42	25MAR96	27MAR96		SINUS INFECTION
	Pseudoephedrine	Semprex-D	14, -43	24MAR96	24MAR96		"A COLD"
			14, -43	24MAR96	24MAR96		"A COLD"

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Pseudoephedrine	Semprex-D	14, -43	24MAR96	24MAR96		"A COLD"
	Salbutamol	Albuterol	43, -14	22APR96	06MAY96	2 PUFF X 4	SINUS INFECTION
			43, -14	22APR96	06MAY96	2 PUFF X 4	SINUS INFECTION
	Theophylline	Marax	202, 146	28SEP96	.		EXERCISE INDUCED ASTHMA
		Slo-Bid	54, -3	03MAY96	10MAY96	150 MG BID	UPPER RESPIRATORY INFECTION AND SINUS IN

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	157, 101	8 Days	30	2	MIL	NO	PBU	Yes	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN	85, 29	Not Stated	30	CON	MOD	NO	PSR	No	No
Nervous System	Nervousness	"JITTERINESS"	225, 169	Not Stated	30	CON	MOD	NO	PSR	No	No
Respiratory System	Asthma	EXERCISE INDUCED ASTHMA	175, 119	Not Stated	30	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	SORE THROAT (COLD SYMPTOM)	8, -49	9 Days	20	CON	MOD	NO	PBU	Yes	No
		STUFFY NOSE (COLD SYMPTOMS)	8, -49	9 Days	20	CON	MOD	NO	PBU	Yes	No
	Sinusitis	SINUS INFECTION	14, -43	7 Days	20		MOD	NO	PBU	Yes	No
			35, -22	37 Days	20	CON	MOD	NO	PBU	Yes	No
Special Senses	Otitis Externa	SWIMMER'S EAR	143, 87	3 Days	30	CON	MOD	NO	PBU	Yes	No
Urogenital System	Haematuria	RBC IN URINE (PT MENSTRUATING WHEN SAMPLE TAKEN)	225, 169	Not Stated	30	CON	MOD	NO	UNR	No	No
	Urinary Tract Infection	YEAST INFECTION (SQUAMOUS EPITHELIAL CELLS IN URINE)	219, 163	Not Stated	30	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	05MAR96	-6, -62	0	110	68	102	100	60	96	112.00	63.0
BL	11MAR96	1, -56	0	90	60	76	90	60	70	112.50	
1	18MAR96	8, -49	20	100	50	80	98	48	98	108.00	
2	25MAR96	15, -42	20	90	60	86	88	58	96	109.00	
3	01APR96	22, -35	20	100	70	74	102	68	86	111.00	
4	08APR96	29, -28	20	110	80	70	110	86	80	112.00	
5	15APR96	36, -21	20	100	60	72	90	52	90	110.00	
6	22APR96	43, -14	30	110	64	84	110	68	80	112.00	
7	29APR96	50, -7	30	100	60	80	100	60	80	112.75	
8	06MAY96	57, 1	30	120	68	86	118	78	94	112.00	
12	03JUN96	85, 29	30	100	70	74	106	80	90	117.25	
16	08JUL96	120, 64	30	112	70	86	108	70	86	122.25 H	
20	07AUG96	150, 94	30	122	72	80	120	80	84	124.50 H	
24	27AUG96	170, 114	30	120	80	84	110	70	86	122.00 H	
28	01OCT96	205, 149	30	118	70	78	118	80	84	123.00 H	
32	21OCT96	225, 169	30	116	72	80	110	70	86	123.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.8	.	.	.	30 - 70	%
				Lymphocytes	22.3	.	.	.	21 - 51	%
				Monocytes	9.5	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	136000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	60 - 110	MG/DL
				Globulin	2.7	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Hemoglobin	24.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	72.4	H	.	.	35 - 46	%
				Red Blood Cell Count	8.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	19.1	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.7	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	17000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.4	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Segmented Neutrophils	58.6	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	3.3	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	129	H	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	150	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	150	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	225	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	30.4	.	.	.	21 - 51	%
				Monocytes	3.6	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 16/CONTINUATION-WEEK 32	225	Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	12MAR96	1	18MAR96	7	7
00258	Oral	2	20 MG	19MAR96	8	25MAR96	14	7
00258	Oral	3	20 MG	26MAR96	15	01APR96	21	7
00258	Oral	4	20 MG	02APR96	22	08APR96	28	7
00258	Oral	5	30 MG	09APR96	29	17APR96	37	9
00258	Oral	6	40 MG	18APR96	38	22APR96	42	5
00258	Oral	6	40 MG	23APR96	43	29APR96	49	7
00258	Oral	6	40 MG	30APR96	50	06MAY96	56	7
	Oral	5	30 MG	07MAY96	57	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	57	30		PT TO HAVE SURGERY UNDER GENERAL ANETHESIA 6/24/96

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCULT BLOOD IN URINE - PATIENT MENSTRUATING	HEMATURIA	GENITOURINARY SYST DIS	CUR	1996
PROTEIN IN URINE - PATIENT MENSTRUATING	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	21,	.	01APR96	01APR96	2 TABS	ORTHODONTIC DISCOMFORT
			28,	.	08APR96	08APR96	2 TABS	ORTHODONTIC DISCOMFORT
RESPIRATORY	Guaifenesin	Robitussin	2,	.	13MAR96	13MAR96		COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	10, .	02:00 Hrs	20	1	MOD	NO	PBU	No	No
			25, .	4 Days	20	4	MOD	NO	PBU	No	No
	Headache	HEADACHE	10, .	4 Days	20	2	MOD	NO	PBU	No	No
			25, .	4 Days	20	3	MOD	NO	PBU	No	No
Digestive System	Tooth Disorder	ORTHODONTIC DISCOMFORT	21, .	03:30 Hrs	20	1	MOD	NO	UNR	Yes	No
			28, .	02:40 Hrs	20	1	MOD	NO	UNR	Yes	No
Respiratory System	Cough Increased	COUGH	-4, .	8 Days	0	1	MOD	NO	UNR	Yes	No
Urogenital System	Urine Abnormality	ABNORMAL URINE ROUTINE & MICROSCOPIC(URINALYSIS	57, .	Not Stated	30	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06FEB96	-35,	.	0	102	60	98	100	60	104	169.50	64.0
BL	20FEB96	-21,	.	0	118	70	100	110	70	104	171.70	
1	19MAR96	8,	.	20	100	60	98	98	68	102	171.00	
2	26MAR96	15,	.	20	120	78	80	110	70	98	168.50	
3	02APR96	22,	.	20	120	70	80	110	70	98	171.00	
4	09APR96	29,	.	30	112	76	82	110	80	100	169.00	
5	18APR96	38,	.	40	104	70	80	100	70	84	169.00	
6	23APR96	43,	.	40	126	70	84	122	76	102	171.50	
7	30APR96	50,	.	40	112	70	88	120	80	106	167.50	
8	07MAY96	57,	.	30	120	80	88	120	80	102	168.75	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-21	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	35.8	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-21		Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 2/UNSCHEDULED LAB 1	-14		Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6		.	.		
					Urine Red Blood Cells/HPF	5		.	.		
					Urine White Blood Cells/HPF	4		.	.		
					Urine Bacteria	4		.	.		
					Urine Protein - Dipstick	2		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	12.2		.	.	12 - 15.6	G/DL
					Hematocrit	35.9		.	.	35 - 46	%
					Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.1		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	47.6		.	.	30 - 70	%
					Lymphocytes	37.2		.	.	21 - 51	%
					Monocytes	7.7		.	.	0 - 10	%
					Eosinophils	6.6	H	.	.	0 - 5	%
					Basophils	0.8		.	.	0 - 2	%
					Platelets	275000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29		.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	95	.	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	+		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	6	.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	12MAR97	1	18MAR97	7	7
00293	Oral	2	0 MG	19MAR97	8	24MAR97	13	6
00293	Oral	3	0 MG	25MAR97	14	01APR97	21	8
00293	Oral	4	0 MG	02APR97	22	08APR97	28	7
00293	Oral	5	0 MG	09APR97	29	15APR97	35	7
00293	Oral	6	0 MG	16APR97	36	22APR97	42	7
00293	Oral	6	0 MG	23APR97	43	29APR97	49	7
00293	Oral	6	0 MG	30APR97	50	07MAY97	57	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	57	0		STUDY MEDICATION FOR PHASE II UNAVAILABLE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
RBC IN URINE POST PARTUM	HEMATURIA	GENITOURINARY SYST DIS	CUR	1997
SQUAMOUS CELLS IN URINE POST PARTUM	URINARY CASTS/WBC'S	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
2 VAGINAL DELIVERY BIRTHS	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTINEOPLASTIC & IMMUNOSUP	Medroxyprogesteron e Acetate	Depo-Provera	21, .	01APR97	01APR97		BIRTH CONTROL
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-23, .	17FEB97	18FEB97#	1 GM	POST PARTUM PAIN
			26, .	06APR97	06APR97	500 MG	HEADACHE
			39, .	19APR97	19APR97	2 TABS	HEADACHE
GU SYSTEM/SEX HORMONES	Medroxyprogesteron e Acetate	Depo-Provera	21, .	01APR97	01APR97		BIRTH CONTROL
RESPIRATORY	Guaifenesin	Humibid	7, .	18MAR97	18MAR97	2 PUFFS	RESPIRATORY CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	26, .	03:30 Hrs	0	1	MOD	NO	PBU	Yes	No
			39, .	01:00 Hrs	0	1	MOD	NO	PBU	Yes	No
			56, .	45 Mins	0	1	MOD	NO	PBU	No	No
Respiratory System	Respiratory Disorder	RESPIRATORY CONGESTION	7, .	8 Days	0	CON	MOD	NO	PBU	Yes	No
Skin and Appendages	Acne	ACNE	15, .	Not Stated	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06MAR97	-6,	.	0	108	70	70	106	70	74	175.00	63.0
BL	12MAR97	1,	.	0	122	78	80	108	70	96	171.75	
1	19MAR97	8,	.	0	110	80	68	110	80	78	174.00	
2	25MAR97	14,	.	0	120	74	90	116	68	106	173.25	
3	02APR97	22,	.	0	120	80	92	110	70	100	173.25	
4	09APR97	29,	.	0	124	80	90	118	80	98	175.00	
5	16APR97	36,	.	0	120	84	80	110	80	90	174.00	
6	23APR97	43,	.	0	128	74	90	118	78	104	172.00	
7	30APR97	50,	.	0	120	82	94	126	76	102	174.50	
8	07MAY97	57,	.	0	120	70	90	120	82	100	172.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.7	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32.3	.	.	.	30 - 70	%
				Lymphocytes	45	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	12.3	H	.	+	0 - 5	%
				Basophils	2.5	H	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	39	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	68	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	30	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	33.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28MAR96	1	03APR96	7	7
00295	Oral	2	100 MG	04APR96	8	10APR96	14	7
00295	Oral	3	150 MG	11APR96	15	17APR96	21	7
00295	Oral	4	200 MG	18APR96	22	23APR96	27	6
00295	Oral	4	200 MG	24APR96	28	05MAY96	39	12
00295	Oral	4	200 MG	06MAY96	40	08MAY96	42	3
00295	Oral	5	250 MG	09MAY96	43	15MAY96	49	7
00295	Oral	5	250 MG	16MAY96	50	19MAY96	53	4
00295	Oral	5	250 MG	20MAY96	54	04JUN96	69	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	69	250	Adverse event, including intercurrent illness	INVESTIGATOR'S DECISION TO DISCONTINUE STUDY BECAUSE PT. THREATENED TO KILL PARENTS.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BODY ACHES	PAIN, GENERAL	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
DIARRHEA	DIARRHEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
FLU	INFLUENZA	RESPIRATORY SYST DIS	CUR	1996
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ascorbic Acid	Vitamin C	-24, .	04MAR96	06MAR96#		COLD SYMPTOMS
	Bismuth Subsalicylate	Pepto-Bismol	-9, .	19MAR96	19MAR96#	2TBSP	DIARRHEA
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-9, .	19MAR96	19MAR96#	500MG	FLU-BODY ACHES
MUSCULO-SKELETAL	Ibuprofen	Advil	-7, .	21MAR96	21MAR96#	250MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN	19, .	2 Days	150	2	MOD	NO	PSR	No	No
	Headache	HEADACHE	22, .	03:30 Hrs	200	CON	MIL	NO	PBU	No	No
			39, .	04:30 Hrs	200	CON	MOD	NO	PSR	No	No
		HEADACHES	-7, .	1 Days	0	1	MOD	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	11, .	55 Days	100	CON	MOD	NO	REL	No	No
	Nausea	NAUSEA	39, .	02:00 Hrs	200	CON	MIL	NO	PSR	No	No
	Vomiting	VOMITING	49, .	30 Mins	250	CON	MOD	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	38, .	2 Days	200	4	MIL	NO	PSR	No	No
	Emotional Lability	SUICIDAL THREAT WITH SCISSORS	23, .	1 Days	200	1	MOD	NO	PBU	No	No
	Hostility	HOMICIDAL TENDENCIES TOWARDS PARENTS	52, .	04:30 Hrs	250	CON	SEV	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	21MAR96	-7,	.	0	110	70	80	100	70	84	120.50	61.0
BL	28MAR96	1,	.	0	110	72	76	104	70	80	120.50	
1	04APR96	8,	.	100	120	78	88	110	68	94	119.20	
2	11APR96	15,	.	150	100	70	84	90	60	88	119.50	
3	18APR96	22,	.	200	100	68	88	94	60	88	119.00	
4	24APR96	28,	.	200	118	80	94	110	70	100	120.00	
6	06MAY96	40,	.	200	116	70	86	110	68	86	121.75	
6	09MAY96	43,	.	250	120	70	96	110	70	100	122.50	
7	16MAY96	50,	.	250	110	70	92	100	70	96	125.00	
8	22MAY96	56,	.	250	110	70	104	104	70	110	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62	.	.	.	30 - 70	%
				Lymphocytes	34	.	.	.	21 - 51	%
				Monocytes	2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	29	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	.	.	.	30 - 70	%
				Lymphocytes	22.7	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	277000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19APR96	1	25APR96	7	7
00297	Oral	2	100 MG	26APR96	8	01MAY96	13	6
00297	Oral	3	150 MG	02MAY96	14	13MAY96	25	12
00297	Oral	4	200 MG	14MAY96	26	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	No	No	26	200	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-5, .	14APR96	16APR96#	1 GM.	HEADCOLD & NASAL CONGESTION
			22, .	10MAY96	11MAY96	2 TABS	HA
RESPIRATORY	Guaifenesin	Robitussin	-5, .	14APR96	16APR96#	4 TSP	HEADCOLD & NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	22, .	02:00 Hrs	150	2	MOD	NO	PSR	Yes	No
Digestive System	Dyspepsia	HEARTBURN	6, .	04:00 Hrs	50	CON	MOD	NO	UNR	No	No
Respiratory System	Respiratory Disorder	HEADCOLD AND NASAL CONGESTION	-5, .	3 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	28MAR96	-22, .	0	124	80	80	114	78	80	184.50	69.0
BL	19APR96	1, .	0	118	72	80	120	70	80	180.00	
1	26APR96	8, .	100	114	74	88	112	78	92	180.50	
2	02MAY96	14, .	150	120	80	88	110	80	90	181.50	
4	14MAY96	26, .	200	130	70	90	120	70	98	181.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-22	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	40 - 75	%
				Lymphocytes	31.3	.	.	.	16 - 46	%
				Monocytes	8.6	.	.	.	0 - 12	%
				Eosinophils	3.8	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	146000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.4	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-22	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-16	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	22MAY96	1	29MAY96	8	8
00298	Oral	2	0 MG	30MAY96	9	05JUN96	15	7
00298	Oral	3	0 MG	06JUN96	16	11JUN96	21	6
00298	Oral	4	0 MG	12JUN96	22	18JUN96	28	7
00298	Oral	4	0 MG	19JUN96	29	25JUN96	35	7
00298	Oral	4	0 MG	26JUN96	36	02JUL96	42	7
00298	Oral	4	0 MG	03JUL96	43	09JUL96	49	7
00298	Oral	4	0 MG	10JUL96	50	16JUL96	56	7
00185	Oral	4	0 MG	17JUL96	57	15AUG96	86	30
00185	Oral	4	0 MG	16AUG96	87	18SEP96	120	34
00185	Oral	4	0 MG	19SEP96	121	16OCT96	148	28
00185	Oral	4	0 MG	17OCT96	149	13NOV96	176	28
00185	Oral	4	0 MC	14NOV96	177	11DEC96	204	28
00185	Oral	4	0 MG	12DEC96	205	12JAN97	236	32
00298	Oral	3	0 MG	13JAN97	237	14JAN97	238	2
00298	Oral	2	0 MG	15JAN97	239	17JAN97	241	3
00298	Oral	1	0 MG	18JAN97	242	24JAN97	248	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	248	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES {SEASONAL}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1988
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol (Teen)	231, 175	07JAN97	09JAN97	4 TABS	MENSTRUAL CRAMPS
	Caffeine	Midol (Teen)	231, 175	07JAN97	09JAN97	4 TABS	MENSTRUAL CRAMPS
	Chlorphenamine Maleate	Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
	Cinnamedrine Hydrochloride	Midol (Teen)	231, 175	07JAN97	09JAN97	4 TABS	MENSTRUAL CRAMPS
	Dextromethorphan	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
	Dextromethorphan Hydrobromide	Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
	Mepyramine Maleate	Pamprin	-7, -63	15MAY96	15MAY96#	PRN	MENSTRUAL CRAMPS
			46, -11	06JUL96	07JUL96	1X DAILY TAB	MENSTRUAL CRAMPS
			167, 111	04NOV96	04NOV96	2 TABS	MENSTRUAL CRAMPS
			200, 144	07DEC96	09DEC96	1 TAB	MENSTRUAL CRAMPS
	Pamabrom	Pamprin	-7, -63	15MAY96	15MAY96#	PRN	MENSTRUAL CRAMPS
			46, -11	06JUL96	07JUL96	1X DAILY TAB	MENSTRUAL CRAMPS
			167, 111	04NOV96	04NOV96	2 TABS	MENSTRUAL CRAMPS
			200, 144	07DEC96	09DEC96	1 TAB	MENSTRUAL CRAMPS
	Paracetamol	Pamprin	-7, -63	15MAY96	15MAY96#	PRN	MENSTRUAL CRAMPS
			46, -11	06JUL96	07JUL96	1X DAILY TAB	MENSTRUAL CRAMPS
			167, 111	04NOV96	04NOV96	2 TABS	MENSTRUAL CRAMPS
			200, 144	07DEC96	09DEC96	1 TAB	MENSTRUAL CRAMPS
		Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
		Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
		Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION
	Pseudoephedrine	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
	Pseudoephedrine Hydrochloride	Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Pseudoephedrine Hydrochloride	Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION
MUSCULO-SKELETAL	Ibuprofen	Advil	26, -31	16JUN96	16JUN96	2X DAILY TABS	RIGHT LEG PAIN
			33, -24	23JUN96	23JUN96	2X DAILY TABS	BACK PAIN
			56, -1	16JUL96	16JUL96	1X DAILY TAB	KNEE INJURY
			133, 77	01OCT96	04OCT96	800 MG	CHARLIE HORSE
		Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
		Ibuprofen	149, 93	17OCT96	17OCT96	300 MG	PULLED MUSCLE
	Pseudoephedrine Hydrochloride	Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
RESPIRATORY	Chlorphenamine Maleate	Tylenol Allergy And Sinus	-26, -82	26APR96	26APR96#	2 DAILY PRN	ALLERGIES
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
			39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
	Dextromethorphan	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
			204, 148	11DEC96	12DEC96	4 TABS	COLD SX
	Dextromethorphan Hydrobromide	Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
			39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
	Ibuprofen	Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
	Loratadine	Claritin	40, -17	30JUN96	01JUL96	2X DAILY TABS	SINUS CONGESTION
	Paracetamol	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
			204, 148	11DEC96	12DEC96	4 TABS	COLD SX
		Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Allergy And Sinus	-26, -82	26APR96	26APR96#	2 DAILY PRN	ALLERGIES
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Paracetamol	Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
		Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION
	Pseudoephedrine	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
			204, 148	11DEC96	12DEC96	4 TABS	COLD SX
	Pseudoephedrine Hydrochloride	Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
		Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Allergy And Sinus	-26, -82	26APR96	26APR96#	2 DAILY PRN	ALLERGIES
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
			39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
		Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK ACHE	114, 58	3 Days	0	CON	MOD	NO	UNR	No	No
		BACK PAIN (OLD SOCCER INJURY)	33, -24	03:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	169, 113	02:30 Hrs	0	CON	MOD	NO	UNR	No	No
	Trauma	CHARLEY HORSE LEFT LEG-THIGH	133, 77	4 Days	0	CON	MOD	NO	UNR	Yes	No
		KNEE INJURY (SOCCER RELATED)	55, -2	3 Days	0	CON	MOD	NO	UNR	Yes	No
		PAIN IN RIGHT LEG (FOLLOWING AUTOMOBILE ACCIDENT)	26, -31	04:30 Hrs	0	CON	MOD	NO	UNR	Yes	No
		PULLED MUSCLE - LEFT SHIN (SOCCER INJURY)	149, 93	06:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Diarrhea	STOMACH ACHE WITH DIARRHEA	-4, -60	4 Days	0	CON	SEV	NO	UNR	No	No
Nervous System	Dizziness	DIZZINESS WHEN STANDING UP	202, 146	3 Days	0	3	MIL	NO	PBU	No	No
	Hypertonia	STIFF NECK	39, -18	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
Respiratory System	Epistaxis	NOSEBLEEDS	230, 174	7 Days	0	8	SEV	NO	PSR	No	No
	Respiratory Disorder	COLD SYMPTOMS:STUFFY NOSE, SORE THROAT, FEVER	201, 145	12 Days	0	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	40, -17	2 Days	0	CON	MOD	NO	UNR	Yes	No
			99, 43	8 Days	0	CON	MOD	NO	UNR	No	No
		SINUS HEADACHE AND CONGESTION	12, -45	4 Days	0	CON	MOD	NO	UNR	Yes	No
Uroçenital System	Dysmenorrhea	MENSTRUAL CRAMPS	46, -11	2 Days	0	CON	MOD	NO	UNR	Yes	No
			167, 111	24:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			200, 144	3 Days	0	CON	MOD	NO	UNR	Yes	No
			231, 175	3 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	15MAY96	-7, -63	0	110	80	68	112	80	68	149.50	64.0
BL	22MAY96	1, -56	0	118	80	74	112	80	76	147.70	
1	30MAY96	9, -48	0	90	60	60	90	56	64	147.50	
2	06JUN96	16, -41	0	118	80	60	114	80	60	146.20	
3	12JUN96	22, -35	0	110	60	58	104	68	60	148.00	
4	19JUN96	29, -28	0	98	60	60	94	60	60	147.70	
5	26JUN96	36, -21	0	118	70	54	110	60	58	148.20	
6	03JUL96	43, -14	0	116	74	56	112	72	60	148.70	
7	10JUL96	50, -7	0	100	60	64	110	70	72	146.50	
8	17JUL96	57, 1	0	104	64	60	90	60	62	147.70	
16	19SEP96	121, 65	0	104	60	54	112	60	64	147.50	
20	17OCT96	149, 93	0	90	64	60	90	60	60	148.00	
24	14NOV96	177, 121	0	92	60	60	90	50	62	148.70	
28	12DEC96	205, 149	0	104	78	64	110	76	64	150.00	
32	13JAN97	237, 181	0	100	60	60	100	60	64	149.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 2/ELIGIBILITY	1	Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	227000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	144	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	149	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	41	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/CONTINUATION-WEEK 32	237	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.1	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	112	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	237	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08JUN96	1	17JUN96	10	10
00299	Oral	2	20 MG	18JUN96	11	24JUN96	17	7
00299	Oral	3	20 MG	25JUN96	18	01JUL96	24	7
00299	Oral	4	20 MG	02JUL96	25	09JUL96	32	8
00299	Oral	4	20 MG	10JUL96	33	21JUL96	44	12
	Oral	4	20 MG	22JUL96	45	30JUL96	53	9
00299	Oral	4	20 MG	31JUL96	54	06AUG96	60	7
00169	Oral	4	20 MG	07AUG96	61	02SEP96	87	27
00169	Oral	4	20 MG	03SEP96	88	01OCT96	116	29
00169	Oral	5	30 MG	02OCT96	117	28OCT96	143	27
00169	Oral	5	30 MG	29OCT96	144	04NOV96	150	7
00299	Oral	4	20 MG	05NOV96	151	06NOV96	152	2
00299	Oral	3	20 MG	07NOV96	153	08NOV96	154	2
00299	Oral	2	20 MG	09NOV96	155	11NOV96	157	3
00299	Oral	1	20 MG	12NOV96	158	18NOV96	164	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	164	20	Lack of Efficacy	PT. REMOVED AT PARENTS REQUEST. PT HAD AN INC IN AFFECTIVE SYMPTOMS AFTER INITIAL IMPROVEMENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
KNEE PAIN {RIGHT-MILD AFTER RUNNING}	PAIN, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Calcium Carbonate	Tums	.,	.		.		STOMACH
			.,	.		.		STOMACH
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	138,	78	23OCT96	23OCT96	2 TABS	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	.,	.		.		HEADACHE
RESPIRATORY	Guaifenesin	Robitussin	109,	49	24SEP96	02OCT96	2 TSP	"COLD"
			140,	80	25OCT96	25OCT96	2 TSP	COLD SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	54, -7	3 Days	20	2	MOD	NO	PSR	Yes	No
	Headache	HEADACHE	54, -7	5 Days	20	2	MOD	NO	PSR	Yes	No
			88, 28	03:00 Hrs	20	4	MOD	NO	PBU	No	No
			138, 78	02:00 Hrs	30	1	MOD	NO	PBU	Yes	No
			165, 105	04:00 Hrs	20	1	MOD	NO	PBU	No	No
		HEADACHE UPON RISING	7, -54	27 Days	20		MOD	NO	PSR	No	No
Carciovascular System	Syncope	FAINTED	10, -51	1 Mins	20	1	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	151, 91	8 Days	20	CON	MOD	NO	PSR	No	No
		DIZZINESS UPON RISING	7, -54	27 Days	20		MOD	NO	PSR	No	No
Respiratory System	Epistaxis	NOSEBLEED	158, 98	10 Mins	20	1	MIL	NO	PSR	No	No
	Respiratory Disorder	COLD {SYMPTOMS}	95, 35	Not Stated	20	CON	MOD	NO	UNR	Yes	No
Special Senses	Abnormal Vision	BLURRED VISION	139, 79	6 Days	30	CON	MIL	NO	PBU	No	No
			151, 91	8 Days	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	28MAY96	-11, -71	0	118	82	72	116	78	78	123.20	63.0
BL	04JUN96	-4, -64	0	120	80	64	120	80	76	124.00	
1	18JUN96	11, -50	20	92	64	84	92	60	100	123.00	
2	25JUN96	18, -43	20	92	64	84	92	60	96	125.75	
3	02JUL96	25, -36	20	110	70	82	110	80	84	124.00	
5	10JUL96	33, -28	20	90	68	80	92	56	88	124.00	
6	22JUL96	45, -16	20	100	48 L	84	90	42 L	100	124.00	
8	31JUL96	54, -7	20	110	60	80	90	54	84	127.20	
8	07AUG96	61, 1	20	106	70	80	100	60	84	125.75	
12	03SEP96	88, 28	20	120	70	72	120	76	86	128.75	
16	01OCT96	116, 56	20	92	58	84	88 L	54	92	128.00	
20	29OCT96	144, 84	30	104	60	82	100	60	88	131.25	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	22.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	67.3	H	.	.	35 - 46	%
				Red Blood Cell Count	7.9	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	14	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	25.1	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	10000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	266	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-11	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-4	Hemoglobin	13.9		.	.	12 - 15.6	G/DL
				Hematocrit	41.3		.	.	35 - 46	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70		.	.	30 - 70	%
				Lymphocytes	18.5	L	.	.	21 - 51	%
				Monocytes	6.9		.	.	0 - 10	%
				Eosinophils	3.2		.	.	0 - 5	%
				Basophils	1.5		.	.	0 - 2	%
				Platelets	232000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 2/ELIGIBILITY	-4	Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.4	.	.	.	30 - 70	%
				Lymphocytes	23.4	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	226	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	144	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.5	H	.	.	30 - 70	%
				Lymphocytes	15.1	L	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	131	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	144	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF		3	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
				Urine Squamous Epithelial Cells		3	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	19SEP96	1	25SEP96	7	7
00300	Oral	2	20 MG	26SEP96	8	02OCT96	14	7
00300	Oral	3	20 MG	03OCT96	15	09OCT96	21	7
00300	Oral	4	20 MG	10OCT96	22	16OCT96	28	7
00300	Oral	4	20 MG	17OCT96	29	23OCT96	35	7
00300	Oral	4	20 MG	24OCT96	36	30OCT96	42	7
00300	Oral	4	20 MG	31OCT96	43	06NOV96	49	7
00300	Oral	4	20 MG	07NOV96	50	13NOV96	56	7
	Oral	3	20 MG	14NOV96	57	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	57	20		

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Action	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	55,	.	02:00 Hrs	20	CON	MOD	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	6,	.	27 Days	20	CON	MOD	NO	REL	No	No
			33,	.	10 Days	20	CON	MIL	NO	REL	No	No
Nervous System	Hostility	OPPOSITIONAL BEHAVIOR (PHYSICALLY AND VERBALLY FIGHTING WITH MOTHER)	30,	.	7 Days	20	6	SEV	NO	PBU	No	No
			37,	.	Not Stated	20		MOD	NO	PBU	No	No
	Somnolence	SLEEPINESS (IN AM)	13,	.	11 Days	20	CON	MOD	NO	REL	No	No
			24,	.	Not Stated	20	CON	SEV	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12SEP96	-7,	.	0	90	60	60	90	58	62	96.20	62.0
BL	19SEP96	1,	.	0	80	50	60	88	50	62	96.50	
1	26SEP96	8,	.	20	80	50	74	84	60	78	95.50	
2	03OCT96	15,	.	20	88	60	64	84	58	68	94.20	
3	10OCT96	22,	.	20	98	60	80	104	50	86	94.75	
4	17OCT96	29,	.	20	90	60	60	80	60	64	97.50	
5	24OCT96	36,	.	20	70	50	60	90	60	62	95.70	
6	31OCT96	43,	.	20	80	60	60	58 L	54	60	95.50	
7	07NOV96	50,	.	20	80	60	60	78	50	62	95.70	
8	14NOV96	57,	.	20	90	60	60	80	58	64	99.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.8	.	.	.	30 - 70	%
				Lymphocytes	46.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	327000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.3	L	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	306	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	38	L	.	.	41 - 50	%
					Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.9		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	44.4		.	.	30 - 70	%
					Lymphocytes	43.1		.	.	21 - 51	%
					Monocytes	8.9		.	.	0 - 10	%
					Eosinophils	3.1		.	.	0 - 5	%
					Basophils	0.4		.	.	0 - 2	%
					Platelets	290000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.9		.	.	25 - 35	PG
					Mean Corpuscle Volume	81		.	.	80 - 100	FL
					Blood Urea Nitrogen	10		.	.	8 - 21	MG/DL
					Creatinine	0.8		.	.	0.4 - 1.1	MG/DL
					Uric Acid	2	L	.	.	2.6 - 7	MG/DL
					Alkaline Phosphatase	259		.	.	44 - 400	U/L
					Aspartate Aminotransferase	22		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21NOV96	1	26NOV96	6	6
00331	Oral	2	0 MG	27NOV96	7	03DEC96	13	7
00331	Oral	3	0 MG	04DEC96	14	11DEC96	21	8
00331	Oral	4	0 MG	12DEC96	22	18DEC96	28	7
00331	Oral	4	0 MG	19DEC96	29	25DEC96	35	7
00331	Oral	4	0 MG	26DEC96	36	01JAN97	42	7
00331	Oral	4	0 MG	02JAN97	43	09JAN97	50	8
00331	Oral	4	0 MG	10JAN97	51	16JAN97	57	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	57	0		DRUG SUPPLIES NOT AVAILABLE FROM SKB

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
25% HEARING LOSS RIGHT EAR	HEARING LOSS	NERVOUS SYST/SENSE ORGAN DIS	CUR	1982
ALLERGIES {CAT AND DOG HAIR, DUST, TREES}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
RECURRENT EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1982
SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1996
TUBES PLACED IN RIGHT EAR X6	OPERATION, EAR	OPERATIONS	CUR	1982

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	27, .	17DEC96	27DEC96	2 CAPS	SINUS INFECTION
	Azithromycin	Zithromax	-22, .	30OCT96	06NOV96#		EAR INFECTION
	Clavulanic Acid	Augmentin	27, .	17DEC96	27DEC96	2 CAPS	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	1, .	21NOV96	21NOV96	500 MG	HEADACHE
			36, .	26DEC96	26DEC96	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	3, .	23NOV96	23NOV96	4 CAPS	HEADACHE
RESPIRATORY	Decongestant Nos	Unknown Decongestant {Nos}	-14, .	07NOV96	17NOV96#		SINUS INFECTION
			-14, .	07NOV96	17NOV96#		SINUS INFECTION
	Guaifenesin	Robitussin	23, .	13DEC96	17DEC96	2 TSP.	SINUS INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	30, .	6 Days	0	CON	MIL	NO	UNR	No	No
			48, .	2 Days	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	1, .	4 Days	0	4	MOD	NO	REL	Yes	No
			3, .	1 Days	0	2	MIL	NO	PSR	No	No
			4, .	1 Days	0	CON	MIL	NO	PSR	No	No
			10, .	2 Days	0	2	MOD	NO	REL	Yes	No
			36, .	02:30 Hrs	0	CON	MOD	NO	UNR	Yes	No
			50, .	02:30 Hrs	0	CON	MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	3, .	5 Days	0	CON	MIL	NO	REL	No	No
Nervous System	Depersonalization	"SPACED OUT" FEELING	18, .	5 Days	0	CON	MIL	DCR	PSR	No	No
	Dizziness	DIZZINESS	29, .	5 Mins	0	CON	MIL	NO	PBU	No	No
		DIZZINESS IN AM	19, .	4 Days	0	3	MIL	NO	PBU	No	No
	Nervousness	FIDGETINESS	3, .	10:00 Hrs	0	CON	MIL	NO	PSR	No	No
Respiratory System	Sinusitis	SINUS INFECTION	27, .	11 Days	0	CON	SEV	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14NOV96	-7,	.	0	100	70	84	90	70	88	163.00	66.0
BL	21NOV96	1,	.	0	90	60	84	90	60	88	162.50	
1	27NOV96	7,	.	0	120	70	88	112	70	100	164.70	
2	04DEC96	14,	.	0	110	70	84	104	70	88	164.00	
3	12DEC96	22,	.	0	100	70	88	110	74	84	164.00	
4	19DEC96	29,	.	0	104	70	92	112	70	96	163.00	
6	02JAN97	43,	.	0	124	80	80	120	70	84	166.70	
7	10JAN97	51,	.	0	100	64	80	90	60	84	162.00	
8	16JAN97	57,	.	0	100	70	74	90	60	80	162.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	24	H	.	.	12 - 15.6	G/DL
				Hematocrit	69.9	H	.	.	35 - 46	%
				Red Blood Cell Count	7.3	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	19.1	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74	H	.	.	30 - 70	%
				Lymphocytes	17	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	12000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	7	Hemoglobin	14.6		.	.	12 - 15.6	G/DL
				Hematocrit	41.6		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4		.	.	30 - 70	%
				Lymphocytes	28.6		.	.	21 - 51	%
				Monocytes	5.1		.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	253000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	96		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 3/ACUTE PHASE-WEEK 1	7	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEC		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	25.6	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	266000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	12DEC96	1	18DEC96	7	7
00332	Oral	2	100 MG	19DEC96	8	25DEC96	14	7
00332	Oral	3	150 MG	26DEC96	15	01JAN97	21	7
00332	Oral	4	200 MG	02JAN97	22	08JAN97	28	7
00332	Oral	5	250 MG	09JAN97	29	15JAN97	35	7
00332	Oral	6	300 MG	16JAN97	36	22JAN97	42	7
00332	Oral	6	300 MG	23JAN97	43	29JAN97	49	7
00332	Oral	6	300 MG	30JAN97	50	05FEB97	56	7
	Oral	5	250 MG	06FEB97	57	21FEB97	72	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	72	250	Lack of Efficacy	

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE - AFTER GYM CLASS OR EXERCISE	5, .	30 Mins	50	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	23, .	4 Days	200	CON	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS IN GYM CLASS X1	9, .	5 Mins	100	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	05DEC96	-7,	.	0	104	70	58	100	68	64	119.00	67.0
BL	12DEC96	1,	.	0	100	70	60	110	70	60	118.70	
1	19DEC96	8,	.	100	120	82	60	112	80	64	120.00	
2	26DEC96	15,	.	150	104	70	68	100	64	72	123.00	
3	02JAN97	22,	.	200	108	68	78	100	60	80	120.70	
4	09JAN97	29,	.	250	100	70	76	100	68	78	121.00	
5	16JAN97	36,	.	300	110	80	76	100	70	76	122.70	
6	23JAN97	43,	.	300	120	80	68	112	80	72	123.70	
7	30JAN97	50,	.	300	112	80	80	110	70	88	123.50	
8	06FEB97	57,	.	250	118	84	80	112	80	84	122.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	UNSATISFACTO	U	.	U	22 - 180	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEC		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.5	.	.	.	41 - 50	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	1	Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.6	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	8.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	46.4	.	.	.	40 - 75	%
				Lymphocytes	37.4	.	.	.	16 - 46	%
				Monocytes	7.3	.	.	.	0 - 12	%
				Eosinophils	8.1	H	.	.	0 - 7	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	183	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	23JAN97	1	30JAN97	8	8
00333	Oral	2	20 MG	31JAN97	9	05FEB97	14	6
00333	Oral	3	20 MG	06FEB97	15	12FEB97	21	7
00333	Oral	4	20 MG	13FEB97	22	19FEB97	28	7
00333	Oral	4	20 MG	20FEB97	29	24FEB97	33	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	33	20	Lack of Efficacy	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
TONSILLECTOMY AND ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1990

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Loperamide Hydrochloride	Imodium-Ad	30,	.	21FEB97	21FEB97	1 TBSP	DIARRHEA
CENTRAL NERVOUS SYSTEM	Caffeine	Vivarin	14,	.	05FEB97	05FEB97	1 TAB	SLEEPINESS
	Paracetamol	Tylenol	2,	.	24JAN97	24JAN97	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	23,	.	14FEB97	16FEB97	800 MG	HEADACHE
			33,	.	24FEB97	24FEB97	400 MG	HEADACHE
RESPIRATORY	Fexofenadine Hydrochloride	Allegra	-236,	.	01JUN96	.		ENVIRONMENTAL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2,	.	03:20 Hrs	20	CON	MIL	NO	UNR	Yes	No
			4,	.	02:30 Hrs	20	CON	MIL	NO	UNR	No	No
			22,	.	8 Days	20	7	MOD	NO	PSR	Yes	No
			33,	.	03:00 Hrs	20	CON	MOD	NO	PBU	Yes	No
Digestive System	Diarrhea	DIARRHEA	30,	.	08:00 Hrs	20	CON	SEV	NO	UNR	Yes	No
Nervous System	Abnormal Dreams	VIVID DREAMS	19,	.	11 Days	20	10	MOD	NO	PSR	No	No
	Emotional Lability	SUICIDAL IDEATION	37,	.	103 Days	20	CON	SEV	NO	UNR	No	Yes
	Somnolence	SLEEPINESS	10,	.	7 Days	20	CON	SEV	NO	PSR	Yes	No
			30,	.	Not Stated	20	CON	SEV	NO	PSR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	20,	.	3 Days	20	5	MIL	NO	PBU	No	No
	Rhinitis	"STUFFY" NOSE	1,	.	Not Stated	20	CON	MOD	NO	UNR	No	No
Skin and Appendages	Rash	BLOTCHES (RED) ON LEGS	19,	.	3 Days	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	15JAN97	-8,	.	0	122	70	82	124	78	86	123.00	64.0
BL	23JAN97	1,	.	0	126	60	80	128	80	88	123.40	
1	31JAN97	9,	.	20	118	70	74	120	74	76	123.70	
2	06FEB97	15,	.	20	132	74	60	128	70	64	125.20	
3	13FEB97	22,	.	20	124	74	88	118	70	100	124.00	
4	20FEB97	29,	.	20	124	70	80	120	70	80	124.70	
5	26FEB97	35,	.	20	120	80	68	120	80	74	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	384000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	31JAN97	1	05FEB97	6	6
00334	Oral	2	0 MG	06FEB97	7	12FEB97	13	7
00334	Oral	3	0 MG	13FEB97	14	20FEB97	21	8
00334	Oral	4	0 MG	21FEB97	22	25FEB97	26	5
00334	Oral	4	0 MG	26FEB97	27	06MAR97	35	9
00334	Oral	5	0 MG	07MAR97	36	13MAR97	42	7
00334	Oral	5	0 MG	14MAR97	43	21MAR97	50	8
00334	Oral	5	0 MG	22MAR97	51	27MAR97	56	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	56	0		LACK OF STUDY MEDICATION AVAILABLE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ABNORMAL LAB VALUES URINALYSIS +3 OCCULT BLOOD/RED	HEMATURIA	GENITOURINARY SYST DIS	CUR	1997
ABNORMAL LAB VALUES URINALYSIS MODERATE BACTERIA/CLOUDY	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	CUR	1997
REPAIR OF LEFT FOOT - BONE REALIGNMENT	OPERATION, BONE/JOINT	OPERATIONS	CUR	1997
BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	7, .	06FEB97	16FEB97	750 MG	SORE THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-50, .	12DEC96	19DEC96#	1 GM	POST-OP FOOT SURGERY
			32, .	03MAR97	03MAR97	500 MG	HEADACHE
			41, .	12MAR97	12MAR97	500 MG	HEADACHE
			48, .	19MAR97	20MAR97	1000 MG	FEVER
MUSCULO-SKELETAL	Ibuprofen	Advil	48, .	19MAR97	20MAR97	800 MG	BACKACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK ACHE	48, .	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
		BACKACHE	21, .	04:00 Hrs	0	CON	MOD	NO	UNR	No	No
	Fever	FEVER - 102 DEGREES[FEVER]	48, .	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	32, .	02:30 Hrs	0	CON	MIL	NO	PBU	Yes	No
			41, .	05:00 Hrs	0	CON	SEV	NO	PBU	Yes	No
Digestive System	Gastrointestinal Disorder	FOOD POISONING	47, .	3 Days	0	CON	SEV	NO	UNR	No	No
	Tooth Disorder	{TOOTH DISORDER}	-2, .	01:00 Hrs	0	CON	SEV	NO	UNR	No	No
Respiratory System	Pharyngitis	SORE THROAT	4, .	8 Days	0	CON	MOD	NO	UNR	Yes	No
Urogenital System	Albuminuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS POSITIVE PROTEIN]	56, .	1 Days	0	CON	MOD	NO	UNR	No	No
	Pyuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS MODERATE BACTERIA]	56, .	1 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JAN97	-7,	.	0	112	70	72	100	70	76	174.00	63.0
BL	29JAN97	-2,	.	0	112	78	84	110	70	88	173.00	
1	06FEB97	7,	.	0	120	80	88	118	80	96	172.50	
2	13FEB97	14,	.	0	112	70	80	114	80	84	173.00	
3	21FEB97	22,	.	0	118	70	78	112	70	80	175.50	
4	26FEB97	27,	.	0	112	70	64	100	60	68	170.00	
5	06MAR97	35,	.	0	118	80	80	104	80	80	171.00	
6	13MAR97	42,	.	0	98	60	80	98	60	80	173.00	
7	21MAR97	50,	.	0	114	70	76	90	60	80	167.50	
8	27MAR97	56,	.	0	98	70	72	90	60	76	167.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	45.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	201000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	16.1	H	.	.	12 - 15.6	G/DL
				Hematocrit	48.2	H	.	.	35 - 46	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7	.	.	.	30 - 70	%
				Lymphocytes	30.9	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	6		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28FEB97	1	06MAR97	7	7
00335	Oral	2	100 MG	07MAR97	8	13MAR97	14	7
00335	Oral	3	150 MG	14MAR97	15	20MAR97	21	7
00335	Oral	4	200 MG	21MAR97	22	26MAR97	27	6
00335	Oral	5	250 MG	27MAR97	28	02APR97	34	7
00335	Oral	4	200 MG	03APR97	35	09APR97	41	7
00335	Oral	4	200 MG	10APR97	42	16APR97	48	7
00335	Oral	4	200 MG	17APR97	49	24APR97	56	8
	Oral	3	150 MG	25APR97	57	06MAY97	68	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	68	150	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1997

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-21, .	07FEB97	08FEB97#	500 MC	MENSTRUAL CRAMPS
			-1, .	27FEB97	27FEB97#	500 MG	HEADACHE
			43, .	11APR97	11APR97	500 MG	HEADACHE
			54, .	22APR97	22APR97	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-20, .	08FEB97	09FEB97#	400 MG	MENSTRUAL CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	-1, .	03:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			11, .	03:30 Hrs	100	CON	MIL	NO	UNR	No	No
			18, .	4 Days	150	6	MOD	NO	UNR	No	No
			22, .	6 Days	200	5	MOD	NO	UNR	No	No
			31, .	4 Days	250	3	MOD	NO	UNR	No	No
			43, .	04:00 Hrs	200	CON	SEV	NO	PBU	Yes	No
			54, .	03:30 Hrs	200	CON	MOD	NO	PBU	Yes	No
Carciovascular System	Electrocardiogram Abnormal	EKG CHANGE	35, .	1 Days	200	CON	MOD	DCR	REL	No	No
Digestive System	Diarrhea	UPSET STOMACH WITH DIARRHEA	11, .	2 Days	100	CON	SEV	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	9, .	Not Stated	100	CON	MOD	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	2, .	4 Days	50	CON	MIL	NO	REL	No	No
			6, .	01:00 Hrs	50	CON	SEV	NO	REL	No	No
	Tremor	HAND TREMORS	2, .	4 Days	50	CON	MIL	NO	REL	No	No
			6, .	12:00 Hrs	50	CON	SEV	NO	REL	No	No
			7, .	14 Days	50	CON	MOD	NO	REL	No	No
			33, .	5 Days	250	CON	MOD	NO	REL	No	No
			38, .	4 Days	200	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20FEB97	-8,	.	0	100	70	60	100	70	64	111.50	65.0
BL	28FEB97	1,	.	0	100	70	64	100	68	68	111.50	
1	07MAR97	8,	.	100	104	78	76	104	70	76	110.50	
2	14MAR97	15,	.	150	108	70	92	90	60	84	113.50	
3	21MAR97	22,	.	200	110	72	72	94	60	74	109.50	
4	27MAR97	28,	.	250	98	70	96	80	60	96	110.70	
5	03APR97	35,	.	200	110	80	104	100	70	88	113.20	
6	10APR97	42,	.	200	112	76	76	90	60	76	112.70	
7	17APR97	49,	.	200	110	80	100	100	70	88	113.00	
8	24APR97	56,	.	200	114	70	80	90	60	80	113.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.3	.	.	.	30 - 70	%
				Lymphocytes	36.8	.	.	.	21 - 51	%
				Monocytes	3.5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	359000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	32.3	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	04MAR97	1	11MAR97	8	8
00336	Oral	2	20 MG	12MAR97	9	18MAR97	15	7
00336	Oral	3	20 MG	19MAR97	16	24MAR97	21	6
00336	Oral	4	20 MG	25MAR97	22	01APR97	29	8
00336	Oral	4	20 MG	02APR97	30	08APR97	36	7
00336	Oral	4	20 MG	09APR97	37	15APR97	43	7
00336	Oral	4	20 MG	16APR97	44	22APR97	50	7
00336	Oral	4	20 MG	23APR97	51	30APR97	58	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	58	20		MEETS CRITERIA FOR ENTRANCE INTO CONTINUATION PHASE BUT NO MEDS ARE AVAILABLE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACKACHE	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1997

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin Extra-Strength	32, .	04APR97	09APR97	2 GM	SORE THROAT WITH COUGH
			38, .	10APR97	12APR97	2 GM	STUFFY NOSE, COUGH
			48, .	20APR97	23APR97	2 GM	BACKACHE
	Caffeine	Excedrin Extra-Strength	32, .	04APR97	09APR97	2 GM	SORE THROAT WITH COUGH
			38, .	10APR97	12APR97	2 GM	STUFFY NOSE, COUGH
			48, .	20APR97	23APR97	2 GM	BACKACHE
	Paracetamol	Excedrin Extra-Strength	32, .	04APR97	09APR97	2 GM	SORE THROAT WITH COUGH
			38, .	10APR97	12APR97	2 GM	STUFFY NOSE, COUGH
			48, .	20APR97	23APR97	2 GM	BACKACHE
		Tylenol	-12, .	20FEB97	21FEB97#	500 MG	BACKACHE
RESPIRATORY	Brompheniramine Maleate	Dimetapp	-18, .	14FEB97	16FEB97#	2	COLD SX
	Phenylephrine Hydrochloride	Dimetapp	-18, .	14FEB97	16FEB97#	2	COLD SX
	Phenylpropanolamine Hydrochloride	Dimetapp	-18, .	14FEB97	16FEB97#	2	COLD SX

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	25, .	2 Days	20	CON	MIL	NO	UNR	No	No
			48, .	4 Days	20	CON	MIL	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	6, .	39 Days	20	CON	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	7, .	13 Days	20	2	MIL	NO	REL	No	No
		GIDDINESS	11, .	4 Days	20	4	MIL	NO	PSR	No	No
			24, .	3 Days	20	CON	MIL	NO	PSR	No	No
	Myoclonus	LEG TWITCHES	47, .	4 Days	20	4	MIL	NO	PSR	No	No
		LEG TWITCHES (NIGHTLY)	26, .	5 Days	20	4	SEV	NO	PSR	No	No
			30, .	8 Days	20	7	MIL	NO	PSR	No	No
	Tremor	HAND TREMORS	5, .	4 Days	20	CON	MOD	NO	REL	No	No
			10, .	7 Days	20	CON	MIL	NO	REL	No	No
			32, .	13 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	32, .	6 Days	20	CON	MOD	NO	UNR	Yes	No
			38, .	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	32, .	6 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	STUFFY NOSE	38, .	3 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26FEB97	-6,	.	0	114	74	64	100	70	68	119.00	65.0
BL	04MAR97	1,	.	0	100	70	64	90	60	68	119.70	
1	12MAR97	9,	.	20	100	70	68	98	60	68	118.70	
2	19MAR97	16,	.	20	104	70	60	90	60	64	116.50	
3	25MAR97	22,	.	20	88	64	68	80	60	72	120.50	
4	02APR97	30,	.	20	82	60	78	80	60	78	121.00	
5	09APR97	37,	.	20	80	60	84	88	60	88	124.00	
6	16APR97	44,	.	20	100	60	68	90	60	72	122.50	
7	23APR97	51,	.	20	110	70	78	90	60	80	123.00	
8	30APR97	58,	.	20	100	70	72	90	60	76	121.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	7.9	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.5	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Lymphocytes	46.4	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEC			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28JAN95	1	02FEB95	6	6
00037	Oral	2	0 MG	03FEB95	7	12FEB95	16	10
00037	Oral	3	0 MG	13FEB95	17	21FEB95	25	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	25	0	Protocol violation, including non-compliance	LOST INTEREST,PATIENT HAS REFUSED FOLLOW-UP SAFETY EVALUATION AND ASSISTANCE WITH REFERRAL

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Doxycycline	Doxycycline	10, .	06FEB95	13FEB95	UNKNOWN	BRONCHITIS
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Ovcon 35	-119, .	01OCT94	.	1 TAB	BIRTH CONTROL
	Norethisterone	Ovcon 35	-119, .	01OCT94	.	1 TAB	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	10, .	Not Stated	0	CON	MOD	NO	REL	No	No
Digestive System	Nausea	NAUSEA	19, .	Not Stated	0	CON	MIL	NO	REL	No	No
Nervous System	Insomnia	INSOMNIA	10, .	Not Stated	0	CON	MOD	NO	REL	No	No
Respiratory System	Bronchitis	BRONCHITIS	10, .	8 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20JAN95	-8,	.	0	135	68	82	.	.	.	144.43	65.0
BL	27JAN95	-1,	.	0	128	70	88	132	70	92	144.43	
1	03FEB95	7,	.	0	125	78	85	.	.	.	144.43	
2	13FEB95	17,	.	0	120	76	84	120	70	72	142.22	
4	22FEB95	26,	.	0	110	80	72	130	70	78	142.22	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7	.	.	.	30 - 70	%
				Lymphocytes	26.1	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	360000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	56	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	15FEB95	1	21FEB95	7	7
00038	Oral	2	20 MG	22FEB95	8	02MAR95	16	9
00038	Oral	3	20 MG	03MAR95	17	07MAR95	21	5
00038	Oral	4	20 MG	08MAR95	22	15MAR95	29	8
00038	Oral	4	20 MG	16MAR95	30	22MAR95	36	7
00038	Oral	4	20 MG	23MAR95	37	29MAR95	43	7
00038	Oral	4	20 MG	30MAR95	44	04APR95	49	6
00038	Oral	4	20 MG	05APR95	50	12APR95	57	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	57	20	Adverse event, including intercurrent illness	SEVERAL PERSONAL CRISIS LED PATIENT TO OVERDOSE ON SEVERAL MEDICATIONS INCLUDING STUDY MEDICATIONS ON 12APR95-MOVE TO WITHDRAW.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CARDIOVASCULAR	Benzocaine	Benzocaine	-410, .	01JAN94	.	9 TABLETS	DIETING
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Fiorinal	57, .	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
	Butalbital	Fiorinal	57, .	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
	Caffeine	Fiorinal	57, .	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
	Paracetamol	Tylenol	57, .	12APR95	12APR95	1300MG	ATTEMPTED SUICIDE
	Phenacetin	Fiorinal	57, .	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
	Tranquilizer	Tranquilizer {Nos}	17, .	03MAR95	03MAR95	UNKNOWN	DENTAL PROCEDURE
DERMATOLOGICALS	Benzocaine	Benzocaine	-410, .	01JAN94	.	9 TABLETS	DIETING
MUSCULO-SKELETAL	Ibuprofen	Advil	57, .	12APR95	12APR95	4600MG	ATTEMPTED SUICIDE
		Ibuprofen	57, .	12APR95	12APR95	4800MG	ATTEMPTED SUICIDE
			57, .	12APR95	12APR95	13800MG	ATTEMPTED SUICIDE
RESPIRATORY	Benzocaine	Benzocaine	-410, .	01JAN94	.	9 TABLETS	DIETING
	Salbutamol	Albuterol	-1871, .	01JAN90	.	1PUFF	ASTHMA
			-1871, .	01JAN90	.	1PUFF	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN-APPROXIMATELY 3 OCCASIONS-INTENSE JAB THEN REMITS	41, .	3 Days	20	3	SEV	NO	PSR	No	No
	Headache	HEADACHE	57, .	3 Days	20	CON	MOD	STP	UNR	No	No
Digestive System	Constipation	CONSTIPATION	57, .	3 Days	20	CON	MOD	STP	UNR	No	No
Musculoskeletal System	Myalgia	MUSCLE ACHE	57, .	3 Days	20	CON	MOD	STP	UNR	No	No
	Myasthenia	MUSCLE WEAKNESS	57, .	3 Days	20	CON	MOD	STP	UNR	No	No
Nervous System	Dizziness	DIZZINESS	57, .	3 Days	20	CON	MOD	STP	UNR	No	No
	Emotional Lability	ATTEMPTED SUICIDE {INTENTIONAL}	57, .	1 Days	20	1	SEV	STP	UNR	No	Yes
	Hostility	ANGRY{PATIENT NOTICED}	29, .	8 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Sinusitis	COLD-SINUS SYMPTOMS	8, .	10 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01FEB95	-14,	.	0	108	60	64	103	61	72	171.00	67.0
BL	08FEB95	-7,	.	0	90	60	80	90	60	80	171.00	
1	22FEB95	8,	.	20	110	80	68	128	68	72	164.49	
2	03MAR95	17,	.	20	100	70	.	110	80	.	166.92	
3	08MAR95	22,	.	20	90	60	60	100	60	80		
4	15MAR95	29,	.	20	100	60	60	100	70	80	161.00	
5	22MAR95	36,	.	20	90	70	60	100	60	100		
6	29MAR95	43,	.	20	110	70	80	120	70	.	168.68	
7	05APR95	50,	.	20	100	80	60	108	68	80	166.48	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	286000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick		2	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria		4	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08FEB95	1	13FEB95	6	6
00039	Oral	2	20 MG	14FEB95	7	21FEB95	14	8
00039	Oral	3	20 MG	22FEB95	15	01MAR95	22	8
00039	Oral	4	20 MG	02MAR95	23	07MAR95	28	6
00039	Oral	4	20 MG	08MAR95	29	17MAR95	38	10
00039	Oral	4	20 MG	18MAR95	39	23MAR95	44	6
00039	Oral	5	30 MG	24MAR95	45	28MAR95	49	5
00039	Oral	5	30 MG	29MAR95	50	09APR95	61	12
00057	Oral	5	30 MG	10APR95	62	30APR95	82	21
00039	Oral	4	20 MG	01MAY95	83	05MAY95	87	5
00039	Oral	3	20 MG	06MAY95	88	07MAY95	89	2
00039	Oral	2	20 MG	08MAY95	90	08MAY95	90	1
00039	Oral	1	20 MG	09MAY95	91	10MAY95	92	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	92	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES-FREQUENT	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-1134,-1195	01JAN92	.	PRN-600MG	HEADACHES
	Naproxen Sodium	Anaprox	76, 15	24APR95	28APR95	275MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	VERY TIRED	43, -19	7 Days	20	CON	SEV	NO	PSR	No	No
	Headache	HEADACHES-MORE SEVERE THAN USUAL	76, 15	5 Days	30	3	SEV	NO	PBU	Yes	No
	Trauma	SUPERFICIAL SCRATCHES	18, -44	12 Days	20	CON	MIL	NO	PBU	No	No
Nervous System	Depression	MORE DEPRESSED	43, -19	7 Days	20	CON	SEV	NO	PSR	No	No
	Myoclonus	GRIMACING FACE WITH BLINKING EYES {TIC}	43, -19	7 Days	20	CON	MIL	NO	PSR	No	No
	Nervousness	IRRITABLE MOOD	43, -19	7 Days	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	03FEB95	-5, -66	0	100	60	68	107	66	88	142.22	64.6
BL	10FEB95	3, -59	20	116	70	71	108	70	66	142.22	
1	13FEB95	6, -56	20	100	60	60	103	66	60	143.33	
2	22FEB95	15, -47	20	98	68	70	100	72	80	143.33	
3	01MAR95	22, -40	20	90	60	60	90	60	66	138.92	
4	08MAR95	29, -33	20	110	70	68	102	70	80		
5	17MAR95	38, -24	20	100	60	84	110	60	80	135.61	
6	22MAR95	43, -19	20	88	58	70	85	62	90		
7	29MAR95	50, -12	30	98	78	80	98	70	90	136.71	
8	05APR95	57, -5	30	100	60	70	96	60	100	136.71	
12	01MAY95	83, 22	20	108	78	80	90	60	80	143.33	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	234000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7		.	.	12 - 15.6	G/DL
				Hematocrit	36		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.3	H	.	.	30 - 70	%
				Lymphocytes	13.2	L	.	.	21 - 51	%
				Monocytes	5.5		.	.	0 - 10	%
				Eosinophils	2.8		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	200000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	16FEB95	1	22FEB95	7	7
00040	Oral	2	100 MG	23FEB95	8	28FEB95	13	6
00040	Oral	1	50 MG	01MAR95	14	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	No	No	14	50	Adverse event, including intercurrent illness	FATIGUE,EYE DILATION,MEDICATION REACTION

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1985
OVARIAN CYST	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Loestrin	-63,	15DEC94	.	120	OVARIAN CYST
			-63,	15DEC94	.	120	OVARIAN CYST
	Norethisterone Acetate	Loestrin	-63,	15DEC94	.	120	OVARIAN CYST
			-63,	15DEC94	.	120	OVARIAN CYST
MUSCULO-SKELETAL	Baclofen	Baclofen	-3698,	01JAN85	.	1TAB PRN	ASTHMA
RESPIRATORY	Beclometasone Dipropionate	Vancenase	-3698,	01JAN85	.	1TAB PRN	ALLERGIES
			-3698,	01JAN85	.	1TAB PRN	ALLERGIES
	Salbutamol	Ventolin	-3698,	01JAN85	.	1TAB PRN	ALLERGIES
			-3698,	01JAN85	.	1TAB PRN	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	7, .	8 Days	50	CON	SEV	STP	REL	No	No
Carciovascular System	Tachycardia	ELEVATED HEART RATE	14, .	14 Days	50	CON	MOD	STP	REL	No	No
Digestive System	Constipation	CONSTIPATION	7, .	8 Days	50	CON	MOD	STP	REL	No	No
	Dyspepsia	INDIGESTION	7, .	8 Days	50	CON	MOD	STP	PSR	No	No
Nervous System	Dizziness	DIZZINESS	7, .	8 Days	50	CON	MOD	STP	REL	No	No
	Nervousness	IRRITABLE MOOD	7, .	8 Days	50	CON	MOD	STP	REL	No	No
Special Senses	Mydriasis	EYE DILATION	7, .	8 Days	50	CON	MOD	STP	REL	No	No
Urogenital System	Urinary Retention	URINARY RETENTION	7, .	8 Days	50	CON	MOD	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	10FEB95	-6,	.	0	113	72	72	110	70	72	102.75	63.4
BL	15FEB95	-1,	.	0	118	70	72	110	70	84	102.75	
1	22FEB95	7,	.	50	110	80	88	106	76	90	102.97	
2	01MAR95	14,	.	50	90	60	132 H	90	60	140 H	103.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.6	.	.	.	40 - 75	%
				Lymphocytes	34	.	.	.	16 - 46	%
				Monocytes	6.7	.	.	.	0 - 12	%
				Eosinophils	1.4	.	.	.	0 - 7	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	310000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	48	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	EGYPTIAN

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05APR95	1	09APR95	5	5
00041	Oral	2	100 MG	10APR95	6	18APR95	14	9
00041	Oral	3	150 MG	19APR95	15	23APR95	19	5
00041	Oral	4	200 MG	24APR95	20	30APR95	26	7
00041	Oral	4	200 MG	01MAY95	27	07MAY95	33	7
00041	Oral	4	200 MG	08MAY95	34	14MAY95	40	7
00041	Oral	4	200 MG	15MAY95	41	23MAY95	49	9
00041	Oral	5	250 MG	24MAY95	50	02JUN95	59	10
00041	Oral	6	300 MG	03JUN95	60	07JUN95	64	5
00059	Oral	6	300 MG	08JUN95	65	04JUL95	91	27
00059	Oral	6	300 MG	05JUL95	92	30JUL95	117	26
00059	Oral	6	300 MG	31JUL95	118	23AUG95	141	24
00059	Oral	6	300 MG	24AUG95	142	20SEP95	169	28
00059	Oral	6	300 MG	21SEP95	170	23OCT95	202	33
00059	Oral	6	300 MG	24OCT95	203	20NOV95	230	28
00041	Oral	5	250 MG	21NOV95	231	22NOV95	232	2
00041	Oral	4	200 MG	23NOV95	233	24NOV95	234	2
00041	Oral	3	150 MG	25NOV95	235	26NOV95	236	2
00041	Oral	2	100 MG	27NOV95	237	29NOV95	239	3
00041	Oral	1	50 MG	30NOV95	240	05DEC95	245	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	Yes	Yes	245	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
RIGHTWARD AXIS ON ELECTROCARDIOGRAM	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
BLOOD/BLOOD FORM ORGANS	Cyanocobalamin	Vitamin B12	-63, -127	01FEB95	05APR95	500MG	VITAMIN SUPPLEMENT
MUSCULO-SKELETAL	Ibuprofen	Advil	12, -53	16APR95	18APR95	600MG	SORE THROAT
		Nuprin	141, 77	23AUG95	23AUG95	TABLETSX2	HEADACHE
RESPIRATORY	Cough Cold Preparations Nos	Osco Brand Cold And Flu Medication {Nos}	12, -53	16APR95	18APR95	2TABS	SORE THROAT
	Dextromethorphan Hydrobromide	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
	Guaifenesin	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
	Paracetamol	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
	Pseudoephedrine Hydrochloride	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
VARIOUS	Nutritional Supplement Nos	Met-Rx {Nutritional Supplement}	134, 70	16AUG95	23AUG95	1PACKET	HEALTH MAINTENANCE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	141, 77	1 Days	300	1	SEV	NO	PBU	Yes	No
Cardiovascular System	Syncope	LIGHTHEADED FAINT SYNCOPE	18, -47	1 Mins	150	1	MIL	NO	PSR	No	No
Digestive System	Vomiting	EMESIS	140, 76	1 Days	300	2	MIL	NO	UNR	No	No
Nervous System	Insomnia	INSOMNIA	134, 70	8 Days	300	6	MOD	NO	UNR	No	No
	Nervousness	IRRITABLE MOOD	12, -53	3 Days	100	1	MOD	NO	UNR	No	No
Respiratory System	Pharyngitis	SORE THROAT	12, -53	3 Days	100	1	MOD	NO	PBU	Yes	No
	Respiratory Disorder	COLD SYMPTOMS	140, 76	3 Days	300	CON	MOD	NO	UNR	Yes	No
Urogenital System	Nocturia	NOCTURIA	50, -15	8 Days	250	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22MAR95	-14, -78	0	100	75	65	100	78	68	151.48	71.3
BL	05APR95	1, -64	0	98	68	60	98	68	66	151.50	
1	10APR95	6, -59	100	98	55	60	100	58	80	151.50	
2	19APR95	15, -50	150	110	65	70	100	80	90	156.50	
3	24APR95	20, -45	200	120	70	88	116	70	100	152.00	
4	01MAY95	27, -38	200	110	65	80	100	80	100	154.00	
5	08MAY95	34, -31	200	110	75	78	90	75	90	154.00	
6	15MAY95	41, -24	200	108	70	78	90	75	95	154.50	
7	24MAY95	50, -15	250	110	80	90	100	70	102	154.00	
8	31MAY95	57, -8	250	108	85	85	100	80	109	160.50	
12	05JUL95	92, 28	300	102	78	78	92	78	120	162.00	
16	31JUL95	118, 54	300	110	70	80	108	80	72	166.00 H	
20	24AUG95	142, 78	300	110	70	100	92	78	100	167.00 H	
24	21SEP95	170, 106	300	114	80	72	90	78	114	167.00 H	
28	24OCT95	203, 139	300	118	80	85	100	80	90	170.00 H	
32	21NOV95	231, 167	250	115	90	90	112	90	96	172.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	40 - 75	%
				Lymphocytes	37.5	.	.	.	16 - 46	%
				Monocytes	7.3	.	.	.	0 - 12	%
				Eosinophils	3.3	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	98	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	53	.	.	.	40 - 75	%
				Lymphocytes	35.5	.	.	.	16 - 46	%
				Monocytes	8	.	.	.	0 - 12	%
				Eosinophils	3.1	.	.	.	0 - 7	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	98	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	39	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	92	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	44.4	.	.	.	40 - 75	%
				Lymphocytes	28.2	.	.	.	16 - 46	%
				Monocytes	12	.	.	.	0 - 12	%
				Eosinophils	14.4	H	.	+	0 - 7	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	201000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	107	.	.	.	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 13/CONTINUATION-WEEK 20	142	Aspartate Aminotransferase	26		.	.	0 - 41	U/L
				Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	48	L	.	.	70 - 115	MG/DL
				Globulin	3		.	.	2.3 - 4.1	G/DL
		VISIT 15/CONTINUATION-WEEK 28	203	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	231	Hemoglobin	14.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.4		.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.8		.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	58.1		.	.	40 - 75	%
				Lymphocytes	31.3		.	.	16 - 46	%
				Monocytes	7.6		.	.	0 - 12	%
				Eosinophils	2.5		.	.	0 - 7	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	252000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3		.	.	27 - 33	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 16/CONTINUATION-WEEK 32	231	Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	07DEC95	1	12DEC95	6	6
00042	Oral	2	0 MG	13DEC95	7	19DEC95	13	7
00042	Oral	3	0 MG	20DEC95	14	26DEC95	20	7
00042	Oral	4	0 MG	27DEC95	21	02JAN96	27	7
00042	Oral	4	0 MG	03JAN96	28	09JAN96	34	7
00042	Oral	5	0 MG	10JAN96	35	16JAN96	41	7
00042	Oral	5	0 MG	17JAN96	42	22JAN96	47	6
00042	Oral	6	0 MG	23JAN96	48	01FEB96	57	10
00111	Oral	6	0 MG	02FEB96	58	28FEB96	84	27
00111	Oral	6	0 MG	29FEB96	85	25MAR96	110	26
00111	Oral	6	0 MG	26MAR96	111	22APR96	138	28
00111	Oral	6	0 MG	23APR96	139	20MAY96	166	28
00111	Oral	6	0 MC	21MAY96	167	17JUN96	194	28
00111	Oral	6	0 MG	18JUN96	195	16JUL96	223	29
00042	Oral	5	0 MG	17JUL96	224	18JUL96	225	2
00042	Oral	4	0 MG	19JUL96	226	20JUL96	227	2
00042	Oral	3	0 MG	21JUL96	228	22JUL96	229	2
00042	Oral	2	0 MG	23JUL96	230	25JUL96	232	3
00042	Oral	1	0 MG	26JUL96	233	31JUL96	238	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	Yes	Yes	238	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ECG-SINUS ARRHYTHMIA(MILD)	ARRHYTHMIA	CIRCULATORY SYST	CUR	1995
OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1990

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	32, -26	07JAN96	07JAN96	2/3C.	STOMACH UPSET
CENTRAL NERVOUS SYSTEM	Paracetamol	Acetaminophen	140, 83	24APR96	24APR96	200 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	108, 51	23MAR96	23MAR96	600 MG	HEADACHE
			209, 152	02JUL96	02JUL96	400 MG	ORTHODONTAL/DENTAL PAIN
			210, 153	03JUL96	03JUL96	800 MG	DENTAL PAIN
			211, 154	04JUL96	04JUL96	200 MG	DENTAL PAIN
			212, 155	05JUL96	05JUL96	600 MG	DENTAL PAIN
			213, 156	06JUL96	06JUL96	400 MG	DENTAL PAIN
			216, 159	09JUL96	09JUL96	200 MG	HEADACHE
			218, 161	11JUL96	11JUL96	200 MG	HEADACHE
			220, 163	13JUL96	13JUL96	200 MG	HEADACHE
	Naproxen Sodium	Aleve	211, 154	04JUL96	04JUL96	220 MG	DENTAL PAIN

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	108, 51	30 Mins	0	1	MOD	NO	PBU	Yes	No
			140, 83	01:30 Hrs	0	1	MOD	NO	PBU	Yes	No
			216, 159	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			218, 161	06:00 Hrs	0	1	SEV	NO	UNR	Yes	No
			220, 163	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
		HEADACHES	22, -36	6 Days	0	7	MIL	NO	UNR	No	No
Carciovascular System	Palpitation	HEART PALPITATION {ONE TIME ONLY}	164, 107	1 Mins	0	1	MIL	NO	PBU	No	No
Digestive System	Dyspepsia	INDIGESTION(MEXICAN SPICY FOOD)	25, -33	3 Days	0	3	MOD	NO	UNR	No	No
		UPSET STOMACH	32, -26	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	32, -26	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	Tooth Disorder	ORTHODONTIC PAIN	209, 152	5 Days	0	CON	SEV	NO	UNR	Yes	No
	Vomiting	EMESIS	32, -26	1 Mins	0	1	MOD	NO	UNR	No	No
Musculoskeletal System	Myalgia	MUSCLE ACHE	32, -26	34:00 Hrs	0	1	MIL	NO	UNR	No	No
Respiratory System	Sinusitis	SINUS HEADACHE	32, -26	5 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01DEC95	-6, -63	0	120	90	84	120	90	96	226.01	65.4
BL	06DEC95	-1, -58	0	123	90	90	125	95	90		
1	13DEC95	7, -51	0	120	80	96	120	85	120	233.00	
2	20DEC95	14, -44	0	125	90	90	125	85	120	234.00	
3	27DEC95	21, -37	0	125	85	80	120	80	110	235.00	
4	03JAN96	28, -30	0	120	90	70	120	95	90	233.30	
5	10JAN96	35, -23	0	120	90	78	120	90	78	237.40	
6	17JAN96	42, -16	0	120	90	68	118	80	76	235.50	
7	23JAN96	48, -10	0	120	90	65	120	94	80	235.00	
8	02FEB96	58, 1	0	120	94	80	120	94	78	236.00	
12	29FEB96	85, 28	0	120	90	78	118	90	90	236.50	
16	26MAR96	111, 54	0	125	95	74	125	95	82	240.00	
20	23APR96	139, 82	0	120	90	80	120	90	80	238.00	
24	21MAY96	167, 110	0	120	85	62	120	85	60	242.00 H	
28	18JUN96	195, 138	0	120	90	70	120	90	80	250.00 H	
32	16JUL96	223, 166	0	125	85	74	120	80	90	248.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	16.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.8	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	40 - 75	%
				Lymphocytes	26.8	.	.	.	16 - 46	%
				Monocytes	8.7	.	.	.	0 - 12	%
				Eosinophils	2	.	.	.	0 - 7	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	46	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 2/ELIGIBILITY	-1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	50.8	.	.	.	40 - 75	%
				Lymphocytes	33.3	.	.	.	16 - 46	%
				Monocytes	13.2	H	.	.	0 - 12	%
				Eosinophils	1.7	.	.	.	0 - 7	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	113	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	38	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	139	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.7	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	10.9	H	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	63.1	.	.	.	40 - 75	%
				Lymphocytes	26.2	.	.	.	16 - 46	%
				Monocytes	7.6	.	.	.	0 - 12	%
				Eosinophils	2.3	.	.	.	0 - 7	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	116	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	35	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 13/CONTINUATION-WEEK 20	139	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	223	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.8	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	45.7	.	.	.	40 - 75	%
				Lymphocytes	35.3	.	.	.	16 - 46	%
				Monocytes	10.7	.	.	.	0 - 12	%
				Eosinophils	7.8	H	.	.	0 - 7	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103	L	.	.	110 - 15	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 16/CONTINUATION-WEEK 32	223	Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	46	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	24MAY96	1	27MAY96	4	4
00259	Oral	2	0 MG	28MAY96	5	05JUN96	13	9
00259	Oral	3	0 MG	06JUN96	14	12JUN96	20	7
00259	Oral	4	0 MG	13JUN96	21	19JUN96	27	7
00259	Oral	5	0 MG	20JUN96	28	27JUN96	35	8
00259	Oral	6	0 MG	28JUN96	36	05JUL96	43	8
00259	Oral	6	0 MG	06JUL96	44	10JUL96	48	5
00259	Oral	6	0 MG	11JUL96	49	17JUL96	55	7
	Oral	6	0 MG	18JUL96	56	02AUG96	71	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	71	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FACIAL ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
FATIGUE	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
NORMAL SINUS RHYTHM WITH SHORT PR ON EKG	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
LOW THYROID FUNCTION	HYPOTHYROIDISM	ENDOCR/METAB/IMMUNITY DISORD	PRV	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Minocycline	Minocin	-540, .	01DEC94	.	50MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22APR96	-32, .	0	125	75	66	120	75	66	136.00	67.0
BL	22MAY96	-2, .	0	120	70	78	110	70	110	132.00	
1	30MAY96	7, .	0	110	70	66	118	84	78	131.00	
2	06JUN96	14, .	0	125	70	78	120	75	68	132.00	
3	13JUN96	21, .	0	120	70	60	113	70	94	130.00	
4	20JUN96	28, .	0	110	70	72	110	75	80	128.50	
5	27JUN96	35, .	0	115	75	60	115	70	76	128.50	
6	03JUL96	41, .	0	120	80	66	115	80	70	128.00	
7	10JUL96	48, .	0	120	70	68	115	70	90	128.50	
8	17JUL96	55, .	0	115	70	60	118	70	60	130.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-32	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	11.2	H	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	280000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	120	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-32	Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-28	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	14.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	249000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	99	.	.	.	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18JUL96	1	26JUL96	9	9
00260	Oral	2	20 MG	27JUL96	10	31JUL96	14	5
00260	Oral	3	20 MG	01AUG96	15	06AUG96	20	6
00260	Oral	4	20 MG	07AUG96	21	13AUG96	27	7
00260	Oral	5	30 MG	14AUG96	28	20AUG96	34	7
00260	Oral	5	30 MG	21AUG96	35	27AUG96	41	7
00260	Oral	5	30 MG	28AUG96	42	03SEP96	48	7
00260	Oral	5	30 MG	04SEP96	49	13SEP96	58	10
00172	Oral	5	30 MG	14SEP96	59	08OCT96	83	25
00172	Oral	5	30 MG	09OCT96	84	08NOV96	114	31
00172	Oral	5	30 MG	09NOV96	115	04DEC96	140	26
00260	Oral	4	20 MG	05DEC96	141	08DEC96	144	4
00260	Oral	3	20 MG	09DEC96	145	11DEC96	147	3
00260	Oral	2	20 MG	12DEC96	148	13DEC96	149	2
00260	Oral	1	20 MG	14DEC96	150	18DEC96	154	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	154	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Tetracycline	Tetracycline	-6, -64	12JUL96	.	1000MG	ACNE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	56, -3	11SEP96	11SEP96	2 TABS	HEADACHE
		Excedrin	-2390,-2448	01JAN90	.	2 TABS	OCCASIONAL HEADACHES
			6, -53	23JUL96	16SEP96	2 TABS: PRN	HEADACHE
			8, -51	25JUL96	25JUL96	4 TABS	TOOTHACHE PAIN
			20, -39	06AUG96	06AUG96	2 TABS	TOOTHACHE
			83, 25	08OCT96	08OCT96	2 TAB	HEADACHE
	Caffeine	Excedrin	-2390,-2448	01JAN90	.	2 TABS	OCCASIONAL HEADACHES
			6, -53	23JUL96	16SEP96	2 TABS: PRN	HEADACHE
			8, -51	25JUL96	25JUL96	4 TABS	TOOTHACHE PAIN
			20, -39	06AUG96	06AUG96	2 TABS	TOOTHACHE
			83, 25	08OCT96	08OCT96	2 TAB	HEADACHE
	Paracetamol	Excedrin	-2390,-2448	01JAN90	.	2 TABS	OCCASIONAL HEADACHES
			6, -53	23JUL96	16SEP96	2 TABS: PRN	HEADACHE
			8, -51	25JUL96	25JUL96	4 TABS	TOOTHACHE PAIN
			20, -39	06AUG96	06AUG96	2 TABS	TOOTHACHE
			83, 25	08OCT96	08OCT96	2 TAB	HEADACHE
DERMATOLOGICALS	Tetracycline	Tetracycline	-6, -64	12JUL96	.	1000MG	ACNE
MUSCULO-SKELETAL	Ibuprofen	Advil	53, -6	08SEP96	08SEP96	2 TABS	HEADACHE
RESPIRATORY	Chlorphenamine Maleate	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
	Dextromethorphan Hydrobromide	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
	Paracetamol	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
	Phenylpropanolamine Hydrochloride	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
SENSORY ORGANS	Tetracycline	Tetracycline	-6, -64	12JUL96	.	1000MG	ACNE
			-6, -64	12JUL96	.	1000MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	6, -53	45 Mins	20	1	MIL	NO	UNR	Yes	No
			7, -52	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No
			10, -49	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			11, -48	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			12, -47	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			13, -46	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			25, -34	45 Mins	20	1	MIL	NO	PBU	Yes	No
			34, -25	30 Mins	30	1	MIL	NO	PBU	Yes	No
			40, -19	40 Mins	30	1	MOD	NO	PBU	Yes	No
			47, -12	30 Mins	30	1	MIL	NO	PBU	Yes	No
			51, -8	45 Mins	30	1	MOD	NO	PBU	Yes	No
			53, -6	45 Mins	30	1	SEV	NO	PBU	Yes	No
			56, -3	30 Mins	30	1	MOD	NO	PBU	Yes	No
			61, 3	02:00 Hrs	30	1	SEV	NO	PBU	Yes	No
			83, 25	01:00 Hrs	30	1	MIL	NO	PBU	Yes	No
			111, 53	01:00 Hrs	30	1	MIL	NO	PBU	No	No
Digestive System	Esophagitis	BURNING ACHE IN UPPER ESOPHAGUS REGION	19, -40	5 Mins	20	3	MOD	NO	PSR	No	No
		BURNING ACHE IN UPPER ESOPHAGUS REGION-BRIEF	21, -38	45 Mins	20	1	MOD	NO	PSR	No	No
	Tooth Disorder	TOOTHACHE	20, -39	30 Mins	20	1	SEV	NO	UNR	Yes	No
		TOOTHACHE PAIN	8, -51	09:00 Hrs	20	1	MOD	NO	UNR	Yes	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	83, 25	08:00 Hrs	30	1	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12JUL96	-6, -64	0	115	70	62	113	75	78	140.00	67.0
BL	18JUL96	1, -58	0	115	80	68	110	70	74	140.00	
1	26JUL96	9, -50	20	113	80	80	113	78	90	138.00	
2	01AUG96	15, -44	20	113	75	84	115	80	90	136.50	
3	07AUG96	21, -38	20	113	78	78	113	80	84	137.00	
4	14AUG96	28, -31	30	100	70	78	100	80	102	133.00	
5	21AUG96	35, -24	30	100	80	72	100	75	94	133.50	
6	28AUG96	42, -17	30	100	70	70	100	80	80	133.50	
7	04SEP96	49, -10	30	110	70	78	105	70	72	135.00	
8	18SEP96	63, 5	30	100	70	72	115	70	80	137.00	
12	09OCT96	84, 26	30	100	80	78	98	70	102	133.00	
16	06NOV96	112, 54	30	100	75	66	100	75	78	134.00	
20	05DEC96	141, 83	20	115	80	66	100	70	80	140.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.2	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	70	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 6/ACUTE PHASE-WEEK 4	28	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13		.	.	12 - 15.6	G/DL
				Hematocrit	42.5		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	81.8	H	.	.	30 - 70	%
				Lymphocytes	9.8	L	.	.	21 - 51	%
				Monocytes	0.4		.	.	0 - 10	%
				Eosinophils	8	H	.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	103000	L	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	99		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	1.2		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72		.	.	22 - 130	U/L
				Aspartate Aminotransferase	13		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 11/UNSCHEDULED LAB 1	98	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	40 - 75	%
				Lymphocytes	38.3	.	.	.	16 - 46	%
				Monocytes	3.3	.	.	.	0 - 12	%
				Eosinophils	3.3	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/UNSCHEDULED LAB 1	98	Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
		VISIT 12/CONTINUATION-WEEK 16	112	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEC		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	40 - 75	%
				Lymphocytes	28.4	.	.	.	16 - 46	%
				Monocytes	3.6	.	.	.	0 - 12	%
				Eosinophils	6.5	.	.	.	0 - 7	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	141	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	LATINO - MEXICO

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	26NOV96	1	02DEC96	7	7
00261	Oral	2	20 MG	03DEC96	8	09DEC96	14	7
00261	Oral	3	20 MG	10DEC96	15	16DEC96	21	7
00261	Oral	4	20 MG	17DEC96	22	23DEC96	28	7
00261	Oral	5	30 MG	24DEC96	29	01JAN97	37	9
00261	Oral	5	30 MG	02JAN97	38	08JAN97	44	7
00261	Oral	5	30 MG	09JAN97	45	14JAN97	50	6
00261	Oral	5	30 MG	15JAN97	51	22JAN97	58	8
00187	Oral	5	30 MG	23JAN97	59	19FEB97	86	28
00187	Oral	5	30 MG	20FEB97	87	02APR97	128	42
00261	Oral	5	30 MG	02APR97	128	03APR97	129	2
00261	Oral	4	20 MG	04APR97	130	05APR97	131	2
00261	Oral	3	20 MG	06APR97	132	07APR97	133	2
00261	Oral	2	20 MG	08APR97	134	10APR97	136	3
00261	Oral	1	20 MG	11APR97	137	29APR97	155	19

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	155	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA {VERY MILD}	ASTHMA	RESPIRATORY SYST DIS	CUR	1984
DYSHYDROSIS {MILD ON HAND AND PENIS}	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
TINEA PEDIS {BOTH FEET}	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	58, -1	22JAN97	22JAN97	2 TABS	HEADACHE
RESPIRATORY	Salbutamol	Proventil	-4713,-4771	01JAN84	01JAN96#	PRN	ASTHMA
			-4713,-4771	01JAN84	01JAN96#	PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	58, -1	01:00 Hrs	30	1	MOD	NO	PBU	Yes	No
	Infection	SCABIES ON BOTH ARMS	85, 27	44 Days	30	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07NOV96	-19, -77	0	100	60	72	98	60	72	172.50	66.0
BL	22NOV96	-4, -62	0	113	70	70	113	80	74	171.00	
1	03DEC96	8, -51	20	113	70	60	113	75	80	172.00	
2	10DEC96	15, -44	20	115	70	72	116	80	66	173.50	
3	17DEC96	22, -37	20	117	75	72	117	80	72	172.50	
4	24DEC96	29, -30	30	160	80	70	160	80	72	173.00	
5	02JAN97	38, -21	30	118	80	66	118	80	78	174.00	
6	09JAN97	45, -14	30	120	80	72	120	80	78	178.00	
7	15JAN97	51, -8	30	120	85	66	120	85	72	178.00	
8	23JAN97	59, 1	30	115	75	66	112	80	72	178.50	
12	20FEB97	87, 29	30	116	75	66	116	80	70	178.00	
20	02APR97	128, 70	30	113	80	72	113	80	80	180.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-4	Hemoglobin	14.1		.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.1		.	.	30 - 70	%
				Lymphocytes	24.8		.	.	21 - 51	%
				Monocytes	7.9		.	.	0 - 10	%
				Eosinophils	6.8	H	.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	278000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	79		.	.	22 - 180	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	20		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	82		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-4	Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.2		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.7		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.3		.	.	30 - 70	%
				Lymphocytes	26		.	.	21 - 51	%
				Monocytes	8.1		.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	263000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	89		.	.	22 - 180	U/L
				Aspartate Aminotransferase	31		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Alanine Aminotransferase	74	H	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	08MAY95	1	17MAY95	10	10
00139	Oral	2	100 MG	18MAY95	11	25MAY95	18	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	No	No	18	100	Adverse event, including intercurrent illness	CHEST PAIN-RESOLVED ON FOLLOW-UP ASSOCIATED WITH SHORTNESS OF BREATH

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FRACTURED RIGHT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Bc Powder	-9, .	29APR95	01MAY95#	1PACK PRN	FRACTURED RIGHT ARM
	Caffeine	Bc Powder	-9, .	29APR95	01MAY95#	1PACK PRN	FRACTURED RIGHT ARM
	Paracetamol	Tylenol	-9, .	29APR95	01MAY95#	325MG PRN	FRACTURED RIGHT ARM
	Salicylamide	Bc Powder	-9, .	29APR95	01MAY95#	1PACK PRN	FRACTURED RIGHT ARM
MUSCULO-SKELETAL	Ibuprofen	Advil	-9, .	29APR95	01MAY95#	200MG PRN	FRACTURED RIGHT ARM

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN	10, .	8 Days	50	4	MOD	STP	PSR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	10, .	8 Days	50	CON	MIL	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04MAY95	-4, .	0	96	60	72	94	64	76	78.00	56.5
BL	05MAY95	-3, .	0	96	60	77	94	64	76	78.00	
1	18MAY95	11, .	100	102	68	72	98	70	76	75.00	
2	25MAY95	18, .	100	102	68	80	98	70	84	76.00	
6	19JUN95	43, .#	0	102	62	64	100	64	76	78.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.1	.	.	.	30 - 70	%
				Lymphocytes	45.9	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	270	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	63	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-3		Urine Squamous Epithelial Cells	3	.	.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	43	(25)	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.8	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	49.7	.	.	.	30 - 70	%
					Lymphocytes	39.7	.	.	.	21 - 51	%
					Monocytes	7.1	.	.	.	0 - 10	%
					Eosinophils	2.7	.	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	296000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
					Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	227	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 5/ACUTE PHASE-WEEK 3	43	(25)	Aspartate Aminotransferase	16	. . .	0 - 41	U/L
					Alanine Aminotransferase	8	. . .	0 - 39	U/L
					Total Bilirubin	0.4	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.3	. . .	5.7 - 8.2	G/DL
					Albumin	4.2	. . .	3.1 - 5.3	G/DL
					Glucose - Random	86	. . .	60 - 110	MG/DL
					Globulin	3.1	. . .	2.1 - 3.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
11	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	15SEP95	1	20SEP95	6	6
00140	Oral	2	20 MG	21SEP95	7	27SEP95	13	7
00140	Oral	3	20 MG	28SEP95	14	04OCT95	20	7
00140	Oral	4	20 MG	05OCT95	21	11OCT95	27	7
00140	Oral	4	20 MG	12OCT95	28	17OCT95	33	6
00140	Oral	4	20 MG	18OCT95	34	25OCT95	41	8
00140	Oral	4	20 MG	26OCT95	42	01NOV95	48	7
00140	Oral	4	20 MG	02NOV95	49	08NOV95	55	7
00005	Oral	4	20 MG	09NOV95	56	21NOV95	68	13
00140	Oral	4	20 MG	22NOV95	69	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	11	Yes	No	69	20	Other reason	PATIENT WENT TO LIVE WITH HIS FATHER.HIS FATHER IS OPPOSED TO MEDICATION TREATMENT FOR DEPRESSION,FATHER WITHDREW CONSENT.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
VESICULAR DYSHIDROSIS	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Triamcinolone	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-622, -677	01JAN94	.	325MG PRN	HEADACHE
DERMATOLOGICALS	Clotrimazole	Clotrimazole	39, -17	23OCT95	24OCT95	ONCE DAILY	RINGWORM
	Griseofulvin	Gris-Peg	41, -15	25OCT95	03NOV95	250MG	RINGWORM
	Triamcinolone	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
GU SYSTEM/SEX HORMONES	Clotrimazole	Clotrimazole	39, -17	23OCT95	24OCT95	ONCE DAILY	RINGWORM
SENSORY ORGANS	Triamcinolone	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
SYSTEMIC HORMONAL	Triamcinolone	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Skin and Appendages	Fungal Dermatitis	RINGWORM	29, -27	21 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07SEP95	-8, -63	0	104	60	64	102	64	68	74.00	54.0
BL	14SEP95	-1, -56	0	110	60	72	104	62	76	74.00	
1	21SEP95	7, -49	20	100	62	60	98	64	68	72.00	
2	28SEP95	14, -42	20	96	60	60	92	62	68	71.00	
3	05OCT95	21, -35	20	110	60	64	106	62	68	72.00	
4	12OCT95	28, -28	20	104	70	68	102	72	72	72.00	
5	18OCT95	34, -22	20	110	70	64	108	72	68	73.00	
6	26OCT95	42, -14	20	100	60	64	98	62	68	70.00	
7	02NOV95	49, -7	20	102	58	64	100	62	68	72.00	
8	09NOV95	56, 1	20	104	72	64	100	74	73	73.00	
12	22NOV95	69, 14	20	104	68	78	98	66	72	74.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4 - 5.2	10^12/L
				White Blood Cell Count	8.6	.	.	.	4.5 - 13.5	10^9/L
				Segmented Neutrophils	48.9	.	.	.	30 - 60	%
				Lymphocytes	36.1	.	.	.	25 - 55	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	222000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 33	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	226	.	.	.	44 - 330	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	60 - 110	MG/DL
				Globulin	2.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.7	L	.	-	41 - 50	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.3		.	.	30 - 70	%
				Lymphocytes	33.2		.	.	21 - 51	%
				Monocytes	6.6		.	.	0 - 10	%
				Eosinophils	6.7	H	.	.	0 - 5	%
				Basophils	1.1		.	.	0 - 2	%
				Platelets	246000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	18		.	.	8 - 21	MG/DL
				Creatinine	0.9		.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.7		.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	175		.	.	44 - 400	U/L
				Aspartate Aminotransferase	27		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 39	U/L
				Total Bilirubin	0.4		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.2		.	.	5.7 - 8.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 10/ACUTE PHASE-WEEK 8	56		Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	122	H	.	.	60 - 110	MG/DL
					Globulin	2.1	.	.	.	2.1 - 3.8	G/DL
		VISIT 11/CONTINUATION-WEEK 12	69	(1)	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	38.3	L	.	.	41 - 50	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	11.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	63.9	.	.	.	30 - 70	%
					Lymphocytes	24	.	.	.	21 - 51	%
					Monocytes	7.1	.	.	.	0 - 10	%
					Eosinophils	3.9	.	.	.	0 - 5	%
					Basophils	1.2	.	.	.	0 - 2	%
					Platelets	249000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 11/CONTINUATION-WEEK 12	69	(1)	Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
					Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21SEP95	1	27SEP95	7	7
00141	Oral	2	0 MG	28SEP95	8	04OCT95	14	7
00141	Oral	3	0 MG	05OCT95	15	12OCT95	22	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	No	No	22	0	Adverse event, including intercurrent illness	PHYSICIAN DISCRETION DUE TO COMPARATOR ARM,VIS-A-VIS AE OF CHEST PAIN.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANGINA	ANGINA PECTORIS	CIRCULATORY SYST	CUR	1995
INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
EUSTACHIAN TUBE PLACEMENT	OPERATION, EAR	OPERATIONS	PRV	1982
HYPERTENSION	HYPERTENSION	CIRCULATORY SYST	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-23, .	29AUG95	30AUG95#	25MG	SLEEP ONSET INSOMNIA
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-23, .	29AUG95	30AUG95#	25MG	SLEEP ONSET INSOMNIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Angina Pectoris	ANGINA ON EXERTION	-8, .	30 Days	0	2	MOD	STP	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14SEP95	-7, .	0	128	78	76	124	80	80	181.00	66.0
BL	21SEP95	1, .	0	128	78	81	126	80	87	183.00	
1	28SEP95	8, .	0	128	70	80	122	76	84	184.00	
2	05OCT95	15, .	0	128	78	72	126	80	68	184.00	
3	12OCT95	22, .	0	126	82	80	122	84	76	185.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	403000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	333	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18OCT95	1	25OCT95	8	8
00142	Oral	2	20 MG	26OCT95	9	01NOV95	15	7
00142	Oral	3	20 MG	02NOV95	16	08NOV95	22	7
00142	Oral	4	20 MG	09NOV95	23	15NOV95	29	7
00142	Oral	5	30 MG	16NOV95	30	21NOV95	35	6
00142	Oral	5	30 MG	22NOV95	36	29NOV95	43	8
00142	Oral	6	40 MG	30NOV95	44	04DEC95	48	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	48	40	Lack of Efficacy	MOTHER WANTS PATIENT TO BE WITHDRAWN BECAUSE HIS DEPRESSION HAS NOT IMPROVED AT MAXIMUM DOSAGE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MILD LYMPHADENOPATHY,LEFT ANTERIOR CERVICAL,PERSISTENT	LYMPHADENOPATHY	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1985
CAT SCRATCH FEVER	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993
INGUINAL HERNIA	HERNIA, ABDOMINAL	DIGESTIVE SYST	PRV	1983
SORE THROAT	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	-14, .	04OCT95	13OCT95#	500MG	SORE THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-3942, .	01JAN85	.	500MG PRN	HEADACHE
RESPIRATORY	Chlorphenamine Maleate	Dristan	44, .	30NOV95	30NOV95	2TABS	NASAL CONGESTION
	Paracetamol	Dristan	44, .	30NOV95	30NOV95	2TABS	NASAL CONGESTION
	Phenylephrine Hydrochloride	Dristan	44, .	30NOV95	30NOV95	2TABS	NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU	45, .	8 Days	40	1	MOD	NO	UNR	Yes	No
Respiratory System	Rhinitis	NASAL CONGESTION	44, .	1 Days	40	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12OCT95	-6,	.	0	124	80	68	120	82	76	212.00	68.0
BL	18OCT95	1,	.	0	124	82	72	120	84	68	213.00	
1	26OCT95	9,	.	20	130	78	68	128	80	72	214.00	
2	02NOV95	16,	.	20	122	84	72	120	88	68	212.00	
3	09NOV95	23,	.	20	124	74	68	118	82	72	211.00	
4	16NOV95	30,	.	30	130	70	80	128	74	72	212.00	
5	22NOV95	36,	.	30	123	78	88	114	79	110	210.00	
6	30NOV95	44,	.	40	140	74	80	132	76	64	214.00	
8	21DEC95	65,	.#	0	128	82	88	132	88	88	214.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1				13.8 - 17.2	G/DL
				Hematocrit	44				41 - 50	%
				Red Blood Cell Count	5.2				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7				4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.9				30 - 70	%
				Lymphocytes	41.6				21 - 51	%
				Monocytes	9.3				0 - 10	%
				Eosinophils	2.9				0 - 5	%
				Basophils	0.4				0 - 2	%
				Platelets	247000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4				25 - 35	PG
				Mean Corpuscle Volume	85				80 - 100	FL
				Blood Urea Nitrogen	11				7 - 25	MG/DL
				Creatinine	0.9				0.8 - 1.5	MG/DL
				Uric Acid	5.5				4 - 8	MG/DL
				Alkaline Phosphatase	179				44 - 400	U/L
				Aspartate Aminotransferase	20				0 - 41	U/L
				Alanine Aminotransferase	28				0 - 48	U/L
				Total Bilirubin	0.7				0.3 - 1.3	MG/DL
				Total Protein	6.8				6.2 - 8.8	G/DL
				Albumin	4.2				3.1 - 5.3	G/DL
				Glucose - Random	123	H			70 - 115	MG/DL
				Globulin	2.6				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	NEG					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6		Urine Amphetamines	NEG	. . .		
					Urine Barbiturates	NEG	. . .		
					Urine Benzodiazepines	NEG	. . .		
					Urine Cannabinoids	NEG	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Opiates	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 9/ACUTE PHASE-WEEK 7	65	(17)	Hemoglobin	15.5	. . .	13.8 - 17.2	G/DL
					Hematocrit	43.6	. . .	41 - 50	%
					Red Blood Cell Count	5.2	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.7	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	46	. . .	30 - 70	%
					Lymphocytes	45	. . .	21 - 51	%
					Monocytes	4	. . .	0 - 10	%
					Eosinophils	3	. . .	0 - 5	%
					Basophils	2	. . .	0 - 2	%
					Platelets	239000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.9	. . .	25 - 35	PG
					Mean Corpuscle Volume	84	. . .	80 - 100	FL
					Blood Urea Nitrogen	9	. . .	7 - 25	MG/DL
					Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
					Uric Acid	4.7	. . .	4 - 8	MG/DL
					Alkaline Phosphatase	159	. . .	44 - 400	U/L
					Aspartate Aminotransferase	20	. . .	0 - 41	U/L
					Alanine Aminotransferase	35	. . .	0 - 48	U/L
					Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.4	. . .	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 9/ACUTE PHASE-WEEK 7	65	(17)	Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	97	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	09NOV95	1	15NOV95	7	7
00143	Oral	2	100 MG	16NOV95	8	21NOV95	13	6
	Oral	2	100 MG	22NOV95	14	01DEC95	23	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	23	100	Adverse event, including intercurrent illness	ACNE

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1995
MILD OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1994
STATUS POST HOSPITALIZATION FOR DEPRESSION	DEPRESSION	MENTAL DISORD	PRV	1994
URINARY TRACT INFECTION	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-1, .	08NOV95	09NOV95	1000MG	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Skin and Appendages	Acne	ACNE	7, .	Not Stated	50	CON	MOD	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26OCT95	-14, .	0	120	72	72	118	76	74	212.00	63.0
BL	09NOV95	1, .	0	120	72	72	116	74	68	215.00	
1	16NOV95	8, .	100	120	70	76	118	74	80	212.00	
2	22NOV95	14, .	100	125	78	84	112	72	120	211.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.2	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	14	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.3	.	.	.	35 - 46	%
				White Blood Cell Count	10	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 4/ACUTE PHASE-WEEK 2	14	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	07DEC95	1	13DEC95	7	7
00144	Oral	2	0 MG	14DEC95	8	20DEC95	14	7
00144	Oral	3	0 MG	21DEC95	15	27DEC95	21	7
00144	Oral	4	0 MG	28DEC95	22	04JAN96	29	8
00144	Oral	4	0 MG	05JAN96	30	10JAN96	35	6
00144	Oral	5	0 MG	11JAN96	36	17JAN96	42	7
00144	Oral	5	0 MG	18JAN96	43	24JAN96	49	7
00144	Oral	5	0 MG	25JAN96	50	31JAN96	56	7
00115	Oral	5	0 MG	01FEB96	57	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	57	0	Lost to follow-up	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	39, -18	14JAN96	15JAN96	1,500MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	39, -18	2 Days	0	1	MIL	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	30NOV95	-7, -63	0	132	52	76	122	70	56	155.00	60.0
BL	07DEC95	1, -56	0	120	70	72	110	70	80	158.00	
1	14DEC95	8, -49	0	110	70	68	92	72	88	160.00	
2	21DEC95	15, -42	0	136	64	76	112	56	88	162.00	
3	28DEC95	22, -35	0	124	72	76	104	74	88	159.00	
4	04JAN96	29, -28	0	128	70	80	124	76	76	160.00	
5	11JAN96	36, -21	0	120	74	80	118	78	78	165.00	
6	18JAN96	43, -14	0	126	70	68	120	74	72	168.00	
7	25JAN96	50, -7	0	128	82	72	126	84	80	165.00	
8	01FEB96	57, 1	0	118	80	76	120	82	72	166.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.3	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	179	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3	. . .		
					Urine Amphetamines	NEG	. . .		
					Urine Barbiturates	NEG	. . .		
					Urine Benzodiazepines	NEG	. . .		
					Urine Cannabinoids	NEG	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Opiates	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	12.8	. . .	12 - 15.6	G/DL
					Hematocrit	37.7	. . .	35 - 46	%
					Red Blood Cell Count	4.4	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.9	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	56.1	. . .	30 - 70	%
					Lymphocytes	32.2	. . .	21 - 51	%
					Monocytes	7.5	. . .	0 - 10	%
					Eosinophils	2.2	. . .	0 - 5	%
					Basophils	2	. . .	0 - 2	%
					Platelets	301000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.1	. . .	25 - 35	PG
					Mean Corpuscle Volume	85	. . .	80 - 100	FL
					Blood Urea Nitrogen	15	. . .	8 - 21	MG/DL
					Creatinine	0.6	. . .	0.4 - 1.1	MG/DL
					Uric Acid	3.2	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	169	. . .	44 - 280	U/L
					Aspartate Aminotransferase	12	. . .	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11JAN96	1	17JAN96	7	7
00145	Oral	2	20 MG	18JAN96	8	24JAN96	14	7
00145	Oral	3	20 MG	25JAN96	15	31JAN96	21	7
	Oral	4	20 MG	01FEB96	22	07FEB96	28	7
00348	Oral	5	30 MG	08FEB96	29	11FEB96	32	4
00348	Oral	5	30 MG	12FEB96	33	20FEB96	41	9
00348	Oral	5	30 MG	21FEB96	42	25FEB96	46	5
00348	Oral	6	40 MG	26FEB96	47	06MAR96	56	10
00190	Oral	6	40 MG	07MAR96	57	03APR96	84	28
00190	Oral	6	40 MG	04APR96	85	01MAY96	112	28
00190	Oral	5	30 MG	02MAY96	113	13MAY96	124	12
00190	Oral	4	20 MG	14MAY96	125	29MAY96	140	16
00190	Oral	4	20 MG	30MAY96	141	26JUN96	168	28
00190	Oral	4	20 MG	27JUN96	169	24JUL96	196	28
00190	Oral	4	20 MG	25JUL96	197	22AUG96	225	29
00348	Oral	3	20 MG	23AUG96	226	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	Yes	226	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ELEVATED MONOCYTES	MONOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
LOW WHITE BLOOD CELL COUNT	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
BROKEN LEFT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1991

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Extra Strength Excedrin	111, 55	30APR96	13MAY96	1 TAB	HEADACHE
	Caffeine	Extra Strength Excedrin	111, 55	30APR96	13MAY96	1 TAB	HEADACHE
	Paracetamol	Extra Strength Excedrin	111, 55	30APR96	13MAY96	1 TAB	HEADACHE
		Extra Strength Tylenol	125, 69	14MAY96	15MAY96	1,000 MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	22, -35	01FEB96	01FEB96	1TSP.	NASAL CONGESTION
RESPIRATORY	Cough Cold Preparations Nos	Ggg-Cold {Cold Preparation Nos}	224, 168	21AUG96	23AUG96	6 TSP	COLD SYMPTOMS
	Diphenhydramine Hydrochloride	Benadryl	22, -35	01FEB96	01FEB96	1TSP.	NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	111, 55	16 Days	40	CON	SEV	DCR	PSR	Yes	No
Carciovascular System	Hypertension	HYPERTENSION	125, 69	17 Days	20	CON	MOD	DCR	PSR	No	No
Hemic and Lymphatic System	Thrombocytopenia	THROMBOCYTOPENIA	141, 85	29 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Hyperkinesia	AKATHISIA	113, 57	29 Days	30	CON	MOD	DCR	REL	No	No
Respiratory System	Respiratory Disorder	FEVER, COLD SYMPTOMS, SORE THROAT	224, 168	3 Days	20	CON	MIL	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	22, -35	2 Days	20	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04JAN96	-7, -63	0	110	60	68	108	64	72	107.00	62.0
BL	11JAN96	1, -56	0	110	68	76	108	70	80	106.00	
1	18JAN96	8, -49	20	118	70	76	116	74	80	106.00	
2	25JAN96	15, -42	20	118	64	72	116	68	64	106.00	
3	01FEB96	22, -35	20	118	76	80	112	78	84	108.00	
4	08FEB96	29, -28	30	112	68	76	110	72	88	107.00	
5	12FEB96	33, -24	30	118	68	72	114	70	80	108.00	
6	21FEB96	42, -15	30	114	68	80	112	70	72	107.00	
7	26FEB96	47, -10	40	112	64	72	110	66	64	106.00	
8	07MAR96	57, 1	40	120	60	80	118	66	72	107.00	
12	04APR96	85, 29	40	114	74	64	110	76	72	106.00	
16	02MAY96	113, 57	30	118	84	68	114	86	74	110.00	
20	30MAY96	141, 85	20	118	70	68	116	74	76	112.00	
24	27JUN96	169, 113	20	98	58	88	100	74	88	110.00	
28	25JUL96	197, 141	20	110	62	58	104	66	58	113.00	
32	23AUG96	226, 170	20	118	68	72	108	60	68	111.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.5	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	22.5	.	.	.	21 - 51	%
				Monocytes	16.5	H	.	+	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	115	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.4	L	.	-	41 - 50	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9		.	.	30 - 70	%
				Lymphocytes	28.7		.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	1.1		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	280000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	82		.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	1	Urine Protein - Dipstick	NEG		.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	15	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.1		.	.	30 - 70	%
				Lymphocytes	42.1		.	.	21 - 51	%
				Monocytes	9.1		.	.	0 - 10	%
				Eosinophils	3.3		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	244000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1.2		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111		.	.	22 - 180	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	47	.	.	.	21 - 51	%
				Monocytes	1	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	107000	L	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	141		Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	98	.	.	.	70 - 115	MG/DL
					Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	169		Platelets	235000	.	.	.	130000 - 400000	PER CUMM
		VISIT 16/CONTINUATION-WEEK 32	226	(1)	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	41.9	.	.	.	41 - 50	%
					Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	48.5	.	.	.	30 - 70	%
					Lymphocytes	37.3	.	.	.	21 - 51	%
					Monocytes	9.3	.	.	.	0 - 10	%
					Eosinophils	4	.	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	239000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 16/CONTINUATION-WEEK 32	226	(1)	Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.5	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	106	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	59	H	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	93	.	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Protein - Dipstick	NEC		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	25JAN96	1	31JAN96	7	7
00347	Oral	2	100 MG	01FEB96	8	04FEB96	11	4
00347	Oral	3	150 MG	05FEB96	12	11FEB96	18	7
00347	Oral	4	200 MG	12FEB96	19	18FEB96	25	7
00347	Oral	5	250 MG	19FEB96	26	25FEB96	32	7
00347	Oral	5	250 MG	26FEB96	33	03MAR96	39	7
00347	Oral	5	250 MG	04MAR96	40	10MAR96	46	7
00347	Oral	4	200 MG	11MAR96	47	17MAR96	53	7
00188	Oral	4	200 MG	18MAR96	54	14APR96	81	28
00188	Oral	5	250 MG	15APR96	82	24APR96	91	10
00188	Oral	4	200 MG	25APR96	92	12MAY96	109	18
00188	Oral	4	200 MG	13MAY96	110	05JUN96	133	24
00188	Oral	4	200 MG	06JUN96	134	07JUL96	165	32
00188	Oral	4	200 MG	08JUL96	166	04AUG96	193	28
00188	Oral	4	200 MG	05AUG96	194	08SEP96	228	35
00347	Oral	4	200 MG	09SEP96	229	09SEP96	229	1
00347	Oral	3	150 MG	10SEP96	230	11SEP96	231	2
00347	Oral	2	100 MG	12SEP96	232	14SEP96	234	3
00347	Oral	1	50 MG	15SEP96	235	21SEP96	241	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	Yes	241	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
JOINT PAIN{RIGHT WRIST}	PAIN, JOINT	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
SWELLING{LEFT CALF}	SWELLING, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	58, 5	22MAR96	22MAR96	2 TABS	UPSET STOMACH
			162, 109	04JUL96	04JUL96	2 TABS	DIARRHEA
CENTRAL NERVOUS SYSTEM	Cyclobenzaprine	Cyclobenzaprine	7, -47	31JAN96	31JAN96	10MG	MUSCLE SORENESS
			238, 185	18SEP96	18SEP96	1 TAB	LEFT KNEE MUSCLE SPASMS
	Paracetamol	Tylenol	-15, -68	10JAN96	10JAN96#	1,000MG	MENSTRUAL CRAMP
			-8, -61	17JAN96	17JAN96#	500MG	WRIST PAIN(RIGHT)
		Tylenol Gelcaps	-754, -807	01JAN94	.	750MG PRN	OCCASIONAL HEADACHE
			172, 119	14JUL96	14JUL96	1,000 MG	ANXIETY
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-24, -77	01JAN96	.	50MG PRN	SEASONAL ALLERGIES
MUSCULO-SKELETAL	Cyclobenzaprine	Cyclobenzaprine	7, -47	31JAN96	31JAN96	10MG	MUSCLE SORENESS
			238, 185	18SEP96	18SEP96	1 TAB	LEFT KNEE MUSCLE SPASMS
RESPIRATORY	Brompheniramine Maleate	Dimetapp	220, 167	31AUG96	01SEP96	1 TAB	NASAL ALLERGIES
	Cough Cold Preparations Nos	Flu Relief {Nos}	12, -42	05FEB96	06FEB96	15TABS	PROPHYLACTIC - FEVER
	Dexbrompheniramine Maleate	Drixoral	-16, -69	09JAN96	09JAN96#	2TABS	COLD
	Diphenhydramine Hydrochloride	Benadryl	-24, -77	01JAN96	.	50MG PRN	SEASONAL ALLERGIES
	Phenylephrine Hydrochloride	Dimetapp	220, 167	31AUG96	01SEP96	1 TAB	NASAL ALLERGIES
	Phenylpropanolamine Hydrochloride	Dimetapp	220, 167	31AUG96	01SEP96	1 TAB	NASAL ALLERGIES
	Pseudoephedrine Hydrochloride	Efidac	222, 169	02SEP96	06SEP96	1 TAB	NASAL ALLERGIES
		Efidac/24	178, 125	20JUL96	22JUL96	1 TAB	COLD
	Pseudoephedrine Sulfate	Drixoral	-16, -69	09JAN96	09JAN96#	2TABS	COLD
VARIOUS	Allergenic Extract, Nos	Homeopathic Allergy Medicine	222, 169	02SEP96	07SEP96	3 TABS	NASAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Diarrhea	DIARRHEA	162, 109	02:00 Hrs	200	CON	MOD	NO	UNR	Yes	No
	Dyspepsia	UPSET STOMACH	58, 5	04:00 Hrs	200	CON	MOD	NO	PBU	Yes	No
Musculoskeletal System	Myalgia	LEFT KNEE MUSCLE SPASMS	238, 185	06:00 Hrs	50	CON	MIL	NO	UNR	Yes	No
Nervous System	Anxiety	ANXIETY	172, 119	04:00 Hrs	200	CON	MIL	NO	UNR	Yes	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS	178, 125	3 Days	200	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JAN96	-7, -60	0	130	80	88	128	86	96	228.00	63.0
BL	25JAN96	1, -53	0	130	80	88	128	84	80	226.00	
1	01FEB96	8, -46	100	138	84	88	136	88	96	227.00	
2	05FEB96	12, -42	150	138	86	72	132	88	88	234.00	
3	12FEB96	19, -35	200	130	84	76	128	88	68	231.00	
4	19FEB96	26, -28	250	126	84	72	126	88	80	231.00	
5	26FEB96	33, -21	250	128	82	76	130	86	84	232.00	
6	04MAR96	40, -14	250	124	82	88	122	86	96	232.00	
7	11MAR96	47, -7	200	128	86	84	126	90	96	234.00	
8	18MAR96	54, 1	200	128	86	88	126	88	96	231.00	
12	15APR96	82, 29	250	120	82	72	124	86	88	235.00	
16	13MAY96	110, 57	200	128	88	88	124	92	96	234.00	
20	06JUN96	134, 81	200	130	86	98	132	90	100	232.00	
24	08JUL96	166, 113	200	116	84	104	124	92	96	234.00	
28	05AUG96	194, 141	200	140	92	100	138	88	92	237.00	
32	09SEP96	229, 176	200	126	98	106	128	99	126 H	235.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.4		.	.	12 - 15.6	G/DL
				Hematocrit	36.6		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5		.	.	30 - 70	%
				Lymphocytes	25.7		.	.	21 - 51	%
				Monocytes	6.8		.	.	0 - 10	%
				Eosinophils	1.5		.	.	0 - 5	%
				Basophils	2.4	H	.	.	0 - 2	%
				Platelets	233000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	89		.	.	44 - 280	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	23		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	8		.	.	6.2 - 8.8	G/DL
				Albumin	4.5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	71		.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	24.7	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	209000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	134	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	134	Alkaline Phosphatase	82	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	34	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	229	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/CONTINUATION-WEEK 32	229	Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/UNSCHEDULED LAB 1	232	Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	01FEB96	1	14FEB96	14	14
00265	Oral	2	20 MG	15FEB96	15	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	15	20	Lost to follow-up	NONCOMPLIANCE WITH MAKING STUDY APPOINTMENTS

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-3, .	29JAN96	31JAN96#	1,000MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25JAN96	-7,	.	0	110	62	66	118	70	70	140.00	64.0
BL	01FEB96	1,	.	0	112	68	68	110	72	72	140.00	
2	15FEB96	15,	.	20	116	64	64	112	66	72	136.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	10.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	32.7	L	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	221000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	21.7	L	.	.	25 - 35	PG
				Mean Corpuscle Volume	67	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7		Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	3		.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1		Hemoglobin	10	L	.	.	12 - 15.6	G/DL
					Hematocrit	30.9	L	.	-	35 - 46	%
					Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.9		.	.	4.5 - 13	THOU/MCL
					Neutrophil Bands	0	L	.	.	4 - 12	%
					Segmented Neutrophils	68.5		.	.	30 - 70	%
					Lymphocytes	21.9		.	.	21 - 51	%
					Monocytes	5.3		.	.	0 - 10	%
					Eosinophils	3.7		.	.	0 - 5	%
					Basophils	0.6		.	.	0 - 2	%
					Platelets	284000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	21.4	L	.	.	25 - 35	PG
					Mean Corpuscle Volume	66	L	.	.	80 - 100	FL
		VISIT 3/ACUTE PHASE-WEEK 1	15	(1)	Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	07MAR96	1	13MAR96	7	7
00266	Oral	2	0 MG	14MAR96	8	24MAR96	18	11
00266	Oral	3	0 MG	25MAR96	19	27MAR96	21	3
00266	Oral	4	0 MG	28MAR96	22	03APR96	28	7
00266	Oral	5	0 MG	04APR96	29	10APR96	35	7
00266	Oral	5	0 MG	11APR96	36	17APR96	42	7
00266	Oral	5	0 MG	18APR96	43	28APR96	53	11
00266	Oral	5	0 MG	29APR96	54	02MAY96	57	4
00266	Oral	4	0 MG	03MAY96	58	16MAY96	71	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	71	0		PATIENT MOVING OUT OF STATE FOR SUMMER.

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Cefalexin Monohydrate	Keflex	52, .	27APR96	10MAY96	1,000MG	SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, .	04:00 Hrs	0	1	SEV	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	2, .	04:00 Hrs	0	1	MIL	NO	PSR	No	No
Nervous System	Hyperkinesia	AKATHISIA	5, .	46 Days	0	CON	MIL	NO	REL	No	No
Respiratory System	Pharyngitis	SORE THROAT	52, .	13 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	29FEB96	-7,	.	0	118	76	72	116	78	68	98.00	61.0
BL	07MAR96	1,	.	0	108	58	60	106	62	68	99.00	
1	14MAR96	8,	.	0	108	70	72	104	74	76	98.00	
3	25MAR96	19,	.	0	112	64	72	110	66	80	100.00	
3	28MAR96	22,	.	0	114	64	72	110	68	76	103.00	
4	04APR96	29,	.	0	110	74	76	108	76	80	103.00	
5	11APR96	36,	.	0	118	76	72	114	78	74	105.00	
6	18APR96	43,	.	0	112	64	68	110	70	72	103.00	
8	29APR96	54,	.	0	110	62	56	106	70	64	102.00	
8	02MAY96	57,	.	0	108	72	60	104	74	68	102.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.8	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	35.9	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	253	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	63	.	.	.	60 - 110	MG/DL
				Globulin	2.5	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.9		.	.	12 - 15.6	G/DL
				Hematocrit	40.3		.	.	35 - 46	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	44		.	.	30 - 70	%
				Lymphocytes	48		.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	1		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	251000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	81		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	8 - 21	MG/DL
				Creatinine	0.7		.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	190		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	07MAR96	1	13MAR96	7	7
00267	Oral	2	0 MG	14MAR96	8	20MAR96	14	7
00267	Oral	3	0 MG	21MAR96	15	27MAR96	21	7
00267	Oral	4	0 MG	28MAR96	22	03APR96	28	7
00267	Oral	4	0 MG	04APR96	29	10APR96	35	7
00267	Oral	4	0 MG	11APR96	36	17APR96	42	7
00267	Oral	5	0 MG	18APR96	43	24APR96	49	7
00267	Oral	5	0 MG	25APR96	50	01MAY96	56	7
	Oral	.		02MAY96	57	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	56	0	Protocol violation, including non-compliance	POSITIVE MULTIPLE DRUG SCREENS,MULTIPLES GIVEN PER JIM MCCAFERTY.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
OBESE{MILDLY}	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
POSITIVE DRUG SCREEN{CANNABINOIDS}	DRUG ABUSE	MENTAL DISORD	CUR	1996
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1981

CUR = Current, PRV = Past

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol Gelcaps	10, .	16MAR96	16MAR96	1000MG	HEADACHE
			31, .	06APR96	06APR96	1000MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	26, .	01APR96	01APR96	400MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE,NO VOMITING	71, .	04:00 Hrs	0	CON	MOD	NO	PBU	No	No
	Headache	HEADACHE	-1, .	01:00 Hrs	0	1	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	29FEB96	-7,	.	0	120	80	64	118	82	64	258.00	73.0
BL	07MAR96	1,	.	0	120	76	72	118	78	76	258.00	
1	14MAR96	8,	.	0	128	70	84	126	78	88	263.00	
2	21MAR96	15,	.	0	130	76	72	128	82	76	262.00	
3	28MAR96	22,	.	0	120	82	76	118	86	80	260.00	
4	04APR96	29,	.	0	132	86	80	130	88	88	257.00	
5	11APR96	36,	.	0	130	74	68	124	80	78	257.00	
6	18APR96	43,	.	0	120	78	68	118	82	72	257.00	
7	25APR96	50,	.	0	120	74	80	118	80	76	257.00	
8	02MAY96	57,	.	0	120	72	64	118	76	72	257.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.8	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3	. . .		
		VISIT 9/ACUTE PHASE-WEEK 7	50		Urine Amphetamines	NEG	. . .		
					Urine Barbiturates	NEG	. . .		
					Urine Benzodiazepines	NEG	. . .		
					Urine Cannabinoids	POS	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Opiates	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	14.7	. . .	13.8 - 17.2	G/DL
					Hematocrit	43.2	. . .	41 - 50	%
					Red Blood Cell Count	4.8	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.4	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	51.8	. . .	30 - 70	%
					Lymphocytes	41.6	. . .	21 - 51	%
					Monocytes	4.5	. . .	0 - 10	%
					Eosinophils	1.6	. . .	0 - 5	%
					Basophils	0.5	. . .	0 - 2	%
					Platelets	245000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.5	. . .	25 - 35	PG
					Mean Corpuscle Volume	90	. . .	80 - 100	FL
					Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
					Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
					Uric Acid	8	. . .	4 - 8	MG/DL
					Alkaline Phosphatase	73	. . .	22 - 180	U/L
					Aspartate Aminotransferase	18	. . .	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEC		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	01APR96	1	10APR96	10	10
00268	Oral	2	20 MG	11APR96	11	17APR96	17	7
00268	Oral	3	20 MG	18APR96	18	24APR96	24	7
00268	Oral	4	20 MG	25APR96	25	01MAY96	31	7
00268	Oral	4	20 MG	02MAY96	32	08MAY96	38	7
00268	Oral	4	20 MG	09MAY96	39	15MAY96	45	7
00268	Oral	5	30 MG	16MAY96	46	23MAY96	53	8
00268	Oral	5	30 MG	24MAY96	54	29MAY96	59	6
00157	Oral	5	30 MG	30MAY96	60	26JUN96	87	28
00157	Oral	5	30 MG	27JUN96	88	31JUL96	122	35
00157	Oral	6	40 MG	01AUG96	123	29AUG96	151	29
00157	Oral	6	40 MG	30AUG96	152	29SEP96	182	31
00157	Oral	5	30 MG	30SEP96	183	06NOV96	220	38
00157	Oral	5	30 MG	07NOV96	221	04DEC96	248	28
00268	Oral	4	20 MG	05DEC96	249	18DEC96	262	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	262	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
LYMPH NODE INFECTION{BILATERAL GROIN NODES}	LYMPHADENITIS, ACUTE	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	1991

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bisacodyl	Dulcolax	233, 174	19NOV96	19NOV96	2 TABS	CONSTIPATION
			233, 174	19NOV96	19NOV96	2 TABS	CONSTIPATION
	Neomycin	Neomycin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
			88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
	Polymyxin B	Polymyxin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
ANTIINFECTIVES,SYSTEMIC	Cefalexin	Cephalexin	82, 23	21JUN96	23JUN96	1000 MG	LEFT EAR INFECTION
			87, 28	26JUN96	29JUN96	1000 MG	LEFT EAR INFECTION
			92, 33	01JUL96	10JUL96	250 MG	LEFT INNER EAR INFECTION
	Cefalexin Monohydrate	Keflex	10, -50	10APR96	14APR96	750MG	EAR INFECTION
	Neomycin	Neomycin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
	Polymyxin B	Polymyxin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	29, -31	29APR96	29APR96	4TABS	NAUSEA{FROM RIDE}
	Prochlorperazine	Compazine	218, 159	04NOV96	04NOV96	5 MG	NAUSEA
DERMATOLOGICALS	Neomycin	Neomycin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	10, -50	10APR96	10APR96	800MG	HEADACHE
			57, -3	27MAY96	30MAY96	1600MG	PAIN{DUE TO ACCIDENT}
		Motrin	-821, -880	01JAN94	.	800MG PRN	HEADACHES
			57, -3	27MAY96	07JUN96	1600 MG	NECK PAIN DUE TO ACCIDENT
			98, 39	07JUL96	10JUL96	1 - 2 TABS	MUSCLE ACHES DUE TO CAR ACCIDENT
			102, 43	11JUL96	07NOV96	800 MG PRN	MUSCLE ACHES DUE TO CAR ACCIDENT
			184, 125	01OCT96	07NOV96	400 MG PRN	HEADACHES
SENSORY ORGANS	Neomycin	Neomycin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
VARIOUS	Nutritional Supplement Nos	T-Lite {Dietary Supplement}	154, 95	01SEP96	02OCT96	4 TABS	WEIGHT GAIN

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	NECK PAIN	56, -4	5 Days	30	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	56, -4	5 Days	30	CON	MOD	NO	UNR	Yes	No
		HEADACHES (DAILY)	184, 125	38 Days	30	35	MIL	NO	PSR	Yes	No
	Trauma	HEADACHE DUE TO ACCIDENT	56, -4	5 Days	30	CON	MOD	NO	UNR	Yes	No
		NECK PAIN DUE TO ACCIDENT	56, -4	13 Days	30	CON	MOD	NO	UNR	Yes	No
		PATIENT ACCIDENTALLY THROWN FROM 3 WHEELER STRIKING HEAD AND A NUMBER OF ABRASIONS	56, -4	5 Mins	30	1	SEV	NO	UNR	Yes	No
Carciovascular System	Syncope	BLACKNESS IN FRONT OF EYES, LIGHTHEADED, SWEATING {PRE-SYNCOPAL EPISODE/HEAT EXPOSURE}	123, 64	20 Mins	40	CON	MIL	NO	UNR	No	No
Digestive System	Constipation	CONSTIPATION	233, 174	02:00 Hrs	30	1	MOD	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	3, -57	8 Days	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	210, 151	10 Days	30	CON	MOD	NO	PBU	Yes	No
		NAUSEA DUE TO RIDES AT AMUSEMENT PARK	29, -31	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN	183, 124	95 Days	30	CON	MOD	NO	PSR	Yes	No
Musculoskeletal System	Myalgia	MUSCLE PAIN	98, 39	124 Days	30	CON	MIL	NO	UNR	Yes	No
Nervous System	Agitation	FIDGETY/PSYCHOMOTOR AGITATION	169, 110	17 Days	40	CON	MIL	DCR	PSR	No	No
	Insomnia	TERMINAL INSOMNIA	162, 103	24 Days	40	12	MOD	DCR	PSR	No	No
	Vestibular Disorder	LEFT INNER EAR INFECTION	92, 33	10 Days	30	CON	MOD	NO	UNR	Yes	No
Special Senses	Otitis Media	EAR INFECTION	10, -50	5 Days	20	CON	MOD	NO	UNR	Yes	No
		LEFT EAR INFECTION	82, 23	9 Days	30	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21MAR96	-11, -70	0	120	70	64	122	76	72	224.00	64.0
BL	01APR96	1, -59	0	118	68	68	116	72	72	225.00	
1	11APR96	11, -49	20	118	68	64	114	74	68	224.00	
2	18APR96	18, -42	20	122	74	72	118	76	76	221.00	
3	25APR96	25, -35	20	122	70	64	120	70	62	221.00	
4	02MAY96	32, -28	20	120	74	72	118	82	76	223.00	
5	09MAY96	39, -21	20	122	80	72	120	84	80	224.00	
6	16MAY96	46, -14	30	124	78	60	122	80	64	220.00	
8	30MAY96	60, 1	30	128	74	72	126	80	80	222.00	
12	27JUN96	88, 29	30	104	72	70	92	58	70	221.00	
16	01AUG96	123, 64	40	130	76	90	140	84	100	227.00	
20	30AUG96	152, 93	40	124	92	90	130	80	92	231.00	
24	30SEP96	183, 124	30	110	78	80	104	74	84	234.00	
32	07NOV96	221, 162	30	122	76	78	124	76	80	244.00 H	
32	05DEC96	249, 190	20	106	78	76	112	92	84	243.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	12.6				12 - 15.6	G/DL
				Hematocrit	37				35 - 46	%
				Red Blood Cell Count	4.5				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.3				4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1				30 - 70	%
				Lymphocytes	37.4				21 - 51	%
				Monocytes	8.1				0 - 10	%
				Eosinophils	5				0 - 5	%
				Basophils	0.5				0 - 2	%
				Platelets	351000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4				25 - 35	PG
				Mean Corpuscle Volume	83				80 - 100	FL
				Blood Urea Nitrogen	6	L			7 - 25	MG/DL
				Creatinine	0.8				0.8 - 1.5	MG/DL
				Uric Acid	3.6				2.3 - 7	MG/DL
				Alkaline Phosphatase	186				44 - 280	U/L
				Aspartate Aminotransferase	14				0 - 41	U/L
				Alanine Aminotransferase	18				0 - 48	U/L
				Total Bilirubin	0.4				0.3 - 1.3	MG/DL
				Total Protein	7				6.2 - 8.8	G/DL
				Albumin	3.9				3.1 - 5.3	G/DL
				Glucose - Random	93				70 - 115	MG/DL
				Globulin	3.1				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	NEG					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-11	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.6	L	.	.	35 - 46	%
				Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.2		.	.	30 - 70	%
				Lymphocytes	39.1		.	.	21 - 51	%
				Monocytes	7.5		.	.	0 - 10	%
				Eosinophils	5		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	285000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	165		.	.	44 - 280	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	12		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	60	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	38	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	150	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	152		Glucose - Random	116	H	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	183		Hemoglobin	12	.	.	.	12 - 15.6	G/DL
					Hematocrit	35.5	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	13	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	53.3	.	.	.	30 - 70	%
					Lymphocytes	38.4	.	.	.	21 - 51	%
					Monocytes	4.8	.	.	.	0 - 10	%
					Eosinophils	3.3	.	.	.	0 - 5	%
					Basophils	0.2	.	.	.	0 - 2	%
					Platelets	382000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
		VISIT 17/DOWN TITRATION	277	(15)	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
					Hematocrit	34.9	L	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	12	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	51.2	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 17/DOWN TITRATION	277	(15)	Lymphocytes	37	.	.	.	21 - 51	%
					Monocytes	6.8	.	.	.	0 - 10	%
					Eosinophils	5	.	.	.	0 - 5	%
					Basophils	0	.	.	.	0 - 2	%
					Platelets	324000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	123	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	80	.	.	.	70 - 115	MG/DL
					Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEC		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11APR96	1	17APR96	7	7
00269	Oral	2	100 MG	18APR96	8	25APR96	15	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	15	100	Adverse event, including intercurrent illness	TACHYCARDIA,NEGATIVE/LOW T-WAVES

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
RECURRENT SINUSITIS{SEASONAL ALLERGIES}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996
UPSET STOMACH	DYSPEPSIA	DIGESTIVE SYST	CUR	1996
ACHILLES TENDON CASTED TIMES 6 WEEKS	THERAPY, REHAB	PROCEDURES	PRV	1994
BILATERAL HERNIA REPAIR	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980
SEVER'S DISEASE	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid Ac	-101,	.	01JAN96	.	2 TABS	UPSET STOMACH
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	.,	.		.	500-1,000	HEADACHES
			11,	.	21APR96	21APR96	1TAB	FOOT PAIN
RESPIRATORY	Pseudoephedrine	Pseudoephed	-101,	.	01JAN96	.	30MG	ALLERGIES
			-101,	.	01JAN96	.	30MG	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Trauma	FOOT PAIN{INJURY}	11, .	2 Days	100	CON	MIL	NO	UNR	Yes	No
Carciovascular System	Electrocardiogram Abnormal	LOW OR NEGATIVE T WAVES	8, .	15 Days	100	CON	MIL	STP	REL	No	No
	Tachycardia	TACHYCARDIA	8, .	15 Days	100	CON	MIL	STP	REL	No	No
Digestive System	Nausea	NAUSEA	6, .	1 Days	50	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	04APR96	-7, .	0	138	80	64	132	86	72	239.00	68.0
BL	11APR96	1, .	0	120	74	80	126	80	88	241.00	
1	18APR96	8, .	100	132	82	96	130	84	92	237.00	
2	25APR96	15, .	100	138	76	96	130	80	92	239.00	
3	02MAY96	22, .	100	130	76	76	.	.	.	238.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	259	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	22	(7)	Hemoglobin	14.3		.	.	13.8 - 17.2	G/DL
					Hematocrit	41		.	.	41 - 50	%
					Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.9		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	42.9		.	.	30 - 70	%
					Lymphocytes	45.4		.	.	21 - 51	%
					Monocytes	9		.	.	0 - 10	%
					Eosinophils	1.8		.	.	0 - 5	%
					Basophils	1		.	.	0 - 2	%
					Platelets	272000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9		.	.	25 - 35	PG
					Mean Corpuscle Volume	89		.	.	80 - 100	FL
					Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
					Creatinine	1		.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.5		.	.	4 - 8	MG/DL
					Alkaline Phosphatase	239		.	.	44 - 400	U/L
					Aspartate Aminotransferase	21		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	22 (7)	Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEC		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	09MAY96	1	15MAY96	7	7
00270	Oral	2	100 MG	16MAY96	8	22MAY96	14	7
00270	Oral	3	150 MG	23MAY96	15	29MAY96	21	7
00270	Oral	4	200 MG	30MAY96	22	05JUN96	28	7
00270	Oral	4	200 MG	06JUN96	29	13JUN96	36	8
00270	Oral	4	200 MG	14JUN96	37	20JUN96	43	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	43	200	Adverse event, including intercurrent illness	CHEST PAIN, CHEST TIGHTNESS, SHORTNESS OF BREATH (PAGE 227, SECOND COL.)

* Relative to Start of Study Medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FOOD ALLERGIES{MILK PRODUCTS}	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1985
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
RINGWORM	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1996
STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	CUR	1996
BROKEN LEFT FEMUR{FELL OUT OF TREE}	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1994

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-8, .	01MAY96	13MAY96	1500MG	STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-494, .	01JAN95	.	750MG PRN	HEADACHE
DERMATOLOGICALS	Bentonite	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Calamine	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Clotrimazole	Lotrimin Cream	-10, .	29APR96	19MAY96	2X	RINGWORM
	Diphenhydramine Hydrochloride	Benadryl	9, .	17MAY96	19MAY96	3 TABS	POISON IVY
	Glycerol	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Phenol, Liquefied	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Sodium Citrate	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Topical Antifungal Nos	Antifungal Cream {Nos}	26, .	03JUN96	15JUN96	3X	RINGWORM
	Zinc Oxide	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
GU SYSTEM/SEX HORMONES	Clotrimazole	Lotrimin Cream	-10, .	29APR96	19MAY96	2X	RINGWORM
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	9, .	17MAY96	19MAY96	3 TABS	POISON IVY

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN, CHEST TIGHTNESS	42, .	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes
			43, .	05:00 Hrs	200	CON	MIL	STP	PSR	No	No
	Headache	HEADACHE	47, .	2 Days	200	CON	MOD	NO	UNR	No	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	24, .	4 Days	200	5	MIL	NO	PSR	No	No
Digestive System	Diarrhea	DIARRHEA	42, .	30 Mins	200	CON	MIL	NO	UNR	No	No
			47, .	2 Days	200	CON	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	15, .	15 Days	150	CON	MIL	NO	PSR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	42, .	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes
Skin and Appendages	Contact Dermatitis	POISON IVY	9, .	3 Days	100	CON	MOD	NO	UNR	Yes	No
	Fungal Dermatitis	RINGWORM	22, .	17 Days	200	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	02MAY96	-7,	.	0	116	70	64	112	72	72	135.00	68.0
BL	09MAY96	1,	.	0	108	74	64	106	76	68	137.00	
1	16MAY96	8,	.	100	108	64	68	106	72	72	135.00	
2	23MAY96	15,	.	150	114	68	68	110	70	76	135.00	
3	30MAY96	22,	.	200	114	70	72	112	72	68	133.00	
4	06JUN96	29,	.	200	110	70	72	108	74	76	135.00	
5	13JUN96	36,	.	200	118	72	64	114	76	68	132.00	
6	20JUN96	43,	.	200	110	72	68	108	80	72	129.00	
7	27JUN96	50,	.	200	108	68	88	102	62	88	130.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.5	.	.	.	30 - 70	%
				Lymphocytes	41.6	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	318	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	50	(7)	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	39.5	L	.	.	41 - 50	%
					Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.7		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.7		.	.	30 - 70	%
					Lymphocytes	38.3		.	.	21 - 51	%
					Monocytes	4.1		.	.	0 - 10	%
					Eosinophils	3.9		.	.	0 - 5	%
					Basophils	1.1		.	.	0 - 2	%
					Platelets	283000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
					Mean Corpuscle Volume	88		.	.	80 - 100	FL
					Blood Urea Nitrogen	16		.	.	7 - 25	MG/DL
					Creatinine	1.3		.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.9		.	.	4 - 8	MG/DL
					Alkaline Phosphatase	343		.	.	44 - 400	U/L
					Aspartate Aminotransferase	15		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	50 (7)	Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEC		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28FEB97	1	09MAR97	10	10
00294	Oral	2	20 MG	10MAR97	11	16MAR97	17	7
00294	Oral	3	20 MG	17MAR97	18	27MAR97	28	11
00294	Oral	4	20 MG	28MAR97	29	02APR97	34	6
00294	Oral	5	30 MG	03APR97	35	09APR97	41	7
00294	Oral	4	20 MG	10APR97	42	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	42	20	Lack of Efficacy	

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACKACHES	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
RASH, PLANTAR SURFACE RIGHT FOOT	RASH/OTHER SKIN ERUPTION	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
10 BONE FUSIONS IN BACK	OPERATION, BONE/JOINT	OPERATIONS	PRV	1995
ROD PLACEMENT {BACK}	OPERATION, BONE/JOINT	OPERATIONS	PRV	1995
SCOLIOSIS	DEFORMITY, ACQUIRED	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Appetite Suppressant	Appetite Suppressant {Nos}	-58, .	01JAN97	10FEB97#	3 TABS	WEIGHT GAIN
CENTRAL NERVOUS SYSTEM	Analgesics	Unknown Headache Medicine {Analgesic Nos}	-4, .	24FEB97	24FEB97#	3 TABS	HEADACHE
	Paracetamol	Extra Strength Tylenol	-2, .	26FEB97	26FEB97#	3 TABS	HEADACHE
		Tylenol	14, .	13MAR97	13MAR97	1,000 MG	HEADACHE
			18, .	17MAR97	17MAR97	1,000 MG	HEADACHE
			22, .	21MAR97	23MAR97	4 TABS	BACKACHE
			40, .	08APR97	08APR97	2 TABS	HEADACHE
		Tylenol Es Gel Caps	5, .	04MAR97	07MAR97	1,000 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-1154, .	01JAN94	.	2 TABS PRN	HEADACHE
	Naproxen Sodium	Aleve	34, .	02APR97	02APR97	2 TABS	HEADACHE
			39, .	07APR97	07APR97	2 TABS	HEADACHE & CRAMPS
RESPIRATORY	Cough Syrup/Med	Unknown Cough Drop	34, .	02APR97	02APR97	1 TAB	URI

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	CRAMPS (ABDOMINAL)	39, .	02:00 Hrs	30	CON	MOD	NO	UNR	Yes	No
	Back Pain	BACKACHE	22, .	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHES (DAILY, 1-2X /DAY)	5, .	Not Stated	20		MOD	NO	PSR	Yes	No
Nervous System	Somnolence	DROWSINESS DURING DAY	1, .	19 Days	20	CON	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	UPPER RESPIRATORY INFECTION	34, .	6 Days	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20FEB97	-8,	.	0	101	64	62	90	64	102	154.00	67.0
BL	27FEB97	-1,	.	0	119	64	85	102	69	108	161.00	
1	10MAR97	11,	.	20	106	63	71	114	68	98	161.00	
2	17MAR97	18,	.	20	109	69	78	106	69	92	159.00	
4	28MAR97	29,	.	20	99	63	88	102	63	76	164.00	
5	03APR97	35,	.	30	105	71	74	94	72	84	166.00	
6	10APR97	42,	.	20	106	72	78	114	74	84	165.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	90	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEC		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	16MAY96	1	22MAY96	7	7
00307	Oral	2	100 MG	23MAY96	8	29MAY96	14	7
00307	Oral	3	150 MG	30MAY96	15	05JUN96	21	7
00307	Oral	4	200 MG	06JUN96	22	12JUN96	28	7
00307	Oral	4	200 MG	13JUN96	29	20JUN96	36	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	36	200	Adverse event, including intercurrent illness	MORBILLIFORM

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1993
SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	18,	.	02JUN96	07JUN96	500 MG	SINUSITIS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-1,	.	15MAY96	15MAY96#	1TAB	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-45,	.	01APR96	01APR96#	1TAB	INSOMNIA
			32,	.	16JUN96	21JUN96	150 MG	RASH
MUSCULO-SKELETAL	Ibuprofen	Advil	2,	.	17MAY96	17MAY96	1 TAB PRN	HEADACHE
			14,	.	29MAY96	29MAY96	200 MG	HEADACHE
			19,	.	03JUN96	04JUN96	200 MG	HEADACHE
		Ibuprofen	-1597,	.	01JAN92	.	2 TABS	HEADACHE
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-45,	.	01APR96	01APR96#	1TAB	INSOMNIA
			32,	.	16JUN96	21JUN96	150 MG	RASH
	Pseudoephedrine Hydrochloride	Actifed	31,	.	15JUN96	16JUN96	2 TABS	ALLERGIES
	Triprolidine Hydrochloride	Actifed	31,	.	15JUN96	16JUN96	2 TABS	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	50, .	Not Stated	0	20	MOD	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	3, .	39 Days	50	CON	MIL	NO	REL	No	No
Nervous System	Tremor	TREMORS	15, .	25 Days	150	CON	MIL	NO	REL	No	No
Respiratory System	Sinusitis	SINUSITIS	18, .	6 Days	150	CON	MIL	NO	UNR	Yes	No
			69, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No
Skin and Appendages	Maculopapular Rash	MORBILLIFORM "MEASLES LIKE" ERUPTION, GENERALIZED SIMILAR TO TRICYCLIC RASH, ON TRUNK, BACK, EXTREMITIES, CHEST, BUTTOCKS, TORSO/FRONT AND BACK, AND LOWER NECK	32, .	10 Days	200	CON	MOD	STP	REL	Yes	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	09MAY96	-7,	.	0	120	72	76	118	76	84	146.00	61.0
BL	16MAY96	1,	.	0	122	72	84	118	74	88	148.00	
1	23MAY96	8,	.	100	120	80	80	118	84	78	145.00	
2	30MAY96	15,	.	150	132	84	82	128	88	88	149.00	
3	06JUN96	22,	.	200	120	76	92	118	80	98	148.00	
4	13JUN96	29,	.	200	124	82	88	120	84	94	154.00	
5	20JUN96	36,	.	200	140	88	92	136	90	98	154.00	
8	25JUL96	71,	.#	0	124	74	98	130	88	108	151.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.4	.	.	.	30 - 70	%
				Lymphocytes	32.9	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	328000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Hemoglobin	13.4		.	.	12 - 15.6	G/DL
				Hematocrit	39.3		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9		.	.	30 - 70	%
				Lymphocytes	20.6	L	.	.	21 - 51	%
				Monocytes	6.8		.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	309000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	93		.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	02JUL96	1	11JUL96	10	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	10	50	Protocol violation, including non-compliance	PATIENT RAN AWAY FROM HOME.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
URINE {1+ PROTEIN}	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SPINAL MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1982

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Loperamide Hydrochloride	Imodium A-D	-2, .	30JUN96	30JUN96#	4 TABS	NAUSEA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	-2, .	01:00 Hrs	0	CON	MIL	NO	PSR	Yes	No
	Vomiting	VOMITING	-2, .	01:00 Hrs	0	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	27JUN96	-5, .	0	102	68	74	102	70	74	142.00	71.0
BL	02JUL96	1, .	0	100	64	72	102	60	72	142.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	256000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	221	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	15JUL96	1	17JUL96	3	3
00309	Oral	2	20 MG	18JUL96	4	24JUL96	10	7
00309	Oral	3	20 MG	25JUL96	11	31JUL96	17	7
00309	Oral	4	20 MG	01AUG96	18	07AUG96	24	7
00309	Oral	4	20 MG	08AUG96	25	14AUG96	31	7
00309	Oral	4	20 MG	15AUG96	32	22AUG96	39	8
00309	Oral	4	20 MG	23AUG96	40	29AUG96	46	7
00309	Oral	4	20 MG	30AUG96	47	04SEP96	52	6
00170	Oral	4	20 MG	05SEP96	53	02OCT96	80	28
00170	Oral	4	20 MG	03OCT96	81	30OCT96	108	28
00170	Oral	4	20 MG	31OCT96	109	12DEC96	151	43
00170	Oral	4	20 MG	13DEC96	152	08JAN97	178	27
00170	Oral	4	20 MG	09JAN97	179	09FEB97	210	32
00170	Oral	5	30 MG	10FEB97	211	12MAR97	241	31
00309	Oral	4	20 MG	13MAR97	242	26MAR97	255	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	Yes	Yes	255	20		DATE OF DOWN TITRATION VISIT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
"ULCER-LIKE" SYMPTOMS (BURNING, INDIGESTION), NO ULCER	DYSPEPSIA	DIGESTIVE SYST	CUR	1996
HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
NAUSEA {CHRONIC}	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ranitidine Hydrochloride	Zantac	-44, -96	01JUN96	20JUN96#	300 MG	ULCER-LIKE SYMPTOMS
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	61, 9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71, 19	23SEP96	01OCT96	2000 MG	TOOTHACHE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	34, -19	17AUG96	19AUG96	2 TABS	MENSTRUAL CRAMP
	Caffeine	Midol	34, -19	17AUG96	19AUG96	2 TABS	MENSTRUAL CRAMP
	Cinnamedrine Hydrochloride	Midol	34, -19	17AUG96	19AUG96	2 TABS	MENSTRUAL CRAMP
	Codeine Phosphate	Tylenol Iii	71, 19	23SEP96	27SEP96	3 TABS	TOOTHPAIN
	Epinephrine	Xylocaine-Epinephrine	74, 22	26SEP96	26SEP96	4 CC	ABSCESSED TOOTH
	Fentanyl	Fentanyl	74, 22	26SEP96	26SEP96	1 CC	ABSCESSED TOOTH
	Lidocaine Hydrochloride	Xylocaine-Epinephrine	74, 22	26SEP96	26SEP96	4 CC	ABSCESSED TOOTH
	Methohexital Sodium	Brevital	74, 22	26SEP96	26SEP96	70 MG	ABSCESSED TOOTH
			74, 22	26SEP96	26SEP96	70 MG	ABSCESSED TOOTH
	Midazolam Hydrochloride	Versed	74, 22	26SEP96	26SEP96	5 MG	ABSCESSED TOOTH
	Nitrous Oxide	Nitrous Oxide	74, 22	26SEP96	26SEP96	3.0 L/M	ABSCESSED TOOTH
	Paracetamol	Tylenol	-15, -67	30JUN96	30JUN96#	1 TAB	HEADACHE
			43, -10	26AUG96	26AUG96	500 MG	TOOTHACHE
			46, -7	29AUG96	29AUG96	500 MG	TOOTHACHE
			107, 55	29OCT96	29OCT96	1 TAB	HEADACHE
			237, 185	08MAR97	08MAR97	500 MG	HEADACHE
		Tylenol Iii	71, 19	23SEP96	27SEP96	3 TABS	TOOTHPAIN
DERMATOLOGICALS	Erythromycin	Erythromycin	61, 9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71, 19	23SEP96	01OCT96	2000 MG	TOOTHACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	29, -24	12AUG96	13AUG96	400 MG	HEADACHE
			33, -20	16AUG96	16AUG96	5 TABS	MENSTRUAL CRAMP
			72, 20	24SEP96	03OCT96	1 TAB	HEADACHES
			176, 124	06JAN97	13JAN97	2 TABS	EARACHE
			184, 132	14JAN97	12FEB97	400 MG PRN	HEADACHES
		Ibuprofen	-44, -96	01JUN96	.	1 TAB	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	-44, -96	01JUN96	.	1-2 TABS	HEADACHE
RESPIRATORY	Chlorphenamine Maleate	Contac	143, 91	04DEC96	04DEC96	1 TAB	FEVER & CONGESTION
			145, 93	06DEC96	06DEC96	1 TAB	FEVER & CONGESTION
			147, 95	08DEC96	08DEC96	1 TAB	CONGESTION
		Histussin Hc	47, -6	30AUG96	02SEP96	2 TSP	URI
	Dexbrompheniramine Maleate	Drixoral	52, -1	04SEP96	04SEP96	2 CAPS	URI
			110, 58	01NOV96	01NOV96	1 TAB	ALLERGIES
	Hydrocodone	Hydrocodone	74, 22	26SEP96	26SEP96	1 TAB	ABSCESSED TOOTH
	Hydrocodone Bitartrate	Histussin Hc	47, -6	30AUG96	02SEP96	2 TSP	URI
	Phenylephrine Hydrochloride	Histussin Hc	47, -6	30AUG96	02SEP96	2 TSP	URI
	Phenylpropanolamine Hydrochloride	Contac	143, 91	04DEC96	04DEC96	1 TAB	FEVER & CONGESTION
			145, 93	06DEC96	06DEC96	1 TAB	FEVER & CONGESTION
			147, 95	08DEC96	08DEC96	1 TAB	CONGESTION
	Pseudoephedrine Sulfate	Drixoral	52, -1	04SEP96	04SEP96	2 CAPS	URI
			110, 58	01NOV96	01NOV96	1 TAB	ALLERGIES
SENSORY ORGANS	Erythromycin	Erythromycin	61, 9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71, 19	23SEP96	01OCT96	2000 MG	TOOTHACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	105, 53	3 Days	20	CON	MIL	NO	UNR	No	No
	Fever	FEVER	143, 91	3 Days	20	CON	MIL	NO	UNR	Yes	No
	Headache	HEADACHE (CHANGE IN SEVERITY)	144, 92	04:00 Hrs	20	CON	SEV	NO	PBU	No	No
		HEADACHES (DAILY)	184, 132	30 Days	20	24	MOD	NO	PBU	Yes	No
		HEADACHES (INCREASED FREQUENCY)	72, 20	19 Days	20	20	MOD	NO	PBU	Yes	No
	Infection	FLU (COUGH, HEAD CONGESTION, LOW-GRADE FEVER)	151, 99	11 Days	20	CON	MOD	NO	UNR	No	No
Digestive System	Gingivitis	ABSCESSED TOOTH	74, 22	1 Days	20	CON	SEV	NO	UNR	Yes	No
	Nausea	NAUSEA	105, 53	3 Days	20	CON	MIL	NO	UNR	No	No
			239, 187	Not Stated	30	CON	MIL	NO	UNR	No	No
	Tooth Disorder	TOOTHACHE (CUTTING WISDOM TEETH)	43, -10	17 Days	20	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS	3, -50	2 Days	20	2	MIL	NO	PSR	No	No
	Tremor	TREMOR (HANDS, HEAD, TEETH)	1, -52	47 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Bronchitis	BRONCHITIS	61, 9	7 Days	20	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	UPPER RESPIRATORY ILLNESS	47, -6	9 Days	20	CON	MOD	NO	UNR	Yes	No
		URI (UPPER RESPIRATORY INFECTION)	12, -41	21 Days	20	CON	MIL	NO	UNR	No	No
	Rhinitis	CONGESTION {NOSE}	143, 91	5 Days	20	CON	MOD	NO	UNR	Yes	No
Special Senses	Ear Pain	EARACHE	176, 124	8 Days	20	CON	MIL	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	33, -20	4 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	02JUL96	-13, -65	0	106	66	80	94	66	96	130.00	67.0
BL	15JUL96	1, -52	0	106	60	78	100	78	110	130.00	
1	18JUL96	4, -49	20	108	58	84	92	60	88	131.00	
1	25JUL96	11, -42	20	120	58	60	104	68	64	128.00	
2	01AUG96	18, -35	20	114	64	77	110	68	80	131.00	
3	08AUG96	25, -28	20	128	76	104	140	78	100	124.00	
4	15AUG96	32, -21	20	118	60	102	120	62	100	130.00	
6	23AUG96	40, -13	20	120	66	82	118	70	82	127.00	
7	30AUG96	47, -6	20	110	70	60	112	70	68	126.00	
7	05SEP96	53, 1	20	109	68	85	114	75	106	128.00	
12	03OCT96	81, 29	20	112	64	86	118	68	80	130.00	
16	31OCT96	109, 57	20	106	72	80	108	76	72	131.00	
20	13DEC96	152, 100	20	104	53	80	103	59	87	128.00	
24	09JAN97	179, 127	20	111	62	94	100	59	88	129.00	
28	10FEB97	211, 159	30	115	61	79	115	74	98	130.00	
32	13MAR97	242, 190	20	100	60	74	100	60	94	129.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-4	Segmented Neutrophils	57	.	.	.	40 - 75	%
				Lymphocytes	33	.	.	.	16 - 46	%
				Monocytes	9	.	.	.	0 - 12	%
				Eosinophils	1	.	.	.	0 - 7	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

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AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.7	. . .	12 - 15.6	G/DL
				Hematocrit	40.1	. . .	35 - 46	%
				Red Blood Cell Count	4.5	. . .	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	10.2	. . .	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	65.4	. . .	40 - 75	%
				Lymphocytes	23.9	. . .	16 - 46	%
				Monocytes	5.5	. . .	0 - 12	%
				Eosinophils	4.5	. . .	0 - 7	%
				Basophils	0.8	. . .	0 - 2	%
				Platelets	289000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	. . .	27 - 33	PG
				Mean Corpuscle Volume	88	. . .	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	53	Hemoglobin	13.7	. . .	12 - 15.6	G/DL
				Hematocrit	39.8	. . .	35 - 46	%
				Red Blood Cell Count	4.5	. . .	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6	. . .	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	59.6	. . .	40 - 75	%
				Lymphocytes	25.8	. . .	16 - 46	%
				Monocytes	9	. . .	0 - 12	%
				Eosinophils	4.4	. . .	0 - 7	%
				Basophils	1.3	. . .	0 - 2	%
				Platelets	256000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	. . .	27 - 33	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	53	Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	2.6	L	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	4.7	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	55.1	.	.	.	40 - 75	%
				Lymphocytes	28.8	.	.	.	16 - 46	%
				Monocytes	7.6	.	.	.	0 - 12	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 13/CONTINUATION-WEEK 20	152	Eosinophils	7.4	H	.	.	0 - 7	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEC		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	242	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 16/CONTINUATION-WEEK 32	242	Red Blood Cell Count	4.6	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	40 - 75	%
				Lymphocytes	32.8	.	.	.	16 - 46	%
				Monocytes	6.1	.	.	.	0 - 12	%
				Eosinophils	9.8	H	.	.	0 - 7	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	216000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 16/CONTINUATION-WEEK 32	242	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	26SEP96	1	02OCT96	7	7
00310	Oral	2	20 MG	03OCT96	8	09OCT96	14	7
00310	Oral	3	20 MG	10OCT96	15	16OCT96	21	7
00310	Oral	4	20 MG	17OCT96	22	27OCT96	32	11
00310	Oral	4	20 MG	28OCT96	33	30OCT96	35	3
00310	Oral	4	20 MG	31OCT96	36	07NOV96	43	8
00310	Oral	4	20 MG	08NOV96	44	17NOV96	53	10
00310	Oral	4	20 MG	18NOV96	54	24NOV96	60	7
00180	Oral	4	20 MG	25NOV96	61	01JAN97	98	38
00180	Oral	4	20 MG	02JAN97	99	13FEB97	141	43
00180	Oral	4	20 MG	14FEB97	142	12MAR97	168	27
00180	Oral	4	20 MG	13MAR97	169	16APR97	203	35
00180	Oral	4	20 MG	17APR97	204	14MAY97	231	28
00180	Oral	4	20 MG	15MAY97	232	11JUN97	259	28
00310	Oral	3	20 MG	12JUN97	260	23JUN97	271	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	271	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1994

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	52, -9	16NOV96	17NOV96	2 TABS	FOOD POISONING
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	85, 25	19DEC96	29DEC96	1,000 MG	SORE THROAT
	Cefaclor	Ceclor	19, -42	14OCT96	27OCT96	750 MG	SORE THROAT, EARACHE
		Ceclor Cd	173, 113	17MAR97	28MAR97	1,000 MG	POSSIBLE STREP THROAT
	Clavulanic Acid	Augmentin	85, 25	19DEC96	29DEC96	1,000 MG	SORE THROAT
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	218, 158	01MAY97	08MAY97	1 TAB	SUNBURN
		Midol	-8, -68	18SEP96	18SEP96#	2 TABS	MENSTRUAL CRAMPS
	Butalbital	Phrenilin	175, 115	19MAR97	23MAR97	1 TAB	STIFF NECK
			236, 176	19MAY97	23MAY97	1 TAB	HEADACHE
	Caffeine	Midol	-8, -68	18SEP96	18SEP96#	2 TABS	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-8, -68	18SEP96	18SEP96#	2 TABS	MENSTRUAL CRAMPS
	Paracetamol	Phrenilin	175, 115	19MAR97	23MAR97	1 TAB	STIFF NECK
			236, 176	19MAY97	23MAY97	1 TAB	HEADACHE
		Tylenol	15, -46	10OCT96	15OCT96	4000 MG	FEVER, HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	14, -47	09OCT96	09OCT96	500 MG	PAIN IN NECK MUSCLES
			50, -11	14NOV96	17NOV96	1,200 MG	LEFT KNEE PAIN
	Ketoprofen	Orudis Kt	53, -8	17NOV96	30NOV96	1-2 TABS	LEFT KNEE PAIN
	Metaxalone	Skelaxin	14, -47	09OCT96	15OCT96	400 MG PRN	PAIN IN NECK MUSCLES
	Naproxen Sodium	Aleve	-56, -116	01AUG96	.	2 TABS	HEADACHE
			14, -47	09OCT96	09OCT96	1 TAB	PAIN IN NECK MUSCLES
RESPIRATORY	Guaifenesin	Panmist La	19, -42	14OCT96	29OCT96	2 TABS PRN	CONGESTION
	Loratadine	Claritin-D	85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION
			85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION
	Pseudoephedrine	Panmist La	19, -42	14OCT96	29OCT96	2 TABS PRN	CONGESTION
	Pseudoephedrine Sulfate	Claritin-D	85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION
			85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	83, 23	3 Days	20	CON	SEV	NO	PBU	No	No
			170, 110	10 Days	20	CON	MOD	NO	PBU	Yes	No
		MILD HEADACHE	22, -39	03:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Infection	"FLU" HEADACHE, SORE THROAT AND WEAKNESS, FEVER, EARACHE	10, -51	12 Days	20	CON	MOD	NO	PBU	No	No
		POSSIBLE STREP THROAT	173, 113	12 Days	20	CON	MOD	NO	UNR	Yes	No
Digestive System	Gastrointestinal Disorder	FOOD POISONING	52, -9	2 Days	20	CON	MOD	NO	UNR	Yes	No
Musculoskeletal System	Arthralgia	LEFT KNEE PAIN	50, -11	Not Stated	20	CON	MOD	NO	UNR	Yes	No
	Myalgia	PAIN IN NECK MUSCLES	12, -49	9 Days	20	CON	MOD	NO	PBU	Yes	No
Nervous System	Hypertonia	STIFF NECK	170, 110	10 Days	20	CON	MOD	NO	UNR	Yes	No
Respiratory System	Pharyngitis	SORE THROAT	85, 25	11 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	85, 25	12 Days	20	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	10, -51	25 Days	20	CON	MOD	NO	PBU	Yes	No
Skin and Appendages	Photosensitivity	SUNBURN	218, 158	8 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19SEP96	-7, -67	0	100	72	80	100	78	76	116.00	60.0
BL	26SEP96	1, -60	0	104	63	99	109	71	119	116.00	
1	03OCT96	8, -53	20	110	78	76	108	76	80	114.00	
2	10OCT96	15, -46	20	112	70	72	110	72	74	115.00	
3	17OCT96	22, -39	20	102	64	60	100	68	60	115.00	
5	28OCT96	33, -28	20	104	68	70	100	66	72	116.00	
5	31OCT96	36, -25	20	100	72	72	98	68	68	114.00	
6	08NOV96	44, -17	20	96	68	74	100	72	76	114.00	
8	18NOV96	54, -7	20	101	51	70	96	52	80	116.00	
8	25NOV96	61, 1	20	96	50	64	94	52	76	115.00	
12	02JAN97	99, 39	20	98	73	81	100	78	101	109.00	
20	14FEB97	142, 82	20	102	59	66	98	60	74	111.00	
24	13MAR97	169, 109	20	103	63	78	98	66	93	113.00	
28	17APR97	204, 144	20	101	51	78	98	69	89	119.00	
32	15MAY97	232, 172	20	98	63	71	109	69	69	118.00	
32	12JUN97	260, 200	20	102	54	86	100	65	97	119.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14		.	.	12 - 15.6	G/DL
				Hematocrit	40.8		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.5	H	.	.	30 - 70	%
				Lymphocytes	20.3	L	.	.	21 - 51	%
				Monocytes	5.4		.	.	0 - 10	%
				Eosinophils	3.8		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	254000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111		.	.	22 - 130	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	8		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	86		.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6		.	.		
				Urine Red Blood Cells/HPF	5		.	+		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	6		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14		.	.	12 - 15.6	G/DL
				Hematocrit	41.5		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7		.	.	30 - 70	%
				Lymphocytes	32.2		.	.	21 - 51	%
				Monocytes	4.9		.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	286000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	169	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	298000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	169	Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	260	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	260	Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	95	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03OCT96	1	09OCT96	7	7
00311	Oral	2	0 MG	10OCT96	8	16OCT96	14	7
00311	Oral	3	0 MG	17OCT96	15	27OCT96	25	11
00311	Oral	4	0 MG	28OCT96	26	30OCT96	28	3
00311	Oral	4	0 MG	31OCT96	29	06NOV96	35	7
00311	Oral	4	0 MG	07NOV96	36	13NOV96	42	7
00311	Oral	4	0 MG	14NOV96	43	21NOV96	50	8
00311	Oral	5	0 MG	22NOV96	51	01DEC96	60	10
00160	Oral	5	0 MG	02DEC96	61	01JAN97	91	31
00160	Oral	5	0 MG	02JAN97	92	29JAN97	119	28
00160	Oral	5	0 MG	30JAN97	120	12MAR97	161	42
00160	Oral	5	0 MG	13MAR97	162	10APR97	190	29
00311	Oral	4	0 MG	11APR97	191	24APR97	204	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	204	0	Lack of Efficacy	*DATE OF FOLLOW-UP VISIT AFTER TAPER FINISHED.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
PROTEIN IN URINE	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	PRV	1996
CONCUSSION	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1994
EUSTACHIAN TUBES LEFT EAR {FOR SEVERE, CHRONIC EAR INFECTION}	OPERATION, EAR	OPERATIONS	PRV	1984
EUSTACHIAN TUBES RIGHT EAR {FOR SEVERE, CHRONIC EAR INFECTION}	OPERATION, EAR	OPERATIONS	PRV	1987

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bisacodyl	Dulcolax	7, -54	09OCT96	09OCT96	1 TAB	ABDOMINAL PAIN
			7, -54	09OCT96	09OCT96	1 TAB	ABDOMINAL PAIN
	Bismuth Subsalicylate	Pepto Bismol	113, 53	23JAN97	24JAN97	2TSP	VOMITING AND DIARRHEA DUE TO FLU SYMPTOM
ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole	Bactrim	-27, -87	06SEP96	20SEP96#	2 TAB	BRONCHITIS
			21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
		Sulfatrim	166, 106	17MAR97	31MAR97	1,000 MG	BRONCHITIS
	Trimethoprim	Bactrim	-27, -87	06SEP96	20SEP96#	2 TAB	BRONCHITIS
			21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
		Sulfatrim	166, 106	17MAR97	31MAR97	1,000 MG	BRONCHITIS
CENTRAL NERVOUS SYSTEM	Venlafaxine Hydrochloride	Effexor	-155, -215	01MAY96	27SEP96#	1 TAB PRN	PRIOR PRESCRIPTION FOR DEPRESSION
DERMATOLOGICALS	Fluticasone Propionate	Flonase	21, -40	23OCT96	23NOV96	2 SPRAYS	SINUSITIS
MUSCULO-SKELETAL	Naproxen	Naprosyn	47, -14	18NOV96	22NOV96	1000 MG	KNEE PAIN
RESPIRATORY	Cough Syrup/Med	Unknown Cough Syrup	166, 106	17MAR97	24MAR97	1 TSP	BRONCHITIS
	Fluticasone Propionate	Flonase	21, -40	23OCT96	23NOV96	2 SPRAYS	SINUSITIS
	Guaifenesin	Entex La	21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
	Phenylpropanolamine Hydrochloride	Entex La	21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
	Pseudoephedrine Hydrochloride	Sudafed	85, 25	26DEC96	26DEC96	1TAB	SINUS CONGESTION
	Salbutamol	Albuterol	166, 106	17MAR97	24MAR97	1 TSP.	BRONCHITIS
			166, 106	17MAR97	24MAR97	1 TSP.	BRONCHITIS
		Proventil	-27, -87	06SEP96	13SEP96#	2 TSP	BRONCHITIS
			-27, -87	06SEP96	13SEP96#	2 TSP	BRONCHITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	ABDOMINAL PAIN	7, -54	01:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
	Infection	FLU SYMPTOMS	113, 53	2 Days	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Diarrhea	DIARRHEA	16, -45	02:00 Hrs	0	1	MIL	NO	UNR	No	No
			113, 53	2 Days	0	12	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	16, -45	02:00 Hrs	0	1	MIL	NO	UNR	No	No
	Vomiting	VOMITING	113, 53	2 Days	0	12	MOD	NO	UNR	Yes	No
Musculoskeletal System	Arthralgia	KNEE PAIN (RIGHT KNEE)	47, -14	5 Days	0	CON	MOD	NO	UNR	Yes	No
Respiratory System	Bronchitis	BRONCHITIS	166, 106	15 Days	0	CON	MOD	NO	UNR	Yes	No
		BRONCHITIS SYMPTOMS: CONGESTION, COUGH	20, -41	12 Days	0	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	85, 25	2 Days	0	CON	MIL	NO	UNR	Yes	No
		SINUSITIS	21, -40	31 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26SEP96	-7, -67	0	102	75	69	123	72	68	118.00	65.0
BL	03OCT96	1, -60	0	120	78	72	118	76	74	122.00	
1	10OCT96	8, -53	0	120	78	74	118	74	78	120.00	
2	17OCT96	15, -46	0	114	66	83	104	66	100	119.00	
4	28OCT96	26, -35	0	120	74	72	122	76	68	121.00	
4	31OCT96	29, -32	0	118	66	84	120	70	88	119.00	
5	07NOV96	36, -25	0	116	72	72	118	78	76	123.00	
6	14NOV96	43, -18	0	118	74	72	120	68	76	123.00	
7	22NOV96	51, -10	0	110	74	60	118	76	64	123.00	
8	02DEC96	61, 1	0	110	65	85	118	81	68	122.00	
12	02JAN97	92, 32	0	123	57	73	114	62	81	127.00	
16	30JAN97	120, 60	0	118	59	66	122	66	73	127.00	
24	13MAR97	162, 102	0	110	80	83	110	76	86	130.00	
28	11APR97	191, 131	0	108	70	68	106	68	72	126.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7		.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.3		.	.	30 - 70	%
				Lymphocytes	34.4		.	.	21 - 51	%
				Monocytes	3		.	.	0 - 10	%
				Eosinophils	9.7	H	.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	224000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	256		.	.	44 - 400	U/L
				Aspartate Aminotransferase	13		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	92		.	.	70 - 115	MG/DL
				Globulin	3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	6		.	+		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	24	.	.	.	21 - 51	%
				Monocytes	13	H	.	.	0 - 10	%
				Eosinophils	11	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	232	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9	.	.	.	30 - 70	%
				Lymphocytes	20.9	L	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	11.2	H	.	+	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	183000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	220	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	162		Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3		.	.		
					Urine Bacteria	3		.	.		
					Urine Protein - Dipstick	6		.	.		
					Urine Squamous Epithelial Cells	3		.	.		
		VISIT 17/DOWN TITRATION	219	(15)	Hemoglobin	15.3		.	.	13.8 - 17.2	G/DL
					Hematocrit	44.5		.	.	41 - 50	%
					Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.3		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54.7		.	.	30 - 70	%
					Lymphocytes	32.5		.	.	21 - 51	%
					Monocytes	3.8		.	.	0 - 10	%
					Eosinophils	8.6	H	.	.	0 - 5	%
					Basophils	0.3		.	.	0 - 2	%
					Platelets	206000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.2		.	.	25 - 35	PG
					Mean Corpuscle Volume	91		.	.	80 - 100	FL
					Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
					Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.2		.	.	4 - 8	MG/DL
					Alkaline Phosphatase	229		.	.	44 - 400	U/L
					Aspartate Aminotransferase	15		.	.	0 - 41	U/L
					Alanine Aminotransferase	10		.	.	0 - 48	U/L
					Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
					Total Protein	8		.	.	6.2 - 8.8	G/DL
					Albumin	4.7		.	.	3.1 - 5.3	G/DL
					Glucose - Random	103		.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 17/DOWN TITRATION	219	(15)	Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Protein - Dipstick	6	.	.	.		
					Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	02DEC96	1	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	No	No	1	20	Lost to follow-up	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	PRV	1984
EUSTACHIAN TUBE {BILATERAL}	OPERATION, EAR	OPERATIONS	PRV	1985

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Methylphenidate Hydrochloride	Ritalin	-854, .	01AUG94	11AUG96#	10 MG	ADHD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22NOV96	-10, .	0	116	68	85	112	70	76	120.00	65.0
BL	02DEC96	1, .	0	111	61	84	101	72	86	123.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)		Hemoglobin	13.9				13.8 - 17.2	G/DL
				Hematocrit	40.2	L			41 - 50	%
				Red Blood Cell Count	4.7				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1				4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3				30 - 70	%
				Lymphocytes	31.7				21 - 51	%
				Monocytes	6				0 - 10	%
				Eosinophils	3				0 - 5	%
				Basophils	0.9				0 - 2	%
				Platelets	254000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6				25 - 35	PG
				Mean Corpuscle Volume	85				80 - 100	FL
				Blood Urea Nitrogen	15				7 - 25	MG/DL
				Creatinine	0.9				0.8 - 1.5	MG/DL
				Uric Acid	3.5	L			4 - 8	MG/DL
				Alkaline Phosphatase	231				44 - 400	U/L
				Aspartate Aminotransferase	18				0 - 41	U/L
				Alanine Aminotransferase	12				0 - 48	U/L
				Total Bilirubin	0.7				0.3 - 1.3	MG/DL
				Total Protein	7.1				6.2 - 8.8	G/DL
				Albumin	4.6				3.1 - 5.3	G/DL
				Glucose - Random	90				70 - 115	MG/DL
				Globulin	2.5				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	NEG					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)		Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	30AUG95	1	04SEP95	6	6
00157	Oral	2	20 MG	05SEP95	7	12SEP95	14	8
00157	Oral	3	20 MG	13SEP95	15	19SEP95	21	7
00157	Oral	4	20 MG	20SEP95	22	26SEP95	28	7
00157	Oral	4	20 MG	27SEP95	29	03OCT95	35	7
00157	Oral	4	20 MG	04OCT95	36	09OCT95	41	6
00157	Oral	4	20 MG	10OCT95	42	15OCT95	47	6
00157	Oral	4	20 MG	16OCT95	48	23OCT95	55	8
	Oral	4	20 MG	24OCT95	56	22NOV95	85	30
00100	Oral	4	20 MG	23NOV95	86	14DEC95	107	22
00100	Oral	4	20 MG	15DEC95	108	22JAN96	146	39
00100	Oral	4	20 MG	23JAN96	147	19FEB96	174	28

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	174	20	Other reason	PATIENT DROPPED OUT. PT. FELT NO FURTHER NEED FOR MEDICATION BECAUSE HE IS DOING WELL.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
SURGERY TO REPAIR A HERNIA	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Antihistamine, Nos	Antihistamine {Nos}	-3893,-3948	01JAN85	.		HAY FEVER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	16AUG95	-14, -69	0	138	68	72	136	68	72	278.00	72.0
BL	29AUG95	-1, -56	0	138	78	78	140	78	74	277.00	
1	05SEP95	7, -49	20	138	78	66	138	76	66	277.00	
2	12SEP95	14, -42	20	136	78	68	134	74	72		
3	20SEP95	22, -34	20	136	80	78	138	84	78	277.00	
4	26SEP95	28, -28	20	136	82	66	134	82	62	278.00	
5	04OCT95	36, -20	20	136	80	64	133	78	60	278.00	
6	10OCT95	42, -14	20	122	74	64	120	74	64		
7	16OCT95	48, -8	20	114	78	66	110	80	70	280.00	
8	24OCT95	56, 1	20	120	78	72	118	72	72	279.00	
12	23NOV95	86, 31	20	112	80	58	106	76	60	278.00	
16	15DEC95	108, 53	20	102	72	72	95	70	78	281.00	
20	23JAN96	147, 92	20	118	78	78	116	78	90	280.00	
24	20FEB96	175, 120	20	118	74	90	122	70	96	280.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.6		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7		.	.	30 - 70	%
				Lymphocytes	41		.	.	21 - 51	%
				Monocytes	6.9		.	.	0 - 10	%
				Eosinophils	7.9	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	348000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.7		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	173		.	.	44 - 400	U/L
				Aspartate Aminotransferase	17		.	.	0 - 41	U/L
				Alanine Aminotransferase	14		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	96		.	.	70 - 115	MG/DL
				Globulin	3.1		.	.	2.3 - 4.1	G/DL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-14	Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells		3	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEC		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	15.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1		.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4		.	.	30 - 70	%
				Lymphocytes	41.1		.	.	21 - 51	%
				Monocytes	4.4		.	.	0 - 10	%
				Eosinophils	4.8		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Platelets	338000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	162	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEC		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	108	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 12/CONTINUATION-WEEK 16	108	Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	388000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	128	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEC		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	147	Hematocrit	43.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.3	.	.	.	30 - 70	%
				Lymphocytes	31.7	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	130	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15 20	M	VISIT 13/CONTINUATION-WEEK	147	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	13SEP95	1	18SEP95	6	6
00158	Oral	2	0 MG	19SEP95	7	26SEP95	14	8
00158	Oral	3	0 MG	27SEP95	15	02OCT95	20	6
00158	Oral	4	0 MG	03OCT95	21	09OCT95	27	7
00158	Oral	4	0 MG	10OCT95	28	15OCT95	33	6
00158	Oral	5	0 MG	16OCT95	34	23OCT95	41	8
00158	Oral	6	0 MG	24OCT95	42	30OCT95	48	7
00158	Oral	6	0 MG	31OCT95	49	13NOV95	62	14
00009	Oral	6	0 MG	14NOV95	63	26DEC95	105	43
00009	Oral	6	0 MG	27DEC95	106	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	106	0	Protocol violation, including non-compliance	PATIENT DROPPED OUT. PT WAS DROPPED BECAUSE OF NON COMPLIANCE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
GASTRIC REFLUX	ESOPHAGITIS	DIGESTIVE SYST	CUR	
APPENDICITIS	APPENDICITIS	DIGESTIVE SYST	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urogenital System	Breast Pain	BREAST SORENESS {FEMALE}	-1, -63	16 Days	0		MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06SEP95	-7, -69	0	110	92	76	110	92	96	156.00	62.0
BL	13SEP95	1, -62	0	112	75	100	110	82	108		
1	19SEP95	7, -56	0	118	82	96	105	90	100	158.30	
2	27SEP95	15, -48	0	108	85	92	110	90	100	156.00	
3	03OCT95	21, -42	0	112	75	76	110	82	92	158.00	
4	10OCT95	28, -35	0	110	70	68	110	85	76	155.00	
5	16OCT95	34, -29	0	112	80	84	120	85	104	156.00	
6	24OCT95	42, -21	0	110	78	72	100	80	88	154.00	
7	31OCT95	49, -14	0	110	84	72	104	90	96	154.00	
8	14NOV95	63, 1	0	105	70	80	100	70	100	153.00	
16	26DEC95	105, 43	0	110	80	72	110	85	100	156.00	
20	23JAN96	133, 71#	0	108	78	68	110	80	80	155.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.4				12 - 15.6	G/DL
				Hematocrit	41.9				35 - 46	%
				Red Blood Cell Count	5				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6				4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.9				30 - 70	%
				Lymphocytes	35.7				21 - 51	%
				Monocytes	7				0 - 10	%
				Eosinophils	4.3				0 - 5	%
				Basophils	2.1	H			0 - 2	%
				Platelets	355000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6				25 - 35	PG
				Mean Corpuscle Volume	83				80 - 100	FL
				Blood Urea Nitrogen	9				7 - 25	MG/DL
				Creatinine	0.8				0.8 - 1.5	MG/DL
				Uric Acid	3				2.3 - 7	MG/DL
				Alkaline Phosphatase	111				22 - 130	U/L
				Aspartate Aminotransferase	13				0 - 41	U/L
				Alanine Aminotransferase	9				0 - 48	U/L
				Total Bilirubin	0.5				0.3 - 1.3	MG/DL
				Total Protein	7.2				6.2 - 8.8	G/DL
				Albumin	4.2				3.1 - 5.3	G/DL
				Glucose - Random	80				70 - 115	MG/DL
				Globulin	3				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.6		.	.	12 - 15.6	G/DL
				Hematocrit	40.2		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.1		.	.	30 - 70	%
				Lymphocytes	34.3		.	.	21 - 51	%
				Monocytes	5.7		.	.	0 - 10	%
				Eosinophils	7.3	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	335000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	13SEP95	1	18SEP95	6	6
00159	Oral	2	100 MG	19SEP95	7	26SEP95	14	8
00159	Oral	3	150 MG	27SEP95	15	02OCT95	20	6
00159	Oral	4	200 MG	03OCT95	21	09OCT95	27	7
00159	Oral	5	250 MG	10OCT95	28	15OCT95	33	6
00159	Oral	5	250 MG	16OCT95	34	23OCT95	41	8
00159	Oral	5	250 MG	24OCT95	42	30OCT95	48	7
00159	Oral	4	200 MG	31OCT95	49	13NOV95	62	14
00022	Oral	4	200 MG	14NOV95	63	25DEC95	104	42
00022	Oral	4	200 MG	26DEC95	105	23JAN96	133	29
00191	Oral	4	200 MG	24JAN96	134	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	134	200	Protocol violation, including non-compliance	PATIENT DROPPED OUT, DUE TO NON COMPLIANCE.

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	., .		.	2TABS PRN	HEADACHES
	Sleeping Pill	Sleep Aid {Nos}	21, -42	03OCT95	10OCT95	1TAB PRN	INSOMNIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	22, -41	29 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	42, -21	9 Days	250		MIL	NO	REL	No	No
	Insomnia	TROUBLE GETTING TO SLEEP AND EARLY AWAKENING	47, -16	8 Days	250	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06SEP95	-7, -69	0	100	70	92	100	73	96	104.00	62.0
BL	13SEP95	1, -62	0	103	70	68	100	65	80		
1	19SEP95	7, -56	100	96	62	.	96	62	.	101.00	
2	27SEP95	15, -48	150	96	62	.	94	64	.	101.00	
3	03OCT95	21, -42	200	94	60	72	92	60	72	101.00	
4	10OCT95	28, -35	250	100	78	84	92	62	88	101.00	
5	16OCT95	34, -29	250	110	72	108	96	70	104	101.00	
6	24OCT95	42, -21	250	102	78	118	100	76	118	101.00	
7	31OCT95	49, -14	200	116	78	100	100	76	122 H	101.00	
8	14NOV95	63, 1	200	110	65	88	110	56	120	102.00	
16	26DEC95	105, 43	200	102	74	80	96	70	90	100.00	
20	23JAN96	133, 71	200	104	76	72	98	68	84	104.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5		.	.	12 - 15.6	G/DL
				Hematocrit	42.2		.	.	35 - 46	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.8		.	.	30 - 70	%
				Lymphocytes	19.2	L	.	.	21 - 51	%
				Monocytes	6.4		.	.	0 - 10	%
				Eosinophils	4.9		.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	333000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75		.	.	22 - 130	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	21		.	.	0 - 48	U/L
				Total Bilirubin	0.4		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	6.2 - 8.8	G/DL
				Albumin	3.9		.	.	3.1 - 5.3	G/DL
				Glucose - Random	78		.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	5		.	+		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.7		.	.	12 - 15.6	G/DL
				Hematocrit	40.5		.	.	35 - 46	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7		.	.	30 - 70	%
				Lymphocytes	29.2		.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	344000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28		.	.	25 - 35	PG
				Mean Corpuscle Volume	83		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	43	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	01NOV95	1	09NOV95	9	9
00160	Oral	2	20 MG	10NOV95	10	19NOV95	19	10
00160	Oral	3	20 MG	20NOV95	20	26NOV95	26	7
00160	Oral	4	20 MG	27NOV95	27	04DEC95	34	8
00160	Oral	4	20 MG	05DEC95	35	12DEC95	42	8
00160	Oral	5	30 MG	13DEC95	43	19DEC95	49	7
00160	Oral	5	30 MG	20DEC95	50	26DEC95	56	7
00160	Oral	5	30 MG	27DEC95	57	05JAN96	66	10
00104	Oral	5	30 MG	06JAN96	67	30JAN96	91	25
00104	Oral	5	30 MG	31JAN96	92	04MAR96	125	34
00104	Oral	5	30 MG	05MAR96	126	08APR96	160	35
00104	Oral	5	30 MG	09APR96	161	15MAY96	197	37
00104	Oral	5	30 MC	16MAY96	198	17JUN96	230	33
00104	Oral	5	30 MG	18JUN96	231	22JUL96	265	35
00160	Oral	5	30 MG	23JUL96	266	24JUL96	267	2
00160	Oral	4	20 MG	25JUL96	268	26JUL96	269	2
00160	Oral	3	20 MG	27JUL96	270	28JUL96	271	2
00160	Oral	2	20 MG	29JUL96	272	31JUL96	274	3
00160	Oral	1	20 MG	01AUG96	275	07AUG96	281	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	Yes	281	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EPIGLOTTITIS	EPIGLOTTITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1990

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Doxycycline	Doxycycline	20, -47	20NOV95	.	50 MG	ACNE
RESPIRATORY	Salbutamol	Ventolin Inhaler	20, -47	20NOV95	.		EXERCISE INDUCED SHORTNESS OF BREATH
			20, -47	20NOV95	.		EXERCISE INDUCED SHORTNESS OF BREATH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Nervousness	JITTERINESS	20, -47	8 Days	20	1	MIL	NO	UNR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	20, -47	8 Days	20	CON	MIL	NO	UNR	Yes	No
Urogenital System	Breast Enlargement	INCREASE IN BREAST SIZE {FEMALE}	27, -40	Not Stated	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25OCT95	-7, -73	0	102	65	68	110	85	80	161.00	76.0
BL	01NOV95	1, -66	0	110	70	84	102	75	92	159.00	
1	10NOV95	10, -57	20	90	58	76	85	80	80	159.00	
3	20NOV95	20, -47	20	110	58	84	105	65	88	160.00	
4	27NOV95	27, -40	20	110	80	80	110	80	92	160.00	
5	05DEC95	35, -32	20	110	75	80	107	78	92	158.00	
6	13DEC95	43, -24	30	100	70	80	105	78	96	159.00	
7	20DEC95	50, -17	30	110	65	76	100	78	84	156.00	
8	27DEC95	57, -10	30	112	72	72	100	80	88	163.00	
8	05JAN96	66, -1	30	110	50	84	110	78	100	160.00	
12	31JAN96	92, 26	30	112	65	92	110	75	96	160.00	
16	05MAR96	126, 60	30	115	60	84	120	80	84	164.00	
24	09APR96	161, 95	30	110	80	100	90	60	96	168.00	
28	16MAY96	198, 132	30	122	78	92	110	80	96	175.00 H	
32	18JUN96	231, 165	30	120	75	108	110	85	100	175.00 H	
32	23JUL96	266, 200	30	120	60	96	90	70	80	175.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7		.	.	12 - 15.6	G/DL
				Hematocrit	40		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2		.	.	30 - 70	%
				Lymphocytes	34.5		.	.	21 - 51	%
				Monocytes	9.6		.	.	0 - 10	%
				Eosinophils	9.4	H	.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	202000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	110		.	.	44 - 280	U/L
				Aspartate Aminotransferase	13		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	86		.	.	70 - 115	MG/DL
				Globulin	2.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6		.	.		
				Urine Red Blood Cells/HPF	5		.	+		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.8		.	.	12 - 15.6	G/DL
				Hematocrit	37.2		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8		.	.	30 - 70	%
				Lymphocytes	28.7		.	.	21 - 51	%
				Monocytes	6.4		.	.	0 - 10	%
				Eosinophils	9.5	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	205000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	107		.	.	44 - 280	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	161	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	30.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	12.4	H	.	+	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	217000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	161	Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	266	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.8	H	.	.	30 - 70	%
				Lymphocytes	16.8	L	.	.	21 - 51	%
				Monocytes	1.2	.	.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	266	Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	16NOV95	1	21NOV95	6	6
00161	Oral	2	100 MG	22NOV95	7	28NOV95	13	7
00161	Oral	3	150 MG	29NOV95	14	06DEC95	21	8
00161	Oral	4	200 MG	07DEC95	22	14DEC95	29	8
00161	Oral	4	200 MG	15DEC95	30	26DEC95	41	12
00161	Oral	4	200 MG	27DEC95	42	02JAN96	48	7
00161	Oral	4	200 MG	03JAN96	49	09JAN96	55	7
00099	Oral	4	200 MG	10JAN96	56	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	56	200	Lost to follow-up	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
NECROTIZING ENTEROCOLITIS AT BIRTH-NO COMPLICATIONS	CONDITIONS, PERINATAL	PERINATAL COND	PRV	1978

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	1, -55	4 Days	50	CON	MIL	NO	REL	No	No
Nervous System	Hostility	INTENSE ANGER	39, -17	30 Mins	200	2	MOD	NO	PSR	No	No
	Insomnia	POOR SLEEP	1, -55	4 Days	50	CON	MIL	NO	REL	No	No
	Nervousness	RESTLESSNESS	1, -55	4 Days	50	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	31OCT95	-16, -71	0	110	72	60	.	.	.	261.00	73.0
BL	16NOV95	1, -55	0	118	78	78	118	72	80	263.00	
1	22NOV95	7, -49	100	104	78	74	100	76	78	263.00	
2	29NOV95	14, -42	150	106	78	72	96	72	78	266.00	
3	07DEC95	22, -34	200	118	74	72	110	78	86	259.00	
4	15DEC95	30, -26	200	114	78	78	100	72	72	265.00	
6	27DEC95	42, -14	200	120	80	72	118	78	90	268.00	
7	03JAN96	49, -7	200	122	78	66	118	74	84		
8	10JAN96	56, 1	200	118	74	72	110	70	82	272.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	26.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	327000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-16		Urine Squamous Epithelial Cells	4	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	(1)	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	41.7	.	.	.	41 - 50	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	67.4	.	.	.	30 - 70	%
					Lymphocytes	23.2	.	.	.	21 - 51	%
					Monocytes	7	.	.	.	0 - 10	%
					Eosinophils	1.5	.	.	.	0 - 5	%
					Basophils	1	.	.	.	0 - 2	%
					Platelets	312000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.2	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	73	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	56 (1)	Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	01NOV95	1	09NOV95	9	9
00162	Oral	2	0 MG	10NOV95	10	19NOV95	19	10
00162	Oral	3	0 MG	20NOV95	20	28NOV95	28	9
00162	Oral	4	0 MG	29NOV95	29	06DEC95	36	8
00162	Oral	5	0 MG	07DEC95	37	13DEC95	43	7
00162	Oral	5	0 MG	14DEC95	44	19DEC95	49	6
00162	Oral	6	0 MG	20DEC95	50	26DEC95	56	7
00162	Oral	6	0 MG	27DEC95	57	04JAN96	65	9
00101	Oral	6	0 MG	05JAN96	66	08FEB96	100	35
00101	Oral	6	0 MG	09FEB96	101	07MAR96	128	28
00101	Oral	6	0 MG	08MAR96	129	10APR96	162	34
	Oral	6	0 MG	11APR96	163	30APR96	182	20
00101	Oral	6	0 MG	01MAY96	183	04JUN96	217	35
00101	Oral	6	0 MG	05JUN96	218	01JUL96	244	27
00162	Oral	5	0 MG	02JUL96	245	03JUL96	246	2
00162	Oral	4	0 MG	04JUL96	247	05JUL96	248	2
00162	Oral	3	0 MG	06JUL96	249	07JUL96	250	2
00162	Oral	2	0 MG	08JUL96	251	10JUL96	253	3
00162	Oral	1	0 MG	11JUL96	254	17JUL96	260	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	260	0		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Antibiotic Nos	Antibiotic {Nos}	29, -37	29NOV95	09DEC95		BRONCHITIS
			37, -29	07DEC95	17DEC95		EYE INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	DROP IN ENERGY	50, -16	8 Days	0	1	MIL	INC	PSR	No	No
Nervous System	Insomnia	DROP IN SLEEP	50, -16	8 Days	0	1	MIL	INC	PSR	No	No
Respiratory System	Bronchitis	BRONCHITIS	29, -37	11 Days	0	1	MIL	NO	UNR	No	No
Special Senses	Eye Disorder	EYE INFECTION	37, -29	11 Days	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26OCT95	-6, -71	0	102	70	66	.	.	.	132.00	74.0
1	10NOV95	10, -56	0	100	68	88	96	70	100		
3	20NOV95	20, -46	0	100	70	76	110	75	84	134.00	
4	29NOV95	29, -37	0	100	60	80	100	68	88	133.00	
5	07DEC95	37, -29	0	100	58	76	100	60	88	132.00	
6	14DEC95	44, -22	0	103	75	96	100	70	100	130.00	
7	20DEC95	50, -16	0	90	58	56	95	70	76	133.00	
8	27DEC95	57, -9	0	105	65	72	105	70	88	131.00	
8	05JAN96	66, 1	0	100	55	68	90	60	88	137.00	
16	09FEB96	101, 36	0	100	70	80	80	50	100	133.00	
20	08MAR96	129, 64	0	90	62	68	90	65	84	136.00	
24	01MAY96	183, 118	0	90	60	84	88	60	80	132.00	
32	05JUN96	218, 153	0	110	55	76	90	60	88	132.00	
32	02JUL96	245, 180	0	128	70	68	138	79	78	133.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.7				12 - 15.6	G/DL
				Hematocrit	37.9				35 - 46	%
				Red Blood Cell Count	4.2				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7				4.5 - 13	THOU/MCL
				Segmented Neutrophils	59				30 - 70	%
				Lymphocytes	34.1				21 - 51	%
				Monocytes	2.9				0 - 10	%
				Eosinophils	3.6				0 - 5	%
				Basophils	0.4				0 - 2	%
				Platelets	415000	H			130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1				25 - 35	PG
				Mean Corpuscle Volume	90				80 - 100	FL
				Blood Urea Nitrogen	8				7 - 25	MG/DL
				Creatinine	1				0.8 - 1.5	MG/DL
				Uric Acid	2.6				2.3 - 7	MG/DL
				Alkaline Phosphatase	50				22 - 130	U/L
				Aspartate Aminotransferase	14				0 - 41	U/L
				Alanine Aminotransferase	9				0 - 48	U/L
				Total Bilirubin	0.8				0.3 - 1.3	MG/DL
				Total Protein	7.7				6.2 - 8.8	G/DL
				Albumin	4.5				3.1 - 5.3	G/DL
				Glucose - Random	86				70 - 115	MG/DL
				Globulin	3.2				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	4					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	37	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 6/ACUTE PHASE-WEEK 4	37	Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	387000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	162	Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	2.5	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	414000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	44	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.8	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	362000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	62	L	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	29NOV95	1	06DEC95	8	8
00187	Oral	2	100 MG	07DEC95	9	14DEC95	16	8
00187	Oral	3	150 MG	15DEC95	17	20DEC95	22	6
00187	Oral	4	200 MG	21DEC95	23	26DEC95	28	6
00187	Oral	4	200 MG	27DEC95	29	03JAN96	36	8
00187	Oral	4	200 MG	04JAN96	37	10JAN96	43	7
00187	Oral	5	250 MG	11JAN96	44	17JAN96	50	7
00187	Oral	4	200 MG	18JAN96	51	25JAN96	58	8
	Oral	4	200 MG	26JAN96	59	09FEB96	73	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	73	200	Lack of Efficacy	PATIENT DEMONSTRATED NO SIGNIFICANT IMPROVEMENT.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLITIS	ENTERITIS/COLITIS	DIGESTIVE SYST	CUR	1981
OCCASIONAL MILD HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
VAGINAL WARTS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Hyoscyamine Sulfate	Levsinex	-5445, .	01JAN81	.	1-3XYR	COLITIS
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	-332, .	01JAN95	.	1-2TABS PRN	HEADACHES
			36, .	03JAN96	04JAN96	2TABLETS	OCCAS.HEADACHE
		Excedrin Extra Strength	44, .	11JAN96	12JAN96	2TABLETS	OCCAS.HEADACHE
			58, .	25JAN96	26JAN96	2TABLETS	OCCAS.HEADACHE
	Caffeine	Excedrin	-332, .	01JAN95	.	1-2TABS PRN	HEADACHES
			36, .	03JAN96	04JAN96	2TABLETS	OCCAS.HEADACHE
		Excedrin Extra Strength	44, .	11JAN96	12JAN96	2TABLETS	OCCAS.HEADACHE
			58, .	25JAN96	26JAN96	2TABLETS	OCCAS.HEADACHE
	Codeine Phosphate	Tylenol #2	19, .	17DEC95	.	2TABS PRN	OCCAS.HEADACHE
	Paracetamol	Excedrin	-332, .	01JAN95	.	1-2TABS PRN	HEADACHES
			36, .	03JAN96	04JAN96	2TABLETS	OCCAS.HEADACHE
		Excedrin Extra Strength	44, .	11JAN96	12JAN96	2TABLETS	OCCAS.HEADACHE
			58, .	25JAN96	26JAN96	2TABLETS	OCCAS.HEADACHE
		Tylenol #2	19, .	17DEC95	.	2TABS PRN	OCCAS.HEADACHE
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Levlen 28	9, .	07DEC95	.	1TAB DAILY	CONTRACEPTION
			9, .	07DEC95	.	1TAB DAILY	CONTRACEPTION
		Ovcon	-332, .	01JAN95	.	1XDAY	BIRTH CONTROL
	Levonorgestrel	Levlen 28	9, .	07DEC95	.	1TAB DAILY	CONTRACEPTION
			9, .	07DEC95	.	1TAB DAILY	CONTRACEPTION
	Norethisterone	Ovcon	-332, .	01JAN95	.	1XDAY	BIRTH CONTROL
MUSCULO-SKELETAL	Ibuprofen	Motrin	4, .	02DEC95	05DEC95	2TABS PRN	NECK SPASMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
	Nausea	INFREQUENTLY NAUSEA	12, .	Not Stated	100	CON	MIL	NO	PSR	No	No
Nervous System	Somnolence	SEDATION	24, .	Not Stated	200	CON	MOD	NO	REL	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH (WITH EXERCISE)	40, .	Not Stated	200	CON	MIL	NO	PSR	No	No
Skin and Appendages	Acne	INCREASED ACNE (FACE,CHEST,BACK)	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
	Sweating	EPISODIC CALOR AND PERSPIRATION	12, .	Not Stated	100	CON	MIL	NO	PSR	No	No
Special Senses	Photophobia	LIGHT SENSITIVITY	20, .	Not Stated	150	CON	MIL	NO	REL	No	No
	Taste Perversion	BITTER TASTE IN MOUTH	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	15NOV95	-14,	.	0	100	70	84	100	70	93	108.00	63.0
BL	29NOV95	1,	.	0	100	70	84	100	70	93		
1	07DEC95	9,	.	100	120	78	88	115	82	92	111.00	
2	14DEC95	16,	.	100	116	84	100	90	70	104	111.00	
3	21DEC95	23,	.	200	118	78	104	104	78	116	113.00	
4	28DEC95	30,	.	200	110	70	108	100	70	120	109.00	
5	04JAN96	37,	.	200	124	98	100	118	90	100	115.00	
6	11JAN96	44,	.	250	110	82	108	104	80	116	112.00	
7	18JAN96	51,	.	200	110	78	100	110	82	100	112.00	
8	26JAN96	59,	.	200	100	70	104	100	76	108	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.6	.	.	.	30 - 70	%
				Lymphocytes	45.5	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	267000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	16	Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72		.	.	22 - 130	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	8		.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	76		.	.	70 - 115	MG/DL
				Globulin	2.8		.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.4		.	.	12 - 15.6	G/DL
				Hematocrit	41.6		.	.	35 - 46	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.3		.	.	30 - 70	%
				Lymphocytes	38.3		.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEC		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	NATIVE AMERICAN

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	04JAN96	1	09JAN96	6	6
00188	Oral	2	20 MG	10JAN96	7	16JAN96	13	7
00188	Oral	3	20 MG	17JAN96	14	23JAN96	20	7
00188	Oral	4	20 MG	24JAN96	21	30JAN96	27	7
00188	Oral	5	30 MG	31JAN96	28	06FEB96	34	7
00188	Oral	6	40 MG	07FEB96	35	13FEB96	41	7
00188	Oral	6	40 MG	14FEB96	42	20FEB96	48	7
00188	Oral	6	40 MG	21FEB96	49	27FEB96	55	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	55	40	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Migraine	MIGRAINES	48, .	04:00 Hrs	40	2	MOD	NO	UNR	No	No
Nervous System	Anxiety	ANXIETY ATTACKS	52, .	30 Mins	40	1	MIL	NO	PBU	No	No
	Nervousness	JITTERINESS	4, .	Not Stated	20	12	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14DEC95	-21,	.	0	110	70	80	100	70	100	156.00	63.0
BL	04JAN96	1,	.	0	112	85	88	100	85	132	160.00	
1	10JAN96	7,	.	20	110	85	80	105	75	100	162.00	
2	17JAN96	14,	.	20	112	60	80	100	75	88	162.00	
3	24JAN96	21,	.	20	100	70	88	105	80	112	159.00	
4	31JAN96	28,	.	30	120	80	72	112	82	88	162.00	
5	07FEB96	35,	.	40	110	75	84	110	70	100	164.00	
6	14FEB96	42,	.	40	110	75	88	105	75	120	162.00	
7	21FEB96	49,	.	40	110	65	96	110	80	128	163.00	
8	27FEB96	55,	.	40	110	80	80	108	75	96	165.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	13.8				12 - 15.6	G/DL
				Hematocrit	39.9				35 - 46	%
				Red Blood Cell Count	4.7				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8				4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.5				30 - 70	%
				Lymphocytes	39				21 - 51	%
				Monocytes	10.1	H			0 - 10	%
				Eosinophils	2.1				0 - 5	%
				Basophils	0.3				0 - 2	%
				Platelets	302000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4				25 - 35	PG
				Mean Corpuscle Volume	85				80 - 100	FL
				Blood Urea Nitrogen	9				7 - 25	MG/DL
				Creatinine	1				0.8 - 1.5	MG/DL
				Uric Acid	4				2.3 - 7	MG/DL
				Alkaline Phosphatase	66				22 - 130	U/L
				Aspartate Aminotransferase	11				0 - 41	U/L
				Alanine Aminotransferase	7				0 - 48	U/L
				Total Bilirubin	0.6				0.3 - 1.3	MG/DL
				Total Protein	7.5				6.2 - 8.8	G/DL
				Albumin	4.4				3.1 - 5.3	G/DL
				Glucose - Random	94				70 - 115	MG/DL
				Globulin	3.1				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	6					
				Urine Red Blood Cells/HPF	5					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	4					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	13.7		.	.	12 - 15.6	G/DL
				Hematocrit	40.3		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.1		.	.	30 - 70	%
				Lymphocytes	28.8		.	.	21 - 51	%
				Monocytes	3.4		.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	238000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	01FEB96	1	11FEB96	11	11
00191	Oral	2	0 MG	12FEB96	12	19FEB96	19	8
00191	Oral	3	0 MG	20FEB96	20	26FEB96	26	7
00191	Oral	4	0 MG	27FEB96	27	04MAR96	33	7
00191	Oral	4	0 MG	05MAR96	34	11MAR96	40	7
00191	Oral	4	0 MG	12MAR96	41	17MAR96	46	6
00191	Oral	4	0 MG	18MAR96	47	25MAR96	54	8
00191	Oral	4	0 MG	26MAR96	55	01APR96	61	7
00141	Oral	4	0 MG	02APR96	62	01MAY96	91	30
00141	Oral	4	0 MG	02MAY96	92	04JUN96	125	34
00141	Oral	4	0 MG	05JUN96	126	12JUN96	133	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	134	0	Other reason	MOVED OUT OF STATE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Tetracycline	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE
DERMATOLOGICALS	Tetracycline	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE
SENSORY ORGANS	Tetracycline	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE
			-51, -112	12DEC95	.	500MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Decreased Appetite	APPETITE DOWN	3, -59	Not Stated	0	CON	MIL	NO	PSR	No	No
Nervous System	Nervousness	RESTLESS AND JUMPY	28, -34	Not Stated	0	CON	MIL	NO	PSR	No	No
	Somnolence	SLEEPINESS	3, -59	Not Stated	0	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12JAN96	-20, -81	0	104	74	67	.	.	.	119.00	60.0
BL	01FEB96	1, -61	0	108	68	72	96	64	78	117.00	
2	12FEB96	12, -50	0	108	72	78	96	66	86	119.00	
3	20FEB96	20, -42	0	102	68	84	92	58	104	121.00	
4	27FEB96	27, -35	0	98	64	82	88	58	90	119.00	
5	05MAR96	34, -28	0	102	68	72	98	58	78	119.00	
6	12MAR96	41, -21	0	102	64	72	99	56	90	119.00	
7	18MAR96	47, -15	0	102	70	90	94	64	94	119.00	
8	26MAR96	55, -7	0	102	70	78	98	68	90	120.00	
8	02APR96	62, 1	0	102	62	78	94	64	90	119.00	
12	01MAY96	91, 30	0	94	60	84	90	60	90	121.00	
16	05JUN96	126, 65	0	96	64	72	89	60	84	120.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7	.	.	.	30 - 70	%
				Lymphocytes	46.5	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.3		.	.	12 - 15.6	G/DL
				Hematocrit	38.9		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51		.	.	30 - 70	%
				Lymphocytes	41		.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	2		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	234000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73		.	.	22 - 130	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick		2	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells		4	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05MAR96	1	11MAR96	7	7
00192	Oral	2	100 MG	12MAR96	8	18MAR96	14	7
00192	Oral	3	150 MG	19MAR96	15	24MAR96	20	6
00192	Oral	4	200 MG	25MAR96	21	03APR96	30	10
00192	Oral	4	200 MG	04APR96	31	11APR96	38	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	No	No	38	200	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid Ac	-2, .	03MAR96	.	1TIMES DAY	HEARTBURN
CENTRAL NERVOUS SYSTEM	Methylphenidate Hydrochloride	Ritalin	-643, .	01JUN94	01FEB96#	5MG/DAY	ATTENTION DEFICIT HYPERACTIVITY DISORDER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	22, .	Not Stated	200	CON	MIL	DCR	PBU	No	No
	Dyspepsia	HEARTBURN	26, .	Not Stated	200	CON	MIL	DCR	PSR	No	No
Nervous System	Dizziness	LIGHTHEADEDNESS	22, .	Not Stated	200	CON	MIL	DCR	PBU	No	No
	Somnolence	DROWSINESS	22, .	Not Stated	200	CON	MIL	DCR	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

					Sitting			Standing				
Week	Visit Date	Relative Days *		Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14FEB96	-20,	.	0	114	66	84	104	60	96	126.00	65.0
BL	05MAR96	1,	.	0	110	72	72	98	64	90	126.00	
1	11MAR96	7,	.	50	100	70	78	94	62	90	133.00	
2	18MAR96	14,	.	100	102	70	78	94	70	90	133.00	
3	25MAR96	21,	.	200	102	60	90	92	60	120	131.00	
4	03APR96	30,	.	200	102	70	90	94	68	98	133.00	
5	12APR96	39,	.	200	100	68	72	96	68	90	130.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-20	Hemoglobin	14.5				13.8 - 17.2	G/DL
				Hematocrit	40.7	L			41 - 50	%
				Red Blood Cell Count	4.9				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.5	L			4.5 - 13	THOU/MCL
				Segmented Neutrophils	35				30 - 70	%
				Lymphocytes	54	H			21 - 51	%
				Monocytes	5				0 - 10	%
				Eosinophils	6	H			0 - 5	%
				Basophils	0				0 - 2	%
				Platelets	244000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7				25 - 35	PG
				Mean Corpuscle Volume	83				80 - 100	FL
				Blood Urea Nitrogen	17				7 - 25	MG/DL
				Creatinine	1				0.8 - 1.5	MG/DL
				Uric Acid	3.8	L			4 - 8	MG/DL
				Alkaline Phosphatase	357				44 - 400	U/L
				Aspartate Aminotransferase	21				0 - 41	U/L
				Alanine Aminotransferase	14				0 - 48	U/L
				Total Bilirubin	0.7				0.3 - 1.3	MG/DL
				Total Protein	7.6				6.2 - 8.8	G/DL
				Albumin	4.4				3.1 - 5.3	G/DL
				Glucose - Random	90				70 - 115	MG/DL
				Globulin	3.2				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	4					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-20	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11MAR96	1	17MAR96	7	7
00271	Oral	2	20 MG	18MAR96	8	24MAR96	14	7
00271	Oral	3	20 MG	25MAR96	15	31MAR96	21	7
00271	Oral	4	20 MG	01APR96	22	07APR96	28	7
00271	Oral	4	20 MG	08APR96	29	14APR96	35	7
00271	Oral	5	30 MG	15APR96	36	21APR96	42	7
00271	Oral	6	40 MG	22APR96	43	01MAY96	52	10
00271	Oral	6	40 MG	02MAY96	53	13MAY96	64	12
00137	Oral	6	40 MG	14MAY96	65	09JUN96	91	27
00137	Oral	6	40 MG	10JUN96	92	11JUL96	123	32
00137	Oral	6	40 MG	12JUL96	124	08AUG96	151	28
00137	Oral	6	40 MG	09AUG96	152	09SEP96	183	32
00137	Oral	6	40 MG	10SEP96	184	06OCT96	210	27
00137	Oral	6	40 MG	07OCT96	211	04NOV96	239	29
00271	Oral	5	30 MG	05NOV96	240	06NOV96	241	2
00271	Oral	4	20 MG	07NOV96	242	08NOV96	243	2
00271	Oral	3	20 MG	09NOV96	244	10NOV96	245	2
00271	Oral	2	20 MG	11NOV96	246	13NOV96	248	3
00271	Oral	1	20 MG	14NOV96	249	20NOV96	255	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	255	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1984

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Clarithromycin	Biaxin	45, -20	24APR96	30APR96	500 MG	RESPIRATORY INFECTION
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	89, 25	07JUN96	07JUN96	X2 TABS	HEADACHE
	Caffeine	Excedrin	89, 25	07JUN96	07JUN96	X2 TABS	HEADACHE
	Paracetamol	Excedrin	89, 25	07JUN96	07JUN96	X2 TABS	HEADACHE
		Tylenol Extra Strength	-5, -69	06MAR96	17MAR96	2 TABS	UPPER RESPIRATORY TRACT INFECTION
			28, -37	07APR96	07APR96	2 TABS	HEADACHE
			63, -2	12MAY96	12MAY96	2 TABS	HEADACHE
			91, 27	09JUN96	09JUN96	X2 TABS	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	21, -44	31MAR96	31MAR96	200 MG	NECK PAIN
	Menthol	Vicks Cough Drop	42, -23	21APR96	21APR96		PHARYNGITIS
RESPIRATORY	Chlorphenamine Maleate	Triaminic Cough Syrup	-5, -69	06MAR96	06MAR96#	X1	RESPIRATORY INFECTION
	Menthol	Vicks Cough Drop	42, -23	21APR96	21APR96		PHARYNGITIS
			42, -23	21APR96	21APR96		PHARYNGITIS
	Phenylpropanolamine Hydrochloride	Triaminic Cough Syrup	-5, -69	06MAR96	06MAR96#	X1	RESPIRATORY INFECTION
	Salbutamol	Albuterol	-3722,-3786	01JAN86	.	1TAB DAY	ASTHMA
			-3722,-3786	01JAN86	.	1TAB DAY	ASTHMA
		Proventil Inhaler	-3722,-3786	01JAN86	.	4PUFFSX1-PRN	ASTHMA
			-3722,-3786	01JAN86	.	4PUFFSX1-PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	DECREASED ENERGY/TIRED	58, -7	Not Stated	40	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE (DAILY)	58, -7	6 Days	40		MIL	NO	PSR	Yes	No
Carciovascular System	Vasodilatation	FEELING HOT	-5, -69	61 Days	0		MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	REDUCED APPETITE	8, -57	24 Days	20	CON	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	27, -38	11 Days	20	CON	MIL	NO	PBU	No	No
Nervous System	Concentration Impaired	DECREASED CONCENTRATION	62, -3	4 Days	40	CON	MIL	NO	PSR	No	No
	Dizziness	COLD CLAMMY LIGHTHEADEDNESS [LIGHTHEADEDNESS]	26, -39	15 Mins	20	1	MIL	DCR	PSR	No	No
		LIGHTHEADED	24, -41	15 Mins	20	2	MIL	DCR	PSR	No	No
		LIGHTHEADED {WHEN STANDING}	62, -3	Not Stated	40	CON	MIL	NO	PSR	No	No
	Hypertonia	STIFF NECK	28, -37	30 Mins	20	3	MIL	NO	PBU	No	No
	Nervousness	INCREASED IRRITABILITY	63, -2	Not Stated	40	CON	MIL	NO	PSR	No	No
	Somnolence	SOMNOLENCE DAYTIME	5, -60	52 Days	20	CON	MIL	NO	PSR	No	No
	Tremor	SHAKY	65, 1	Not Stated	40	CON	MIL	NO	PSR	No	No
		SUBJECTIVE FEELINGS OF SHAKINESS	24, -41	14 Days	20	3	MIL	DCR	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT SWALLOWING	27, -38	11 Days	20	CON	MIL	NO	PBU	No	No
Skin and Appendages	Skin Disorder	COLD, CLAMMY LIGHTHEADEDNESS [COLD, CLAMMY]	26, -39	15 Mins	20	1	MIL	DCR	PSR	No	No
Special Senses	Conjunctivitis	DRY ITCHY EYES	28, -37	2 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25JAN96	-46,-110	0	98	76	68	96	70	72	170.00	63.5
BL	11MAR96	1, -64	0	98	74	68	96	70	70	172.00	
1	18MAR96	8, -57	20	132	78	82	116	78	94	175.00	
2	25MAR96	15, -50	20	115	73	74	126	84	86	174.00	
3	01APR96	22, -43	20	129	75	76	128	78	67	173.00	
4	08APR96	29, -36	20	135	73	69	125	66	80	172.00	
5	15APR96	36, -29	30	124	78	69	127	85	75	168.00	
6	22APR96	43, -22	40	133	78	76	129	78	73	168.00	
7	02MAY96	53, -12	40	126	76	67	116	76	75	164.00	
8	14MAY96	65, 1	40	92	66	73	123	87	87	163.00	
12	10JUN96	92, 28	40	130	76	76	126	84	78	168.00	
16	12JUL96	124, 60	40	120	70	76	110	80	92	167.00	
20	09AUG96	152, 88	40	98	75	80	90	60	112	162.00	
24	06SEP96	180, 116	40	105	80	80	90	70	100	160.00	
28	07OCT96	211, 147	40	105	75	72	95	80	92	162.00	
32	05NOV96	240, 176	30	120	80	80	120	80	84	164.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-46	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.5	L	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.9	.	.	.	30 - 70	%
				Lymphocytes	35.3	.	.	.	21 - 51	%
				Monocytes	3.8	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-46	Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Hemoglobin	12		.	.	12 - 15.6	G/DL
				Hematocrit	34.5	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.2	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37		.	.	30 - 70	%
				Lymphocytes	49		.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	225000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	65	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	180	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.8	.	.	.	30 - 70	%
				Lymphocytes	37.8	.	.	.	21 - 51	%
				Monocytes	3.8	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 14/CONTINUATION-WEEK 24	180	Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	240	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.8	.	.	.	30 - 70	%
				Lymphocytes	21	.	.	.	21 - 51	%
				Monocytes	2.6	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	240	Basophils	0.5	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	110	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	03APR96	1	10APR96	8	8
00272	Oral	2	100 MG	11APR96	9	17APR96	15	7
00272	Oral	3	150 MG	18APR96	16	26APR96	24	9
00272	Oral	4	200 MG	27APR96	25	30APR96	28	4
00272	Oral	4	200 MG	01MAY96	29	06MAY96	34	6
00272	Oral	4	200 MG	07MAY96	35	14MAY96	42	8
00272	Oral	4	200 MG	15MAY96	43	21MAY96	49	7
00272	Oral	4	200 MG	22MAY96	50	28MAY96	56	7
00142	Oral	4	200 MG	29MAY96	57	25JUN96	84	28
00142	Oral	4	200 MG	26JUN96	85	23JUL96	112	28
00142	Oral	4	200 MG	24JUL96	113	20AUG96	140	28
00142	Oral	4	200 MG	21AUG96	141	18SEP96	169	29

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	169	200	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-37, -93	26FEB96	19MAR96#	500MG/WK	HEADACHES
			8, -49	10APR96	10APR96	500 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	2, -55	Not Stated	50	CON	MIL	NO	PSR	No	No
Nervous System	Somnolence	DROWSINESS	113, 57	Not Stated	200	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19MAR96	-15, -71	0	106	62	60	100	68	66	120.00	61.0
BL	03APR96	1, -56	0	102	70	72	94	68	82	122.00	
1	10APR96	8, -49	50	102	72	78	96	64	96	120.00	
2	17APR96	15, -42	100	102	70	78	96	66	84	120.00	
3	26APR96	24, -33	150	102	70	84	98	68	108	122.00	
4	01MAY96	29, -28	200	98	64	90	102	64	102	123.00	
5	07MAY96	35, -22	200	116	72	90	98	66	96	125.00	
7	22MAY96	50, -7	200	110	78	108	100	80	116	127.00	
8	29MAY96	57, 1	200	110	75	100	110	80	108	128.00	
12	26JUN96	85, 29	200	112	78	90	106	78	102	131.00 H	
16	24JUL96	113, 57	200	118	96	96	100	58	110	135.00 H	
20	21AUG96	141, 85	200	112	76	108	114	80	138 H	141.00 H	
24	18SEP96	169, 113	200	168	72	72	116	60	96	145.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	13.8				13.8 - 17.2	G/DL
				Hematocrit	39.7	L			41 - 50	%
				Red Blood Cell Count	4.6				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6				4.5 - 13	THOU/MCL
				Segmented Neutrophils	39				30 - 70	%
				Lymphocytes	48.9				21 - 51	%
				Monocytes	8.1				0 - 10	%
				Eosinophils	3.1				0 - 5	%
				Basophils	0.9				0 - 2	%
				Platelets	451000	H			130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30				25 - 35	PG
				Mean Corpuscle Volume	86				80 - 100	FL
				Blood Urea Nitrogen	14				8 - 21	MG/DL
				Creatinine	0.8				0.4 - 1.1	MG/DL
				Uric Acid	4.2				2.6 - 7	MG/DL
				Alkaline Phosphatase	305				44 - 400	U/L
				Aspartate Aminotransferase	15				0 - 41	U/L
				Alanine Aminotransferase	14				0 - 39	U/L
				Total Bilirubin	0.5				0.3 - 1.3	MG/DL
				Total Protein	7.7				5.7 - 8.2	G/DL
				Albumin	4.5				3.1 - 5.3	G/DL
				Glucose - Random	64				60 - 110	MG/DL
				Globulin	3.2				2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	4					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-15	Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.4		.	.	30 - 70	%
				Lymphocytes	40.8		.	.	21 - 51	%
				Monocytes	7.3		.	.	0 - 10	%
				Eosinophils	4.9		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	320000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	8 - 21	MG/DL
				Creatinine	0.8		.	.	0.4 - 1.1	MG/DL
				Uric Acid	4		.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	274		.	.	44 - 400	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37	L	.	-	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	31.9	.	.	.	30 - 70	%
				Lymphocytes	44.8	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	15.9	H	.	+	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.5	.	.	.	2.6 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	141	Alkaline Phosphatase	285	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	17MAY96	1	23MAY96	7	7
00273	Oral	2	100 MG	24MAY96	8	29MAY96	13	6
00273	Oral	3	150 MG	30MAY96	14	09JUN96	24	11
00273	Oral	4	200 MG	10JUN96	25	16JUN96	31	7
00273	Oral	4	200 MG	17JUN96	32	23JUN96	38	7
00273	Oral	5	250 MG	24JUN96	39	30JUN96	45	7
00273	Oral	6	300 MG	01JUL96	46	10JUL96	55	10
00273	Oral	6	300 MG	11JUL96	56	18JUL96	63	8
00153	Oral	6	300 MG	19JUL96	64	03SEP96	110	47
00153	Oral	6	300 MG	04SEP96	111	09SEP96	116	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	116	300	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
TEMPOROMANDIBULAR JOINT PAIN	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-37, -100	10APR96	.	(ALMOST DAILY) AS NEEDED	TMJ PAIN
MUSCULO-SKELETAL	Flurbiprofen	Ansaid	-58, -121	20MAR96	10APR96#	3 PILLS/DAY	TMJ PAIN

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Accidental Overdose	TRICYCLIC TOXICITY	116, 53	8 Days	300		SEV	STP	REL	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19APR96	-28, -91	0	120	85	80	120	85	92	152.00	72.0
BL	17MAY96	1, -63	0	120	80	96	105	83	102	153.00	
1	24MAY96	8, -56	100	110	85	112	105	82	136 H	150.00	
2	31MAY96	15, -49	150	112	84	92	108	85	100	150.00	
3	10JUN96	25, -39	200	100	80	96	100	80	112	147.00	
4	17JUN96	32, -32	200	110	85	96	100	85	108	145.00	
5	24JUN96	39, -25	250	110	80	100	110	80	108	145.00	
6	01JUL96	46, -18	300	124	79	104	131	81	104	140.00 L	
8	11JUL96	56, -8	300	112	82	106	110	80	120	138.00 L	
8	19JUL96	64, 1	300	105	85	96	100	80	100	140.00 L	
16	04SEP96	111, 48	300	110	85	104	110	80	112	140.00 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-28	Hemoglobin	13.4		.	.	12 - 15.6	G/DL
				Hematocrit	40.6		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.1		.	.	30 - 70	%
				Lymphocytes	38.2		.	.	21 - 51	%
				Monocytes	4.5		.	.	0 - 10	%
				Eosinophils	2.7		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	427000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8		.	.	0.4 - 1.1	MG/DL
				Uric Acid	5.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	263		.	.	44 - 280	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 39	U/L
				Total Bilirubin	0.4		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	5.7 - 8.2	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	99		.	.	60 - 110	MG/DL
				Globulin	3.1		.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-28	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-10	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Basophils	1.1	.	.	.	0 - 2	%
				Platelets	341000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	251	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	60 - 110	MG/DL
				Globulin	3.9	H	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08MAY96	1	14MAY96	7	7
00275	Oral	2	20 MG	15MAY96	8	20MAY96	13	6
00275	Oral	3	20 MG	21MAY96	14	27MAY96	20	7
00275	Oral	4	20 MG	28MAY96	21	03JUN96	27	7
00275	Oral	5	30 MG	04JUN96	28	10JUN96	34	7
00275	Oral	5	30 MG	11JUN96	35	24JUN96	48	14
00275	Oral	6	40 MG	25JUN96	49	01JUL96	55	7
00163	Oral	5	30 MG	02JUL96	56	22JUL96	76	21
00163	Oral	5	30 MG	23JUL96	77	19AUG96	104	28
00163	Oral	5	30 MG	20AUG96	105	15SEP96	131	27
00163	Oral	5	30 MG	16SEP96	132	20OCT96	166	35
	Oral	5	30 MG	21OCT96	167	24NOV96	201	35
00163	Oral	5	30 MG	25NOV96	202	16DEC96	223	22

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	Yes	223	30		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Antibiotic Nos	Antibiotic {Nos}	49, -7	25JUN96	09JUL96		FOOT INFECTION
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-738, -793	01MAY94	.	PRN	ALLERGIES, INSOMNIA
			-1, -56	07MAY96	07MAY96#	50 MG	ALLERGY
			8, -48	15MAY96	.	50 MG	ALLERGY
			56, 1	02JUL96	.		ITCHINESS
			77, 22	23JUL96	24JUL96	50 MG	ALLERGIES
			132, 77	16SEP96	17SEP96	50 MG	ALLERGIES
			202, 147	25NOV96	26NOV96	50 MG	ALLERGIES
MUSCULO-SKELETAL	Ibuprofen	Advil	-493, -548	01JAN95	.	PRN	HEADACHES
			-1, -56	07MAY96	.		HEADACHES
			56, 1	02JUL96	.		ANKLE SPRAIN
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-738, -793	01MAY94	.	PRN	ALLERGIES, INSOMNIA
			-1, -56	07MAY96	07MAY96#	50 MG	ALLERGY
			8, -48	15MAY96	.	50 MG	ALLERGY
			56, 1	02JUL96	.		ITCHINESS
			77, 22	23JUL96	24JUL96	50 MG	ALLERGIES
			132, 77	16SEP96	17SEP96	50 MG	ALLERGIES
			202, 147	25NOV96	26NOV96	50 MG	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	1, -55	Not Stated	20	CON	MIL	NO	PSR	No	No
			75, 20	06:00 Hrs	30	1	MIL	NO	REL	No	No
			97, 42	9 Days	30	3	MIL	NO	REL	No	No
			119, 64	2 Days	30	3	MIL	NO	REL	No	No
			181, 126	26:00 Hrs	30	2	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	49, -7	9 Days	40	3	MIL	NO	REL	No	No
			73, 18	5 Days	30	3	MIL	NO	REL	No	No
			95, 40	3 Mins	30	1	MIL	NO	REL	No	No
			124, 69	3 Days	30	2	MIL	NO	REL	No	No
		LIGHTHEADEDNESS	29, -27	3 Days	30	2	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	30APR96	-8, -63	0	100	70	80	110	80	100	166.00	64.0
BL	07MAY96	-1, -56	0	100	60	100	110	70	76	166.00	
1	15MAY96	8, -48	20	110	80	80	105	80	100	164.00	
2	21MAY96	14, -42	20	110	82	100	90	65	76	163.00	
3	28MAY96	21, -35	20	100	72	88	100	80	96	167.00	
4	04JUN96	28, -28	30	108	72	66	98	70	90	170.00	
5	11JUN96	35, -21	30	104	72	66	96	72	88	170.00	
7	25JUN96	49, -7	40	98	70	72	96	70	88	165.00	
8	02JUL96	56, 1	30	110	62	72	94	60	90	165.00	
12	23JUL96	77, 22	30	110	70	78	90	62	108	163.00	
16	20AUG96	105, 50	30	104	74	74	86	70	96	158.00	
20	16SEP96	132, 77	30	100	74	72	92	68	96	154.00 L	
24	21OCT96	167, 112	30	60 L	72	76	88	68	86	154.00 L	
28	25NOV96	202, 147	30	98	88	78	94	56	90	154.00 L	
32	16DEC96	223, 168	30	98	64	90	92	60	112	154.00 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	231	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.1		.	.	30 - 70	%
				Lymphocytes	22.1		.	.	21 - 51	%
				Monocytes	12.4	H	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.2		.	.	0 - 2	%
				Platelets	266000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28		.	.	25 - 35	PG
				Mean Corpuscle Volume	83		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	216		.	.	44 - 400	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	132	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67	.	.	.	30 - 70	%
				Lymphocytes	23.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	219	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	132	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	53	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	223	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4	.	.	.	30 - 70	%
				Lymphocytes	35.9	.	.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	223	Alkaline Phosphatase	240	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	10APR95	1	16APR95	7	7
00127	Oral	2	100 MG	17APR95	8	23APR95	14	7
00127	Oral	3	150 MG	24APR95	15	30APR95	21	7
00127	Oral	4	200 MG	01MAY95	22	08MAY95	29	8
00127	Oral	4	200 MG	09MAY95	30	14MAY95	35	6
00127	Oral	4	200 MG	15MAY95	36	26MAY95	47	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	No	No	47	200	Adverse event, including intercurrent illness	NONCOMPLIANT SECONDARY TO NAUSEA

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
INITIAL INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
SEPARATION ANXIETY	STRESS REACTION	MENTAL DISORD	CUR	1995

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN WHEN TAKING MEDS	8, .	45 Days	100	CON	MIL	NO	PBU	No	No
	Headache	OCCASIONAL HEADACHE	3, .	Not Stated	50		MIL	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	15, .	38 Days	150		MOD	STP	REL	No	No
Nervous System	Dizziness	DIZZINESS	15, .	38 Days	150		MOD	NO	REL	No	No
	Insomnia	INITIAL INSOMNIA	8, .	45 Days	100	CON	MOD	NO	PSR	No	No
	Somnolence	DAYTIME DROWSINESS	3, .	Not Stated	50	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03APR95	-7,	.	0	104	66	62	105	55	68	79.90	58.0
BL	10APR95	1,	.	0	114	54	75	.	.	.	79.70	
1	17APR95	8,	.	100	112	61	78	119	53	91	80.90	
2	24APR95	15,	.	150	111	62	74	111	63	83	78.20	
3	01MAY95	22,	.	200	115	54	74	118	78	72	79.60	
4	08MAY95	29,	.	200	127	52	79	111	82	89	77.60	
5	15MAY95	36,	.	200	118	57	91	111	68	103	78.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	338000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	8 - 21	MG/DL
				Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 39	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	60 - 110	MG/DL
				Globulin	2.8	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11APR95	1	17APR95	7	7
00128	Oral	2	0 MG	18APR95	8	24APR95	14	7
00128	Oral	3	0 MG	25APR95	15	25APR95	15	1
	Oral	4	0 MG	26APR95	16	02MAY95	22	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	No	No	22	0	Adverse event, including intercurrent illness	RIGHT BBB

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
GENERALIZED ANXIETY DISORDER	NEUROSES	MENTAL DISORD	CUR	1994
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1993
ATTENTION DEFICIT DISORDER	MENTAL STATUS, IMPAIRED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Brompheniramine Maleate	Dimetapp	-830, .	01JAN93	.	4TABS PRN	SEASONAL ALLERGIES
	Phenylephrine Hydrochloride	Dimetapp	-830, .	01JAN93	.	4TABS PRN	SEASONAL ALLERGIES
	Phenylpropanolamine Hydrochloride	Dimetapp	-830, .	01JAN93	.	4TABS PRN	SEASONAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	8, .	Not Stated	0	CON	MIL	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05APR95	-6, .	0	121	65	91	84	74	101	114.88	62.2
BL	11APR95	1, .	0	115	61	98	122	54	114	111.60	
1	18APR95	8, .	0	123	66	98	107	68	96	111.50	
2	25APR95	15, .	0	115	53	85	114	68	90	112.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.3	L	.	-	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3	.	.	.	30 - 70	%
				Lymphocytes	45.8	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	232000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	216	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00129 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11APR95	1	17APR95	7	7
00129	Oral	2	0 MG	18APR95	8	24APR95	14	7
00129	Oral	3	0 MG	25APR95	15	01MAY95	21	7
00129	Oral	4	0 MG	02MAY95	22	08MAY95	28	7
00129	Oral	5	0 MG	09MAY95	29	16MAY95	36	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	No	No	36	0	Lack of Efficacy	PATIENT DOING SOME WHAT WORSE-MOTHER ANXIOUS ABOUT INCREASE DEATH WISHES

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00129 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BROKEN COLLAR BONE	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1992

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22MAR95	-20, .	0	115	42	68	108	50	79	187.80	69.3
BL	11APR95	1, .	0	131	53	64	130	49	68	189.50	
1	18APR95	8, .	0	131	53	58	137	89	64	188.70	
2	25APR95	15, .	0	115	54	64	123	57	64	186.70	
3	02MAY95	22, .	0	114	57	67	123	60	69	189.40	
4	09MAY95	29, .	0	106	40	59	108	56	75	187.50	
5	16MAY95	36, .	0	123	49	57	115	49	65	190.07	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00129 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	33.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	141000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	127	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00129 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18APR95	1	24APR95	7	7
00130	Oral	2	20 MG	25APR95	8	01MAY95	14	7
00130	Oral	3	20 MG	02MAY95	15	08MAY95	21	7
00130	Oral	4	20 MG	09MAY95	22	15MAY95	28	7
00130	Oral	4	20 MG	16MAY95	29	22MAY95	35	7
00130	Oral	4	20 MG	23MAY95	36	29MAY95	42	7
00130	Oral	4	20 MG	30MAY95	43	05JUN95	49	7
00130	Oral	4	20 MG	06JUN95	50	12JUN95	56	7
00010	Oral	4	20 MG	13JUN95	57	06AUG95	111	55
00010	Oral	4	20 MG	07AUG95	112	18SEP95	154	43
00010	Oral	4	20 MG	19SEP95	155	02OCT95	168	14
00130	Oral	4	20 MG	03OCT95	169	04OCT95	170	2
00130	Oral	3	20 MG	05OCT95	171	06OCT95	172	2
00130	Oral	2	20 MG	07OCT95	173	09OCT95	175	3
00130	Oral	1	20 MG	10OCT95	176	16OCT95	182	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	182	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
NERVOUS STOMACH	STOMACH/DUODENUM DISORD	DIGESTIVE SYST	CUR	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Atropine Sulfate	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
	Calcium Carbonate	Tums	149, 93	13SEP95	.	1TAB PRN	STOMACH ACHE
			149, 93	13SEP95	.	1TAB PRN	STOMACH ACHE
	Hyoscine Hydrobromide	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
	Hyoscyamine Sulfate	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
	Phenobarbital	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	140, 84	04SEP95	13SEP95	1500MG	SINUS INFECTION
	Amoxicillin Trihydrate	Amoxil	8, -49	25APR95	04MAY95	1500MG	SINUSITIS
CENTRAL NERVOUS SYSTEM	Nefazodone	Nefazodone	170, 114	04OCT95	.	100MG	DEPRESSION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	149, 93	Not Stated	20		MIL	NO	PBU	Yes	No
Digestive System	Nausea	NAUSEA	36, -21	3 Days	20	2	MIL	NO	PSR	No	No
Nervous System	Agitation	["HYPER"{AGITATION}]	32, -25	26 Days	20	3	MOD	NO	PSR	No	No
Respiratory System	Sinusitis	SINUS INFECTION	140, 84	10 Days	20	CON	MOD	NO	PBU	Yes	No
		SINUSITIS	8, -49	10 Days	20	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12APR95	-6, -62	0	139	58	57	130	70	74	146.30	66.3
BL	18APR95	1, -56	0	128	56	76	144	71	90	147.60	
1	25APR95	8, -49	20	135	60	64	137	69	94	145.00	
2	02MAY95	15, -42	20	128	55	52	131	65	54	145.80	
3	09MAY95	22, -35	20	130	53	65	137	64	86	145.80	
4	16MAY95	29, -28	20	133	67	59	122	61	76	145.09	
5	23MAY95	36, -21	20	130	61	72	131	62	102	145.10	
6	30MAY95	43, -14	20	130	64	64	122	63	88	147.60	
7	06JUN95	50, -7	20	129	64	66	130	72	82	148.62	
8	13JUN95	57, 1	20	130	60	79	138	76	93	151.10	
16	07AUG95	112, 56	20	.	.	.	138	73	85	162.70 H	
20	19SEP95	155, 99	20	137	60	65	137	66	71	165.30 H	
24	03OCT95	169, 113	20	139	66	59	123	76	67	162.40 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	223	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 5/ACUTE PHASE-WEEK 3	22	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEC	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.2	. . .	13.8 - 17.2	G/DL
				Hematocrit	45	. . .	41 - 50	%
				Red Blood Cell Count	5.1	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.8	. . .	30 - 70	%
				Lymphocytes	27.9	. . .	21 - 51	%
				Monocytes	6.4	. . .	0 - 10	%
				Eosinophils	3.1	. . .	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Basophils	0.8	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	155	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	155	Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	28000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	207	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEC		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	02MAY95	1	08MAY95	7	7
00131	Oral	2	20 MG	09MAY95	8	15MAY95	14	7
00131	Oral	3	20 MG	16MAY95	15	22MAY95	21	7
00131	Oral	4	20 MG	23MAY95	22	29MAY95	28	7
00131	Oral	4	20 MG	30MAY95	29	05JUN95	35	7
00131	Oral	4	20 MG	06JUN95	36	12JUN95	42	7
00131	Oral	4	20 MG	13JUN95	43	19JUN95	49	7
00131	Oral	4	20 MG	20JUN95	50	26JUN95	56	7
00011	Oral	4	20 MG	27JUN95	57	24JUL95	84	28
00011	Oral	4	20 MG	25JUL95	85	23AUG95	114	30
00011	Oral	4	20 MG	24AUG95	115	27AUG95	118	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	118	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
HEART MURMUR, GRADE 1, ASYMPTOMATIC	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1984

CUR = Current, PRV = Past

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CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Docusate Sodium	Correctol	21, -36	22MAY95	22MAY95	2TABLETS	CONSTIPATION
	Yellow Phenolphthalein	Correctol	21, -36	22MAY95	22MAY95	2TABLETS	CONSTIPATION
DERMATOLOGICALS	Sulfur	Clearasil	29, -28	30MAY95	.	1GRAM	ACNE
	Triclosan	Clearasil	29, -28	30MAY95	.	1GRAM	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Constipation	CONSTIPATION	19, -38	3 Days	20	1	MOD	NO	PSR	Yes	No
Hemic and Lymphatic System	Thrombocythemia	INCREASED PLATELET COUNT	57, 1	29 Days	20	CON	MIL	NO	PBU	No	No
Skin and Appendages	Acne	ACNE-FACIAL	29, -28	Not Stated	20	CON	MOD	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26APR95	-6, -62	0	130	64	63	114	56	62	160.90	66.8
BL	02MAY95	1, -56	0	106	60	64	122	56	72	158.70	
1	09MAY95	8, -49	20	107	53	63	122	63	84	157.60	
2	16MAY95	15, -42	20	121	60	69	123	65	85	159.64	
3	23MAY95	22, -35	20	121	68	66	106	57	71	157.50	
4	30MAY95	29, -28	20	115	60	73	130	65	100	156.50	
5	06JUN95	36, -21	20	124	55	64	130	68	80	158.98	
6	13JUN95	43, -14	20	115	52	67	130	72	86	160.40	
7	20JUN95	50, -7	20	115	71	70	124	65	67	162.20	
8	27JUN95	57, 1	20	130	68	69	115	81	102	162.10	
12	25JUL95	85, 29	20	124	65	70	123	76	84	163.80	
16	24AUG95	115, 59	20	115	44	63	94	60	72	159.00	
20	26SEP95	148, 92#	0	106	63	75	107	56	83	155.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2				12 - 15.6	G/DL
				Hematocrit	38				35 - 46	%
				Red Blood Cell Count	4.3				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2				4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.4				30 - 70	%
				Lymphocytes	40.8				21 - 51	%
				Monocytes	6.7				0 - 10	%
				Eosinophils	3.8				0 - 5	%
				Basophils	0.4				0 - 2	%
				Platelets	374000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7				25 - 35	PG
				Mean Corpuscle Volume	89				80 - 100	FL
				Blood Urea Nitrogen	6	L			7 - 25	MG/DL
				Creatinine	0.9				0.8 - 1.5	MG/DL
				Uric Acid	4.2				2.3 - 7	MG/DL
				Alkaline Phosphatase	103				22 - 130	U/L
				Aspartate Aminotransferase	16				0 - 41	U/L
				Alanine Aminotransferase	5				0 - 48	U/L
				Total Bilirubin	0.8				0.3 - 1.3	MG/DL
				Total Protein	7.8				6.2 - 8.8	G/DL
				Albumin	4.6				3.1 - 5.3	G/DL
				Glucose - Random	120	H			70 - 115	MG/DL
				Globulin	3.2				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8		.	.	12 - 15.6	G/DL
				Hematocrit	39.7		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39.4		.	.	30 - 70	%
				Lymphocytes	46.2		.	.	21 - 51	%
				Monocytes	9.7		.	.	0 - 10	%
				Eosinophils	3.5		.	.	0 - 5	%
				Basophils	1.2		.	.	0 - 2	%
				Platelets	410000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	100		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57		Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
					Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	100	.	.	.	70 - 115	MG/DL
					Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	85		Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.6	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	46.9	.	.	.	30 - 70	%
					Lymphocytes	41.1	.	.	.	21 - 51	%
					Monocytes	8.2	.	.	.	0 - 10	%
					Eosinophils	2.9	.	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	381000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 13/CONTINUATION-WEEK 20	148	(30)	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	148	(30)	Hematocrit	36.9				35 - 46	%
					Red Blood Cell Count	4.2				4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.2				4.5 - 13	THOU/MCL
					Segmented Neutrophils	33.8				30 - 70	%
					Lymphocytes	54.5	H			21 - 51	%
					Monocytes	7.4				0 - 10	%
					Eosinophils	3.9				0 - 5	%
					Basophils	0.5				0 - 2	%
					Platelets	315000				130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.7				25 - 35	PG
					Mean Corpuscle Volume	88				80 - 100	FL
					Blood Urea Nitrogen	8				7 - 25	MG/DL
					Creatinine	0.9				0.8 - 1.5	MG/DL
					Uric Acid	3.3				2.3 - 7	MG/DL
					Alkaline Phosphatase	102				22 - 130	U/L
					Aspartate Aminotransferase	15				0 - 41	U/L
					Alanine Aminotransferase	4				0 - 48	U/L
					Total Bilirubin	0.9				0.3 - 1.3	MG/DL
					Total Protein	7.1				6.2 - 8.8	G/DL
					Albumin	4.3				3.1 - 5.3	G/DL
					Glucose - Random	94				70 - 115	MG/DL
					Globulin	2.8				2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG					
					Urine Blood - Dipstick	NEG					
					Urine Red Blood Cells/HPF	NEG					
					Urine White Blood Cells/HPF	3					
					Urine Bacteria	3					
					Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16 20	F	VISIT 13/CONTINUATION-WEEK	148	(30)	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	23MAY95	1	29MAY95	7	7
00132	Oral	2	100 MG	30MAY95	8	05JUN95	14	7
00132	Oral	3	150 MG	06JUN95	15	12JUN95	21	7
00132	Oral	4	200 MG	13JUN95	22	19JUN95	28	7
00132	Oral	4	200 MG	20JUN95	29	26JUN95	35	7
00132	Oral	4	200 MG	27JUN95	36	04JUL95	43	8
00132	Oral	4	200 MG	05JUL95	44	10JUL95	49	6
00132	Oral	4	200 MG	11JUL95	50	18JUL95	57	8
00001	Oral	4	200 MG	19JUL95	58	23AUG95	93	36
00001	Oral	4	200 MG	24AUG95	94	14SEP95	115	22
00001	Oral	4	200 MG	15SEP95	116	23OCT95	154	39
00132	Oral	4	200 MG	24OCT95	155	24OCT95	155	1
00132	Oral	3	150 MG	25OCT95	156	26OCT95	157	2
00132	Oral	2	100 MG	27OCT95	158	29OCT95	160	3
00132	Oral	1	50 MG	30OCT95	161	05NOV95	167	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	167	50	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES(OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	27, -31	3 Days	200	CON	MIL	NO	UNR	No	No
Digestive System	Nausea	NAUSEA	27, -31	3 Days	200		MIL	NO	UNR	No	No
			94, 37	62 Days	200		MIL	NO	PSR	No	No
	Vomiting	VOMITING	28, -30	06:00 Hrs	200		MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	17MAY95	-6, -63	0	114	77	54	112	70	79	111.35	62.0
BL	23MAY95	1, -57	0	117	58	85	123	72	94	112.90	
1	30MAY95	8, -50	100	131	68	79	108	64	108	110.50	
2	06JUN95	15, -43	150	114	63	95	113	67	106	111.79	
3	13JUN95	22, -36	200	115	69	103	123	80	106	114.00	
4	20JUN95	29, -29	200	121	69	89	114	68	112	109.30	
5	27JUN95	36, -22	200	122	71	91	122	72	105	110.30	
6	05JUL95	44, -14	200	122	68	95	123	72	112	111.30	
7	11JUL95	50, -8	200	114	64	93	116	72	105	109.50	
8	19JUL95	58, 1	200	131	84	108	140	81	97	111.30	
12	24AUG95	94, 37	200	116	79	96	115	72	96	112.50	
16	15SEP95	116, 59	200	116	62	95	114	67	99	113.30	
20	24OCT95	155, 98	200	114	67	95	116	62	99	112.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.1				13.8 - 17.2	G/DL
				Hematocrit	40.8	L			41 - 50	%
				Red Blood Cell Count	4.9				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7				4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1				30 - 70	%
				Lymphocytes	40.1				21 - 51	%
				Monocytes	7.4				0 - 10	%
				Eosinophils	1.7				0 - 5	%
				Basophils	0.7				0 - 2	%
				Platelets	242000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29				25 - 35	PG
				Mean Corpuscle Volume	84				80 - 100	FL
				Blood Urea Nitrogen	13				8 - 21	MG/DL
				Creatinine	0.8				0.4 - 1.1	MG/DL
				Uric Acid	3.6				2.6 - 7	MG/DL
				Alkaline Phosphatase	234				44 - 400	U/L
				Aspartate Aminotransferase	18				0 - 41	U/L
				Alanine Aminotransferase	7				0 - 39	U/L
				Total Bilirubin	0.5				0.3 - 1.3	MG/DL
				Total Protein	7.8				5.7 - 8.2	G/DL
				Albumin	4.6				3.1 - 5.3	G/DL
				Glucose - Random	90				60 - 110	MG/DL
				Globulin	3.2				2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	NEG					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.1		.	.	13.8 - 17.2	G/DL
				Hematocrit	39.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.5		.	.	30 - 70	%
				Lymphocytes	35.5		.	.	21 - 51	%
				Monocytes	7.1		.	.	0 - 10	%
				Eosinophils	7.2	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	211000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	82		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	255		.	.	44 - 400	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	155	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	41.7	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	267	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	155	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	13JUN95	1	19JUN95	7	7
00133	Oral	2	20 MG	20JUN95	8	26JUN95	14	7
00133	Oral	3	20 MG	27JUN95	15	04JUL95	22	8
00133	Oral	4	20 MG	05JUL95	23	10JUL95	28	6
00133	Oral	5	30 MG	11JUL95	29	17JUL95	35	7
00133	Oral	6	40 MG	18JUL95	36	27JUL95	45	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	45	40	Lost to follow-up	PT DECIDED TO STOP STUDY HERSELF NOT FOR LACK OF EFFICACY,PT WAS LOST TO FU

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
PREMENSTRUAL TENSION{OCCASIONAL)	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993
SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1985
FEVER OF UNKNOWN ORIGIN	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993
STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	PRV	1985

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	28, .	10JUL95	.	2TBSP.PRN	LOOSE STOOLS
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	32, .	14JUL95	20JUL95	500MG	EXTRACTED WISDOM TOOTH
CENTRAL NERVOUS SYSTEM	Pain Reliever	Premenstrual Syndrome Pain Relief {Nos}	-893, .	01JAN93	.	500MG PRN	PREMENSTRUAL TENSION
	Paracetamol	Tylenol	-893, .	01JAN93	.	500MG PRN	HEADACHE
MUSCULO-SKELETAL	Etodolac	Lodine	32, .	14JUL95	17JUL95	200MG	EXTRACTED WIDSOM TEETH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Diarrhea	LOOSE STOOLS	17, .	Not Stated	20		MOD	NO	PSR	Yes	No
	Nausea	NAUSEA	17, .	Not Stated	20	CON	MOD	NO	PSR	No	No
	Tooth Disorder	WISDOM TOOTH EXTRACTION {TOOTH DISORDER}	32, .	03:00 Hrs	30	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Sweating	SWEATING INCREASED	25, .	Not Stated	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	07JUN95	-6,	.	0	138	72	132	144	59	95	308.26	68.1
BL	13JUN95	1,	.	0	144	98	105	149	85	114	308.80	
1	20JUN95	8,	.	20	152	80	95	155	58	105	308.00	
2	27JUN95	15,	.	20	145	55	88	145	79	97	307.80	
3	05JUL95	23,	.	20	145	79	95	147	72	108	309.50	
4	11JUL95	29,	.	30	138	76	80	138	83	87	308.30	
5	18JUL95	36,	.	40	131	72	109	148	69	111	308.40	
6	27JUL95	45,	.	40	148	72	91	146	62	109	308.90	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	33.3	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	233000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	109	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	06JUL95	1	13JUL95	8	8
00134	Oral	2	100 MG	14JUL95	9	18JUL95	13	5
00134	Oral	3	150 MG	19JUL95	14	25JUL95	20	7
00134	Oral	4	200 MG	26JUL95	21	02AUG95	28	8
00134	Oral	4	200 MG	03AUG95	29	07AUG95	33	5
00134	Oral	4	200 MG	08AUG95	34	14AUG95	40	7
00134	Oral	4	200 MG	15AUG95	41	23AUG95	49	9
00134	Oral	4	200 MG	24AUG95	50	28AUG95	54	5
00134	Oral	3	150 MG	29AUG95	55	09SEP95	66	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	66	150	Adverse event, including intercurrent illness	PATIENT WITHDRAWN FOR TACHYCARDIA&INCREASED QT/QTC

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DERMATOLOGICAL FUNGUS	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993
OCCASIONAL STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
SPRAINED ARM MUSCLES	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Ketoconazole	Nizoral	-1, .	05JUL95	10JUL95	200MG	FUNGUS
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	38, .	12AUG95	.	500MG PRN	HEADACHE
		Midol	-916, .	01JAN93	.	2TABLETS	MENSTRUAL CRAMPS
	Caffeine	Midol	-916, .	01JAN93	.	2TABLETS	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-916, .	01JAN93	.	2TABLETS	MENSTRUAL CRAMPS
DERMATOLOGICALS	Ketoconazole	Nizoral	-1, .	05JUL95	10JUL95	200MG	FUNGUS
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Triphasil	-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
			-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
	Levonorgestrel	Triphasil	-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
			-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
MUSCULO-SKELETAL	Naproxen	Naproxen	-34, .	02JUN95	09JUN95#	500MG PRN	SPRAINED MUSCLE
	Naproxen Sodium	Anaprox	-916, .	01JAN93	.	550MG PRN	MENSTRUAL CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	5, .	65 Days	50	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE{OCCASIONAL}	38, .	Not Stated	200		MIL	NO	PSR	Yes	No
Carciovascular System	Postural Hypotension	POSTURAL HYPOTENSION	37, .	33 Days	200	3	MOD	NO	PSR	No	No
	Qt Interval Prolonged	INCREASED QT/{CORRECTED}QTC RATIO	55, .	15 Days	150	CON	MOD	STP	REL	No	No
	Syncope	BLACKOUTS	37, .	33 Days	200	3	MOD	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	37, .	33 Days	200		MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	22, .	48 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	37, .	33 Days	200	CON	MOD	STP	REL	No	No
	Somnolence	HYPERSOMNOLENCE	5, .	65 Days	50	CON	MOD	NO	PSR	No	No
Skin and Appendages	Sweating	INCREASED SWEATING	22, .	48 Days	200	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	28JUN95	-8,	.	0	114	60	76	115	76	93	122.50	66.0
BL	06JUL95	1,	.	0	122	68	93	128	73	119	122.50	
1	14JUL95	9,	.	100	114	56	95	106	72	111	122.70	
2	19JUL95	14,	.	150	122	72	101	122	75	105	124.70	
3	26JUL95	21,	.	200	114	76	93	121	84	112	122.20	
4	03AUG95	29,	.	200	115	76	98	122	72	114	123.90	
5	08AUG95	34,	.	200	122	76	115	115	80	117	123.50	
6	15AUG95	41,	.	200	122	90	108	131	84	108	124.00	
7	24AUG95	50,	.	200	136	81	88	129	82	101	124.20	
8	29AUG95	55,	.	150	115	69	94	104	88	115	122.80	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.1		.	.	12 - 15.6	G/DL
				Hematocrit	40.8		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5		.	.	30 - 70	%
				Lymphocytes	25.5		.	.	21 - 51	%
				Monocytes	4.9		.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.2		.	.	0 - 2	%
				Platelets	325000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77		.	.	44 - 280	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	14		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	93		.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick NEG			.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	34.9	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	363000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	02OCT95	1	08OCT95	7	7
00135	Oral	2	0 MG	09OCT95	8	15OCT95	14	7
00135	Oral	3	0 MG	16OCT95	15	22OCT95	21	7
00135	Oral	4	0 MG	23OCT95	22	29OCT95	28	7
00135	Oral	5	0 MG	30OCT95	29	05NOV95	35	7
00135	Oral	4	0 MG	06NOV95	36	19NOV95	49	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	49	0	Lack of Efficacy	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DYSMENORRHEA{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
HYPOTHYROID	HYPOTHYROIDISM	ENDOCR/METAB/IMMUNITY DISORD	CUR	1992
MENSTRUAL CRAMPS{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
PARTIAL THYROIDECTOMY	OPERATION, ENDOCR	OPERATIONS	PRV	1991

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Amitriptyline Hydrochloride	Elavil	-9,	.	23SEP95	24SEP95#	25MG	DEPRESSION
	Paroxetine	Paxil	36,	.	06NOV95	.	10MG	DEPRESSION
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	-274,	.	01JAN95	.	220MG PRN	HEADACHES
SYSTEMIC HORMONAL	Levothyroxine Sodium	Synthroid	-1370,	.	01JAN92	.	150MG	HYPOTHYROID

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	29, .	21 Days	0	CON	MIL	NO	PSR	No	No
Digestive System	Diarrhea	DIARRHEA	20, .	1 Days	0	CON	MIL	NO	UNR	No	No
	Nausea	NAUSEA	20, .	2 Days	0	CON	MIL	NO	UNR	No	No
	Vomiting	VOMITING	20, .	2 Days	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25SEP95	-7,	.	0	113	74	89	122	60	100	133.60	71.0
BL	02OCT95	1,	.	0	113	63	78	.	.	.	131.60	
1	09OCT95	8,	.	0	118	56	83	124	59	91	132.70	
2	16OCT95	15,	.	0	119	60	80	121	70	88	131.70	
3	23OCT95	22,	.	0	123	56	86	122	56	88	133.90	
4	30OCT95	29,	.	0	122	64	74	122	56	80	132.40	
5	06NOV95	36,	.	0	107	82	86	123	68	105	133.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	.	.	.	30 - 70	%
				Lymphocytes	23.4	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03OCT95	1	09OCT95	7	7
00136	Oral	2	0 MG	10OCT95	8	16OCT95	14	7
00136	Oral	3	0 MG	17OCT95	15	23OCT95	21	7
00136	Oral	4	0 MG	24OCT95	22	02NOV95	31	10
00136	Oral	5	0 MG	03NOV95	32	06NOV95	35	4
00136	Oral	5	0 MG	07NOV95	36	13NOV95	42	7
00136	Oral	5	0 MG	14NOV95	43	20NOV95	49	7
00136	Oral	5	0 MG	21NOV95	50	27NOV95	56	7
00136	Oral	4	0 MG	28NOV95	57	11DEC95	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	70	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1992
SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1995
SPRAINED LEFT ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	-1005, .	01JAN93	.	2 TABS PRN	MENSTRUAL CRAMPS
	Caffeine	Midol	-1005, .	01JAN93	.	2 TABS PRN	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-1005, .	01JAN93	.	2 TABS PRN	MENSTRUAL CRAMPS
MUSCULO-SKELETAL	Ibuprofen	Advil	-275, .	01JAN95	.	750 MG PRN	OCCASSIONAL HEADACHE
RESPIRATORY	Dexbrompheniramine Maleate	Drixoral	-275, .	01JAN95	.	500 PRN	SINUS CONGESTION
	Pseudoephedrine Sulfate	Drixoral	-275, .	01JAN95	.	500 PRN	SINUS CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	33, .	11 Days	0	3	MIL	NO	PBU	Yes	No
Metabolic and Nutritional Disorders	Thirst	INCREASE IN THIRST	8, .	15 Days	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Contact Dermatitis	CONTACT DERMATITIS LOWER AND UPPER HIP	8, .	15 Days	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26SEP95	-7,	.	0	131	56	109	105	72	115	287.60	66.5
BL	03OCT95	1,	.	0	119	76	102	124	66	115	299.60	
1	10OCT95	8,	.	0	132	57	81	84 L	63	114	296.40	
2	17OCT95	15,	.	0	124	48 L	90	102	73	117	288.90	
3	24OCT95	22,	.	0	101	50	86	114	56	115	292.80	
4	03NOV95	32,	.	0	109	54	54	117	67	86		
5	07NOV95	36,	.	0	133	80	66	131	50	103	294.00	
6	14NOV95	43,	.	0	124	60	84	109	55	111	287.40	
7	21NOV95	50,	.	0	116	62	74	110	82	100	293.80	
8	28NOV95	57,	.	0	125	57	86	105	49	96	296.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7				12 - 15.6	G/DL
				Hematocrit	38.2				35 - 46	%
				Red Blood Cell Count	4.4				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3				4.5 - 13	THOU/MCL
				Segmented Neutrophils	61				30 - 70	%
				Lymphocytes	25.1				21 - 51	%
				Monocytes	6.6				0 - 10	%
				Eosinophils	6.2	H			0 - 5	%
				Basophils	1.1				0 - 2	%
				Platelets	346000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7				25 - 35	PG
				Mean Corpuscle Volume	86				80 - 100	FL
				Blood Urea Nitrogen	11				7 - 25	MG/DL
				Creatinine	0.9				0.8 - 1.5	MG/DL
				Uric Acid	5.4				2.3 - 7	MG/DL
				Alkaline Phosphatase	130				44 - 280	U/L
				Aspartate Aminotransferase	21				0 - 41	U/L
				Alanine Aminotransferase	15				0 - 48	U/L
				Total Bilirubin	0.6				0.3 - 1.3	MG/DL
				Total Protein	7.9				6.2 - 8.8	G/DL
				Albumin	4.2				3.1 - 5.3	G/DL
				Glucose - Random	82				70 - 115	MG/DL
				Globulin	3.7				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.1		.	.	12 - 15.6	G/DL
				Hematocrit	34.7	L	.	.	35 - 46	%
				Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.1	H	.	.	30 - 70	%
				Lymphocytes	19	L	.	.	21 - 51	%
				Monocytes	3.7		.	.	0 - 10	%
				Eosinophils	3.1		.	.	0 - 5	%
				Basophils	1.1		.	.	0 - 2	%
				Platelets	288000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	119		.	.	44 - 280	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	10OCT95	1	16OCT95	7	7
00137	Oral	2	100 MG	17OCT95	8	23OCT95	14	7
00137	Oral	3	150 MG	24OCT95	15	30OCT95	21	7
00137	Oral	4	200 MG	31OCT95	22	06NOV95	28	7
00137	Oral	4	200 MG	07NOV95	29	13NOV95	35	7
00137	Oral	4	200 MG	14NOV95	36	20NOV95	42	7
00137	Oral	4	200 MG	21NOV95	43	27NOV95	49	7
00137	Oral	4	200 MG	28NOV95	50	04DEC95	56	7
	Oral	3	150 MG	05DEC95	57	16DEC95	68	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	No	68	150		TEAM FELT THAT DUE TO CONTINUING ADHD SYMPTOMS PATIENT NEEDED TREATMENT WITH STIMULANT

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	36,	.	22 Days	200	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	39,	.	4 Days	200		MIL	NO	PSR	No	No
Nervous System	Somnolence	SOMNOLENCE	16,	.	42 Days	150	CON	MOD	NO	PSR	No	No
Urogenital System	Urinary Frequency	INCREASED URINATION	8,	.	8 Days	100	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03OCT95	-7,	.	0	101	53	100	111	64	115	87.30	62.0
BL	10OCT95	1,	.	0	99	54	85	98	57	101	88.30	
1	17OCT95	8,	.	100	114	60	98	106	60	101	86.50	
2	24OCT95	15,	.	150	120	72	105	109	64	114	85.70	
3	31OCT95	22,	.	200	111	60	88	102	63	.	84.80	
4	07NOV95	29,	.	200	93	50	108	84	52	117	85.10	
5	14NOV95	36,	.	200	106	56	101	91	56	126	85.60	
6	21NOV95	43,	.	200	118	69	102	98	54	114	86.00	
7	28NOV95	50,	.	200	99	60	112	98	52	111	84.90	
8	05DEC95	57,	.	150	130	59	111	103	56	119	85.90	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	2.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	310000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	426	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.7	L	.	-	41 - 50	%
				Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.7		.	.	30 - 70	%
				Lymphocytes	24.5		.	.	21 - 51	%
				Monocytes	5.9		.	.	0 - 10	%
				Eosinophils	1.1		.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	288000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	367		.	.	44 - 400	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00138 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	10OCT95	1	13OCT95	4	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	4	20	Other reason	PATIENT WITHDREW CONSENT

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00138 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
OCCASIONAL STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02OCT95	-8, .	0	114	64	76	107	71	84	116.50	65.5
BL	10OCT95	1, .	0	122	61	83	115	65	98	117.70	
1	17OCT95	8, .	20	104	54	70	107	71	85	117.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00138 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	4.8	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	296000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	149	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00138 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	31OCT95	1	06NOV95	7	7
00169	Oral	2	0 MG	07NOV95	8	13NOV95	14	7
00169	Oral	3	0 MG	14NOV95	15	20NOV95	21	7
00169	Oral	4	0 MG	21NOV95	22	27NOV95	28	7
00169	Oral	4	0 MG	28NOV95	29	04DEC95	35	7
00169	Oral	4	0 MG	05DEC95	36	11DEC95	42	7
00169	Oral	4	0 MG	12DEC95	43	18DEC95	49	7
00169	Oral	4	0 MG	19DEC95	50	27DEC95	58	9
00098	Oral	4	0 MG	04JAN96	66	22JAN96	84	19
00169	Oral	4	0 MG	23JAN96	85	23JAN96	85	1
00169	Oral	3	0 MG	24JAN96	86	25JAN96	87	2
00169	Oral	2	0 MG	26JAN96	88	28JAN96	90	3
00169	Oral	1	0 MG	29JAN96	91	04FEB96	97	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	97	0	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Permethrin	Elimite	36, -30	05DEC95	05DEC95	5 %	SCABIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	SCABIES	34, -32	13 Days	0	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	SLIGHT DIZZINESS WHEN TAKING MEDS	50, -16	Not Stated	0	CON	MOD	NO	PSR	No	No
	Insomnia	MILD INITIAL INSOMNIA	43, -23	Not Stated	0	CON	MIL	NO	PSR	No	No
	Manic Reaction	HYPOMANIA	64, -2	Not Stated	0	CON	SEV	STP	REL	No	No
	Somnolence	DAYTIME SLEEPINESS	23, -43	17 Days	0		MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25OCT95	-6, -71	0	110	57	70	110	69	67	80.90	56.0
BL	31OCT95	1, -65	0	108	52	94	111	57	98	80.20	
1	07NOV95	8, -58	0	92	42	74	99	45	90	80.40	
2	14NOV95	15, -51	0	113	63	86	110	56	106	81.90	
3	21NOV95	22, -44	0	110	53	80	106	53	79	83.40	
4	28NOV95	29, -37	0	106	56	102	107	57	106	83.00	
5	05DEC95	36, -30	0	119	54	74	112	61	75	83.30	
6	12DEC95	43, -23	0	99	45	86	98	46	97	83.10	
7	19DEC95	50, -16	0	108	57	84	99	57	95	84.10	
8	27DEC95	58, -8	0	95	53	76	98	52	93	82.50	
12	23JAN96	85, 20	0	122	68	108	107	44	111	86.20 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.4	.	.	.	30 - 70	%
				Lymphocytes	32.2	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	203	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2		.	.	30 - 70	%
				Lymphocytes	35.1		.	.	21 - 51	%
				Monocytes	7.8		.	.	0 - 10	%
				Eosinophils	4.3		.	.	0 - 5	%
				Basophils	1.5		.	.	0 - 2	%
				Platelets	267000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	210		.	.	44 - 400	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07NOV95	1	13NOV95	7	7
00170	Oral	2	20 MG	14NOV95	8	20NOV95	14	7
00170	Oral	3	20 MG	21NOV95	15	27NOV95	21	7
00170	Oral	4	20 MG	28NOV95	22	04DEC95	28	7
00170	Oral	5	30 MG	05DEC95	29	11DEC95	35	7
00170	Oral	6	40 MG	12DEC95	36	20DEC95	44	9
00170	Oral	6	40 MG	21DEC95	45	28DEC95	52	8
00170	Oral	5	30 MG	29DEC95	53	02JAN96	57	5
00102	Oral	5	30 MG	03JAN96	58	28JAN96	83	26
00102	Oral	5	30 MG	29JAN96	84	25FEB96	111	28
00102	Oral	5	30 MG	26FEB96	112	31MAR96	146	35
00102	Oral	5	30 MG	01APR96	147	21APR96	167	21
00102	Oral	5	30 MC	22APR96	168	22MAY96	198	31
00102	Oral	5	30 MG	23MAY96	199	24JUN96	231	33
00358	Oral	4	20 MG	25JUN96	232	26JUN96	233	2
00358	Oral	3	20 MG	27JUN96	234	28JUN96	235	2
00358	Oral	2	20 MG	29JUN96	236	01JUL96	238	3
00358	Oral	1	20 MG	02JUL96	239	08JUL96	245	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	Yes	245	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BILATERAL LEG PAIN:MUSCULAR ORIGIN	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SCOLIOSIS	DEFORMITY, ACQUIRED	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Maalox Liquid	238, 181	01JUL96	.	8-16 TSP	NAUSEA
	Magnesium Hydroxide	Maalox Liquid	238, 181	01JUL96	.	8-16 TSP	NAUSEA
MUSCULO-SKELETAL	Ibuprofen	Motrin	246, 189	09JUL96	.	400 MG	DYSMENORRHEA
RESPIRATORY	Dimenhydrinate	Dramamine	238, 181	01JUL96	.	100 MG	NAUSEA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	234, 177	11 Days	20	CON	MOD	NO	PSR	No	Yes
Digestive System	Constipation	CONSTIPATION	244, 187	Not Stated	20	CON	MIL	NO	UNR	No	No
	Decreased Appetite	LOSS OF APPETITE	3, -55	43 Days	20	CON	MIL	NO	PSR	No	No
			45, -13	14 Days	40	CON	MOD	DCR	PSR	No	No
	Increased Appetite	INCREASED APPETITE	147, 90	85 Days	30	CON	MIL	NO	PSR	No	No
			237, 180	9 Days	20	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	234, 177	12 Days	20	CON	SEV	NO	REL	Yes	Yes
	Vomiting	VOMITING	238, 181	6 Days	20	CON	SEV	NO	REL	Yes	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS	45, -13	14 Days	40	CON	MIL	NO	PBU	No	No
Nervous System	Agitation	AGITATION	246, 189	12:00 Hrs	20	CON	MOD	NO	PSR	No	Yes
	Insomnia	MIDDLE INSOMNIA	17, -41	6 Days	20	CON	MIL	NO	PSR	No	No
			22, -36	37 Days	20	CON	MOD	NO	PSR	No	No
	Somnolence	DROWSY	234, 177	11 Days	20	CON	MOD	NO	PSR	No	Yes
		SLEEPINESS WHEN TAKING EVENING MEDS	45, -13	14 Days	40	CON	MOD	NO	PSR	No	No
	Tremor	SHAKY TREMORS	234, 177	2 Days	20	CON	MOD	NO	PSR	No	Yes
Urogenital System	Dysmenorrhea	DYSMENORRHEA	244, 187	Not Stated	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26OCT95	-12, -69	0	135	86	112	126	86	115	101.60	65.5
1	14NOV95	8, -50	20	130	68	112	146	96	133	101.60	
2	21NOV95	15, -43	20	128	79	114	124	80	126	101.10	
3	28NOV95	22, -36	20	128	90	109	114	79	109	100.30	
4	05DEC95	29, -29	30	129	83	115	126	91	119	100.90	
5	12DEC95	36, -22	40	106	70	97	116	68	108	100.60	
6	21DEC95	45, -13	40	107	68	84	100	73	90	98.80	
7	29DEC95	53, -5	30	124	90	108	116	84	105	100.60	
8	03JAN96	58, 1	30	130	80	125	124	81	125	101.50	
12	29JAN96	84, 27	30	105	65	105	99	57	100	103.40	
16	26FEB96	112, 55	30	114	52	106	114	49 L	108	105.90	
20	01APR96	147, 90	30	93	76	78	115	60	102	106.30	
24	22APR96	168, 111	30	114	72	93	128	67	98	109.00 H	
28	23MAY96	199, 142	30	113	96	74	111	74	99	113.40 H	
32	24JUN96	231, 174	30	128	82	99	131	85	99	114.60 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	301000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	141	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	114	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
			-5	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	26.4	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	2.9	H	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	6	.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.4	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	147	Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	122	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	231	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.9	.	.	.	30 - 70	%
				Lymphocytes	48.3	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	231		Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	125	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	45	H	.	.	0 - 41	U/L
					Alanine Aminotransferase	61	H	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	89	.	.	.	70 - 115	MG/DL
					Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 17/DOWN TITRATION	247	(2)	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	55.3	.	.	.	30 - 70	%
					Lymphocytes	38.6	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 17/DOWN TITRATION	247	(2)	Monocytes	3.5		.	.	0 - 10	%
					Eosinophils	1.7		.	.	0 - 5	%
					Basophils	0.9		.	.	0 - 2	%
					Platelets	216000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.9		.	.	25 - 35	PG
					Mean Corpuscle Volume	88		.	.	80 - 100	FL
					Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
					Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
					Uric Acid	3		.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	115		.	.	44 - 280	U/L
					Aspartate Aminotransferase	17		.	.	0 - 41	U/L
					Alanine Aminotransferase	16		.	.	0 - 48	U/L
					Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
					Total Protein	7.8		.	.	6.2 - 8.8	G/DL
					Albumin	4.2		.	.	3.1 - 5.3	G/DL
					Glucose - Random	62	L	.	.	70 - 115	MG/DL
					Globulin	3.6		.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	07NOV95	1	14NOV95	8	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	8	50	Adverse event, including intercurrent illness	MACULAR RASH

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGY TO IODINE	ADVERSE EFF/OTHER DRUG	EXT CAUSES OF INJURY/POISONING	CUR	1994
PREGNANCY	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1994
SEXUAL ASSAULT{STATUS POST,NO POST-TRAUMATIC STRESS DISORDER SYNDROME}	RAPE	EXT CAUSES OF INJURY/POISONING	PRV	1992
SUICIDE ATTEMPT{NOT IN CURRENT EPISODE}	SUICIDE	EXT CAUSES OF INJURY/POISONING	PRV	1994
WEIGHT LOSS{52LBS.-PLANNED}	WEIGHT LOSS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1995
{CHILDBIRTH}	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Triphasil	1, .	07NOV95	.	1TAB	BIRTH CONTROL
			1, .	07NOV95	.	1TAB	BIRTH CONTROL
	Levonorgestrel	Triphasil	1, .	07NOV95	.	1TAB	BIRTH CONTROL
			1, .	07NOV95	.	1TAB	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory System	Pharyngitis	SORE THROAT	8, .	Not Stated	50	CON	MIL	NO	PBU	No	No
	Sinusitis	SINUS CONGESTION	8, .	Not Stated	50	CON	MIL	NO	PBU	No	No
Skin and Appendages	Maculopapular Rash	RASH{FINE MACULAR ON FACE,INSIDE ELBOWS,BACK}	4, .	Not Stated	50	CON	SEV	STP	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	31OCT95	-7, .	0	131	69	79	135	74	109	200.60	62.0
BL	07NOV95	1, .	0	116	60	98	116	59	97	201.90	
1	14NOV95	8, .	50	122	71	93	115	74	105	199.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.6				12 - 15.6	G/DL
				Hematocrit	41.1				35 - 46	%
				Red Blood Cell Count	5				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6				4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1				30 - 70	%
				Lymphocytes	22.1				21 - 51	%
				Monocytes	2.7				0 - 10	%
				Eosinophils	8.3	H			0 - 5	%
				Basophils	0.8				0 - 2	%
				Platelets	404000	H			130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27				25 - 35	PG
				Mean Corpuscle Volume	82				80 - 100	FL
				Blood Urea Nitrogen	13				7 - 25	MG/DL
				Creatinine	0.8				0.8 - 1.5	MG/DL
				Uric Acid	5.1				2.3 - 7	MG/DL
				Alkaline Phosphatase	128				22 - 130	U/L
				Aspartate Aminotransferase	17				0 - 41	U/L
				Alanine Aminotransferase	17				0 - 48	U/L
				Total Bilirubin	0.5				0.3 - 1.3	MG/DL
				Total Protein	8.6				6.2 - 8.8	G/DL
				Albumin	4.6				3.1 - 5.3	G/DL
				Glucose - Random	95				70 - 115	MG/DL
				Globulin	4				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	13NOV95	1	19NOV95	7	7
00172	Oral	2	100 MG	20NOV95	8	26NOV95	14	7
00172	Oral	3	150 MG	27NOV95	15	03DEC95	21	7
00172	Oral	4	200 MG	04DEC95	22	10DEC95	28	7
00172	Oral	4	200 MG	11DEC95	29	20DEC95	38	10
00172	Oral	4	200 MG	21DEC95	39	26DEC95	44	6
00172	Oral	4	200 MG	27DEC95	45	02JAN96	51	7
00172	Oral	4	200 MG	03JAN96	52	08JAN96	57	6
00097	Oral	4	200 MG	09JAN96	58	06FEB96	86	29
00097	Oral	4	200 MG	07FEB96	87	03MAR96	112	26
00097	Oral	4	200 MG	04MAR96	113	31MAR96	140	28
00097	Oral	4	200 MG	01APR96	141	28APR96	168	28
00097	Oral	4	200 MC	29APR96	169	09JUN96	210	42
00097	Oral	4	200 MG	10JUN96	211	07JUL96	238	28
00360	Oral	4	200 MG	08JUL96	239	08JUL96	239	1
00360	Oral	3	150 MG	09JUL96	240	10JUL96	241	2
00360	Oral	2	100 MG	11JUL96	242	13JUL96	244	3
00360	Oral	1	50 MG	14JUL96	245	20JUL96	251	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	251	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-681, -738	01JAN94	.	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Tachycardia	TACHYCARDIA	2, -56	14 Days	50	2	MIL	NO	PBU	No	No
Digestive System	Diarrhea	DIARRHEA	249, 192	2 Days	50	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	23, -35	231 Days	200	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	249, 192	2 Days	50	CON	MIL	NO	PBU	No	No
Nervous System	Abnormal Dreams	NIGHTMARES	36, -22	52 Days	200		MOD	NO	PSR	No	No
	Dizziness	DIZZINESS	21, -37	233 Days	150	CON	MOD	NO	PSR	No	No
	Insomnia	INITIAL INSOMNIA	211, 154	29 Days	200	CON	MIL	NO	PBU	No	No
	Somnolence	SOMNOLENCE	17, -41	6 Days	150	CON	MOD	NO	PSR	No	No
	Thinking Abnormal	RACING THOUGHTS	40, -18	13 Days	200		MIL	NO	PBU	No	No
Special Senses	Tinnitus	RINGING IN EARS	21, -37	30 Days	150		MIL	NO	PSR	No	No
Urogenital System	Urinary Retention	URINARY RETENTION	58, 1	8 Days	200	CON	MOD	NO	PBU	No	No
	Urination Impaired	HARD TO INITIATE URINATION	58, 1	8 Days	200	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06NOV95	-7, -64	0	125	71	100	147	76	115	126.50	64.0
BL	13NOV95	1, -57	0	129	63	84	124	73	109	126.50	
1	20NOV95	8, -50	100	122	70	129 H	115	57	137	123.60	
2	27NOV95	15, -43	150	98	66	101	104	58	92	123.00	
3	04DEC95	22, -36	200	126	81	92	121	69	96	125.00	
4	11DEC95	29, -29	200	102	53	88	129	67	100	122.50	
5	21DEC95	39, -19	200	117	67	108	108	56	.	121.40	
6	27DEC95	45, -13	200	131	81	104	112	47 L	108	121.90	
7	03JAN96	52, -6	200	115	61	102	102	56	110	121.70	
8	09JAN96	58, 1	200	101	76	102	85 L	33 L	108	121.50	
12	07FEB96	87, 30	200	99	49	104	91	37 L	108	122.80	
16	04MAR96	113, 56	200	107	53	109	118	57	114	121.20	
20	01APR96	141, 84	200	123	65	120	108	41 L	120	125.10	
24	29APR96	169, 112	200	123	74	92	114	79	104	123.30	
28	10JUN96	211, 154	200	123	77	112	106	68	115	122.40	
32	08JUL96	239, 182	200	114	64	114	91	41 L	90	121.90	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4				12 - 15.6	G/DL
				Hematocrit	38.5				35 - 46	%
				Red Blood Cell Count	4.2				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6				4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7				30 - 70	%
				Lymphocytes	36.6				21 - 51	%
				Monocytes	5.9				0 - 10	%
				Eosinophils	2.3				0 - 5	%
				Basophils	0.5				0 - 2	%
				Platelets	255000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1				25 - 35	PG
				Mean Corpuscle Volume	92				80 - 100	FL
				Blood Urea Nitrogen	6	L			7 - 25	MG/DL
				Creatinine	0.8				0.8 - 1.5	MG/DL
				Uric Acid	3.6				2.3 - 7	MG/DL
				Alkaline Phosphatase	151				44 - 280	U/L
				Aspartate Aminotransferase	17				0 - 41	U/L
				Alanine Aminotransferase	14				0 - 48	U/L
				Total Bilirubin	0.5				0.3 - 1.3	MG/DL
				Total Protein	7.6				6.2 - 8.8	G/DL
				Albumin	4.4				3.1 - 5.3	G/DL
				Glucose - Random	99				70 - 115	MG/DL
				Globulin	3.2				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	6					
				Urine Red Blood Cells/HPF	5			+		
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13		.	.	12 - 15.6	G/DL
				Hematocrit	37.6		.	.	35 - 46	%
				Red Blood Cell Count	4.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.6		.	.	30 - 70	%
				Lymphocytes	34.4		.	.	21 - 51	%
				Monocytes	5.5		.	.	0 - 10	%
				Eosinophils	1.8		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	283000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	92		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131		.	.	44 - 280	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.7	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.1	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	141	Alkaline Phosphatase	127	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	239	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.3	.	.	.	30 - 70	%
				Lymphocytes	42.9	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	267000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	239	Mean Corpuscle Volume	93	. . .	80 - 100	FL
				Blood Urea Nitrogen	11	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.3	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	. . .	44 - 280	U/L
				Aspartate Aminotransferase	18	. . .	0 - 41	U/L
				Alanine Aminotransferase	16	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.3	. . .	3.1 - 5.3	G/DL
				Glucose - Random	76	. . .	70 - 115	MG/DL
				Globulin	3.5	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		. . .		
				Urine Blood - Dipstick NEG		. . .		
				Urine Red Blood Cells/HPF NEG		. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	4	. . .		
				Urine Protein - Dipstick NEC		. . .		
				Urine Squamous Epithelial Cells	4	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	20NOV95	1	26NOV95	7	7
00173	Oral	2	20 MG	27NOV95	8	03DEC95	14	7
00173	Oral	3	20 MG	04DEC95	15	10DEC95	21	7
00173	Oral	4	20 MG	11DEC95	22	17DEC95	28	7
00173	Oral	5	30 MG	18DEC95	29	28DEC95	39	11
00173	Oral	5	30 MG	29DEC95	40	07JAN96	49	10
00173	Oral	4	20 MG	08JAN96	50	14JAN96	56	7
00173	Oral	4	20 MG	15JAN96	57	21JAN96	63	7
00108	Oral	4	20 MG	22JAN96	64	26FEB96	99	36
00173	Oral	4	20 MG	27FEB96	100	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	100	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
UPPER RESPIRATORY TRACT INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Chlorphenamine Maleate	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
	Dextromethorphan Hydrobromide	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
	Paracetamol	Tylenol	-19, -82	01NOV95	.	650MG PRN	UPPER RESP. TRACT INFECTION
		Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
	Pseudoephedrine Hydrochloride	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
			-19, -82	01NOV95	.	2TABS PRN	URI
	Dextromethorphan Hydrobromide	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
			-19, -82	01NOV95	.	2TABS PRN	URI
	Paracetamol	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
			-19, -82	01NOV95	.	2TABS PRN	URI
	Pseudoephedrine Hydrochloride	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
			-19, -82	01NOV95	.	2TABS PRN	URI

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	43, -21	Not Stated	30	CON	MOD	NO	PSR	No	No
Nervous System	Insomnia	INSOMNIA	57, -7	Not Stated	20	CON	MOD	NO	PSR	No	No
	Nervousness	RESTLESSNESS	40, -24	18 Days	30	CON	MOD	DCR	PSR	No	No
	Somnolence	INCREASED DAYTIME SLEEPINESS SOMNOLENCE	24, -40	Not Stated	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	08NOV95	-12, -75	0	131	68	84	129	68	86	145.80	64.2
BL	20NOV95	1, -63	0	133	80	85	131	73	96	142.60	
1	27NOV95	8, -56	20	130	64	80	132	67	84	147.10	
2	04DEC95	15, -49	20	110	67	66	123	64	74	142.90	
3	11DEC95	22, -42	20	117	59	80	115	69	83	144.60	
4	18DEC95	29, -35	30	121	60	75	122	68	80	145.60	
6	29DEC95	40, -24	30	131	65	87	122	56	88	144.30	
7	08JAN96	50, -14	20	124	57	98	131	68	96	139.00	
8	15JAN96	57, -7	20	131	69	88	122	74	94	140.10	
8	22JAN96	64, 1	20	114	61	80	116	66	87	141.60	
12	26FEB96	99, 36	20	100	50	80	124	61	85	139.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-12	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	33	.	.	.	30 - 70	%
				Lymphocytes	46	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	8	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	382	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEC		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.8		.	.	12 - 15.6	G/DL
				Hematocrit	36.3		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48		.	.	30 - 70	%
				Lymphocytes	43		.	.	21 - 51	%
				Monocytes	5.4		.	.	0 - 10	%
				Eosinophils	1.9		.	.	0 - 5	%
				Basophils	1.6		.	.	0 - 2	%
				Platelets	309000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.2		.	.	12 - 15.6	G/DL
				Hematocrit	38		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	36		.	.	30 - 70	%
				Lymphocytes	57	H	.	.	21 - 51	%
				Monocytes	0		.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	293000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Blood Urea Nitrogen	7	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	289	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21NOV95	1	27NOV95	7	7
00174	Oral	2	0 MG	28NOV95	8	04DEC95	14	7
00174	Oral	3	0 MG	05DEC95	15	11DEC95	21	7
00174	Oral	4	0 MG	12DEC95	22	18DEC95	28	7
00174	Oral	5	0 MG	19DEC95	29	26DEC95	36	8
00174	Oral	5	0 MG	27DEC95	37	01JAN96	42	6
00174	Oral	5	0 MG	02JAN96	43	08JAN96	49	7
00174	Oral	5	0 MG	09JAN96	50	16JAN96	57	8
00107	Oral	5	0 MG	17JAN96	58	30JAN96	71	14
00174	Oral	4	0 MG	31JAN96	72	01FEB96	73	2
00174	Oral	3	0 MG	02FEB96	74	03FEB96	75	2
00174	Oral	2	0 MG	04FEB96	76	06FEB96	78	3
00174	Oral	1	0 MG	07FEB96	79	13FEB96	85	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	85	0	Lack of Efficacy	PT.HAD RELAPSE-NEEDED TX

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES(SEASONAL)	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
MILD OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
TEMPOROMANDIBULAR JOINT SYNDROME	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	13, -45	03DEC95	07DEC95	2TBS.PRN	FLU
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	-689, -746	01JAN94	.	500 MG PRN	HEADACHES
			13, -45	03DEC95	07DEC95	500MG	FLU
	Caffeine	Excedrin	-689, -746	01JAN94	.	500 MG PRN	HEADACHES
			13, -45	03DEC95	07DEC95	500MG	FLU
	Paracetamol	Excedrin	-689, -746	01JAN94	.	500 MG PRN	HEADACHES
			13, -45	03DEC95	07DEC95	500MG	FLU
MUSCULO-SKELETAL	Oxaprozin	Daypro	-13, -70	08NOV95	.	600MG PRN	TMJ
RESPIRATORY	Dexbrompheniramine Maleate	Drixoral	-385, -442	01NOV94	.	2TABS PRN	ALLERGIES
	Pseudoephedrine Sulfate	Drixoral	-385, -442	01NOV94	.	2TABS PRN	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	13, -45	Not Stated	0		MOD	NO	PSR	Yes	No
	Infection	FLU(STOMACH ACHE)	13, -45	5 Days	0	CON	MIL	NO	UNR	Yes	No
Digestive System	Constipation	CONSTIPATION	20, -38	Not Stated	0		MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14NOV95	-7, -64	0	115	60	64	123	85	98	219.20	65.5
BL	21NOV95	1, -57	0	132	74	91	124	66	105	219.60	
1	28NOV95	8, -50	0	125	77	101	135	72	111	222.40	
2	05DEC95	15, -43	0	145	89	84	158	84	105	218.90	
3	12DEC95	22, -36	0	135	66	81	136	71	100	223.00	
4	19DEC95	29, -29	0	129	79	106	137	67	114	222.40	
5	27DEC95	37, -21	0	145	88	105	138	72	126	224.00	
6	02JAN96	43, -15	0	123	68	80	147	78	86	224.10	
7	09JAN96	50, -8	0	136	83	104	150	85	109	222.40	
8	17JAN96	58, 1	0	138	83	108	149	76	104	220.40	
12	31JAN96	72, 15	0	114	68	95	122	70	105	221.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	56	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14		.	.	12 - 15.6	G/DL
				Hematocrit	40.3		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4		.	.	30 - 70	%
				Lymphocytes	34		.	.	21 - 51	%
				Monocytes	3.8		.	.	0 - 10	%
				Eosinophils	1.4		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	304000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62		.	.	44 - 280	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28NOV95	1	04DEC95	7	7
00193	Oral	2	20 MG	05DEC95	8	11DEC95	14	7
00193	Oral	3	20 MG	12DEC95	15	18DEC95	21	7
00193	Oral	4	20 MG	19DEC95	22	26DEC95	29	8
00193	Oral	5	30 MG	27DEC95	30	04JAN96	38	9
00193	Oral	5	30 MG	05JAN96	39	08JAN96	42	4
00193	Oral	5	30 MG	09JAN96	43	15JAN96	49	7
00193	Oral	5	30 MG	16JAN96	50	23JAN96	57	8
	Oral	1	20 MG	24JAN96	58	06FEB96	71	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	71	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	-331, .	01JAN95	.	500PRN	HEADACHE
	Caffeine	Excedrin	-331, .	01JAN95	.	500PRN	HEADACHE
	Paracetamol	Excedrin	-331, .	01JAN95	.	500PRN	HEADACHE
MUSCULO-SKELETAL	Eucalyptus Oil	Hall'S Cough Drops	15, .	12DEC95	27DEC95	1PRN	URI
	Ibuprofen	Ibuprofen	15, .	12DEC95	27DEC95	200MG PRN	URI
	Menthol	Hall'S Cough Drops	15, .	12DEC95	27DEC95	1PRN	URI
RESPIRATORY	Dextromethorphan Hydrobromide	Nyquil	15, .	12DEC95	27DEC95	1TBS PRN	URI
	Doxylamine Succinate	Nyquil	15, .	12DEC95	27DEC95	1TBS PRN	URI
	Eucalyptus Oil	Hall'S Cough Drops	15, .	12DEC95	27DEC95	1PRN	URI
	Menthol	Hall'S Cough Drops	15, .	12DEC95	27DEC95	1PRN	URI
	Paracetamol	Nyquil	15, .	12DEC95	27DEC95	1TBS PRN	URI
	Pseudoephedrine Hydrochloride	Nyquil	15, .	12DEC95	27DEC95	1TBS PRN	URI

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Nervousness	RESTLESSNESS	4, .	12 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD SYNDROME (URI) {UPPER RESPIRATORY INFECTION}	13, .	18 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	21NOV95	-7,	.	0	121	63	89	127	65	101	131.90	63.8
BL	28NOV95	1,	.	0	111	51	90	130	64	100	134.60	
1	05DEC95	8,	.	20	127	64	80	129	63	79	132.40	
2	12DEC95	15,	.	20	115	57	76	114	57	93	132.90	
3	19DEC95	22,	.	20	105	65	91	117	65	119	133.20	
4	27DEC95	30,	.	30	123	57	95	122	60	103	136.10	
5	05JAN96	39,	.	30	109	46	91	99	52	103	134.00	
6	09JAN96	43,	.	30	123	53	94	122	60	108	139.00	
7	16JAN96	50,	.	30	114	52	93	122	62	72	137.50	
8	24JAN96	58,	.	20	114	64	103	134	69	105	139.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2		.	.	12 - 15.6	G/DL
				Hematocrit	41.6		.	.	35 - 46	%
				Red Blood Cell Count	5.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	14	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H	.	.	30 - 70	%
				Lymphocytes	16.7	L	.	.	21 - 51	%
				Monocytes	5.1		.	.	0 - 10	%
				Eosinophils	4.6		.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	324000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	81		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	8 - 21	MG/DL
				Creatinine	0.8		.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	173		.	.	44 - 280	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 39	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	5.7 - 8.2	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	84		.	.	60 - 110	MG/DL
				Globulin	2.9		.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	6		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	162	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05DEC95	1	11DEC95	7	7
00194	Oral	2	100 MG	12DEC95	8	18DEC95	14	7
00194	Oral	3	150 MG	19DEC95	15	26DEC95	22	8
00194	Oral	4	200 MG	27DEC95	23	01JAN96	28	6
00194	Oral	4	200 MG	02JAN96	29	08JAN96	35	7
00194	Oral	4	200 MG	09JAN96	36	15JAN96	42	7
00194	Oral	4	200 MG	16JAN96	43	22JAN96	49	7
00194	Oral	4	200 MG	23JAN96	50	29JAN96	56	7
00105	Oral	4	200 MG	30JAN96	57	26FEB96	84	28
00105	Oral	4	200 MG	27FEB96	85	01APR96	119	35
00105	Oral	4	200 MG	02APR96	120	29APR96	147	28
00105	Oral	4	200 MG	30APR96	148	04JUN96	183	36
00194	Oral	4	200 MG	05JUN96	184	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	184	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES TO MILK	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1993
ANKLE PAIN{SECONDARY TO SURGICAL CORRECTION RIGHT FOOT{CLUB)}	OPERATION, MUSCLE/TENDON	OPERATIONS	CUR	1984
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MYALGIA{UNSPECIFIED}	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Cimetidine	Tagamet	28, -29	01JAN96	.	200MG	STOMACH ACHE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-703, -759	01JAN94	.	250MG PRN	ANKLE PAIN
		Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI
	Pseudoephedrine Hydrochloride	Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI
RESPIRATORY	Cough Syrup/Med	Cough Syrup {Nos}	29, -28	02JAN96	16JAN96	2TBL PRN	UPPER RESPIRATORY TRACT INFECTION
	Paracetamol	Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI
	Pseudoephedrine Hydrochloride	Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	15, -42	181 Days	150	CON	MOD	NO	REL	Yes	No
Digestive System	Nausea	NAUSEA	43, -14	153 Days	200	CON	MOD	STP	PSR	No	No
Nervous System	Abnormal Dreams	INCREASED DREAMING	3, -54	34 Days	50		MOD	NO	PSR	No	No
		NIGHTMARES	3, -54	13 Days	50	1	MOD	NO	PSR	No	No
	Insomnia	INITIAL INSOMNIA	85, 29	64 Days	200	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD SYNDROME UPPER RESPIRATORY TRACT INFECTION(URI)	29, -28	15 Days	200	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Sweating	NIGHT SWEATS	120, 64	76 Days	200	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	28NOV95	-7, -63	0	109	58	66	98	69	68	90.40	56.8
BL	05DEC95	1, -56	0	116	55	77	95	62	88	91.40	
1	12DEC95	8, -49	100	105	53	88	104	54	83	90.20	
2	19DEC95	15, -42	150	112	69	95	118	62	89	90.20	
3	27DEC95	23, -34	200	114	65	98	108	62	111	91.30	
4	02JAN96	29, -28	200	116	80	117	138	73	119	90.00	
5	09JAN96	36, -21	200	109	57	105	106	62	109	91.00	
6	16JAN96	43, -14	200	114	68	106	116	66	102	90.80	
7	23JAN96	50, -7	200	107	62	106	100	56	108	91.10	
8	30JAN96	57, 1	200	106	57	98	113	62	102	89.90	
12	27FEB96	85, 29	200	93	48	97	114	48	87	89.90	
16	02APR96	120, 64	200	95	60	88	97	65	87	87.00	
20	30APR96	148, 92	200	106	53	81	111	52	83	86.70	
24	04JUN96	183, 127	200	104	56	99	117	53	100	87.40	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36	L	.	-	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.3	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	316000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	244	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	125	H	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.9	L	.	-	41 - 50	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.1		.	.	30 - 70	%
				Lymphocytes	32.7		.	.	21 - 51	%
				Monocytes	8.8		.	.	0 - 10	%
				Eosinophils	3.1		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	284000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	78	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	8 - 21	MG/DL
				Creatinine	0.8		.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.1		.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	259		.	.	44 - 400	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	12.8	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	28.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	289000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	239	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12 20	M	VISIT 13/CONTINUATION-WEEK	148	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	15DEC95	1	18DEC95	4	4
00195	Oral	2	100 MG	19DEC95	5	26DEC95	12	8
00195	Oral	3	150 MG	27DEC95	13	01JAN96	18	6
00195	Oral	4	200 MG	02JAN96	19	07JAN96	24	6
	Oral	3	150 MG	08JAN96	25	19JAN96	36	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	36	150	Adverse event, including intercurrent illness	CARDIAC ARRHYTHYMIA(PVC'S)

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Codeine Phosphate	Tylenol Number 3	-14, .	01DEC95	02DEC95#	650MG	HEADACHE
	Paracetamol	Tylenol	-1809, .	01JAN91	.	650MG PRN	HEADACHE
		Tylenol Number 3	-14, .	01DEC95	02DEC95#	650MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	-1809, .	01JAN91	.	200MG PRN	HEADACHE
	Naproxen Sodium	Anaprox	-713, .	01JAN94	.	275MG PRN	MENSTRUAL CRAMPS
RESPIRATORY	Salbutamol	Proventil	-348, .	01JAN95	.	2PUFFS PRN	SEASONAL ALLERGIES
			-348, .	01JAN95	.	2PUFFS PRN	SEASONAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN	21, .	19 Days	200	2	MOD	NO	PSR	No	No
	Headache	HEAD PAIN	19, .	21 Days	200	20	MOD	NO	PSR	No	No
Carciovascular System	Extrasystoles	CARIDAC ARRHYTHMIA [PREMATURE VENTRICULAR CONTRACTIONS]	25, .	15 Days	150	CON	MOD	STP	REL	No	No
	Vasodilatation	FACIAL FLUSHING	11, .	29 Days	100	CON	MOD	NO	PSR	No	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS	13, .	13 Days	150	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	21, .	19 Days	200	CON	MOD	NO	PSR	No	No
Skin and Appendages	Sweating	SWEATING	11, .	29 Days	100	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06DEC95	-9,	.	0	115	65	72	122	71	86	112.40	64.0
BL	15DEC95	1,	.	0	123	58	63	107	63	77	112.30	
1	19DEC95	5,	.	100	116	47	65	107	60	86	112.80	
2	27DEC95	13,	.	150	106	65	79	115	54	79	110.70	
3	02JAN96	19,	.	200	115	57	98	106	62	129 H	111.20	
3	08JAN96	25,	.	150	140	85	96	139	73	125 H		

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	38.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	220000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	96	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	61	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	-1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	13	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEC		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18DEC95	1	26DEC95	9	9
00196	Oral	2	20 MG	27DEC95	10	01JAN96	15	6
00196	Oral	3	20 MG	02JAN96	16	07JAN96	21	6
00196	Oral	4	20 MG	08JAN96	22	14JAN96	28	7
00196	Oral	5	30 MG	15JAN96	29	21JAN96	35	7
00196	Oral	5	30 MG	22JAN96	36	28JAN96	42	7
00196	Oral	5	30 MG	29JAN96	43	04FEB96	49	7
00196	Oral	5	30 MG	05FEB96	50	11FEB96	56	7
00196	Oral	4	20 MG	12FEB96	57	25FEB96	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	70	20	Other reason	PATIENT WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES TO ASPIRIN	ADVERSE EFF/ANALGESIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
ALLERGIES TO SULFA DRUGS	ADVERSE EFF/ANTI-INFECT	EXT CAUSES OF INJURY/POISONING	CUR	1995
ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1995
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1993
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
MENSTRUAL CRAMPS{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
OBESITY{MILD}	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Dihydroxyaluminum Sodium Carbonate	Rolaids	10, .	27DEC95	.	2TABS PRN	HEARTBURN
	Famotidine	Pepcid Ac	10, .	27DEC95	.	75MG	HEARTBURN
ANTIINFECTIVES,SYSTEMIC	Cefixime	Cefixime	56, .	11FEB96	.	400MG	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-716, .	01JAN94	.	975MG	HEADACHES
		Tylenol Sinus	55, .	10FEB96	.	975MG	SINUS INFECTION
	Pseudoephedrine Hydrochloride	Tylenol Sinus	55, .	10FEB96	.	975MG	SINUS INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-716, .	01JAN94	.	800MG PRN	HEADACHES
RESPIRATORY	Carbinoxamine Maleate	Rondec Dm	56, .	11FEB96	.	4TABS	SINUS INFECTION
	Dextromethorphan Hydrobromide	Rondec Dm	56, .	11FEB96	.	4TABS	SINUS INFECTION
	Guaifenesin	Entex	54, .	09FEB96	09FEB96	4TABS	SINUS INFECTION
	Paracetamol	Tylenol Sinus	55, .	10FEB96	.	975MG	SINUS INFECTION
	Phenylephrine Hydrochloride	Entex	54, .	09FEB96	09FEB96	4TABS	SINUS INFECTION
	Phenylpropanolamine Hydrochloride	Entex	54, .	09FEB96	09FEB96	4TABS	SINUS INFECTION
	Prednisone	Prednisone	56, .	11FEB96	.	5MG QD	ASTHMA
	Pseudoephedrine Hydrochloride	Rondec Dm	56, .	11FEB96	.	4TABS	SINUS INFECTION
		Tylenol Sinus	55, .	10FEB96	.	975MG	SINUS INFECTION
	Salbutamol	Albuterol	-1081, .	01JAN93	.	2TSP PRN	ASTHMA
			-1081, .	01JAN93	.	2TSP PRN	ASTHMA
		Albuterol Inhaler	-1081, .	01JAN93	.	2PUFFS PRN	ASTHMA
			-1081, .	01JAN93	.	2PUFFS PRN	ASTHMA
SYSTEMIC HORMONAL	Prednisone	Prednisone	56, .	11FEB96	.	5MG QD	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Constipation	CONSTIPATION	3, .	Not Stated	20	7	MIL	NO	PBU	No	No
	Decreased Appetite	DECREASED APPETITE	2, .	21 Days	20	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	17, .	6 Days	20	CON	MIL	NO	PSR	No	No
	Dyspepsia	HEARTBURN	41, .	Not Stated	30	CON	MIL	NO	PBU	Yes	No
	Nausea	NAUSEA	2, .	21 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Insomnia	INSOMNIA (INITIAL)	2, .	21 Days	20	CON	MIL	NO	PBU	No	No
Respiratory System	Asthma	ASTHMA	43, .	Not Stated	30	CON	SEV	NO	UNR	Yes	No
	Sinusitis	SINUS INFECTION	43, .	Not Stated	30	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	11DEC95	-7,	.	0	148	85	102	146	76	106	237.00	65.0
BL	18DEC95	1,	.	0	137	75	90	138	71	91	232.40	
1	27DEC95	10,	.	20	146	80	90	138	77	100	231.00	
2	02JAN96	16,	.	20	144	79	75	140	79	86	233.80	
3	08JAN96	22,	.	20	153	87	88	153	87	98	237.90	
4	15JAN96	29,	.	30	146	80	87	146	80	90	237.50	
5	22JAN96	36,	.	30	137	83	74	129	85	85	235.90	
6	29JAN96	43,	.	30	138	77	91	139	66	94	236.00	
7	05FEB96	50,	.	30	137	72	95	150	90	96	239.50	
8	12FEB96	57,	.	20	117	66	100	114	60	102	234.10	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	10.9	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.1	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.1	.	.	.	30 - 70	%
				Lymphocytes	22.9	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	1.4	.	.	.	0 - 2	%
				Platelets	386000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	130	H	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	11.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.1	L	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	16.7	H	.	+	3.8 - 10.8	THOU/MCL
				Neutrophil Bands	5	.	.	.	0 - 8	%
				Segmented Neutrophils	89	H	.	.	40 - 75	%
				Lymphocytes	5	L	.	.	16 - 46	%
				Monocytes	1	.	.	.	0 - 12	%
				Eosinophils	0	.	.	.	0 - 7	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	417000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.1	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.1	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	123	H	.	.	70 - 115	MG/DL
				Globulin	4.9	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	29DEC95	1	01JAN96	4	4
00197	Oral	2	0 MG	02JAN96	5	07JAN96	10	6
00197	Oral	3	0 MG	08JAN96	11	15JAN96	18	8
00197	Oral	4	0 MG	16JAN96	19	22JAN96	25	7
00197	Oral	4	0 MG	23JAN96	26	29JAN96	32	7
00197	Oral	4	0 MG	30JAN96	33	05FEB96	39	7
00197	Oral	4	0 MG	06FEB96	40	12FEB96	46	7
00197	Oral	4	0 MG	13FEB96	47	20FEB96	54	8
00139	Oral	4	0 MG	21FEB96	55	18MAR96	81	27
00139	Oral	4	0 MG	19MAR96	82	22APR96	116	35
00139	Oral	4	0 MG	23APR96	117	20MAY96	144	28
00139	Oral	4	0 MG	21MAY96	145	24JUN96	179	35
00139	Oral	4	0 MG	25JUN96	180	15JUL96	200	21
00139	Oral	4	0 MG	16JUL96	201	19AUG96	235	35
00197	Oral	4	0 MG	20AUG96	236	20AUG96	236	1
00197	Oral	3	0 MG	21AUG96	237	22AUG96	238	2
00197	Oral	2	0 MG	23AUG96	239	25AUG96	241	3
00197	Oral	1	0 MG	26AUG96	242	01SEP96	248	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	Yes	248	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
STOMACH PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid	-58, -112	01NOV95	.	20MG PRN	STOMACH PAIN
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	174, 120	19JUN96	23JUN96	1000 MG	SCALP LACERATIONS
	Clavulanic Acid	Augmentin	174, 120	19JUN96	23JUN96	1000 MG	SCALP LACERATIONS
MUSCULO-SKELETAL	Ibuprofen	Advil	-362, -416	01JAN95	.	200MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Trauma	SCALP LACERATIONS (TOP OF HEAD)	172, 118	2 Days	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	236, 182	4 Days	0		MOD	NO	UNR	No	No
	Vomiting	VOMITING	236, 182	4 Days	0	3	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZY	21, -34	1 Days	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20DEC95	-9, -63	0	118	54	88	110	59	115	99.40	58.0
BL	29DEC95	1, -54	0	106	49	86	124	60	95	97.80	
1	02JAN96	5, -50	0	92	40	72	101	55	86	98.60	
1	08JAN96	11, -44	0	102	50	79	107	50	96	100.00	
3	16JAN96	19, -36	0	100	38	71	97	49	81	99.60	
4	23JAN96	26, -29	0	94	43	81	100	46	83	101.60	
5	30JAN96	33, -22	0	115	68	81	116	49	105	100.30	
6	06FEB96	40, -15	0	82	47	96	86 L	53	100	99.70	
7	13FEB96	47, -8	0	89	40	75	90	52	84	98.80	
8	20FEB96	54, -1	0	90	47	91	98	52	120	99.10	
12	19MAR96	82, 28	0	100	49	83	107	42	95	100.00	
16	23APR96	117, 63	0	99	53	71	99	57	94	99.60	
20	21MAY96	145, 91	0	97	63	76	83 L	61	90	102.30	
24	25JUN96	180, 126	0	114	61	98	112	63	112	106.94 H	
28	16JUL96	201, 147	0	106	53	93	105	52	100	107.40 H	
32	20AUG96	236, 182	0	103	44	89	98	62	84	109.20 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	155	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	13.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49		.	.	30 - 70	%
				Lymphocytes	38.4		.	.	21 - 51	%
				Monocytes	6.5		.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	248000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28		.	.	25 - 35	PG
				Mean Corpuscle Volume	81		.	.	80 - 100	FL
				Blood Urea Nitrogen	18		.	.	8 - 21	MG/DL
				Creatinine	0.7		.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6		.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	134		.	.	44 - 400	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	13		.	.	0 - 39	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4		.	.	5.7 - 8.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	54	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	145	Hemoglobin	13	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.6	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	7.2	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	123	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	145	Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	236	Hemoglobin	13.9		.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5		.	.	30 - 70	%
				Lymphocytes	43.8		.	.	21 - 51	%
				Monocytes	7.3		.	.	0 - 10	%
				Eosinophils	4.8		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	239000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	82		.	.	80 - 100	FL
				Blood Urea Nitrogen	17		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	147		.	.	44 - 400	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	97		.	.	70 - 115	MG/DL
				Globulin	3.6		.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 16/CONTINUATION-WEEK 32	236	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	02JAN96	1	07JAN96	6	6
00198	Oral	2	0 MG	08JAN96	7	15JAN96	14	8
00198	Oral	3	0 MG	16JAN96	15	22JAN96	21	7
00198	Oral	4	0 MG	23JAN96	22	29JAN96	28	7
00198	Oral	4	0 MG	30JAN96	29	05FEB96	35	7
00198	Oral	4	0 MG	06FEB96	36	12FEB96	42	7
00198	Oral	4	0 MG	13FEB96	43	19FEB96	49	7
00198	Oral	4	0 MG	20FEB96	50	26FEB96	56	7
	Oral	3	0 MG	27FEB96	57	09MAR96	68	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	68	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGY TO CODEINE	ADVERSE EFF/ANALGESIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
OTITIS MEDIA BILATERAL{PROBABLE}	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
UPPER RESPIRATORY TRACT INFECTION(FLU)	INFLUENZA	RESPIRATORY SYST DIS	CUR	1994
GRAVIDA 1,PARA 0,ABORTION {PREGNANCY}	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Tetanus Toxoid	Tetanus {Toxoid}	48, .	18FEB96	18FEB96	1CC	VACCINATION(FACIAL CUTS)
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-366, .	01JAN95	.	650MG PRN	HEADACHE
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Triphasil	-1096, .	01JAN93	.	1PILL	BIRTH CONTROL
			-1096, .	01JAN93	.	1PILL	BIRTH CONTROL
	Levonorgestrel	Triphasil	-1096, .	01JAN93	.	1PILL	BIRTH CONTROL
			-1096, .	01JAN93	.	1PILL	BIRTH CONTROL
RESPIRATORY	Guaifenesin	Robitussin	-366, .	01JAN95	.	2TBLS	FLU SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	2, .	Not Stated	0	CON	MOD	NO	PSR	No	No
	Trauma	FACIAL CUTS {LEFT CHEEK}	48, .	1 Days	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	7, .	13 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Abnormal Dreams	NIGHTMARE	2, .	7 Days	0	6	MOD	NO	PSR	No	No
	Nervousness	RESTLESSNESS	15, .	8 Days	0	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19DEC95	-14,	.	0	116	66	86	123	68	94	103.00	61.5
BL	02JAN96	1,	.	0	112	63	91	115	66	95	103.90	
1	08JAN96	7,	.	0	113	67	91	108	65	93	102.80	
2	16JAN96	15,	.	0	107	57	81	105	59	88	105.60	
3	23JAN96	22,	.	0	108	65	80	115	64	81	105.90	
4	30JAN96	29,	.	0	131	65	94	124	64	115	104.50	
5	06FEB96	36,	.	0	97	50	86	106	48	105	104.60	
6	13FEB96	43,	.	0	132	70	91	126	75	90	105.10	
7	20FEB96	50,	.	0	99	52	76	99	53	97	105.00	
8	27FEB96	57,	.	0	106	59	86	106	57	88	105.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	44	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.9		.	.	12 - 15.6	G/DL
				Hematocrit	40		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.7		.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	52.2		.	.	40 - 75	%
				Lymphocytes	35.1		.	.	16 - 46	%
				Monocytes	6		.	.	0 - 12	%
				Eosinophils	5.1		.	.	0 - 7	%
				Basophils	1.5		.	.	0 - 2	%
				Platelets	183000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	27 - 33	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	44		.	.	22 - 130	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	23		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	16JAN96	1	22JAN96	7	7
00199	Oral	2	100 MG	23JAN96	8	28JAN96	13	6
00199	Oral	3	150 MG	29JAN96	14	06FEB96	22	9
00199	Oral	4	200 MG	07FEB96	23	13FEB96	29	7
00199	Oral	4	200 MG	14FEB96	30	20FEB96	36	7
00199	Oral	5	250 MG	21FEB96	37	27FEB96	43	7
00199	Oral	5	250 MG	28FEB96	44	05MAR96	50	7
00199	Oral	5	250 MG	06MAR96	51	12MAR96	57	7
	Oral	4	200 MG	13MAR96	58	26MAR96	71	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	71	200	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGY TO CECLOR	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MUSCULAR NECK PAIN	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	58, .	Not Stated	200	5	MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	9, .	15 Days	100	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	2, .	42 Days	50	CON	MOD	NO	PSR	No	No
			44, .	15 Days	250	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	2, .	Not Stated	50	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	10JAN96	-6,	.	0	130	65	73	136	81	96	160.30	66.0
BL	16JAN96	1,	.	0	114	61	69	106	56	88	158.90	
1	23JAN96	8,	.	100	138	59	95	107	69	108	160.50	
2	29JAN96	14,	.	150	111	61	88	103	53	100	158.90	
3	07FEB96	23,	.	200	123	49	109	91	54	114	159.80	
4	14FEB96	30,	.	200	114	50	101	98	41	105	158.10	
5	21FEB96	37,	.	250	114	61	95	105	58	98	156.10	
6	28FEB96	44,	.	250	137	76	96	112	64	105	157.70	
7	06MAR96	51,	.	250	100	62	86	98	48	94	158.20	
8	13MAR96	58,	.	200	122	72	96	90	55	105	155.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.8		.	.	12 - 15.6	G/DL
				Hematocrit	39.8		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.3		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63.2		.	.	30 - 70	%
				Lymphocytes	28.6		.	.	21 - 51	%
				Monocytes	6.1		.	.	0 - 10	%
				Eosinophils	1.5		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	148000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73		.	.	44 - 280	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	12		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	97		.	.	70 - 115	MG/DL
				Globulin	2.8		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.5		.	.	12 - 15.6	G/DL
				Hematocrit	42.7		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.7		.	.	30 - 70	%
				Lymphocytes	30		.	.	21 - 51	%
				Monocytes	6.7		.	.	0 - 10	%
				Eosinophils	0.1		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	261000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2		.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alkaline Phosphatase	65	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	23JAN96	1	01FEB96	10	10
00200	Oral	2	0 MG	02FEB96	11	05FEB96	14	4
00200	Oral	3	0 MG	06FEB96	15	12FEB96	21	7
00200	Oral	4	0 MG	13FEB96	22	19FEB96	28	7
00200	Oral	4	0 MG	20FEB96	29	27FEB96	36	8
00200	Oral	4	0 MG	28FEB96	37	07MAR96	45	9
	Oral	3	0 MG	08MAR96	46	19MAR96	57	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	57	0	Lack of Efficacy	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANEMIC	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
{COMMON} COLD	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Diphenhydramine Hydrochloride	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
	Paracetamol	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
		Tylenol	-752, .	01JAN94	.	500MG	HEADACHE
	Pseudoephedrine Hydrochloride	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
			-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
	Paracetamol	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
			-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
	Pseudoephedrine Hydrochloride	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
			-22, .	01JAN96	05JAN96#	2TAB PRN	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Av Block	SINUS ARRHYTHMIA(MOBITZ I)	15, .	43 Days	0	2	MIL	NO	PBU	No	No
Digestive System	Nausea	NAUSEA	29, .	9 Days	0	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Thirst	INCREASE IN THIRST	21, .	3 Days	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Rash	NON PAPULAR RASH (UPPER TORSO AND BACK)	57, .	Not Stated	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	17JAN96	-6,	.	0	115	76	70	121	79	74	118.20	62.0
BL	23JAN96	1,	.	0	122	72	81	.	.	.	121.40	
1	02FEB96	11,	.	0	110	60	79	114	59	78	119.30	
2	06FEB96	15,	.	0	110	80	91	123	69	106	123.00	
3	13FEB96	22,	.	0	100	62	105	122	60	101	120.20	
4	20FEB96	29,	.	0	122	83	84	107	69	105	119.90	
5	28FEB96	37,	.	0	107	56	86	112	77	95	120.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	11.4	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72	H	.	.	30 - 70	%
				Lymphocytes	19.4	L	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	313000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	23.5	L	.	.	25 - 35	PG
				Mean Corpuscle Volume	72	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	37	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	06FEB96	1	12FEB96	7	7
00201	Oral	2	20 MG	13FEB96	8	19FEB96	14	7
00201	Oral	3	20 MG	20FEB96	15	27FEB96	22	8
00201	Oral	4	20 MG	28FEB96	23	04MAR96	28	6
00201	Oral	4	20 MG	05MAR96	29	11MAR96	35	7
00201	Oral	4	20 MG	12MAR96	36	18MAR96	42	7
00201	Oral	4	20 MG	19MAR96	43	25MAR96	49	7
00201	Oral	5	30 MG	26MAR96	50	01APR96	56	7
	Oral	4	20 MG	02APR96	57	04APR96	59	3

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	No	59	20	Adverse event, including intercurrent illness	PHYSICIAN DISCRETIONS DUE TO IRREGULAR PARANOID BEHAVIOR

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FEVER	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	-9, .	28JAN96	06FEB96	750MG	STREP THROAT
			56, .	01APR96	.	750 MG	TONSILLITIS
	Clavulanic Acid	Augmentin	-9, .	28JAN96	06FEB96	750MG	STREP THROAT
			56, .	01APR96	.	750 MG	TONSILLITIS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-9, .	28JAN96	.	650 PRN	FEVER
RESPIRATORY	Hydrocodone Bitartrate	Codimal Dh	56, .	01APR96	.	2 TSP. PRN	TONSILLITIS
	Mepyramine Maleate	Codimal Dh	56, .	01APR96	.	2 TSP. PRN	TONSILLITIS
	Phenylephrine Hydrochloride	Codimal Dh	56, .	01APR96	.	2 TSP. PRN	TONSILLITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	TONSILLITIS {STREP PHARYNGITIS}	56, .	Not Stated	30	CON	MIL	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	31, .	1 Days	20	CON	MIL	NO	PBU	No	No
	Vomiting	VOMITING	31, .	1 Days	20		MIL	NO	UNR	No	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN {11LBS}[WEIGHT GAIN]	57, .	Not Stated	20	CON	MOD	NO	PSR	No	No
Nervous System	Agitation	AGITATION	58, .	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Hostility	AGGRESSIVE ASSAULTIVE BEHAVIOR	58, .	Not Stated	20	CON	SEV	STP	PSR	Yes	Yes
	Insomnia	INITIAL INSOMNIA	23, .	Not Stated	20	CON	MOD	NO	PSR	No	No
	Paranoid Reaction	PARANOIA	58, .	Not Stated	20	CON	MOD	STP	PSR	No	Yes
	Somnolence	SOMNOLENCE	50, .	Not Stated	30	CON	MIL	NO	PSR	No	No
Respiratory System	Rhinitis	NASAL CONGESTION	62, .	3 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	31JAN96	-6,	.	0	106	51	85	122	67	110	151.80	67.0
BL	06FEB96	1,	.	0	127	53	87	130	95	112	150.80	
1	13FEB96	8,	.	20	130	69	85	158	74	102	151.40	
2	20FEB96	15,	.	20	124	57	86	120	61	97	152.40	
3	28FEB96	23,	.	20	118	59	93	121	65	108	153.90	
4	05MAR96	29,	.	20	131	63	101	114	64	105	154.30	
5	12MAR96	36,	.	20	131	80	90	129	65	103	158.90	
6	19MAR96	43,	.	20	125	78	100	131	85	106	157.20	
7	26MAR96	50,	.	30	124	49	90	122	68	97	158.40	
8	02APR96	57,	.	20	136	59	109	121	77	106	163.80 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.2				13.8 - 17.2	G/DL
				Hematocrit	40.9	L			41 - 50	%
				Red Blood Cell Count	4.9				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5				4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.1				30 - 70	%
				Lymphocytes	41.5				21 - 51	%
				Monocytes	9.9				0 - 10	%
				Eosinophils	2.2				0 - 5	%
				Basophils	1.3				0 - 2	%
				Platelets	180000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8				25 - 35	PG
				Mean Corpuscle Volume	83				80 - 100	FL
				Blood Urea Nitrogen	14				7 - 25	MG/DL
				Creatinine	1				0.8 - 1.5	MG/DL
				Uric Acid	2.8	L			4 - 8	MG/DL
				Alkaline Phosphatase	208				44 - 400	U/L
				Aspartate Aminotransferase	20				0 - 41	U/L
				Alanine Aminotransferase	23				0 - 48	U/L
				Total Bilirubin	0.6				0.3 - 1.3	MG/DL
				Total Protein	7.5				6.2 - 8.8	G/DL
				Albumin	4.4				3.1 - 5.3	G/DL
				Glucose - Random	82				70 - 115	MG/DL
				Globulin	3.1				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	NEG					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.3		.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2		.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.2		.	.	30 - 70	%
				Lymphocytes	27.3		.	.	21 - 51	%
				Monocytes	10.2	H	.	.	0 - 10	%
				Eosinophils	1.8		.	.	0 - 5	%
				Basophils	1.6		.	.	0 - 2	%
				Platelets	163000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	18		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	214		.	.	44 - 400	U/L
				Aspartate Aminotransferase	26		.	.	0 - 41	U/L
				Alanine Aminotransferase	29		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	4.3	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	20FEB96	1	26FEB96	7	7
00202	Oral	2	0 MG	27FEB96	8	07MAR96	17	10
00202	Oral	3	0 MG	08MAR96	18	18MAR96	28	11
00202	Oral	4	0 MG	19MAR96	29	26MAR96	36	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	36	0	Protocol violation, including non-compliance	PATIENT WAS NON-COMPLIANT DUE TO POSITIVE DRUG SCREEN

* Relative to Start of Study Medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
SEASONAL ALLERGY	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Metacycline	Metacycline	-415, .	01JAN95	.	1TAB	SEASONAL ALLERGY
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	-50, .	01JAN96	.	2TABS PRN	MENSTRUAL CRAMPS
	Caffeine	Midol	-50, .	01JAN96	.	2TABS PRN	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-50, .	01JAN96	.	2TABS PRN	MENSTRUAL CRAMPS
	Paracetamol	Tylenol	-415, .	01JAN95	.	650 PRN	HEADACHES
GU SYSTEM/SEX HORMONES	Mestranol	Ortho Novum	-50, .	01JAN96	.	1PILL	BIRTH CONTROL
			-50, .	01JAN96	.	1PILL	BIRTH CONTROL
	Norethisterone	Ortho Novum	-50, .	01JAN96	.	1PILL	BIRTH CONTROL
			-50, .	01JAN96	.	1PILL	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES IN AM	18, .	12 Days	0	CON	MOD	NO	PSR	No	No
		STOMACH CRAMPS{VIRAL}	3, .	3 Days	0	CON	MIL	NO	PBU	No	No
Digestive System	Diarrhea	DIARRHEA{VIRAL}	3, .	3 Days	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	14FEB96	-6, .	0	101	65	83	107	71	93	103.80	62.0
BL	20FEB96	1, .	0	114	75	88	102	59	98	105.30	
1	27FEB96	8, .	0	100	50	86	106	60	90	103.70	
2	08MAR96	18, .	0	107	56	86	113	66	102	104.80	
4	19MAR96	29, .	0	110	71	79	122	75	84	105.50	
5	26MAR96	36, .	0	130	78	108	135	67	100	103.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	273000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	36	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEC		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	04MAR96	1	10MAR96	7	7
00203	Oral	2	100 MG	11MAR96	8	18MAR96	15	8
00203	Oral	3	150 MG	19MAR96	16	26MAR96	23	8
	Oral	2	100 MG	27MAR96	24	05APR96	33	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	No	No	33	100	Adverse event, including intercurrent illness	BORDERLINE PROLONGED QT-QTC 1ST DEGREE AV BLOCK

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
LEFT AXIS DEVIATION	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-63, .	01JAN96	.	600MG	SEASONAL ALLERGIES
RESPIRATORY	Hydrocodone Bitartrate	Codimal Dh	-63, .	01JAN96	.	1/2TAB	SEASONAL ALLERGIES
	Mepyramine Maleate	Codimal Dh	-63, .	01JAN96	.	1/2TAB	SEASONAL ALLERGIES
	Phenylephrine Hydrochloride	Codimal Dh	-63, .	01JAN96	.	1/2TAB	SEASONAL ALLERGIES
VARIOUS	Allergenic Extract, Nos	Allergy Shots	-793, .	01JAN94	.	1X	SEASONAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Av Block	1ST DEGREE AV BLOCK	23, .	Not Stated	150	CON	MOD	STP	REL	No	No
	Palpitation	PALPITATIONS	21, .	Not Stated	150	CON	MOD	NO	PSR	No	No
	Qt Interval Prolonged	PROLONGED QT-QUANTITATIVE TIP CULTURES	23, .	Not Stated	150	CON	MOD	STP	REL	No	No
	Vasodilatation	HOT FLASHES(FACIAL FLUSHING)	21, .	Not Stated	150	CON	MOD	NO	PSR	No	No
Digestive System	Nausea	NAUSEA WHEN TAKING PM MEDS	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Thirst	INCREASED THIRST	21, .	Not Stated	150	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	28FEB96	-5,	.	0	95	65	103	103	49	109	85.80	57.5
BL	04MAR96	1,	.	0	115	68	77	107	71	103	85.00	
1	11MAR96	8,	.	100	108	61	100	110	65	105	84.00	
2	19MAR96	16,	.	150	113	58	105	99	58	106	84.70	
3	26MAR96	23,	.	150	110	55	104	109	54	109	84.67	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.6	.	.	.	30 - 70	%
				Lymphocytes	39.8	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	227	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	60 - 110	MG/DL
				Globulin	2.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	19MAR96	1	25MAR96	7	7
00204	Oral	2	20 MG	26MAR96	8	01APR96	14	7
00204	Oral	3	20 MG	02APR96	15	08APR96	21	7
00204	Oral	4	20 MG	09APR96	22	15APR96	28	7
00204	Oral	4	20 MG	16APR96	29	22APR96	35	7
00204	Oral	4	20 MG	23APR96	36	29APR96	42	7
00204	Oral	4	20 MG	30APR96	43	06MAY96	49	7
00204	Oral	4	20 MG	07MAY96	50	13MAY96	56	7
00149	Oral	4	20 MG	14MAY96	57	10JUN96	84	28
00149	Oral	4	20 MG	11JUN96	85	08JUL96	112	28
00149	Oral	4	20 MG	09JUL96	113	12AUG96	147	35
00149	Oral	4	20 MG	13AUG96	148	09SEP96	175	28
00149	Oral	4	20 MG	10SEP96	176	14OCT96	210	35
00149	Oral	4	20 MG	15OCT96	211	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	211	20	Lost to follow-up	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1986
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Methylphenidate Hydrochloride	Ritalin	-808, -864	01JAN94	01MAR96#	20MG SR	ATTENTION DEFICIT HYPERACTIVITY DISORDER
	Paracetamol	Tylenol	-808, -864	01JAN94	.	675MG PRN	OCCASIONAL HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	8, -49	22 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	13MAR96	-6, -62	0	108	59	93	102	64	98	113.20	63.0
BL	19MAR96	1, -56	0	105	64	87	105	51	89	117.10	
1	26MAR96	8, -49	20	145	73	89	136	96	100	115.80	
2	02APR96	15, -42	20	110	56	80	111	63	83	114.40	
3	09APR96	22, -35	20	106	53	74	97	56	84	115.90	
4	16APR96	29, -28	20	116	58	88	123	58	102	116.60	
5	23APR96	36, -21	20	115	50	78	109	62	89	118.10	
6	30APR96	43, -14	20	123	50	86	104	67	86	119.70	
7	07MAY96	50, -7	20	122	63	93	122	59	98	120.10	
8	14MAY96	57, 1	20	114	61	80	114	63	80	117.90	
12	11JUN96	85, 29	20	115	62	93	108	67	102	119.90	
16	09JUL96	113, 57	20	119	57	91	115	67	105	121.60	
20	13AUG96	148, 92	20	118	57	86	120	68	101	123.00	
24	10SEP96	176, 120	20	118	58	90	105	66	106	126.10 H	
28	14OCT96	210, 154	20	120	57	74	126	55	91	129.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2		.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	31		.	.	30 - 70	%
				Lymphocytes	53	H	.	.	21 - 51	%
				Monocytes	10		.	.	0 - 10	%
				Eosinophils	3		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	261000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	8 - 21	MG/DL
				Creatinine	0.9		.	.	0.4 - 1.1	MG/DL
				Uric Acid	4		.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	339		.	.	44 - 400	U/L
				Aspartate Aminotransferase	27		.	.	0 - 41	U/L
				Alanine Aminotransferase	18		.	.	0 - 39	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7		.	.	5.7 - 8.2	G/DL
				Albumin	4.5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	85		.	.	60 - 110	MG/DL
				Globulin	3.2		.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	36.4		.	.	30 - 70	%
				Lymphocytes	51.7	H	.	.	21 - 51	%
				Monocytes	6.1		.	.	0 - 10	%
				Eosinophils	5		.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	293000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	8 - 21	MG/DL
				Creatinine	0.9		.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.1		.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	319		.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	122	H	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	34	.	.	.	30 - 70	%
				Lymphocytes	51	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	148	Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	329	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18DEC96	1	22DEC96	5	5
00235	Oral	2	20 MG	23DEC96	6	29DEC96	12	7
00235	Oral	3	20 MG	30DEC96	13	05JAN97	19	7
00235	Oral	4	20 MG	06JAN97	20	14JAN97	28	9
00235	Oral	4	20 MG	15JAN97	29	19JAN97	33	5
00235	Oral	4	20 MG	20JAN97	34	26JAN97	40	7
00235	Oral	4	20 MG	27JAN97	41	02FEB97	47	7
00235	Oral	4	20 MG	03FEB97	48	09FEB97	54	7
00109	Oral	4	20 MG	10FEB97	55	17MAR97	90	36
00109	Oral	4	20 MG	17MAR97	90	13APR97	117	28
00235	Oral	4	20 MG	14APR97	118	14APR97	118	1
00235	Oral	3	20 MG	15APR97	119	16APR97	120	2
00235	Oral	2	20 MG	17APR97	121	19APR97	123	3
00235	Oral	1	20 MG	20APR97	124	26APR97	130	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	130	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
FLU SYMPTOMS	INFLUENZA	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Minocycline	Minocycline	-33, -87	15NOV96	.	100MG	ACNE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol (Liquid)	-11, -65	07DEC96	07DEC96#	2 TEASPOONS	FLU SYMPTOMS
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Ortho Novum 1/35-28	40, -15	26JAN97	.	1 PILL	BIRTH CONTROL
	Norethisterone	Ortho Novum 1/35-28	40, -15	26JAN97	.	1 PILL	BIRTH CONTROL
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-11, -65	07DEC96	07DEC96#	200 MG PRN	FLU SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	90, 36	29 Days	20	CON	MIL	NO	PSR	No	No
Carciovascular System	Arrhythmia	SINUS ARRHYTHMIA (PER EKG)	90, 36	Not Stated	20	CON	MIL	NO	UNR	No	No
	Tachycardia	ELEVATED PULSE	20, -35	36 Days	20	CON	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	13, -42	43 Days	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	41, -14	50 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Insomnia	INSOMNIA (INITIAL)	48, -7	8 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	10DEC96	-8, -62	0	119	66	82	107	70	109	121.70	65.0
BL	17DEC96	-1, -55	0	112	66	86	98	65	109	121.60	
1	23DEC96	6, -49	20	111	67	80	116	66	82	123.60	
2	30DEC96	13, -42	20	104	59	76	110	63	74	122.20	
3	06JAN97	20, -35	20	122	63	95	112	54	135	121.50	
4	15JAN97	29, -26	20	99	57	93	106	61	100	119.40	
5	20JAN97	34, -21	20	138	91	102	121	55	125	120.20	
6	27JAN97	41, -14	20	114	60	97	104	66	133	118.00	
7	03FEB97	48, -7	20	107	57	81	112	58	105	119.80	
8	10FEB97	55, 1	20	121	60	86	112	70	117	122.20	
12	17MAR97	90, 36	20	130	65	106	120	77	109	123.30	
16	14APR97	118, 64	20	145	82	86	135	78	115	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	30 - 70	%
				Lymphocytes	33.9	.	.	.	21 - 51	%
				Monocytes	9.9	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	103	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	1.9	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	59	L	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-1	Glucose - Random	83	.	.	.	60 - 110	MG/DL
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEC		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Segmented Neutrophils	73.2	H	.	.	30 - 70	%
				Lymphocytes	14.6	L	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	30DEC96	1	05JAN97	7	7
00236	Oral	2	100 MG	06JAN97	8	14JAN97	16	9
00236	Oral	3	150 MG	15JAN97	17	19JAN97	21	5
00236	Oral	4	200 MG	20JAN97	22	26JAN97	28	7
	Oral	4	200 MG	27JAN97	29	08FEB97	41	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	41	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	-168, .	15JUL96	.	1 TAB PRN	MENSTRUAL CRAMPS
	Caffeine	Midol	-168, .	15JUL96	.	1 TAB PRN	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-168, .	15JUL96	.	1 TAB PRN	MENSTRUAL CRAMPS
	Paracetamol	Tylenol	-45, .	15NOV96	.	250 MG PRN	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Dizziness	DIZZINESS	22, .	Not Stated	200	CON	MOD	STP	REL	No	No
	Insomnia	MIDDLE INSOMNIA	17, .	6 Days	150	CON	MIL	NO	PSR	No	No
	Somnolence	DAYTIME SEDATION	22, .	Not Stated	200	CON	MOD	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	17DEC96	-13, .	0	136	72	87	124	56	94	146.90	63.1
BL	30DEC96	1, .	0	113	44	75	103	57	86	147.30	
1	06JAN97	8, .	100	115	57	98	100	52	121 H	144.30	
2	15JAN97	17, .	150	115	66	90	121	71	106	141.50	
3	20JAN97	22, .	200	131	74	109	108	58	133 H	143.30	
4	27JAN97	29, .	200	130	69	84	114	63	103	137.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	183	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-13	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11NOV96	1	19NOV96	9	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	No	No	9	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	P&C	
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	P&C	
SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	P&C	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Isotretinoin	Accutane	., .		.		ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	04NOV96	-7,	.	0	124	58	66	114	64	75	149.50	68.0
BL	11NOV96	1,	.	0	113	63	96	111	51	103	146.60	
1	18NOV96	8,	.	0	115	57	84	107	64	98	148.80	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.9		.	.	13.8 - 17.2	G/DL
				Hematocrit	44.8		.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.6		.	.	30 - 70	%
				Lymphocytes	46.1		.	.	21 - 51	%
				Monocytes	6.6		.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	223000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	213	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	102		.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	12NOV96	1	18NOV96	7	7
00238	Oral	2	0 MG	19NOV96	8	25NOV96	14	7
00238	Oral	3	0 MG	26NOV96	15	02DEC96	21	7
00238	Oral	4	0 MG	03DEC96	22	09DEC96	28	7
00238	Oral	4	0 MG	10DEC96	29	16DEC96	35	7
00238	Oral	4	0 MG	17DEC96	36	22DEC96	41	6
00238	Oral	4	0 MG	23DEC96	42	30DEC96	49	8
00238	Oral	4	0 MG	31DEC96	50	06JAN97	56	7
	Oral	4	0 MG	07JAN97	57	19JAN97	69	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	69	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-681, .	01JAN95	.	325MG PRN	HEADACHES
			50, .	31DEC96	.	250 MG	HEADACHE
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	38, .	19DEC96	31DEC96	60 MG	CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	INCREASE HEADACHE	22, .	Not Stated	0	CON	MOD	NO	PSR	Yes	No
Carciovascular System	Av Block	SERIAL INCREASE PR INTERVAL	15, .	15 Days	0	CON	MIL	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	22, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Nervous System	Abnormal Dreams	VIVID DREAMING	15, .	8 Days	0	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	42, .	9 Days	0	CON	MIL	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	42, .	9 Days	0	CON	MIL	NO	UNR	Yes	No
	Rhinitis	CONGESTION {NOSE}	42, .	9 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	28OCT96	-15,	.	0	115	60	83	106	55	100	112.20	66.5
BL	12NOV96	1,	.	0	107	53	88	106	52	97	113.60	
1	19NOV96	8,	.	0	106	48	74	112	62	95	114.80	
2	26NOV96	15,	.	0	108	47	74	99	57	86	115.00	
3	03DEC96	22,	.	0	99	42	78	105	47	88	115.80	
4	10DEC96	29,	.	0	107	49	72	105	54	78	114.50	
5	17DEC96	36,	.	0	112	51	82	115	59	100	112.80	
6	23DEC96	42,	.	0	97	45	76	108	47	88	114.40	
7	31DEC96	50,	.	0	111	54	77	109	58	86	115.00	
8	07JAN97	57,	.	0	104	56	72	110	52	87	112.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	14.9		.	.	12 - 15.6	G/DL
				Hematocrit	43.3		.	.	35 - 46	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58		.	.	30 - 70	%
				Lymphocytes	31.3		.	.	21 - 51	%
				Monocytes	6.4		.	.	0 - 10	%
				Eosinophils	3.4		.	.	0 - 5	%
				Basophils	0.9		.	.	0 - 2	%
				Platelets	211000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104		.	.	22 - 130	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L
				Alanine Aminotransferase	6		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	75		.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.4		.	.	12 - 15.6	G/DL
				Hematocrit	41.9		.	.	35 - 46	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3		.	.	30 - 70	%
				Lymphocytes	37		.	.	21 - 51	%
				Monocytes	6.3		.	.	0 - 10	%
				Eosinophils	2.8		.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	240000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	88		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	14	. . .	0 - 41	U/L
				Alanine Aminotransferase	9	. . .	0 - 48	U/L
				Total Bilirubin	0.8	. . .	0.3 - 1.3	MG/DL
				Total Protein	8.4	. . .	6.2 - 8.8	G/DL
				Albumin	4.6	. . .	3.1 - 5.3	G/DL
				Glucose - Random	97	. . .	70 - 115	MG/DL
				Globulin	3.8	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19NOV96	1	24NOV96	6	6
00239	Oral	2	100 MG	25NOV96	7	01DEC96	13	7
00239	Oral	3	150 MG	02DEC96	14	08DEC96	20	7
00239	Oral	4	200 MG	09DEC96	21	15DEC96	27	7
00239	Oral	4	200 MG	16DEC96	28	22DEC96	34	7
00239	Oral	4	200 MG	23DEC96	35	29DEC96	41	7
00239	Oral	4	200 MG	30DEC96	42	05JAN97	48	7
00239	Oral	4	200 MG	06JAN97	49	14JAN97	57	9
00183	Oral	4	200 MG	15JAN97	58	17FEB97	91	34
00183	Oral	4	200 MG	18FEB97	92	16MAR97	118	27
00183	Oral	4	200 MG	17MAR97	119	13APR97	146	28
00183	Oral	4	200 MG	14APR97	147	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	147	200	Protocol violation, including non-compliance	PT. STOPPED MEDS ON OWN.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MIGRAINES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1991
SINUS ARRHYTHMIA	ARRHYTHMIA	CIRCULATORY SYST	CUR	1996
SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	CUR	1996
DRUG ALLERGY - PENICILLIN	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	P&C	1995
MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
		Excedrin	92, 35	18FEB97	17MAR97		HEADACHE
	Caffeine	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
		Excedrin	92, 35	18FEB97	17MAR97		HEADACHE
	Citric Acid	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
	Paracetamol	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
		Excedrin	92, 35	18FEB97	17MAR97		HEADACHE
	Sodium Bicarbonate	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
DERMATOLOGICALS	Clobetasol Propionate	Temovate Emollient Cream	119, 62	17MAR97	.	1 APPLICATION PRN	DRY FINGERTIPS
	Promethazine Hydrochloride	Phenergan	41, -17	29DEC96	29DEC96	25 MG	VOMITING
RESPIRATORY	Dexbrompheniramine Maleate	Drixoral	92, 35	18FEB97	17MAR97		SINUS CONGESTION
	Promethazine Hydrochloride	Phenergan	41, -17	29DEC96	29DEC96	25 MG	VOMITING
	Pseudoephedrine Sulfate	Drixoral	92, 35	18FEB97	17MAR97		SINUS CONGESTION
SYSTEMIC HORMONAL	Melatonin	Melatonin	42, -16	30DEC96	.	1TAB	INSOMNIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	92, 35	Not Stated	200	CON	MIL	NO	PSR	No	No
Carciovascular System	Bradycardia	SINUS BRADYCARDIA PER EKG	175, 118	Not Stated	0	CON	MIL	NO	PBU	No	No
	Tachycardia	ELEVATED PULSE	7, -51	141 Days	100	CON	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	21, -37	8 Days	200	CON	MIL	NO	PSR	No	No
			49, -9	10 Days	200	CON	MIL	NO	PSR	No	No
	Dysphagia	DIFFICULTY SWALLOWING PILL	28, -30	8 Days	200	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	38, -20	5 Days	200	CON	MOD	NO	PBU	No	No
	Vomiting	VOMITING	38, -20	5 Days	200	CON	MOD	NO	PBU	Yes	No
Nervous System	Insomnia	MIDDLE INSOMNIA	42, -16	8 Days	200	CON	MIL	NO	PSR	Yes	No
	Somnolence	DAYTIME SOMNOLENCE	21, -37	22 Days	200	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	HEAD COLD	49, -9	10 Days	200	CON	MIL	NO	UNR	No	No
	Sinusitis	SINUS CONGESTION	92, 35	28 Days	200	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Dry Skin	DRY FINGERTIPS	119, 62	Not Stated	200	CON	MIL	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11NOV96	-8, -65	0	122	60	54	113	62	53	148.90	65.5
BL	18NOV96	-1, -58	0	114	60	53	123	57	74	149.40	
1	25NOV96	7, -51	100	115	61	88	106	63	96	147.70	
2	02DEC96	14, -44	150	115	69	85	112	60	109	146.80	
3	09DEC96	21, -37	200	124	74	94	107	68	117	147.70	
4	16DEC96	28, -30	200	121	66	86	113	58	115	149.10	
5	23DEC96	35, -23	200	126	77	106	121	77	121 H	149.50	
6	30DEC96	42, -16	200	113	75	100	115	73	102	143.40	
7	06JAN97	49, -9	200	121	59	108	119	81	131 H	146.50	
8	15JAN97	58, 1	200	120	74	68	131	82	91	143.40	
12	18FEB97	92, 35	200	115	55	80	106	64	97	144.90	
16	17MAR97	119, 62	200	114	52	65	105	54	80	149.80	
20	14APR97	147, 90	200	126	62	64	122	66	65	144.40	
24	12MAY97	175, 118#	0	114	65	59	115	65	71	153.60	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.5		.	.	12 - 15.6	G/DL
				Hematocrit	40.3		.	.	35 - 46	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63		.	.	30 - 70	%
				Lymphocytes	31		.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	1		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	67000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	17		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	43		.	.	22 - 130	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.7		.	.	3.1 - 5.3	G/DL
				Glucose - Random	72		.	.	70 - 115	MG/DL
				Globulin	3.1		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	5		.	+		
				Urine Bacteria	4		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.2		.	.	12 - 15.6	G/DL
				Hematocrit	37.6		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.3		.	.	30 - 70	%
				Lymphocytes	28.5		.	.	21 - 51	%
				Monocytes	4		.	.	0 - 10	%
				Eosinophils	1.6		.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	189000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1		.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58		Alkaline Phosphatase	42	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	108	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	(1)	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.2	.	.	.	35 - 46	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	70.7	H	.	.	30 - 70	%
					Lymphocytes	22.2	.	.	.	21 - 51	%
					Monocytes	5.2	.	.	.	0 - 10	%
					Eosinophils	1	.	.	.	0 - 5	%
					Basophils	1	.	.	.	0 - 2	%
					Platelets	191000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16 20	F	VISIT 13/CONTINUATION-WEEK	147	(1)	Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	37	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	54	L	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	14JAN97	1	20JAN97	7	7
00240	Oral	2	20 MG	21JAN97	8	27JAN97	14	7
00240	Oral	3	20 MG	28JAN97	15	03FEB97	21	7
00240	Oral	4	20 MG	04FEB97	22	10FEB97	28	7
00240	Oral	4	20 MG	11FEB97	29	17FEB97	35	7
00240	Oral	5	30 MG	18FEB97	36	25FEB97	43	8
00240	Oral	5	30 MG	25FEB97	43	04MAR97	50	8
	Oral	5	30 MG	04MAR97	50	05MAR97	51	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	51	30	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SLEEP DISTURBANCE	DISTURBANCE, SLEEP, UNSPEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1984

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-13, .	01JAN97	.	400 MG PRN	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Concentration Impaired	ATTENTION DEFICIT HYPERACTIVITY DISORDER	72, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No
	Depression	WORSENING OF DEPRESSION	48, .	Not Stated	30	CON	SEV	STP	UNR	Yes	Yes
	Insomnia	WORSENING OF SLEEP DISTURBANCE	51, .	Not Stated	30	CON	SEV	NO	PSR	Yes	Yes
Respiratory System	Sinusitis	SINUS CONGESTION	29, .	14 Days	20	CON	MIL	NO	UNR	No	No
Skin and Appendages	Rash	BILATERAL ERYTHEMATOUS EYELIDS	29, .	8 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03JAN97	-11,	.	0	120	84	85	124	82	91	168.00	67.7
BL	10JAN97	-4,	.	0	138	65	80	128	74	93	171.40	
1	21JAN97	8,	.	20	122	56	67	112	66	73	172.50	
2	28JAN97	15,	.	20	108	57	76	114	64	81	168.10	
3	04FEB97	22,	.	20	127	64	71	123	71	88	171.80	
4	11FEB97	29,	.	20	117	46	72	114	68	81	167.40	
5	18FEB97	36,	.	30	123	58	88	115	65	103	173.80	
6	25FEB97	43,	.	30	129	64	89	121	71	106	173.00	
7	04MAR97	50,	.	30	121	63	85	112	66	96	173.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	298000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	193	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-11	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	17FEB97	1	23FEB97	7	7
00262	Oral	2	100 MG	24FEB97	8	02MAR97	14	7
00262	Oral	3	150 MG	03MAR97	15	06MAR97	18	4
00262	Oral	4	200 MG	07MAR97	19	16MAR97	28	10
00262	Oral	4	200 MG	17MAR97	29	23MAR97	35	7
00262	Oral	4	200 MG	24MAR97	36	30MAR97	42	7
00262	Oral	4	200 MG	31MAR97	43	06APR97	49	7
00262	Oral	4	200 MG	07APR97	50	14APR97	57	8
	Oral	4	200 MG	14APR97	57	26APR97	69	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	69	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ENCOPRETIC	PSYCHOGENIC PHYSIOL DYSFUNC	MENTAL DISORD	CUR	1993
EYE INFECTION (LEFT AND RIGHT EYE)	EYE DISORD, OTHER	NERVOUS SYST/SENSE ORGAN DIS	CUR	1997
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
CHRONIC EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1986
TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1986

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	40, .	28MAR97	28MAR97	500 MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	27, .	15MAR97	15MAR97	1 TAB	COUGH
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	27, .	15MAR97	15MAR97	1 TAB	COUGH
SENSORY ORGANS	Sulfacetamide Sodium	Sulfacetamide Sodium	-7, .	10FEB97	07APR97	15 ML	EYE INFECTION (LEFT AND RIGHT EYE)

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Av Block	INCREASED PR INTERVAL (PER EKG)	19, .	11 Days	200	CON	MIL	NO	PSR	No	No
	Heart Malformation	POSSIBLE RIGHT ATRIAL ENLARGEMENT (PER EKG)	29, .	15 Days	200	CON	MIL	NO	PSR	No	No
	Postural Hypotension	MILD OTHOSTATIC STATE (1X) {DUE TO BLOOD DRAW} {ORTHOSTATIC HYPOTENSION}	57, .	5 Mins	200	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	8, .	64 Days	100	CON	MIL	NO	REL	No	No
Nervous System	Somnolence	DAYTIME SOMNOLENCE	8, .	8 Days	100	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	27, .	2 Days	200	CON	MIL	NO	PBU	Yes	No
Special Senses	Ear Pain	EARACHE	15, .	5 Days	150	CON	MIL	NO	PBU	No	No
	Eye Disorder	EYE INFECTION (LEFT AND RIGHT EYE)	-7, .	57 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	07FEB97	-10,	.	0	122	69	54	134	75	68	145.40	62.3
BL	17FEB97	1,	.	0	126	83	74	131	79	84	145.90	
1	24FEB97	8,	.	100	129	63	77	120	70	112	141.20	
2	03MAR97	15,	.	150	130	85	91	120	72	119	143.60	
3	07MAR97	19,	.	200	131	75	90	113	63	119	141.90	
4	17MAR97	29,	.	200	127	85	103	119	65	129 H	139.20	
5	24MAR97	36,	.	200	147	91	106	147	84	112	136.70	
6	31MAR97	43,	.	200	143	83	96	122	74	117	136.90	
7	07APR97	50,	.	200	139	81	108	116	76	121 H	134.50 L	
8	14APR97	57,	.	200	139	74	102	116	79	114	135.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	399	.	.	+	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8		.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4		.	.	30 - 70	%
				Lymphocytes	27.3		.	.	21 - 51	%
				Monocytes	3.9		.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	191000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	285		.	.	44 - 400	U/L
				Aspartate Aminotransferase	17		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	01NOV96	1	07NOV96	7	7
00264	Oral	2	100 MG	08NOV96	8	10NOV96	10	3
00264	Oral	3	150 MG	11NOV96	11	17NOV96	17	7
00264	Oral	4	200 MG	18NOV96	18	24NOV96	24	7
00264	Oral	4	200 MG	25NOV96	25	01DEC96	31	7
00264	Oral	4	200 MG	02DEC96	32	10DEC96	40	9
00264	Oral	4	200 MG	11DEC96	41	15DEC96	45	5
00264	Oral	4	200 MG	16DEC96	46	22DEC96	52	7
	Oral	4	200 MG	23DEC96	53	04JAN97	65	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	65	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
ASTHMA - NO PROBLEMS FOR 2 YRS	ASTHMA	RESPIRATORY SYST DIS	PRV	1991

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-732, .	31OCT94	.	325MG PRN	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE
	Pseudoephedrine Hydrochloride	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE
RESPIRATORY	Ibuprofen	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE
	Pseudoephedrine Hydrochloride	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Electrocardiogram Abnormal	NONSPECIFIC T-WAVE ABNORMALITY (PER EKG) BASELINE ARTIFACT	53, .	Not Stated	200	CON	MIL	NO	PSR	No	No
	Tachycardia	INCREASED HEART RATE	11, .	Not Stated	150	CON	MIL	NO	PSR	No	No
		SINUS TACHYCARDIA	53, .	Not Stated	200	CON	MIL	NO	PSR	No	No
Nervous System	Agitation	AGITATION	11, .	8 Days	150	CON	MOD	NO	PSR	No	No
	Insomnia	DECREASED SLEEP (INITIAL, MIDDLE)	41, .	6 Days	200	CON	MIL	NO	PSR	No	No
	Somnolence	DAYTIME SOMNOLENCE	8, .	25 Days	100	CON	MOD	NO	PSR	No	No
			46, .	Not Stated	200	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

					Sitting			Standing				
Week	Visit Date	Relative Days *		Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25OCT96	-7,	.	0	138	73	71	129	82	83	171.00	62.5
BL	01NOV96	1,	.	0	109	72	102	122	66	82	171.00	
1	08NOV96	8,	.	100	121	79	108	.	.	.	170.30	
1	11NOV96	11,	.	150	145	80	105	126	87	140 H		
2	18NOV96	18,	.	200	130	88	104	130	68	133 H	168.00	
3	25NOV96	25,	.	200	145	88	117	120	73	145 H	168.00	
4	02DEC96	32,	.	200	137	76	115	104	57	137 H	169.40	
6	11DEC96	41,	.	200	135	86	126	123	61	150 H	165.80	
6	16DEC96	46,	.	200	144	91	137 H	125	72	140 H	169.60	
7	23DEC96	53,	.	200	128	66	131	115	55	148 H	169.10	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.7	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	354000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	25	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.3	.	.	.	30 - 70	%
				Lymphocytes	42	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	287000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	53	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	53	Segmented Neutrophils	67.2	. . .	30 - 70	%
				Lymphocytes	26	. . .	21 - 51	%
				Monocytes	4.5	. . .	0 - 10	%
				Eosinophils	1.6	. . .	0 - 5	%
				Basophils	0.7	. . .	0 - 2	%
				Platelets	314000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	. . .	25 - 35	PG
				Mean Corpuscle Volume	84	. . .	80 - 100	FL
				Blood Urea Nitrogen	9	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.6	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	96	. . .	44 - 280	U/L
				Aspartate Aminotransferase	15	. . .	0 - 41	U/L
				Alanine Aminotransferase	16	. . .	0 - 48	U/L
				Total Bilirubin	0.5	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.4	. . .	6.2 - 8.8	G/DL
				Albumin	4.1	. . .	3.1 - 5.3	G/DL
				Glucose - Random	99	. . .	70 - 115	MG/DL
				Globulin	3.3	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21JAN97	1	27JAN97	7	7
00276	Oral	2	0 MG	28JAN97	8	03FEB97	14	7
00276	Oral	3	0 MG	04FEB97	15	10FEB97	21	7
00276	Oral	4	0 MG	11FEB97	22	17FEB97	28	7
00276	Oral	5	0 MG	18FEB97	29	24FEB97	35	7
00276	Oral	5	0 MG	25FEB97	36	03MAR97	42	7
00276	Oral	6	0 MG	04MAR97	43	12MAR97	51	9
00276	Oral	6	0 MG	13MAR97	52	17MAR97	56	5
	Oral	5	0 MG	18MAR97	57	01APR97	71	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	71	0	Lack of Efficacy	ALTHOUGH IMPROVED REMAINS SYMPTOMATIC

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EARLY REPOLARIZATION {EKG}	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Loperamide Hydrochloride	Imodium	70, .	31MAR97	31MAR97	1 TAB PRN	STOMACH VIRUS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-386, .	01JAN96	.	500 MG PRN	OCCASIONAL HEADACHE
			-314, .	13MAR96	.	500 MG PRN	SORE THROAT
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	53, .	14MAR97	14MAR97	440 MG	SORE THROAT
RESPIRATORY	Guaifenesin	Robitussin	51, .	12MAR97	18MAR97	1 TSP PRN	SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Fever	FEVER	52, .	6 Days	0	CON	MIL	NO	PBU	Yes	No
	Headache	HEADACHES	15, .	15 Days	0	CON	MIL	NO	PSR	No	No
	Infection	STOMACH VIRUS	70, .	2 Days	0	CON	MIL	NO	PSR	Yes	No
Digestive System	Decreased Appetite	DECREASED APPETITE	57, .	Not Stated	0	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	15, .	29 Days	0	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS	52, .	20 Days	0	CON	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	31, .	12:00 Hrs	0	CON	MIL	NO	PBU	No	No
			52, .	6 Days	0	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	17JAN97	-4,	.	0	123	39	77	116	64	101	127.40	66.6
BL	21JAN97	1,	.	0	115	59	85	.	.	.	128.60	
1	28JAN97	8,	.	0	116	58	78	109	54	90	125.10	
2	04FEB97	15,	.	0	115	56	85	114	64	93	127.00	
3	11FEB97	22,	.	0	112	43	73	119	49	100	126.50	
4	18FEB97	29,	.	0	122	64	91	115	59	97	129.00	
5	25FEB97	36,	.	0	123	61	80	121	49	95	128.10	
6	04MAR97	43,	.	0	121	62	91	107	70	111	128.10	
7	13MAR97	52,	.	0	125	67	82	112	68	101	123.70	
8	18MAR97	57,	.	0	105	49	76	107	57	98	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	1	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.6	.	.	.	30 - 70	%
				Lymphocytes	44.4	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14		.	.	13.8 - 17.2	G/DL
				Hematocrit	40.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5		.	.	30 - 70	%
				Lymphocytes	34.3		.	.	21 - 51	%
				Monocytes	9.6		.	.	0 - 10	%
				Eosinophils	1.2		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	210000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	140		.	.	44 - 400	U/L
				Aspartate Aminotransferase	58	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	36		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19MAR96	1	25MAR96	7	7
00301	Oral	2	100 MG	26MAR96	8	04APR96	17	10
00301	Oral	3	150 MG	05APR96	18	11APR96	24	7
00301	Oral	4	200 MG	12APR96	25	15APR96	28	4
00301	Oral	4	200 MG	16APR96	29	22APR96	35	7
00301	Oral	4	200 MG	23APR96	36	29APR96	42	7
00301	Oral	4	200 MG	30APR96	43	06MAY96	49	7
00301	Oral	4	200 MG	07MAY96	50	13MAY96	56	7
00140	Oral	4	200 MG	14MAY96	57	10JUN96	84	28
00301	Oral	4	200 MG	11JUN96	85	11JUN96	85	1
00301	Oral	3	150 MG	12JUN96	86	13JUN96	87	2
00301	Oral	2	100 MG	14JUN96	88	16JUN96	90	3
00301	Oral	1	50 MG	17JUN96	91	23JUN96	97	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	97	50	Other reason	WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1983
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
ASTHMA ATTACKS{HOSPITALIZED}	ASTHMA	RESPIRATORY SYST DIS	PRV	1990
BROKEN LEFT ARM{X2}	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1988
BROKEN RIGHT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CARDIOVASCULAR	Theophylline	Theo-Dur	-443, -499	01JAN95	.	600MGI	ASTHMA
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-443, -499	01JAN95	.	375MG PRN	HEADACHES
RESPIRATORY	Orciprenaline Sulfate	Alupent	-808, -864	01JAN94	.	2PUFFS PRN	ASTHMA
	Theophylline	Theo-Dur	-443, -499	01JAN95	.	600MGI	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	INCREASED SWEATING(VIRAL SYNDROME)	22, -35	20 Mins	150	CON	MIL	NO	PBU	No	No
		NAUSEA(VIRAL SYNDROME)	22, -35	1 Days	150	CON	MIL	NO	PBU	No	No
		VOMITING(VIRAL SYNDOME)	22, -35	1 Days	150	CON	MIL	NO	PBU	No	No
Carciovascular System	Tachycardia	INCREASE IN PULSE(SECONDARY TO ALUPENT)	36, -21	15 Mins	200	CON	MOD	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	22, -35	1 Days	150	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06MAR96	-13, -69	0	91	45	79	108	59	101	127.00	80.0
BL	19MAR96	1, -56	0	93	45	75	95	57	75	129.00	
1	26MAR96	8, -49	100	91	44	84	114	49	72	129.50	
2	05APR96	18, -39	150	105	59	77	107	65	89	125.20	
3	12APR96	25, -32	200	106	52	90	99	61	108	126.50	
4	16APR96	29, -28	200	116	63	74	108	58	90	125.70	
5	23APR96	36, -21	200	124	70	114	107	59	126 H	124.80	
6	30APR96	43, -14	200	97	46	83	93	62	95	127.40	
7	07MAY96	50, -7	200	101	53	86	115	62	92	128.60	
8	14MAY96	57, 1	200	99	52	66	105	57	88	127.10	
12	11JUN96	85, 29	200	107	56	66	107	75	78	129.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-6	Neutrophil Bands	1	L	.	.	4 - 12	%
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	229	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEC		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.4		.	.	30 - 70	%
				Lymphocytes	32.5		.	.	21 - 51	%
				Monocytes	5.9		.	.	0 - 10	%
				Eosinophils	8.7	H	.	.	0 - 5	%
				Basophils	2.5	H	.	.	0 - 2	%
				Platelets	272000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6		.	.	30 - 70	%
				Lymphocytes	34		.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	245000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	171	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	27MAR96	1	02APR96	7	7
00302	Oral	2	0 MG	03APR96	8	10APR96	15	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	No	No	15	0	Adverse event, including intercurrent illness	PATIENT WAS WITHDRAWN DUE TO MACULOPAPULAR RASH,SINUS BRADYCARDIA WITH ARRHYTHMIA AND JUNCTIONAL ESCAPE PATTERN

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ABDOMINAL CYST-SURGERY	OPERATION, OTHER ABDOM	OPERATIONS	PRV	1990
TENDONITIS	RHEUMATIC DISORD	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-86, .	01JAN96	20MAR96#	500MG	TENDONITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Nodal Arrhythmia	JUNCTIONAL ESCAPE PATTERN(EKG)	8, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Maculopapular Rash	RASH ON WRIST ELBOWS,ANKLE,(MACULOPAPULAR)	8, .	Not Stated	0	CON	MOD	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20MAR96	-7, .	0	145	51	56	147	50	77	157.10	68.0
BL	27MAR96	1, .	0	138	59	85	130	44	85	158.20	
1	03APR96	8, .	0	122	50	64	123	43	84	157.10	
2	10APR96	15, .	0	123	50	66	115	50	60	158.60	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7	.	.	.	30 - 70	%
				Lymphocytes	35.4	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	11.4	H	.	+	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	108	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	02APR96	1	08APR96	7	7
00303	Oral	2	20 MG	09APR96	8	15APR96	14	7
00303	Oral	3	20 MG	16APR96	15	22APR96	21	7
00303	Oral	4	20 MG	23APR96	22	29APR96	28	7
00303	Oral	4	20 MG	30APR96	29	06MAY96	35	7
00303	Oral	4	20 MG	07MAY96	36	13MAY96	42	7
00303	Oral	4	20 MG	14MAY96	43	21MAY96	50	8
00303	Oral	4	20 MG	22MAY96	51	27MAY96	56	6
00155	Oral	4	20 MG	28MAY96	57	24JUN96	84	28
00155	Oral	4	20 MG	25JUN96	85	29JUL96	119	35
00155	Oral	4	20 MG	30JUL96	120	26AUG96	147	28
00155	Oral	4	20 MG	27AUG96	148	24SEP96	176	29
00155	Oral	4	20 MG	25SEP96	177	29OCT96	211	35
00155	Oral	4	20 MG	30OCT96	212	09DEC96	252	41
00303	Oral	4	20 MG	10DEC96	253	10DEC96	253	1
00303	Oral	3	20 MG	11DEC96	254	12DEC96	255	2
00303	Oral	2	20 MG	13DEC96	256	15DEC96	258	3
00303	Oral	1	20 MG	16DEC96	259	22DEC96	265	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	Yes	265	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Clarithromycin	Biaxin	-32, -88	01MAR96	.	500MG	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Chlorphenamine Maleate	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Fluoxetine	Prozac	-23, -79	10MAR96	17MAR96#	10MG	DEPRESSION
	Paracetamol	Tylenol	-32, -88	01MAR96	.	650 PRN	SINUS INFECTION
		Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	23, -34	24APR96	24APR96	20MG	NASAL CONGESTION
MUSCULO-SKELETAL	Ibuprofen	Advil	-822, -878	01JAN94	.	200MG	OCCASIONAL HEADACHE
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
			-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
			-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Diphenhydramine Hydrochloride	Benadryl	23, -34	24APR96	24APR96	20MG	NASAL CONGESTION
	Paracetamol	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
			-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
			-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	SEASONAL ALLERGIES	28, -29	1 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25MAR96	-8, -64	0	116	66	59	123	71	54	166.20	71.0
BL	02APR96	1, -56	0	108	59	68	122	58	76	166.90	
1	09APR96	8, -49	20	116	56	62	121	45	65	166.20	
2	16APR96	15, -42	20	122	57	61	121	60	64	165.00	
3	23APR96	22, -35	20	123	57	62	120	48	66	165.00	
4	30APR96	29, -28	20	130	58	61	125	51	59	165.60	
5	07MAY96	36, -21	20	130	58	62	121	63	60	165.00	
6	14MAY96	43, -14	20	115	50	62	123	61	64	167.00	
7	22MAY96	51, -6	20	115	65	72	123	65	72	166.90	
8	28MAY96	57, 1	20	107	49	49	107	46	56	164.90	
12	25JUN96	85, 29	20	138	69	75	133	65	72	166.26	
16	30JUL96	120, 64	20	109	47	62	116	59	68	170.67	
20	27AUG96	148, 92	20	122	52	64	128	58	70	169.60	
24	25SEP96	177, 121	20	122	59	68	121	67	68	169.30	
32	30OCT96	212, 156	20	116	58	67	117	71	72	170.20	
32	10DEC96	253, 197	20	127	60	67	118	60	76	172.80	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	42.9		.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.3		.	.	30 - 70	%
				Lymphocytes	38.1		.	.	21 - 51	%
				Monocytes	11.8	H	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.9		.	.	0 - 2	%
				Platelets	167000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	64		.	.	22 - 180	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.4		.	.	13.8 - 17.2	G/DL
				Hematocrit	44.6		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.1	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7		.	.	30 - 70	%
				Lymphocytes	35.5		.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	177000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1.2		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	71		.	.	22 - 180	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L
				Total Bilirubin	0.9		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.6	.	.	.	30 - 70	%
				Lymphocytes	40.6	.	.	.	21 - 51	%
				Monocytes	10.7	H	.	.	0 - 10	%
				Eosinophils	5.6	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	177000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	148	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	253	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	30000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 16/CONTINUATION-WEEK 32	253	Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	56	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/UNSCHEDULED LAB 1	256	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 16/UNSCHEDULED LAB 1	256	Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	59	. . .	22 - 180	U/L
				Aspartate Aminotransferase	18	. . .	0 - 41	U/L
				Alanine Aminotransferase	9	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.7	. . .	6.2 - 8.8	G/DL
				Albumin	4.3	. . .	3.1 - 5.3	G/DL
				Glucose - Random	93	. . .	70 - 115	MG/DL
				Globulin	3.4	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	09APR96	1	15APR96	7	7
00304	Oral	2	20 MG	16APR96	8	22APR96	14	7
00304	Oral	3	20 MG	23APR96	15	29APR96	21	7
00304	Oral	4	20 MG	30APR96	22	06MAY96	28	7
00304	Oral	5	30 MG	07MAY96	29	13MAY96	35	7
00304	Oral	5	30 MG	14MAY96	36	20MAY96	42	7
00304	Oral	5	30 MG	21MAY96	43	27MAY96	49	7
00304	Oral	5	30 MG	28MAY96	50	03JUN96	56	7
00159	Oral	5	30 MG	04JUN96	57	01JUL96	84	28
00159	Oral	5	30 MG	02JUL96	85	29JUL96	112	28
00159	Oral	5	30 MG	30JUL96	113	26AUG96	140	28
00159	Oral	5	30 MG	27AUG96	141	22SEP96	167	27
00159	Oral	5	30 MG	23SEP96	168	21OCT96	196	29
00304	Oral	4	20 MG	22OCT96	197	23OCT96	198	2
00304	Oral	3	20 MG	24OCT96	199	24OCT96	199	1
00304	Oral	2	20 MG	25OCT96	200	28OCT96	203	4
00304	Oral	1	20 MG	29OCT96	204	04NOV96	210	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	210	20	Other reason	PATIENT WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-464, -520	01JAN95	.	400MG	OCCASIONAL HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE{WORSENING FROM BASELINE}	43, -14	8 Days	30	CON	MOD	NO	PSR	No	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	43, -14	30 Mins	30	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN {10 LBS}[WEIGHT GAIN]	113, 57	Not Stated	30	CON	MIL	NO	PSR	No	No
Nervous System	Somnolence	DAYTIME SLEEPINESS	36, -21	15 Days	30	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03APR96	-6, -62	0	122	56	73	131	65	70	201.00	67.0
BL	09APR96	1, -56	0	118	59	80	121	52	82	200.80	
1	16APR96	8, -49	20	138	60	72	139	57	73	199.90	
2	23APR96	15, -42	20	138	59	74	145	63	86	195.90	
3	30APR96	22, -35	20	140	70	90	145	83	102	198.10	
4	07MAY96	29, -28	30	132	71	91	139	73	100	197.20	
5	14MAY96	36, -21	30	137	60	100	139	74	102	195.20	
6	21MAY96	43, -14	30	138	65	91	68 L	56	109	198.70	
7	28MAY96	50, -7	30	137	64	69	120	59	79	200.70	
8	04JUN96	57, 1	30	130	64	99	128	60	102	198.70	
12	02JUL96	85, 29	30	131	64	70	120	67	75	202.20	
16	30JUL96	113, 57	30	113	52	78	120	54	98	213.00	
20	27AUG96	141, 85	30	129	61	88	142	61	96	207.20	
24	23SEP96	168, 112	30	118	57	88	91	56	89	207.40	
28	21OCT96	196, 140	30	140	54	70	139	60	73	210.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.8	.	.	.	30 - 70	%
				Lymphocytes	39.8	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	217000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	143	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	24	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	17.2		.	.	13.8 - 17.2	G/DL
				Hematocrit	49.9		.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.6		.	.	30 - 70	%
				Lymphocytes	31		.	.	21 - 51	%
				Monocytes	6.2		.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	230000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	165		.	.	22 - 180	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	30		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	16.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	141	Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	07MAY96	1	13MAY96	7	7
00305	Oral	2	100 MG	14MAY96	8	20MAY96	14	7
00305	Oral	3	150 MG	21MAY96	15	27MAY96	21	7
00305	Oral	4	200 MG	28MAY96	22	03JUN96	28	7
00305	Oral	4	200 MG	04JUN96	29	10JUN96	35	7
00305	Oral	4	200 MG	11JUN96	36	18JUN96	43	8
00305	Oral	4	200 MG	19JUN96	44	24JUN96	49	6
00305	Oral	4	200 MG	25JUN96	50	02JUL96	57	8
00151	Oral	4	200 MG	03JUL96	58	05AUG96	91	34
00151	Oral	4	200 MG	06AUG96	92	26AUG96	112	21
00151	Oral	4	200 MG	27AUG96	113	23SEP96	140	28
00151	Oral	4	200 MG	24SEP96	141	28OCT96	175	35
00151	Oral	4	200 MG	29OCT96	176	02DEC96	210	35
00151	Oral	4	200 MG	03DEC96	211	09JAN97	248	38
00305	Oral	4	200 MG	10JAN97	249	10JAN97	249	1
00305	Oral	3	150 MG	11JAN97	250	12JAN97	251	2
00305	Oral	2	100 MG	13JAN97	252	15JAN97	254	3
00305	Oral	1	50 MG	16JAN97	255	22JAN97	261	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	Yes	261	50		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Loperamide Hydrochloride	Imodium A-D	57, -1	02JUL96	02JUL96	4 MG	NAUSEA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Electrocardiogram Abnormal	POSITIVE/NEGATIVE RIGHT AXIS DEVIATION (EKG)	249, 192	19 Days	200	CON	MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	8, -50	22 Days	100	CON	MOD	NO	PSR	No	No
			58, 1	35 Days	200	CON	MIL	NO	PSR	No	No
			126, 69	142 Days	200	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	8, -50	15 Days	100	CON	MOD	NO	PSR	No	No
			22, -36	23 Days	200	CON	MIL	NO	PSR	No	No
			57, -1	1 Days	200	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS	8, -50	15 Days	100	CON	MOD	NO	PSR	No	No
			22, -36	71 Days	200	CON	MIL	NO	PSR	No	No
			126, 69	142 Days	200	CON	MIL	NO	PSR	No	No
Special Senses	Abnormal Vision	BLURRED VISION	58, 1	35 Days	200	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	01MAY96	-6, -63	0	114	53	80	111	66	105	136.50	72.3
BL	07MAY96	1, -57	0	108	54	86	107	53	89	135.90	
1	14MAY96	8, -50	100	107	65	92	108	69	98	135.10	
2	21MAY96	15, -43	150	96	54	94	99	37	98	133.80	
3	28MAY96	22, -36	200	123	62	96	106	64	96	133.70	
4	04JUN96	29, -29	200	126	76	100	93	47	132 H	135.60	
5	11JUN96	36, -22	200	123	72	96	98	38	.	135.60	
6	19JUN96	44, -14	200	115	65	96	103	53	120	133.90	
7	25JUN96	50, -8	200	120	74	100	114	60	135 H	134.06	
8	03JUL96	58, 1	200	105	60	115	95	53	140 H	134.50	
12	06AUG96	92, 35	200	113	61	96	99	46	120	136.30	
16	27AUG96	113, 56	200	114	56	89	105	55	123 H	134.30	
20	24SEP96	141, 84	200	103	57	91	90	53	117	132.80	
24	29OCT96	176, 119	200	115	65	88	100	50	126 H	137.00	
28	03DEC96	211, 154	200	115	62	100	105	71	121 H	138.60	
32	10JAN97	249, 192	200	122	65	98	106	68	125 H	137.40	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.5	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	200	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.6		.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7		.	.	41 - 50	%
				Red Blood Cell Count	5.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.3		.	.	30 - 70	%
				Lymphocytes	30		.	.	21 - 51	%
				Monocytes	12.2	H	.	.	0 - 10	%
				Eosinophils	2		.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Basophils	0.5	.	.	.	0 - 2	%
				Platelets	154000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	225	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4	.	.	.	30 - 70	%
				Lymphocytes	39	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	141	Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	164000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	200	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	1.4	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEC		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	249	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	249	Hematocrit	44.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	33.6	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	195	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	70	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11JUN96	1	17JUN96	7	7
00306	Oral	2	0 MG	18JUN96	8	24JUN96	14	7
00306	Oral	3	0 MG	25JUN96	15	01JUL96	21	7
00306	Oral	4	0 MG	02JUL96	22	08JUL96	28	7
00306	Oral	4	0 MG	09JUL96	29	15JUL96	35	7
00306	Oral	4	0 MG	16JUL96	36	22JUL96	42	7
00306	Oral	4	0 MG	23JUL96	43	29JUL96	49	7
00306	Oral	5	0 MG	30JUL96	50	05AUG96	56	7
	Oral	5	0 MG	06AUG96	57	19AUG96	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	70	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
NON MALIGNANT LUMP REMOVED FROM(LEFT)BREAST	OPERATION, BREAST	OPERATIONS	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
BLOOD/BLOOD FORM ORGANS	Ferrous Sulfate	Feosol Liquid	44, .	24JUL96	.	4 TSP.	ANEMIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Vasodilatation	HOT FLASHES	22, .	50 Days	0	CON	MIL	NO	PSR	No	No
Hemic and Lymphatic System	Anemia	ANEMIA	-8, .	Not Stated	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03JUN96	-8,	.	0	106	60	57	99	53	89	115.40	64.0
BL	11JUN96	1,	.	0	115	49	70	117	70	98	120.30	
1	18JUN96	8,	.	0	94	53	99	98	58	96	118.50	
2	25JUN96	15,	.	0	140	90	90	131	76	87	116.20	
3	02JUL96	22,	.	0	117	59	79	118	72	93	118.40	
4	09JUL96	29,	.	0	114	66	78	92	60	100	117.60	
5	16JUL96	36,	.	0	104	55	85	114	58	94	117.20	
6	23JUL96	43,	.	0	110	55	79	107	67	98	118.60	
7	30JUL96	50,	.	0	98	45	76	93	58	95	119.40	
8	06AUG96	57,	.	0	105	40	91	94	44 L	96	118.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	36	.	.	.	30 - 70	%
				Lymphocytes	60	H	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-5	Hemoglobin	12.1		.	.	12 - 15.6	G/DL
				Hematocrit	35.9		.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.6		.	.	30 - 70	%
				Lymphocytes	30.3		.	.	21 - 51	%
				Monocytes	5.9		.	.	0 - 10	%
				Eosinophils	4.4		.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	191000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	11.8	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5		.	.	30 - 70	%
				Lymphocytes	30.3		.	.	21 - 51	%
				Monocytes	7.8		.	.	0 - 10	%
				Eosinophils	3.6		.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	242000		.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	114	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	04NOV96	1	14NOV96	11	11
00312	Oral	2	0 MG	15NOV96	12	17NOV96	14	3
00312	Oral	3	0 MG	18NOV96	15	01DEC96	28	14
00312	Oral	4	0 MG	02DEC96	29	08DEC96	35	7
00312	Oral	4	0 MG	09DEC96	36	15DEC96	42	7
00312	Oral	4	0 MG	16DEC96	43	26DEC96	53	11
00312	Oral	4	0 MG	27DEC96	54	29DEC96	56	3
00312	Oral	5	0 MG	30DEC96	57	06JAN97	64	8
	Oral	5	0 MG	06JAN97	64	20JAN97	78	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	78	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES TO ERYTHROCIN	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
SINUS ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996
STOMACH ULCER	ULCER, GASTRIC	DIGESTIVE SYST	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ranitidine Hydrochloride	Zantac	-308, .	01JAN96	.	300 MG PRN	STOMACH ULCER
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Tri-Levlen	-1038, .	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
			-1038, .	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
	Levonorgestrel	Tri-Levlen	-1038, .	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
			-1038, .	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-673, .	01JAN95	.	400 MG PRN	OCCASIONAL HEADACHE
RESPIRATORY	Guaifenesin	Entex	-308, .	01JAN96	.	4 TABS	SINUS ALLERGIES
	Loratadine	Claritin	-308, .	01JAN96	.	10 MG	SINUS ALLERGIES
	Phenylephrine Hydrochloride	Entex	-308, .	01JAN96	.	4 TABS	SINUS ALLERGIES
	Phenylpropanolamine Hydrochloride	Entex	-308, .	01JAN96	.	4 TABS	SINUS ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHES	64, .	15 Days	0	CON	MIL	NO	PBU	No	No
	Headache	INCREASE IN HEADACHES	54, .	Not Stated	0		MOD	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	30OCT96	-5,	.	0	129	66	89	119	83	102	152.40	58.0
BL	04NOV96	1,	.	0	103	54	.	109	56	.	151.70	
2	15NOV96	12,	.	0	106	67	81	122	68	87	154.60	
2	18NOV96	15,	.	0	106	78	100	112	50	106	153.30	
4	02DEC96	29,	.	0	129	61	94	127	61	97	157.30	
5	09DEC96	36,	.	0	121	57	96	120	62	103	156.70	
6	16DEC96	43,	.	0	126	65	83	117	70	97	156.80	
8	27DEC96	54,	.	0	111	61	82	114	68	68	160.00	
8	30DEC96	57,	.	0	126	66	91	121	73	97	154.60	
8	06JAN97	64,	.	0	122	64	88	128	46	102	159.40	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.2	.	.	.	30 - 70	%
				Lymphocytes	31.3	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	6.8	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	421000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	419000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28OCT96	1	03NOV96	7	7
00324	Oral	2	20 MG	04NOV96	8	10NOV96	14	7
00324	Oral	3	20 MG	11NOV96	15	17NOV96	21	7
00324	Oral	4	20 MG	18NOV96	22	24NOV96	28	7
00324	Oral	4	20 MG	25NOV96	29	01DEC96	35	7
00324	Oral	4	20 MG	02DEC96	36	08DEC96	42	7
00324	Oral	4	20 MG	09DEC96	43	15DEC96	49	7
00324	Oral	4	20 MG	16DEC96	50	26DEC96	60	11
	Oral	4	20 MG	27DEC96	61	08JAN97	73	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	73	20	Adverse event, including intercurrent illness	RASH DEVELOPED BETWEEN WEEK 7 & 8

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1996
UNCONSCIOUS AT AGE 1 - HIT HEAD IN FALL	COMA AND STUPOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1984

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol Extra Strength	-88,	.	01AUG96	.	500 MG PRN	OCCASIONAL HEADACHES
		Tylenol Sinus	-88,	.	01AUG96	.	1 TAB PRN	SINUS CONGESTION
	Pseudoephedrine Hydrochloride	Tylenol Sinus	-88,	.	01AUG96	.	1 TAB PRN	SINUS CONGESTION
MUSCULO-SKELETAL	Ibuprofen	Advil	-88,	.	01AUG96	.	200 MG PRN	OCCASSIONAL HEADACHES
RESPIRATORY	Paracetamol	Tylenol Sinus	-88,	.	01AUG96	.	1 TAB PRN	SINUS CONGESTION
	Pseudoephedrine Hydrochloride	Sudafed	-88,	.	01AUG96	.	120 MG PRN	SINUS CONGESTION
		Tylenol Sinus	-88,	.	01AUG96	.	1 TAB PRN	SINUS CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Decreased Appetite	DECREASED APPETITE	50, .	31 Days	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	2, .	21 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Abnormal Dreams	INCREASED DREAMING	29, .	Not Stated	20	CON	MIL	NO	PSR	No	No
		NIGHTMARES	15, .	15 Days	20	CON	MIL	NO	PSR	No	No
	Insomnia	INSOMNIA	15, .	8 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	43, .	8 Days	20	CON	MIL	NO	UNR	No	No
Skin and Appendages	Rash	RASH	61, .	20 Days	20	CON	MOD	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	21OCT96	-7,	.	0	126	59	88	116	62	98	127.70	61.0
BL	28OCT96	1,	.	0	130	64	82	131	75	85	126.30	
1	04NOV96	8,	.	20	116	69	78	115	55	86	125.10	
2	11NOV96	15,	.	20	114	66	86	127	66	83	126.50	
3	18NOV96	22,	.	20	114	64	77	106	67	80	123.40	
4	25NOV96	29,	.	20	119	59	89	77 L	55	94	124.80	
5	02DEC96	36,	.	20	115	65	85	107	73	100	127.30	
6	09DEC96	43,	.	20	114	72	85	106	57	86	124.90	
7	16DEC96	50,	.	20	122	73	88	108	61	84	123.20	
8	27DEC96	61,	.	20	115	62	86	132	68	89	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9	.	.	.	30 - 70	%
				Lymphocytes	29.1	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	328000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	65	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	27AUG96	1	02SEP96	7	7
00325	Oral	2	100 MG	03SEP96	8	08SEP96	13	6
00325	Oral	3	150 MG	09SEP96	14	15SEP96	20	7
00325	Oral	4	200 MG	16SEP96	21	22SEP96	27	7
00325	Oral	4	200 MG	23SEP96	28	29SEP96	34	7
00325	Oral	4	200 MG	30SEP96	35	09OCT96	44	10
00325	Oral	4	200 MG	10OCT96	45	13OCT96	48	4
00325	Oral	4	200 MG	14OCT96	49	20OCT96	55	7
00166	Oral	4	200 MG	21OCT96	56	17NOV96	83	28
00166	Oral	4	200 MG	18NOV96	84	15DEC96	111	28
00325	Oral	4	200 MG	16DEC96	112	16DEC96	112	1
00325	Oral	3	150 MG	17DEC96	113	18DEC96	114	2
00325	Oral	2	100 MG	19DEC96	115	21DEC96	117	3
00325	Oral	1	50 MG	22DEC96	118	28DEC96	124	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	124	50	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
HEADACHE {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
NAUSEA {STOMACH UPSET}	DYSPEPSIA	DIGESTIVE SYST	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ranitidine Hydrochloride	Zantac	-604, -659	01JAN95	.	2TABS PRN	STOMACH UPSET
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol Extra Strength	-604, -659	01JAN95	.	1TAB PRN	MENSTRUAL CRAMPS
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	45, -11	10OCT96	.	150 MG	NASAL CONGESTION
	Dofamium Chloride	Desogen	27, -29	22SEP96	.	1 TAB DAILY	BIRTH CONTROL
MUSCULO-SKELETAL	Ketoprofen	Orudis Kt	-2430,-2485	01JAN90	.	2CAPS PRN	OCCASIONAL HEADACHE
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	45, -11	10OCT96	.	150 MG	NASAL CONGESTION
	Salbutamol	Ventolin Inhaler	-2430,-2485	01JAN90	.	2PUFFS PRN	ASTHMA
			-2430,-2485	01JAN90	.	2PUFFS PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chills	CHILLS	45, -11	40 Days	200	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHES	45, -11	40 Days	200	CON	MOD	NO	PBU	Yes	No
Carciovascular System	Syncope	DIZZINESS WITH SYNCOPE	6, -50	1 Days	50	CON	MIL	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	58, 3	27 Days	200		MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	28, -28	8 Days	200	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	11, -45	11 Days	100	CON	MIL	NO	PSR	No	No
			28, -28	8 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Abnormal Dreams	INCREASED DREAMING	35, -21	11 Days	200	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	6, -50	16 Days	50	CON	MOD	NO	PSR	No	No
			22, -34	Not Stated	200	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	45, -11	40 Days	200	CON	MOD	NO	UNR	Yes	No
	Dyspnea	SHORTNESS OF BREATH	6, -50	16 Days	50	CON	MIL	NO	PSR	No	No
	Rhinitis	NASAL CONGESTION	45, -11	40 Days	200	CON	MOD	NO	UNR	Yes	No
Special Senses	Keratoconjunctivitis	IRRITATION IN EYES (DRY EYES)	14, -42	8 Days	150	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	21AUG96	-6, -61	0	103	53	72	106	45	90	118.63	67.0
BL	27AUG96	1, -55	0	108	53	65	96	55	97	116.00	
1	03SEP96	8, -48	100	107	73	88	94	57	108	114.80	
2	09SEP96	14, -42	150	113	67	109	100	65	114	114.44	
3	16SEP96	21, -35	200	102	53	93	90	.	115	120.39	
4	23SEP96	28, -28	200	112	56	103	99	51	131 H	115.32	
5	30SEP96	35, -21	200	123	61	74	101	61	114	116.30	
6	10OCT96	45, -11	200	121	63	93	107	59	119	117.40	
7	14OCT96	49, -7	200	149	70	94	118	60	123	117.80	
8	21OCT96	56, 1	200	130	68	93	128	58	119	117.20	
12	18NOV96	84, 29	200	131	67	89	113	74	125	118.90	
16	16DEC96	112, 57	200	113	60	87	92	47	131 H	118.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.2	.	.	.	30 - 70	%
				Lymphocytes	40.1	.	.	.	21 - 51	%
				Monocytes	9.3	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.1		.	.	12 - 15.6	G/DL
				Hematocrit	38.2		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3		.	.	30 - 70	%
				Lymphocytes	32.2		.	.	21 - 51	%
				Monocytes	8.8		.	.	0 - 10	%
				Eosinophils	0.5		.	.	0 - 5	%
				Basophils	0.2		.	.	0 - 2	%
				Platelets	313000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58		.	.	44 - 280	U/L
				Aspartate Aminotransferase	12		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	112	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	44.2	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	0.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	340000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 12/CONTINUATION-WEEK 16	112	Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05SEP96	1	08SEP96	4	4
00326	Oral	2	100 MG	09SEP96	5	15SEP96	11	7
00326	Oral	3	150 MG	16SEP96	12	22SEP96	18	7
00326	Oral	4	200 MG	23SEP96	19	29SEP96	25	7
00326	Oral	4	200 MG	30SEP96	26	06OCT96	32	7
00326	Oral	4	200 MG	07OCT96	33	16OCT96	42	10
00326	Oral	4	200 MG	17OCT96	43	23OCT96	49	7
00326	Oral	4	200 MG	24OCT96	50	27OCT96	53	4
00167	Oral	4	200 MG	28OCT96	54	24NOV96	81	28
00167	Oral	4	200 MG	25NOV96	82	15DEC96	102	21
00326	Oral	4	200 MG	16DEC96	103	16DEC96	103	1
00326	Oral	3	150 MG	17DEC96	104	18DEC96	105	2
00326	Oral	2	100 MG	19DEC96	106	21DEC96	108	3
00326	Oral	1	50 MG	22DEC96	109	28DEC96	115	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	115	50	Lack of Efficacy	THIS WAS PATIENTS ACTUD LAST VISIT TO CLINIC PATIENT WAS GIVEN DOWN TITRATION MEDS, FINISHED ON 28 DEC 96 BUT DID NOT RETURN TO CLINIC - MAILED MED PACKET TO US

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Dextromethorphan Hydrobromide	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS
	Doxylamine Succinate	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS
	Paracetamol	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS
	Pseudoephedrine Hydrochloride	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Tachycardia	TACHYCARDIA	26, -28	Not Stated	200	CON	MIL	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	40, -14	4 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	40, -14	4 Days	200	CON	MIL	NO	PSR	No	No
	Hyperkinesia	AKATHISIA	26, -28	18 Days	200	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26AUG96	-10, -63	0	139	64	93	143	74	98	227.10	68.0
BL	05SEP96	1, -53	0	152	81	91	158	87	108	227.70	
1	09SEP96	5, -49	100	139	58	88	124	69	98	226.50	
2	16SEP96	12, -42	150	136	63	88	95	70	98	223.60	
3	23SEP96	19, -35	200	139	78	98	138	76	105	223.50	
4	30SEP96	26, -28	200	125	65	111	105	57	126	222.00	
5	07OCT96	33, -21	200	139	72	108	129	86	121	221.50	
6	17OCT96	43, -11	200	141	67	98	124	51	112	215.30	
7	24OCT96	50, -4	200	152	76	96	134	55	125	218.90	
8	28OCT96	54, 1	200	139	70	106	123	86	105	215.50	
12	25NOV96	82, 29	200	146	74	112	85 L	74	126	213.00	
16	16DEC96	103, 50	200	.	.	.	.	.	.	211.10 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	35.7	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	181	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	78	H	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	27.7	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	234000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	54	Alanine Aminotransferase	34	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	120	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 12/CONTINUATION-WEEK 16	103	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	134	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16SEP96	1	22SEP96	7	7
00327	Oral	2	0 MG	23SEP96	8	29SEP96	14	7
00327	Oral	3	0 MG	30SEP96	15	06OCT96	21	7
00327	Oral	4	0 MG	07OCT96	22	13OCT96	28	7
00327	Oral	5	0 MG	14OCT96	29	20OCT96	35	7
	Oral	5	0 MG	21OCT96	36	04NOV96	50	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	50	0	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
INSECT BITES	INJURY, SUPERFICIAL	INJURY/POISONING	CUR	1996
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
SINUS ALLERGIES {CONGESTION}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996
STOMACHACHE {OCCASIONAL}	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Mylanta Double Strength	-624, .	01JAN95	.	800 MG PRN	STOMACHE
	Dicycloverine	Dicyclomine	-624, .	01JAN95	.	20 MG PRN	STOMACH ACHE
	Dimeticone, Activated	Mylanta Double Strength	-624, .	01JAN95	.	800 MG PRN	STOMACHE
	Magnesium Hydroxide	Mylanta Double Strength	-624, .	01JAN95	.	800 MG PRN	STOMACHE
	Ranitidine Hydrochloride	Zantac	-624, .	01JAN95	.	150 MG PRN	STOMACH ACHE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-989, .	01JAN94	.	1000 MG PRN	OCCASIONAL HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-259, .	01JAN96	.	25 MG PRN	INSECT BITES
MUSCULO-SKELETAL	Ibuprofen	Midol Ib	-989, .	01JAN94	.	400 MG PRN	MENSTRUAL CRAMPS
RESPIRATORY	Chlorphenamine Maleate	Codimal La	-259, .	01JAN96	.	24 MG PRN	SINUS ALLERGIES CONGESTION
	Diphenhydramine Hydrochloride	Benadryl	-259, .	01JAN96	.	25 MG PRN	INSECT BITES
	Pseudoephedrine Hydrochloride	Codimal La	-259, .	01JAN96	.	24 MG PRN	SINUS ALLERGIES CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	09SEP96	-7,	.	0	111	56	93	109	49	101	90.80	60.1
BL	16SEP96	1,	.	0	88	50	87	94	47	93	94.40	
1	23SEP96	8,	.	0	88	45	93	96	53	106	89.90	
2	30SEP96	15,	.	0	98	43	93	109	68	106	90.70	
3	07OCT96	22,	.	0	96	46	91	92	66	112	90.40	
4	14OCT96	29,	.	0	118	53	84	118	57	94	92.10	
5	21OCT96	36,	.	0	99	50	79	104	55	89	91.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	27.6	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Hemoglobin	13.2		.	.	12 - 15.6	G/DL
				Hematocrit	38.1		.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.6		.	.	30 - 70	%
				Lymphocytes	28.5		.	.	21 - 51	%
				Monocytes	5.1		.	.	0 - 10	%
				Eosinophils	1.7		.	.	0 - 5	%
				Basophils	1.1		.	.	0 - 2	%
				Platelets	239000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	95		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 7/ACUTE PHASE-WEEK 5	36	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick		6	.	.		
				Urine Red Blood Cells/HPF		5	.	+		
				Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		4	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells		4	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00328 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07OCT96	1	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	1	20	Other reason	WITHDREW CONSENT

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00328 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BIVENTRICULAR HYPERTROPHY	CARDIOMEGALY	CIRCULATORY SYST	CUR	1996
HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
STOMACH ACHES {OCCASIONAL}	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	30SEP96	-7, .	0	123	67	70	112	85	79	85.30	59.5
BL	07OCT96	1, .	0	111	68	71	112	76	86	86.60	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00328 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)		Hemoglobin	13.9				13.8 - 17.2	G/DL
				Hematocrit	40.9	L			41 - 50	%
				Red Blood Cell Count	4.8				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6				4.5 - 13	THOU/MCL
				Segmented Neutrophils	35				30 - 70	%
				Lymphocytes	56	H			21 - 51	%
				Monocytes	6				0 - 10	%
				Eosinophils	3				0 - 5	%
				Basophils	0				0 - 2	%
				Platelets	197000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2				25 - 35	PG
				Mean Corpuscle Volume	86				80 - 100	FL
				Blood Urea Nitrogen	10				7 - 25	MG/DL
				Creatinine	0.9				0.8 - 1.5	MG/DL
				Uric Acid	2.3	L			4 - 8	MG/DL
				Alkaline Phosphatase	398			+	44 - 400	U/L
				Aspartate Aminotransferase	27				0 - 41	U/L
				Alanine Aminotransferase	15				0 - 48	U/L
				Total Bilirubin	0.7				0.3 - 1.3	MG/DL
				Total Protein	8.3				6.2 - 8.8	G/DL
				Albumin	4.6				3.1 - 5.3	G/DL
				Glucose - Random	101				70 - 115	MG/DL
				Globulin	3.7				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	6					
				Urine Red Blood Cells/HPF	5					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	6					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00328 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)		Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	09OCT96	1	15OCT96	7	7
00329	Oral	2	20 MG	16OCT96	8	22OCT96	14	7
00329	Oral	3	20 MG	23OCT96	15	28OCT96	20	6
00329	Oral	4	20 MG	29OCT96	21	04NOV96	27	7
00329	Oral	4	20 MG	05NOV96	28	11NOV96	34	7
00329	Oral	4	20 MG	12NOV96	35	18NOV96	41	7
00329	Oral	5	30 MG	19NOV96	42	25NOV96	48	7
00329	Oral	5	30 MG	26NOV96	49	02DEC96	55	7
	Oral	5	30 MG	03DEC96	56	17DEC96	70	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	No	70	30	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
REPOLARIZATION ON ECG {EARLY}	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SINUS BRADYCARDIA {MARKED}	BRADYCARDIA	CIRCULATORY SYST	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-647, .	01JAN95	.	500 MG PRN	HEADACHE OCCASIONAL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Depression	WORSENING OF DEPRESSION	35, .	22 Days	20	CON	MOD	NO	PBU	No	No
	Dizziness	DIZZINESS IN AM	6, .	10 Days	20	CON	MIL	NO	REL	No	No
	Somnolence	SLEEPINESS IN AM	6, .	16 Days	20	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01OCT96	-8,	.	0	108	62	59	101	67	65	122.30	66.1
BL	09OCT96	1,	.	0	119	56	64	128	62	88	121.60	
1	16OCT96	8,	.	20	123	58	57	122	60	67	120.70	
2	23OCT96	15,	.	20	126	57	66	125	64	71	120.30	
3	29OCT96	21,	.	20	123	57	54	129	71	58	123.50	
4	05NOV96	28,	.	20	124	65	73	114	63	97	119.10	
5	12NOV96	35,	.	20	107	58	50	107	64	62	121.70	
6	19NOV96	42,	.	30	130	64	64	133	63	80	122.20	
7	26NOV96	49,	.	30	114	61	54	115	61	66	120.50	
8	03DEC96	56,	.	30	115	58	62	121	60	66	120.90	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	16.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	49.1		.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2		.	.	30 - 70	%
				Lymphocytes	34.5		.	.	21 - 51	%
				Monocytes	3.5		.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	207000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	346		.	.	44 - 400	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	7		.	.	0 - 48	U/L
				Total Bilirubin	0.9		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9		.	.	6.2 - 8.8	G/DL
				Albumin	4.6		.	.	3.1 - 5.3	G/DL
				Glucose - Random	118	H	.	.	70 - 115	MG/DL
				Globulin	3.3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.	.	
				Urine Blood - Dipstick	NEG			.	.	
				Urine Red Blood Cells/HPF	NEG			.	.	
				Urine White Blood Cells/HPF	NEG			.	.	
				Urine Protein - Dipstick	NEG			.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.8	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	298	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		
				Urine Amphetamines	NEG			.		
				Urine Barbiturates	NEG			.		
				Urine Benzodiazepines	NEG			.		
				Urine Cannabinoids	NEG			.		
				Urine Cocaine	NEG			.		
				Urine Methadone	NEG			.		
				Urine Methaqualone	NEG			.		
				Urine Opiates	NEG			.		
				Urine Phencyclidine	NEC			.		
				Urine Propoxyphene	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21OCT96	1	27OCT96	7	7
00330	Oral	2	0 MG	28OCT96	8	04NOV96	15	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	No	No	15	0	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ATTENTION-DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1996
BROKEN EAR DRUM	EAR/MASTOID DISORD	NERVOUS SYST/SENSE ORGAN DIS	CUR	1996
POSSIBLE VENTRICULAR HYPERTROPHY	CARDIOMEGALY	CIRCULATORY SYST	CUR	1996
SINUS ARRHYTHMIA	ARRHYTHMIA	CIRCULATORY SYST	CUR	1996
SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	-20, .	01OCT96	.	750 MG	BROKEN EAR DRUM
	Clavulanic Acid	Augmentin	-20, .	01OCT96	.	750 MG	BROKEN EAR DRUM
CENTRAL NERVOUS SYSTEM	Pemoline Magnesium	Cylert	-13, .	08OCT96	08OCT96#	37.5 MG	ADHD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Bradycardia	SINUS BRADYCARDIA	8, .	8 Days	0	CON	MIL	NO	PSR	No	No
	Heart Malformation	POSSIBLE LEFT VENTRICULAR HYPERTROPHY	8, .	8 Days	0	CON	MIL	NO	PSR	No	No
	Supraventricular Extrasystoles	OCCASIONAL PREMATURE ATRIAL COMPLEXES	8, .	8 Days	0	CON	MIL	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	1, .	Not Stated	0	CON	MOD	STP	REL	No	No
	Vomiting	VOMITING	12, .	2 Days	0	2	MIL	STP	PSR	No	No
Nervous System	Dizziness	DIZZINESS	1, .	Not Stated	0	CON	MOD	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	15OCT96	-6,	.	0	117	79	68	106	88	70	93.50	59.0
BL	21OCT96	1,	.	0	106	68	65	120	71	80	94.00	
1	28OCT96	8,	.	0	115	72	68	106	71	73	96.80	
2	04NOV96	15,	.	0	112	66	62	106	72	72	96.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1	.	.	.	30 - 70	%
				Lymphocytes	26.3	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	340000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	3.7	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
00182	Oral	3	20 MG	19DEC95	1	11JAN96	24	24
00182	Oral	4	20 MG	12JAN96	25	18JAN96	31	7
00182	Oral	4	20 MG	19JAN96	32	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	No	No	32	20	Lost to follow-up	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	10, .	28DEC95	28DEC95	325	HEADACHE
	Cannabis	Marijuana	-1448, .	01JAN92	.		ILLICIT USE
	Paracetamol	Tylenol	-7, .	12DEC95	12DEC95#	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	10, .	1 Days	20	CON	MIL	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05DEC95	-14, .	0	.	.	.	.	.	.	137.50	71.0
BL	19DEC95	1, .	0	110	80	68	112	87	84	140.50	
3	12JAN96	25, .	20	118	72	72	122	82	84	135.50	
4	19JAN96	32, .	20	118	75	66	124	70	74	130.00 L	
SC	12DEC97	725, .#	0	118	70	82	118	75	94		

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.4				13.8 - 17.2	G/DL
				Hematocrit	45.2				41 - 50	%
				Red Blood Cell Count	5.1				4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9.7				3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	73.5				40 - 75	%
				Lymphocytes	16				16 - 46	%
				Monocytes	6.7				0 - 12	%
				Eosinophils	2.7				0 - 7	%
				Basophils	1.2				0 - 2	%
				Platelets	270000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1				27 - 33	PG
				Mean Corpuscle Volume	88				80 - 100	FL
				Blood Urea Nitrogen	10				7 - 25	MG/DL
				Creatinine	1				0.8 - 1.5	MG/DL
				Uric Acid	3.8	L			4 - 8	MG/DL
				Alkaline Phosphatase	71				22 - 180	U/L
				Aspartate Aminotransferase	9				0 - 41	U/L
				Alanine Aminotransferase	8				0 - 48	U/L
				Total Bilirubin	0.7				0.3 - 1.3	MG/DL
				Total Protein	7.9				6.2 - 8.8	G/DL
				Albumin	4.9				3.1 - 5.3	G/DL
				Glucose - Random	93				70 - 115	MG/DL
				Globulin	3				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	25	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 5/ACUTE PHASE-WEEK 3	25	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03DEC95	1	11DEC95	9	9
00183	Oral	2	0 MG	12DEC95	10	19DEC95	17	8
00183	Oral	3	0 MG	20DEC95	18	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	18	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
INCREASED CREATININE	CREATININE, INCREASED	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
INCREASED URINE NITROGEN	URINE, ABN, OTHER	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
ASTHMATIC REACTION{BRIEF}	ASTHMA	RESPIRATORY SYST DIS	PRV	1994
SEIZURE{UNKNOWN ETIOLOGY 1X}	CONVULSIONS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1989

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21NOV95	-12, .	0	112	78	68	105	80	80	150.20	71.0
BL	28NOV95	-5, .	0	100	60	65	100	50	72	155.50	
1	05DEC95	3, .	0	125	75	68	110	70	82	154.00	
1	12DEC95	10, .	0	115	70	72	98	65	92	153.50	
2	19DEC95	17, .	0	122	78	68	108	68	92	158.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.8				13.8 - 17.2	G/DL
				Hematocrit	40.8	L			41 - 50	%
				Red Blood Cell Count	5				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4				4.5 - 13	THOU/MCL
				Segmented Neutrophils	37				30 - 70	%
				Lymphocytes	51				21 - 51	%
				Monocytes	5.2				0 - 10	%
				Eosinophils	6	H			0 - 5	%
				Basophils	1.1				0 - 2	%
				Platelets	262000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4				25 - 35	PG
				Mean Corpuscle Volume	81				80 - 100	FL
				Blood Urea Nitrogen	107	H		+	7 - 25	MG/DL
				Creatinine	13.2	H		+	0.8 - 1.5	MG/DL
				Uric Acid	8.8	H			4 - 8	MG/DL
				Alkaline Phosphatase	285				44 - 400	U/L
				Aspartate Aminotransferase	12				0 - 41	U/L
				Alanine Aminotransferase	8				0 - 48	U/L
				Total Bilirubin	1.2				0.3 - 1.3	MG/DL
				Total Protein	7.1				6.2 - 8.8	G/DL
				Albumin	4.1				3.1 - 5.3	G/DL
				Glucose - Random	72				70 - 115	MG/DL
				Globulin	3				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	NEG					
				Urine Bacteria	3					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-5	Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	322		.	.	44 - 400	U/L
				Aspartate Aminotransferase	17		.	.	0 - 41	U/L
				Alanine Aminotransferase	9		.	.	0 - 48	U/L
				Total Bilirubin	1.1		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	83		.	.	70 - 115	MG/DL
				Globulin	3.3		.	.	2.3 - 4.1	G/DL
		VISIT 3/ACUTE PHASE-WEEK 1	3	Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	335		.	.	44 - 400	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	7		.	.	0 - 48	U/L
				Total Bilirubin	1		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 3/ACUTE PHASE-WEEK 1	3	Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	09AUG96	1	13AUG96	5	5
00263	Oral	2	0 MG	14AUG96	6	20AUG96	12	7
00263	Oral	3	0 MG	21AUG96	13	27AUG96	19	7
00263	Oral	4	0 MG	28AUG96	20	03SEP96	26	7
00263	Oral	5	0 MG	04SEP96	27	10SEP96	33	7
00263	Oral	6	0 MG	11SEP96	34	17SEP96	40	7
00263	Oral	6	0 MG	18SEP96	41	24SEP96	47	7
00263	Oral	6	0 MG	25SEP96	48	03OCT96	56	9
	Oral	5	0 MG	04OCT96	57	19OCT96	72	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	Yes	No	72	0		PT. DOES NOT FEEL HE CAN BE COMPLIANT FOR NEXT SIX MONTHS. ALSO DOES NOT WANT TO TAKE THAT MANY PILLS ANYMORE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	6, .	14AUG96	14AUG96	375 MG	HEADACHE
			9, .	17AUG96	17AUG96	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	33, .	10SEP96	10SEP96	400 MG	ACHE IN SIDE
RESPIRATORY	Guaifenesin	Entex	45, .	22SEP96	23SEP96	250 MG	CONGESTION
	Phenylephrine Hydrochloride	Entex	45, .	22SEP96	23SEP96	250 MG	CONGESTION
	Phenylpropanolamine Hydrochloride	Entex	45, .	22SEP96	23SEP96	250 MG	CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE HEADACHE {SIMULTANEOUS} [STOMACH ACHE]	31, .	10 Mins	0	1	MIL	NO	PSR	No	No
	Back Pain	BACK ACHE	30, .	06:00 Hrs	0	1	MIL	NO	UNR	No	No
	Headache	HEADACHE	6, .	03:00 Hrs	0	1	MIL	NO	PBU	Yes	No
			9, .	02:00 Hrs	0	1	MIL	NO	PBU	Yes	No
			27, .	15 Mins	0	1	MIL	NO	PBU	No	No
		STOMACH ACHE HEADACHE {SIMULTANEOUS} [HEADACHE]	31, .	10 Mins	0	1	MIL	NO	PSR	No	No
	Pain	SIDE ACHE LEFT SIDE	33, .	01:30 Hrs	0	1	MIL	NO	UNR	Yes	No
Digestive System	Ulcerative Stomatitis	MOUTH SORES	59, .	8 Days	0	CON	MIL	NO	UNR	No	No
Musculoskeletal System	Arthralgia	SHOULDER PAIN RIGHT SHOULDER	34, .	12:00 Hrs	0	1	MIL	NO	UNR	No	No
Respiratory System	Respiratory Disorder	COLD AND CONGESTION	45, .	8 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JUL96	-16,	.	0	125	85	80	125	85	96	224.00	72.0
BL	09AUG96	1,	.	0	130	82	68	125	78	74	230.00	
1	14AUG96	6,	.	0	130	76	70	125	80	76	235.00	
2	21AUG96	13,	.	0	126	80	80	118	74	88	232.20	
3	28AUG96	20,	.	0	124	76	84	118	70	90	230.50	
4	04SEP96	27,	.	0	126	84	78	116	76	90	233.20	
5	11SEP96	34,	.	0	122	78	78	116	74	92	235.00	
6	18SEP96	41,	.	0	130	86	92	118	78	96	236.50	
7	25SEP96	48,	.	0	118	80	88	112	74	92	233.50	
8	09OCT96	62,	.	0	118	76	100	108	70	108	237.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	16	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.6	.	.	.	40 - 75	%
				Lymphocytes	35.4	.	.	.	16 - 46	%
				Monocytes	5.9	.	.	.	0 - 12	%
				Eosinophils	1.3	.	.	.	0 - 7	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-16	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	58	.	.	.	40 - 75	%
				Lymphocytes	34.9	.	.	.	16 - 46	%
				Monocytes	5.4	.	.	.	0 - 12	%
				Eosinophils	1.7	.	.	.	0 - 7	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 10/ACUTE PHASE-WEEK 8	62	Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	01MAR96	1	07MAR96	7	7
00277	Oral	2	0 MG	08MAR96	8	14MAR96	14	7
00277	Oral	3	0 MG	15MAR96	15	21MAR96	21	7
00277	Oral	4	0 MG	22MAR96	22	28MAR96	28	7
00277	Oral	5	0 MG	29MAR96	29	04APR96	35	7
00277	Oral	5	0 MG	05APR96	36	14APR96	45	10
00277	Oral	6	0 MG	15APR96	46	18APR96	49	4
00277	Oral	6	0 MG	19APR96	50	25APR96	56	7
00156	Oral	6	0 MG	26APR96	57	24MAY96	85	29
00156	Oral	6	0 MG	25MAY96	86	21JUN96	113	28

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	113	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
PROTEINURIA	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	.,	.		.	PRN	HEADACHE
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	159,	103	06AUG96	06AUG96	220 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	159, 103	02:00 Hrs	0	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	23FEB96	-7, -63	0	130	90	88	115	70	92	203.00	64.0
BL	01MAR96	1, -56	0	130	80	96	110	70	108	205.80	
1	08MAR96	8, -49	0	130	90	96	125	75	110	206.50	
3	22MAR96	22, -35	0	115	60	72	110	68	80	204.50	
4	29MAR96	29, -28	0	122	88	80	112	80	82	201.50	
6	15APR96	46, -11	0	105	90	87	134	78	87		
7	19APR96	50, -7	0	130	70	80	130	85	90	198.00	
8	26APR96	57, 1	0	129	78	77	136	78	92	198.00	
12	24MAY96	85, 29	0	130	90	72	118	80	90	204.00	
16	21JUN96	113, 57	0	132	90	90	135	96	95	208.50	
24	07AUG96	160, 104#	0	125	75	84	118	70	96	219.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.4	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	332000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	1	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick		6	.	.		
				Urine Red Blood Cells/HPF		5	.	.		
				Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		4	.	.		
				Urine Protein - Dipstick		6	.	.		
				Urine Squamous Epithelial Cells		4	.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	18	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick		6	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 4/ACUTE PHASE-WEEK 2	18	Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.7	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	312000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57		Urine White Blood Cells/HPF	3		.	.		
					Urine Bacteria	3		.	.		
					Urine Protein - Dipstick	2		.	.		
					Urine Squamous Epithelial Cells	3		.	.		
		VISIT 16	165	(52)	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
					Hematocrit	33.9	L	.	.	35 - 46	%
					Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54		.	.	30 - 70	%
					Lymphocytes	31.4		.	.	21 - 51	%
					Monocytes	11	H	.	.	0 - 10	%
					Eosinophils	2.9		.	.	0 - 5	%
					Basophils	0.6		.	.	0 - 2	%
					Platelets	317000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.6		.	.	25 - 35	PG
					Mean Corpuscle Volume	86		.	.	80 - 100	FL
					Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
					Creatinine	1.2		.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.8		.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	70		.	.	44 - 280	U/L
					Aspartate Aminotransferase	19		.	.	0 - 41	U/L
					Alanine Aminotransferase	15		.	.	0 - 48	U/L
					Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
					Total Protein	6.7		.	.	6.2 - 8.8	G/DL
					Albumin	3.7		.	.	3.1 - 5.3	G/DL
					Glucose - Random	82		.	.	70 - 115	MG/DL
					Globulin	3		.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16	165	(52)	Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3		.	.		
					Urine Bacteria	4		.	.		
					Urine Protein - Dipstick	6		.	.		
					Urine Squamous Epithelial Cells	4		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	09FEB96	1	15FEB96	7	7
00278	Oral	2	20 MG	16FEB96	8	22FEB96	14	7
00278	Oral	3	20 MG	23FEB96	15	29FEB96	21	7
00278	Oral	4	20 MG	01MAR96	22	07MAR96	28	7
00278	Oral	4	20 MG	08MAR96	29	14MAR96	35	7
00278	Oral	5	30 MG	15MAR96	36	21MAR96	42	7
00278	Oral	6	40 MG	22MAR96	43	28MAR96	49	7
00278	Oral	6	40 MG	29MAR96	50	04APR96	56	7
00132	Oral	6	40 MG	05APR96	57	02MAY96	84	28
00132	Oral	6	40 MG	03MAY96	85	30MAY96	112	28
00132	Oral	6	40 MG	31MAY96	113	26JUN96	139	27
00132	Oral	6	40 MG	27JUN96	140	24JUL96	167	28
00132	Oral	6	40 MG	25JUL96	168	21AUG96	195	28
00132	Oral	6	40 MG	22AUG96	196	19SEP96	224	29
00278	Oral	5	30 MG	20SEP96	225	21SEP96	226	2
00278	Oral	4	20 MG	22SEP96	227	23SEP96	228	2
00278	Oral	3	20 MG	24SEP96	229	25SEP96	230	2
00278	Oral	2	20 MG	26SEP96	231	28SEP96	233	3
00278	Oral	1	20 MG	29SEP96	234	05OCT96	240	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	Yes	240	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ABDOMINAL PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
POLYCYSTIC OVARY	OVARIAN DYSFUNC	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
ACUTE PANCREATITIS	PANCREATITIS	DIGESTIVE SYST	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Cefalexin Monohydrate	Keflex	221, 165	16SEP96	19SEP96	4000 MG	MONONUCLEOSIS
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-39, -95	01JAN96	.	325	ABDOMINAL PAIN
	Oxycodone Hydrochloride	Percocet	37, -20	16MAR96	17MAR96	PRN	ABDOMINAL PAIN
	Oxycodone Terephthalate	Percocet	37, -20	16MAR96	17MAR96	PRN	ABDOMINAL PAIN
	Paracetamol	Percocet	37, -20	16MAR96	17MAR96	PRN	ABDOMINAL PAIN
	Tramadol Hydrochloride	Ultram	38, -19	17MAR96	19MAR96	PRN	ABDOMINAL PAIN
RESPIRATORY	Prednisone	Prednisone	221, 165	16SEP96	17SEP96	80 MG	MONONUCLEOSIS
			223, 167	18SEP96	19SEP96	60 MG	MONONUCLEOSIS
			225, 169	20SEP96	21SEP96	40 MG	MONONUCLEOSIS
			227, 171	22SEP96	23SEP96	20 MG	MONONUCLEOSIS
			229, 173	24SEP96	25SEP96	10 MG	MONONUCLEOSIS
SYSTEMIC HORMONAL	Prednisone	Prednisone	221, 165	16SEP96	17SEP96	80 MG	MONONUCLEOSIS
			223, 167	18SEP96	19SEP96	60 MG	MONONUCLEOSIS
			225, 169	20SEP96	21SEP96	40 MG	MONONUCLEOSIS
			227, 171	22SEP96	23SEP96	20 MG	MONONUCLEOSIS
			229, 173	24SEP96	25SEP96	10 MG	MONONUCLEOSIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	ABDOMINAL PAIN(PRESENT PREVIOUSLY)	43, -14	5 Days	40	CON	SEV	NO	PBU	Yes	No
	Infection	MONONUCLEOSIS	206, 150	Not Stated	40	CON	SEV	NO	PBU	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	50, -7	6 Days	40	CON	MIL	NO	REL	No	No
Nervous System	Nervousness	RESTLESSNESS	24, -33	5 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Larynx Disorder	LARYNGITIS	22, -35	4 Days	20	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	02FEB96	-7, -63	0	122	82	64	118	88	88	182.00	65.0
BL	09FEB96	1, -56	0	127	78	.	118	70	118	184.50	
1	16FEB96	8, -49	20	120	80	68	118	85	88	180.75	
2	23FEB96	15, -42	20	124	78	60	118	70	88	181.00	
3	01MAR96	22, -35	20	135	88	60	115	80	92	179.80	
4	08MAR96	29, -28	20	118	83	68	120	88	96	179.50	
5	15MAR96	36, -21	30	120	78	68	118	82	92	177.00	
6	22MAR96	43, -14	40	110	78	62	104	72	72	179.50	
7	29MAR96	50, -7	40	118	70	80	114	80	104	178.70	
8	05APR96	57, 1	40	112	78	60	108	72	96	178.00	
12	03MAY96	85, 29	40	123	58	72	115	72	85	182.00	
16	31MAY96	113, 57	40	110	70	60	100	80	96	176.00	
20	27JUN96	140, 84	40	110	70	72	105	80	92	179.50	
24	25JUL96	168, 112	40	105	80	72	100	75	88	178.00	
28	22AUG96	196, 140	40	124	80	68	122	85	92	179.00	
32	19SEP96	224, 168	40	100	65	76	100	70	96	181.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7				12 - 15.6	G/DL
				Hematocrit	37.3				35 - 46	%
				Red Blood Cell Count	4.5				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6				4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2				30 - 70	%
				Lymphocytes	33.4				21 - 51	%
				Monocytes	9.7				0 - 10	%
				Eosinophils	3.4				0 - 5	%
				Basophils	1.4				0 - 2	%
				Platelets	257000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28				25 - 35	PG
				Mean Corpuscle Volume	82				80 - 100	FL
				Blood Urea Nitrogen	15				7 - 25	MG/DL
				Creatinine	0.8				0.8 - 1.5	MG/DL
				Uric Acid	4				2.3 - 7	MG/DL
				Alkaline Phosphatase	69				22 - 130	U/L
				Aspartate Aminotransferase	14				0 - 41	U/L
				Alanine Aminotransferase	9				0 - 48	U/L
				Total Bilirubin	0.6				0.3 - 1.3	MG/DL
				Total Protein	7.4				6.2 - 8.8	G/DL
				Albumin	4.2				3.1 - 5.3	G/DL
				Glucose - Random	31	L			70 - 115	MG/DL
				Globulin	3.2				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	4					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58		.	.	22 - 130	U/L
				Aspartate Aminotransferase	21		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7		.	.	12 - 15.6	G/DL
				Hematocrit	36.4		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3		.	.	30 - 70	%
				Lymphocytes	22.3		.	.	21 - 51	%
				Monocytes	7.4		.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	24.6	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	140	Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	224	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.6	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 16/CONTINUATION-WEEK 32	224	Basophils	0.9	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	82	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	48	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22MAR96	1	28MAR96	7	7
00279	Oral	2	100 MG	29MAR96	8	04APR96	14	7
00279	Oral	3	150 MG	05APR96	15	11APR96	21	7
00279	Oral	4	200 MG	12APR96	22	18APR96	28	7
00279	Oral	5	250 MG	19APR96	29	24APR96	34	6
00279	Oral	6	300 MG	25APR96	35	02MAY96	42	8
00279	Oral	6	300 MG	03MAY96	43	09MAY96	49	7
00279	Oral	6	300 MG	10MAY96	50	16MAY96	56	7
00147	Oral	6	300 MG	17MAY96	57	13JUN96	84	28
00147	Oral	6	300 MG	14JUN96	85	10JUL96	111	27
00147	Oral	6	300 MG	11JUL96	112	07AUG96	139	28
00147	Oral	6	300 MG	08AUG96	140	04SEP96	167	28
00147	Oral	6	300 MG	05SEP96	168	01OCT96	194	27
00147	Oral	6	300 MG	02OCT96	195	04OCT96	197	3
00147	Oral	5	250 MG	05OCT96	198	06NOV96	230	33
00279	Oral	5	250 MG	07NOV96	231	08NOV96	232	2
00279	Oral	4	200 MG	09NOV96	233	10NOV96	234	2
00279	Oral	3	150 MG	11NOV96	235	12NOV96	236	2
00279	Oral	2	100 MG	13NOV96	237	15NOV96	239	3
00279	Oral	1	50 MG	16NOV96	240	22NOV96	246	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	246	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
THYROID-STIMULATING HORMONE DECREASE	THYROID FUNCTION, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
WBC DECREASE	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Calcium Carbonate	Tums	193, 137	30SEP96	30SEP96	2 TABS	STOMACH PAIN
			193, 137	30SEP96	30SEP96	2 TABS	STOMACH PAIN
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erycette 2% Cream	91, 35	20JUN96	.		ACNE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	11, -46	01APR96	01APR96	325 MG	HEADACHE
			139, 83	07AUG96	07AUG96	325 MG	MOLAR ERUPTING
DERMATOLOGICALS	Benzoyl Peroxide	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Camphor	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Chlorophyllin Sodium	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Diphenhydramine Hydrochloride	Benadryl	162, 106	30AUG96	05SEP96	50 MG	POISON IVY
		Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Edetic Acid	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Erythromycin	Erycette 2% Cream	91, 35	20JUN96	.		ACNE
	Ethanol	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Glycerol	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Hydrocortisone Acetate	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Isopropanol	Ivy Dry	161, 105	29AUG96	04SEP96		POISON IVY
	Parabens	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
		Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Paraffin, Liquid	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Propylene Glycol	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Tannic Acid	Ivy Dry	161, 105	29AUG96	04SEP96		POISON IVY
	Zinc Oxide	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	162, 106	30AUG96	05SEP96	50 MG	POISON IVY
SENSORY ORGANS	Erythromycin	Erycette 2% Cream	91, 35	20JUN96	.		ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH PAIN	195, 139	6 Days	300	5	MOD	DCR	PBU	No	No
		STOMACH PAINS	193, 137	02:00 Hrs	300	CON	MIL	NO	PSR	Yes	No
	Headache	HEADACHE	11, -46	03:00 Hrs	100	1	MOD	NO	PBU	Yes	No
	Infection	FLU	41, -16	3 Days	300	CON	MIL	NO	PBU	No	No
Digestive System	Nausea	NAUSEA	194, 138	03:00 Hrs	300	CON	MIL	NO	PSR	No	No
			195, 139	6 Days	300	5	MOD	DCR	PBU	No	No
	Tooth Disorder	MOLAR ERUPTING	139, 83	02:00 Hrs	300	CON	MOD	NO	UNR	Yes	No
	Ulcerative Stomatitis	MOUTH SORES	196, 140	Not Stated	300	CON	MOD	NO	PBU	No	No
Nervous System	Thinking Abnormal	"STRANGE THOUGHTS"	33, -24	2 Days	250	1	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	COLD - RUNNY NOSE, CONGESTION	48, -9	4 Days	300	CON	MIL	NO	PBU	No	No
Skin and Appendages	Acne	ACNE	86, 30	Not Stated	300	CON	MOD	NO	PBU	Yes	No
	Contact Dermatitis	POISON IVY	110, 54	11 Days	300	CON	MIL	NO	UNR	Yes	No
			155, 99	51 Days	300	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	08MAR96	-14, -70	0	115	82	88	110	75	96	127.80	66.0
BL	22MAR96	1, -56	0	170	70	75	106	85	92	129.00	
1	29MAR96	8, -49	100	98	60	80	100	70	110	128.00	
2	05APR96	15, -42	150	110	70	92	108	78	108	128.00	
3	12APR96	22, -35	200	128	78	92	118	88	108	129.25	
4	19APR96	29, -28	250	110	60	70	110	70	72	129.00	
5	25APR96	35, -22	300	118	77	78	117	61	87		
6	03MAY96	43, -14	300	118	70	65	115	80	74	129.20	
7	10MAY96	50, -7	300	112	88	85	110	80	96	129.00	
8	17MAY96	57, 1	300	120	80	85	114	85	90	128.50	
12	14JUN96	85, 29	300	120	80	85	108	70	95	127.00	
16	11JUL96	112, 56	300	115	70	84	110	70	88	125.50	
20	08AUG96	140, 84	300	115	65	84	110	70	92	129.50	
24	05SEP96	168, 112	300	115	70	72	118	75	88	128.00	
28	02OCT96	195, 139	300	116	68	78	120	78	92	129.50	
32	06NOV96	230, 174	250	114	68	82	110	68	96	129.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.3		.	.	12 - 15.6	G/DL
				Hematocrit	39.2		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2		.	.	30 - 70	%
				Lymphocytes	34.8		.	.	21 - 51	%
				Monocytes	13.5	H	.	.	0 - 10	%
				Eosinophils	2.5		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	168000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	164		.	.	44 - 280	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L
				Alanine Aminotransferase	18		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	78		.	.	70 - 115	MG/DL
				Globulin	3.1		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	68		.	.	30 - 70	%
				Lymphocytes	23		.	.	21 - 51	%
				Monocytes	7		.	.	0 - 10	%
				Eosinophils	1		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEC		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13.5		.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	140	Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	163000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	132	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	67	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	140	Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	230	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	178000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.8	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	17MAY96	1	23MAY96	7	7
00280	Oral	2	20 MG	24MAY96	8	30MAY96	14	7
00280	Oral	3	20 MG	31MAY96	15	06JUN96	21	7
00280	Oral	4	20 MG	07JUN96	22	13JUN96	28	7
00280	Oral	4	20 MG	14JUN96	29	20JUN96	35	7
00280	Oral	5	30 MG	21JUN96	36	26JUN96	41	6
00280	Oral	6	40 MG	27JUN96	42	02JUL96	47	6
00280	Oral	6	40 MG	03JUL96	48	10JUL96	55	8
	Oral	6	40 MG	11JUL96	56	29JUL96	74	19

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	74	40	Protocol violation, including non-compliance	PT. HAS SOME SYMPTOMS OF CONDUCT DISORDER AND OPPOSITIONAL DEFIANT DISORDER AND REFUSED TO PARTICIPATE FURTHER. PT.'S DEPRESSION DID RESPOND DURING TREATMENT, BUT HER OTHER PROBLEMS SEEMED TO WORSEN.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
ASTHMA ATTACK	ASTHMA	RESPIRATORY SYST DIS	PRV	

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Acetaminophen	-10, -65	07MAY96	07MAY96#	650 MG	HEADACHE
		Tylenol	40, -16	25JUN96	25JUN96	1,000 MG	HEADACHE
			42, -14	27JUN96	27JUN96	1,000 MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	34, -22	19JUN96	21JUN96	25 MG	ALLERGIES
			39, -17	24JUN96	26JUN96	25 MG + QHS	ALLERGIES
RESPIRATORY	Clemastine Fumarate	Tavist-D	-2, -57	15MAY96	15MAY96#	1X PILL DAY	CONGESTION
	Diphenhydramine Hydrochloride	Benadryl	34, -22	19JUN96	21JUN96	25 MG	ALLERGIES
			39, -17	24JUN96	26JUN96	25 MG + QHS	ALLERGIES
	Phenylpropanolamine Hydrochloride	Tavist-D	-2, -57	15MAY96	15MAY96#	1X PILL DAY	CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	40, -16	60 Mins	30	1	MIL	NO	PSR	Yes	No
			42, -14	60 Mins	40	1	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	LIGHT-HEADED (X2 MINUTES)	55, -1	2 Mins	40	1	MIL	NO	PSR	No	No
Respiratory System	Rhinitis	CONGESTION (NASAL)	-2, -57	2 Days	0	1	MIL	NO	UNR	Yes	No
Skin and Appendages	Acne	ACNE	31, -25	Not Stated	20	CON	MIL	NO	PSR	No	No
Urogenital System	Urine Abnormality	ABNORMAL URINALYSIS	97, 42	Not Stated	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	10MAY96	-7, -62	0	117	60	90	110	70	104	192.00	64.0
BL	17MAY96	1, -55	0	117	60	90	110	70	104	192.00	
1	24MAY96	8, -48	20	110	68	72	112	80	85	185.00	
2	31MAY96	15, -41	20	112	80	76	108	60	98	182.00	
3	07JUN96	22, -34	20	112	78	92	100	72	96	185.50	
4	14JUN96	29, -27	20	100	70	80	110	78	98	186.00	
5	21JUN96	36, -20	30	108	60	80	108	78	110	183.00	
6	27JUN96	42, -14	40	100	70	80	100	80	84	185.00	
7	03JUL96	48, -8	40	112	80	72	105	80	104	182.00	
8	11JUL96	56, 1	40	105	70	80	120	80	88	183.00	
12	21AUG96	97, 42#	0	.	76	78	110	80	92	193.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9		.	.	12 - 15.6	G/DL
				Hematocrit	38.3		.	.	35 - 46	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1		.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	52		.	.	30 - 70	%
				Lymphocytes	35		.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	314000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102		.	.	44 - 280	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	7		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	85		.	.	70 - 115	MG/DL
				Globulin	2.6		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	48	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEC		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.2		.	.	12 - 15.6	G/DL
				Hematocrit	39.3		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47		.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	61	Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		3100.ZZ2	71	Urine Glucose - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	3100.ZZ2	71		Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	97	(23)	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
					Hematocrit	37.9	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	10.4	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	73	H	.	.	30 - 70	%
					Lymphocytes	20	L	.	.	21 - 51	%
					Monocytes	3.8	.	.	.	0 - 10	%
					Eosinophils	3	.	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	298000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	109	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.1	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 11/CONTINUATION-WEEK 12	97 (23)	Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	26JUL96	1	01AUG96	7	7
00281	Oral	2	100 MG	02AUG96	8	08AUG96	14	7
00281	Oral	3	150 MG	09AUG96	15	18AUG96	24	10
00281	Oral	4	200 MG	19AUG96	25	25AUG96	31	7
00281	Oral	5	250 MG	26AUG96	32	03SEP96	40	9
00281	Oral	6	300 MG	04SEP96	41	08SEP96	45	5
00281	Oral	6	300 MG	09SEP96	46	17SEP96	54	9
00281	Oral	6	300 MG	18SEP96	55	24SEP96	61	7
00158	Oral	6	300 MG	25SEP96	62	24OCT96	91	30
00158	Oral	6	300 MG	25OCT96	92	19NOV96	117	26
00158	Oral	6	300 MG	20NOV96	118	19DEC96	147	30
00158	Oral	6	300 MG	20DEC96	148	03JAN97	162	15
00281	Oral	5	250 MG	04JAN97	163	05JAN97	164	2
00281	Oral	4	200 MG	06JAN97	165	07JAN97	166	2
00281	Oral	3	150 MG	08JAN97	167	09JAN97	168	2
00281	Oral	2	100 MG	10JAN97	169	12JAN97	171	3
00281	Oral	1	50 MG	13JAN97	172	19JAN97	178	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	178	50	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BILATERAL TUBE PLACEMENT IN EARS	OPERATION, EAR	OPERATIONS	PRV	1984
CHICKEN POX	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	PRV	1987
JAUNDICE DUE TO ABO INCOMPATIBILTY {NOS}	COMPLIC OF MED CARE	INJURY/POISONING	PRV	1983
REMOVAL OF BAKER'S CYST FROM RIGHT LEG	OPERATION, SOFT TISSUE	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	40, -22	03SEP96	03SEP96	1000 MG	HEADACHE
			146, 85	18DEC96	19DEC96	1500 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	146, 85	2 Days	300	CON	MIL	NO	PBU	No	No
	Asthenia	FATIGUE	133, 72	20 Days	300	CON	MOD	NO	PSR	No	No
			152, 91	30 Days	300	CON	SEV	STP	PSR	No	No
	Headache	HEADACHE	40, -22	16:00 Hrs	250	1	MOD	NO	PSR	Yes	No
			146, 85	2 Days	300	CON	MIL	NO	PBU	Yes	No
Carciovascular System	Bundle Branch Block	PROLONGED QRS DURATION	55, -7	15 Days	300	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19JUL96	-7, -68	0	118	78	68	115	78	70	138.20	67.0
BL	26JUL96	1, -61	0	110	80	62	108	76	80	138.20	
1	02AUG96	8, -54	100	118	70	80	115	68	92	138.50	
2	09AUG96	15, -47	150	122	74	68	120	72	74	138.50	
3	19AUG96	25, -37	200	122	68	76	118	65	88	135.00	
4	26AUG96	32, -30	250	118	80	64	118	78	72	133.00	
6	04SEP96	41, -21	300	120	76	86	114	70	92	138.00	
6	09SEP96	46, -16	300	120	78	80	118	74	88	136.00	
8	18SEP96	55, -7	300	116	78	92	112	72	98	138.50	
8	25SEP96	62, 1	300	118	80	80	110	76	88	138.00	
12	25OCT96	92, 31	300	122	72	84	118	66	92	141.00	
16	20NOV96	118, 57	300	118	76	88	114	80	96	140.20	
20	20DEC96	148, 87	300	116	72	88	112	76	96	137.50	
24	03JAN97	162, 101	300	128	80	88	120	70	96	139.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.8	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	256000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	252	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	40	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8		.	.	30 - 70	%
				Lymphocytes	34.1		.	.	21 - 51	%
				Monocytes	9.7		.	.	0 - 10	%
				Eosinophils	0.9		.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	250000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	235		.	.	44 - 400	U/L
				Aspartate Aminotransferase	19		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	62	Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.4	H	.	.	30 - 70	%
				Lymphocytes	18.2	L	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	0.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	148	Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	215	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Amphetamines	NEG			.		
				Urine Barbiturates	NEG			.		
				Urine Benzodiazepines	NEG			.		
				Urine Cannabinoids	NEC			.		
				Urine Cocaine	NEG			.		
				Urine Methadone	NEG			.		
				Urine Methaqualone	NEG			.		
				Urine Opiates	NEG			.		
				Urine Phencyclidine	NEG			.		
				Urine Propoxyphene	NEG			.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 14/CONTINUATION-WEEK 24	162	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.1	.	.	.	30 - 70	%
				Lymphocytes	42.5	.	.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	0.2	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	275000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	26JUL96	1	01AUG96	7	7
00282	Oral	2	0 MG	02AUG96	8	08AUG96	14	7
00282	Oral	3	0 MG	09AUG96	15	15AUG96	21	7
00282	Oral	4	0 MG	16AUG96	22	25AUG96	31	10
00282	Oral	5	0 MG	26AUG96	32	02SEP96	39	8
00282	Oral	6	0 MG	03SEP96	40	12SEP96	49	10
00282	Oral	6	0 MG	13SEP96	50	18SEP96	55	6
00282	Oral	6	0 MG	19SEP96	56	26SEP96	63	8
	Oral	5	0 MG	27SEP96	64	12OCT96	79	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	79	0		CONTINUATION PHASE MEDICATION IS NOT AVAILABLE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	CUR	1996
MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1980
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-17, .	09JUL96	14JUL96#	750 MG	BRONCHITIS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	21, .	15AUG96	15AUG96	1000 MG	BACKACHE
			39, .	02SEP96	02SEP96	1000 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Motrin	56, .	19SEP96	19SEP96	800 MG	MENSTRUAL CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	21, .	12 Days	0	CON	MIL	NO	UNR	Yes	No
	Headache	HEADACHE	39, .	30 Mins	0	1	MOD	NO	PBU	Yes	No
Digestive System	Diarrhea	DIARRHEA	56, .	6 Days	0	20	MOD	NO	PSR	No	No
Urogenital System	Dysmenorrhea	CRAMPS (MENSTRUAL)	56, .	12:00 Hrs	0	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19JUL96	-7,	.	0	115	68	70	110	65	74	158.00	66.0
BL	26JUL96	1,	.	0	118	78	78	100	72	92	157.80	
1	02AUG96	8,	.	0	118	70	62	110	68	74	159.00	
2	09AUG96	15,	.	0	118	74	64	110	70	78	161.00	
3	16AUG96	22,	.	0	122	74	64	114	68	76	162.00	
4	26AUG96	32,	.	0	116	74	70	112	70	86	160.20	
6	03SEP96	40,	.	0	118	74	68	112	68	76	161.00	
7	13SEP96	50,	.	0	114	78	68	110	70	76	161.00	
8	19SEP96	56,	.	0	116	76	64	120	80	64	160.50	
8	27SEP96	64,	.	0	118	72	72	110	68	78	161.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.1	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	339000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	4	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	326000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	68	L	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	25NOV95	1	01DEC95	7	7
00163	Oral	2	100 MG	02DEC95	8	11DEC95	17	10
00163	Oral	3	150 MG	12DEC95	18	18DEC95	24	7
00163	Oral	4	200 MG	19DEC95	25	22DEC95	28	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	28	200	Adverse event, including intercurrent illness	WHEN PT.GOT SICK,THEY STOPPED GIVING MED.WITHOUT CONTACTING ANYONE.

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MIGRAINE HEADACHES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1989
STRESS INDUCED ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1994
TEMPOROMANDIBULAR JOINT SYNDROME	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1994
CORRECTIVE SURGERY(BOTH EYES)FOR STRABISMUS	OPERATION, EYE	OPERATIONS	PRV	1985

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-2519, .	01JAN89	.	500MG	MIGRAINES
			-693, .	01JAN94	.	500MG	TEMPOROMANDIBULAR JOINT SYNDROME
			-2, .	23NOV95	.	500MG	HEADACHE
			4, .	28NOV95	.	500MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-4, .	21NOV95	21NOV95#	25MG	DERMATITIS
			-4, .	21NOV95	21NOV95#	OINTMENT	DERMATITIS
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-4, .	21NOV95	21NOV95#	25MG	DERMATITIS
			-4, .	21NOV95	21NOV95#	OINTMENT	DERMATITIS
	Guaifenesin	Robitussin	6, .	30NOV95	01DEC95	1 1/2TSP	SORE THROAT
	Salbutamol	Ventolin	-603, .	01APR94	.	2PUFFS	ASTHMA
			-603, .	01APR94	.	2PUFFS	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	4, .	18:00 Hrs	50	1	MOD	NO	PBU	Yes	No
			-2, .	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	4, .	18:00 Hrs	50	1	MIL	NO	PBU	No	No
			23, .	5 Days	150	CON	MIL	NO	PBU	No	No
			28, .	Not Stated	200	CON	MOD	STP	PSR	No	No
			29, .	Not Stated	200	CON	MOD	STP	PSR	No	No
	Vomiting	VOMITING	28, .	4 Days	200	4	MOD	STP	PSR	No	No
Nervous System	Dizziness	DIZZINESS	4, .	18:00 Hrs	50	1	MIL	NO	PBU	No	No
Respiratory System	Pharyngitis	SORE THROAT	6, .	20:00 Hrs	50	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Rash	RASH	-4, .	Not Stated	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	18NOV95	-7,	.	0	108	60	90	104	60	90	136.00	58.0
BL	24NOV95	-1,	.	0	110	60	76	110	68	80	134.00	
1	01DEC95	7,	.	50	90	50	90	90	52	92	134.20	
2	11DEC95	17,	.	100	90	50	90	92	50	90	134.70	
3	18DEC95	24,	.	150	110	76	94	110	76	96	130.00	
5	27DEC95	33,	.	200	110	70	80	110	70	80	130.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Segmented Neutrophils	SMEARS RECEI	U	.	U	30 - 70	%
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.3	H	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	4.3	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	7	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.2	H	.	.	30 - 70	%
				Lymphocytes	19.7	L	.	.	21 - 51	%
				Monocytes	1.9	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	251000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	22DEC95	1	28DEC95	7	7
00164	Oral	2	0 MG	29DEC95	8	04JAN96	14	7
00164	Oral	3	0 MG	05JAN96	15	11JAN96	21	7
00164	Oral	4	0 MG	12JAN96	22	18JAN96	28	7
00164	Oral	5	0 MG	19JAN96	29	25JAN96	35	7
00164	Oral	6	0 MG	26JAN96	36	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	36	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
LYME DISEASE	ARTHROPOD-BORNE DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993
MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1993

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	19, .	09JAN96	.	400MG	HEADACHE BACKACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	21, .	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	Headache	HEADACHE	21, .	01:00 Hrs	0	1	MIL	NO	PBU	Yes	No
Nervous System	Dizziness	DIZZINESS	34, .	06:00 Hrs	0	7	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15DEC95	-7, .	0	130	90	60	130	80	68	136.50	71.0
1	28DEC95	7, .	0	120	80	60	118	80	68	134.20	
2	04JAN96	14, .	0	120	80	60	118	78	68	136.70	
3	11JAN96	21, .	0	118	70	64	118	70	64	137.20	
4	18JAN96	28, .	0	118	70	64	118	70	68	138.00	
5	25JAN96	35, .	0	120	80	58	118	78	64	140.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.7	.	.	.	30 - 70	%
				Lymphocytes	29.4	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	1028	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	59	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	06SEP96	1	11SEP96	6	6
00208	Oral	2	100 MG	12SEP96	7	17SEP96	12	6
00208	Oral	3	150 MG	18SEP96	13	26SEP96	21	9
00208	Oral	4	200 MG	27SEP96	22	03OCT96	28	7
00208	Oral	5	250 MG	04OCT96	29	10OCT96	35	7
00208	Oral	6	300 MG	11OCT96	36	17OCT96	42	7
00208	Oral	6	300 MG	18OCT96	43	24OCT96	49	7
00208	Oral	6	300 MG	25OCT96	50	03NOV96	59	10
00171	Oral	6	300 MG	04NOV96	60	07NOV96	63	4
00208	Oral	5	250 MG	08NOV96	64	09NOV96	65	2
00208	Oral	4	200 MG	10NOV96	66	11NOV96	67	2
00208	Oral	3	150 MG	12NOV96	68	13NOV96	69	2
00208	Oral	2	100 MG	14NOV96	70	16NOV96	72	3
00208	Oral	1	50 MG	17NOV96	73	23NOV96	79	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	79	50	Adverse event, including intercurrent illness	TOXIC IMIPRAMINE LEVEL (592)

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-1344,-1403	01JAN93	.	1000MG	HEADACHE
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	-249, -308	01JAN96	.	1 TAB DAILY	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	11, -49	03:00 Hrs	100	1	MIL	NO	UNR	No	No
			15, -45	3 Days	150	6	MIL	NO	PBU	No	No
	Abnormal Laboratory Value	TOXIC IMIPRAMINE LEVEL	63, 4	Not Stated	300		MIL	STP	REL	No	No
Digestive System	Constipation	CONSTIPATION	37, -23	13 Days	300	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22AUG96	-15, -74	0	110	60	84	110	60	88	84.50	57.5
BL	05SEP96	-1, -60	0	110	60	80	110	62	84	84.50	
1	11SEP96	6, -54	50	108	62	80	110	60	84	82.00	
2	17SEP96	12, -48	100	118	70	84	116	74	88	83.20	
3	26SEP96	21, -39	150	110	80	90	110	84	86	83.20	
4	03OCT96	28, -32	200	110	70	90	110	76	90	82.70	
5	10OCT96	35, -25	250	108	70	80	110	70	84	83.00	
6	17OCT96	42, -18	300	102	60	80	100	60	86	85.50	
7	24OCT96	49, -11	300	110	70	96	110	76	100	84.70	
8	03NOV96	59, -1	300	110	72	88	112	72	90	86.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.5	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	182000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	208	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.5	.	.	.	30 - 70	%
				Lymphocytes	36.9	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	171000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	174	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11SEP96	1	19SEP96	9	9
00209	Oral	2	100 MG	20SEP96	10	26SEP96	16	7
00209	Oral	3	150 MG	27SEP96	17	03OCT96	23	7
00209	Oral	4	200 MG	04OCT96	24	11OCT96	31	8
00209	Oral	4	200 MG	12OCT96	32	17OCT96	37	6
00209	Oral	4	200 MG	18OCT96	38	24OCT96	44	7
00209	Oral	4	200 MG	25OCT96	45	01NOV96	52	8
00209	Oral	5	250 MG	02NOV96	53	11NOV96	62	10
00173	Oral	5	250 MG	12NOV96	63	18DEC96	99	37
00209	Oral	5	250 MG	19DEC96	100	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	100	250	Other reason	PATIENT WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES {ENVIRONMENTAL}	ALLERGY, NEC	INJURY/POISONING	CUR	1996
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-254, -316	01JAN96	.	325MG	HEADACHE
RESPIRATORY	Loratadine	Claritin	-72, -134	01JUL96	.	1PILL	ALLERGIES
	Pseudoephedrine Hydrochloride	Sudafed	20, -43	30SEP96	03OCT96	30 MG	RUNNY NOSE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory System	Rhinitis	RUNNY NOSE	20, -43	4 Days	150	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23AUG96	-19, -81	0	120	90	80	120	90	80	122.00	64.0
BL	10SEP96	-1, -63	0	118	88	86	120	90	88	122.00	
1	19SEP96	9, -54	50	110	80	84	112	84	84	117.70	
2	26SEP96	16, -47	100	120	90	90	114	88	96	115.00	
3	03OCT96	23, -40	150	120	80	100	118	78	100	117.00	
4	11OCT96	31, -32	200	118	72	96	116	74	100	117.00	
5	17OCT96	37, -26	200	118	80	80	110	78	84	116.20	
6	24OCT96	44, -19	200	118	78	80	110	76	88	116.70	
7	01NOV96	52, -11	200	120	80	86	112	84	88	116.50	
8	11NOV96	62, -1	250	120	76	84	120	80	92	115.50	
12	18DEC96	99, 37	250	108	68	80	100	64	84	110.50 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	293	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	14.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8		.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52		.	.	30 - 70	%
				Lymphocytes	41		.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	1		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	311000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	81		.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8		.	.	0.4 - 1.1	MG/DL
				Uric Acid	5		.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	230		.	.	44 - 400	U/L
				Aspartate Aminotransferase	25		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	62	Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	107	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28SEP96	1	03OCT96	6	6
00210	Oral	2	0 MG	04OCT96	7	09OCT96	12	6
00210	Oral	3	0 MG	10OCT96	13	17OCT96	20	8
00210	Oral	4	0 MG	18OCT96	21	24OCT96	27	7
00210	Oral	4	0 MG	25OCT96	28	03NOV96	37	10
00210	Oral	5	0 MG	04NOV96	38	12NOV96	46	9
00210	Oral	5	0 MG	13NOV96	47	22NOV96	56	10
00210	Oral	5	0 MG	23NOV96	57	02DEC96	66	10
00177	Oral	5	0 MG	03DEC96	67	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	67	0	Lost to follow-up	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	., .		.	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	27, -40	12 Days	0	CON	MIL	NO	PSR	No	No
	Chest Pain	CHEST PAIN	6, -61	20 Mins	0	1	MIL	NO	PBU	No	No
	Headache	HEADACHE	6, -61	20 Mins	0	1	MIL	NO	PBU	No	No
Cardiovascular System	Arrhythmia	SINUS ARRHYTHMIA	27, -40	40 Days	0	2	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	13SEP96	-15, -81	0	108	72	84	110	70	80	113.50	64.2
BL	27SEP96	-1, -67	0	110	70	80	112	70	84	113.50	
1	03OCT96	6, -61	0	110	60	70	110	60	70	114.20	
2	09OCT96	12, -55	0	110	70	80	108	70	88	115.00	
3	17OCT96	20, -47	0	100	70	72	102	70	76	112.00	
4	24OCT96	27, -40	0	100	72	76	102	70	80	114.00	
5	04NOV96	38, -29	0	100	70	80	100	74	86	113.00	
6	12NOV96	46, -21	0	110	70	84	112	74	86	112.00	
8	22NOV96	56, -11	0	102	74	80	106	76	86	113.50	
8	02DEC96	66, -1	0	104	74	80	106	74	80	111.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	194000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	137	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1	.	.	.	30 - 70	%
				Lymphocytes	24.8	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	155000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	133	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick		2	.	.		
				Urine Red Blood Cells/HPF		3	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick		6	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08FEB96	1	14FEB96	7	7
00283	Oral	2	20 MG	15FEB96	8	21FEB96	14	7
00283	Oral	3	20 MG	22FEB96	15	29FEB96	22	8
00283	Oral	4	20 MG	01MAR96	23	07MAR96	29	7
00283	Oral	4	20 MG	08MAR96	30	15MAR96	37	8
00283	Oral	4	20 MG	16MAR96	38	22MAR96	44	7
00283	Oral	4	20 MG	23MAR96	45	28MAR96	50	6
00283	Oral	4	20 MG	29MAR96	51	04APR96	57	7
00130	Oral	4	20 MG	05APR96	58	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	58	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	33, -25	11MAR96	11MAR96	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	18, -40	01:00 Hrs	20	1	MIL	NO	PBU	No	No
			33, -25	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
Nervous System	Tremor	"SHAKINESS"	27, -31	6 Days	20	6	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	30JAN96	-9, -66	0	108	70	64	108	70	68	125.00	67.0
1	14FEB96	7, -51	20	120	80	80	120	76	80	127.00	
2	21FEB96	14, -44	20	110	76	60	108	76	62	124.70	
3	29FEB96	22, -36	20	110	76	76	110	76	84	128.70	
4	07MAR96	29, -29	20	108	70	76	108	70	76	128.20	
5	15MAR96	37, -21	20	110	70	60	110	70	70	128.00	
6	22MAR96	44, -14	20	110	60	76	104	60	70	127.20	
7	28MAR96	50, -8	20	120	80	60	120	80	72	129.50	
8	04APR96	57, -1	20	110	70	70	110	70	70	129.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	44		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7		.	.	30 - 70	%
				Lymphocytes	24.9		.	.	21 - 51	%
				Monocytes	5.4		.	.	0 - 10	%
				Eosinophils	3.9		.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	228000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	15		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150		.	.	22 - 180	U/L
				Aspartate Aminotransferase	34		.	.	0 - 41	U/L
				Alanine Aminotransferase	15		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL
				Albumin	5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.9		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.6		.	.	13.8 - 17.2	G/DL
				Hematocrit	44		.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.6	H	.	.	30 - 70	%
				Lymphocytes	17.9	L	.	.	21 - 51	%
				Monocytes	4.2		.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	264000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	127		.	.	22 - 180	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22MAR96	1	28MAR96	7	7
00284	Oral	2	100 MG	29MAR96	8	05APR96	15	8
00284	Oral	3	150 MG	06APR96	16	11APR96	21	6
00284	Oral	4	200 MG	12APR96	22	19APR96	29	8
00284	Oral	4	200 MG	20APR96	30	25APR96	35	6
00284	Oral	5	250 MG	26APR96	36	02MAY96	42	7
00284	Oral	5	250 MG	03MAY96	43	09MAY96	49	7
00284	Oral	5	250 MG	10MAY96	50	16MAY96	56	7
00134	Oral	5	250 MG	17MAY96	57	10JUN96	81	25
00134	Oral	5	250 MG	11JUN96	82	08JUL96	109	28
00134	Oral	5	250 MG	09JUL96	110	05AUG96	137	28
00134	Oral	5	250 MG	06AUG96	138	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	138	250	Protocol violation, including non-compliance	STOPPED TAKING MEDS. WITHOUT NOTIFICATION OR DOWN TITRATION

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
LOW NEUTROPHILS	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
LOW WHITE BLOOD CELLS	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
CROUP	LARYNGITIS/TRACH, ACUTE	RESPIRATORY SYST DIS	PRV	1979
PECTUS EXCAVATUM	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1978
PSEUDOMONAS INFECTION	BACT DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1988

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Hepatitis B Vaccine	Hepatitis B Vaccine	29, -28	19APR96	19APR96		VACCINATION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-21, -77	01MAR96	.	650MG	HEADACHE
			31, -26	21APR96	21APR96	650MG	HEADACHE
RESPIRATORY	Dextromethorphan Hydrobromide	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT
	Guaifenesin	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT
	Paracetamol	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT
	Pseudoephedrine Hydrochloride	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	31, -26	01:00 Hrs	200	1	MOD	NO	PBU	Yes	No
			78, 22	01:00 Hrs	250	CON	MIL	NO	PBU	Yes	No
Digestive System	Constipation	CONSTIPATION	32, -25	11 Days	200	CON	MIL	NO	PSR	No	No
	Diarrhea	DIARRHEA	79, 23	03:00 Hrs	250	3	MIL	NO	PBU	No	No
	Nausea	NAUSEA	-1, -57	13 Days	0	4	MIL	NO	PSR	No	No
Hemic and Lymphatic System	Leukopenia	LOW NEUTROPHILS	56, -1	Not Stated	250	CON	MOD	NO	PBU	No	No
		LOW WHITE CELL COUNT	56, -1	Not Stated	250	CON	MOD	NO	PBU	No	No
Respiratory System	Pharyngitis	SORE THROAT	9, -48	4 Days	100	CON	MIL	NO	UNR	Yes	No
Urogenital System	Dysuria	DYSURIA	80, 24	2 Days	250	3	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	13MAR96	-9, -65	0	122	78	80	122	70	80	154.70	72.0
BL	21MAR96	-1, -57	0	122	78	80	122	70	80	154.70	
1	28MAR96	7, -50	50	120	78	76	120	80	80	151.70	
2	05APR96	15, -42	100	108	70	80	110	70	88	151.70	
3	11APR96	21, -36	150	110	80	90	110	86	96	152.00	
4	19APR96	29, -28	200	110	80	80	118	80	90	152.20	
5	25APR96	35, -22	200	110	70	80	110	76	80	153.00	
6	02MAY96	42, -15	250	120	80	80	120	80	80	152.00	
7	09MAY96	49, -8	250	120	78	80	120	84	86	152.00	
8	16MAY96	56, -1	250	120	80	80	120	80	80	150.00	
12	10JUN96	81, 25	250	110	72	80	116	70	88	147.00	
16	08JUL96	109, 53	250	126	78	80	120	70	96	147.00	
20	05AUG96	137, 81	250	122	88	76	120	84	80	147.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.5		.	.	41 - 50	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	41		.	.	30 - 70	%
				Lymphocytes	49		.	.	21 - 51	%
				Monocytes	6		.	.	0 - 10	%
				Eosinophils	3		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	180000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33		.	.	25 - 35	PG
				Mean Corpuscle Volume	98		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81		.	.	22 - 180	U/L
				Aspartate Aminotransferase	17		.	.	0 - 41	U/L
				Alanine Aminotransferase	14		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.4		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14		.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3		.	.	41 - 50	%
				Red Blood Cell Count	4.3		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	2	L	.	.	4 - 12	%
				Segmented Neutrophils	43		.	.	30 - 70	%
				Lymphocytes	47		.	.	21 - 51	%
				Monocytes	7		.	.	0 - 10	%
				Eosinophils	1		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Platelets	216000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	96		.	.	80 - 100	FL
				Blood Urea Nitrogen	8		.	.	7 - 25	MG/DL
				Creatinine	1.2		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	92		.	.	22 - 180	U/L
				Aspartate Aminotransferase	23		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	137	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	2.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	21	L	.	.	30 - 70	%
				Lymphocytes	72	H	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	165000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	97	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	137	Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	85	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	4.7	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	18MAY96	1	27MAY96	10	10
00285	Oral	2	0 MG	28MAY96	11	03JUN96	17	7
00285	Oral	3	0 MG	04JUN96	18	10JUN96	24	7
00285	Oral	4	0 MG	11JUN96	25	20JUN96	34	10
00285	Oral	5	0 MG	21JUN96	35	28JUN96	42	8
00285	Oral	6	0 MG	29JUN96	43	08JUL96	52	10
00285	Oral	6	0 MG	09JUL96	53	18JUL96	62	10
00285	Oral	6	0 MG	19JUL96	63	24JUL96	68	6
	Oral	5	0 MG	25JUL96	69	31JUL96	75	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	75	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
KNEE PROBLEMS{RIGHT}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
EPSTEIN BARR VIRUS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-503, .	01JAN95	.	500MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Motrin	18, .	04JUN96	.	400 MG	TOOTHACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Tooth Disorder	TOOTHACHE	18, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	08MAY96	-10,	.	0	110	70	70	100	70	80	184.70	69.5
BL	17MAY96	-1,	.	0	110	70	70	106	70	80	184.70	
1	27MAY96	10,	.	0	110	60	80	110	60	80	185.20	
2	03JUN96	17,	.	0	108	70	80	108	70	84	185.20	
3	10JUN96	24,	.	0	108	68	80	110	70	80	185.00	
5	21JUN96	35,	.	0	104	72	84	110	76	88	184.50	
6	28JUN96	42,	.	0	110	60	80	110	60	84	182.70	
7	08JUL96	52,	.	0	120	60	80	120	60	84	185.50	
8	18JUL96	62,	.	0	118	60	80	114	64	84	184.50	
8	24JUL96	68,	.	0	120	70	88	120	74	88	186.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14				13.8 - 17.2	G/DL
				Hematocrit	40.3	L			41 - 50	%
				Red Blood Cell Count	4.4				4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7				4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4				30 - 70	%
				Lymphocytes	36.9				21 - 51	%
				Monocytes	8.6				0 - 10	%
				Eosinophils	2.6				0 - 5	%
				Basophils	0.5				0 - 2	%
				Platelets	309000				130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1				25 - 35	PG
				Mean Corpuscle Volume	92				80 - 100	FL
				Blood Urea Nitrogen	13				7 - 25	MG/DL
				Creatinine	1				0.8 - 1.5	MG/DL
				Uric Acid	5				4 - 8	MG/DL
				Alkaline Phosphatase	81				22 - 180	U/L
				Aspartate Aminotransferase	17				0 - 41	U/L
				Alanine Aminotransferase	17				0 - 48	U/L
				Total Bilirubin	0.9				0.3 - 1.3	MG/DL
				Total Protein	7.7				6.2 - 8.8	G/DL
				Albumin	4.4				3.1 - 5.3	G/DL
				Glucose - Random	74				70 - 115	MG/DL
				Globulin	3.3				2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG					
				Urine Blood - Dipstick	NEG					
				Urine Red Blood Cells/HPF	NEG					
				Urine White Blood Cells/HPF	3					
				Urine Bacteria	4					
				Urine Protein - Dipstick	NEG					

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	68	Hemoglobin	15		.	.	13.8 - 17.2	G/DL
				Hematocrit	44		.	.	41 - 50	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1		.	.	30 - 70	%
				Lymphocytes	33.9		.	.	21 - 51	%
				Monocytes	8.4		.	.	0 - 10	%
				Eosinophils	3.9		.	.	0 - 5	%
				Basophils	0.7		.	.	0 - 2	%
				Platelets	281000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	93		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	80		.	.	22 - 180	U/L
				Aspartate Aminotransferase	15		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	68	Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	06JUN96	1	14JUN96	9	9
00286	Oral	2	100 MG	15JUN96	10	21JUN96	16	7
00286	Oral	3	150 MG	22JUN96	17	28JUN96	23	7
00286	Oral	4	200 MG	29JUN96	24	08JUL96	33	10
00286	Oral	5	250 MG	09JUL96	34	17JUL96	42	9
00286	Oral	5	250 MG	18JUL96	43	24JUL96	49	7
00286	Oral	6	300 MG	25JUL96	50	02AUG96	58	9
00286	Oral	6	300 MG	03AUG96	59	12AUG96	68	10
00154	Oral	6	300 MG	13AUG96	69	17SEP96	104	36
00154	Oral	6	300 MG	18SEP96	105	24OCT96	141	37
00154	Oral	6	300 MG	25OCT96	142	24NOV96	172	31
00154	Oral	6	300 MG	25NOV96	173	30DEC96	208	36
00154	Oral	6	300 MG	31DEC96	209	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	209	300	Lost to follow-up	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-2348,-2416	01JAN90	.	1000MG	HEADACHE
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	-2348,-2416	01JAN90	.	2PILLS	SINUSITIS
	Salbutamol	Proventil	-2348,-2416	01JAN90	.	2PUFFS	ASTHMA
			-2348,-2416	01JAN90	.	2PUFFS	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15MAY96	-22, -90	0	118	80	80	110	80	80	166.20	61.5
BL	05JUN96	-1, -69	0	112	80	72	110	70	76	166.20	
1	14JUN96	9, -60	50	110	80	65	100	70	65	164.00	
2	21JUN96	16, -53	100	100	80	96	114	82	96	165.50	
3	28JUN96	23, -46	150	106	82	92	110	80	90	164.00	
5	08JUL96	33, -36	200	120	78	90	120	80	96	167.00	
6	17JUL96	42, -27	250	118	80	88	120	80	92	164.20	
7	24JUL96	49, -20	250	120	80	86	120	76	84	163.20	
8	02AUG96	58, -11	300	116	80	84	120	80	88	160.00	
8	09AUG96	65, -4	300	110	70	80	112	74	84	160.00	
16	17SEP96	104, 36	300	110	70	88	110	72	84	160.50	
20	24OCT96	141, 73	300	104	70	84	106	72	88	156.70	
24	25NOV96	173, 105	300	110	70	86	110	74	90	153.70 L	
28	30DEC96	208, 140	300	110	80	80	110	80	84	151.20 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	8.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	RESULT INVAL	U	.	U	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	69	Hemoglobin	15.2		.	.	12 - 15.6	G/DL
				Hematocrit	43.7		.	.	35 - 46	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3		.	.	30 - 70	%
				Lymphocytes	19.9	L	.	.	21 - 51	%
				Monocytes	10.9	H	.	.	0 - 10	%
				Eosinophils	0.8		.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	262000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7		.	.	25 - 35	PG
				Mean Corpuscle Volume	85		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49		.	.	44 - 280	U/L
				Aspartate Aminotransferase	16		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	69	Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	173	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.2	.	.	.	30 - 70	%
				Lymphocytes	23.2	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	173	Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03JUL96	1	09JUL96	7	7
00287	Oral	2	0 MG	10JUL96	8	17JUL96	15	8
00287	Oral	3	0 MG	18JUL96	16	23JUL96	21	6
00287	Oral	4	0 MG	24JUL96	22	30JUL96	28	7
00287	Oral	5	0 MG	31JUL96	29	06AUG96	35	7
00287	Oral	6	0 MG	07AUG96	36	13AUG96	42	7
00287	Oral	6	0 MG	14AUG96	43	20AUG96	49	7
00287	Oral	6	0 MG	21AUG96	50	27AUG96	56	7
	Oral	5	0 MG	28AUG96	57	10SEP96	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	70	0		DID NOT WANT TO CONTINUE

* Relative to Start of Study Medication

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25JUN96	-8, .	0	104	70	60	104	72	64	121.70	61.0
BL	02JUL96	-1, .	0	106	70	64	106	74	66	121.70	
1	09JUL96	7, .	0	110	70	70	110	74	72	124.00	
2	17JUL96	15, .	0	110	70	76	110	70	80	120.50	
3	23JUL96	21, .	0	110	70	80	112	70	84	119.20	
4	30JUL96	28, .	0	110	70	80	112	70	84	120.00	
5	06AUG96	35, .	0	110	70	80	112	72	84	120.00	
6	13AUG96	42, .	0	110	70	80	110	70	84	121.50	
7	20AUG96	49, .	0	106	70	80	110	78	84	119.00	
8	27AUG96	56, .	0	110	70	80	108	72	84	120.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.2	.	.	.	30 - 70	%
				Lymphocytes	26.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	4	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.1	. . .	12 - 15.6	G/DL
				Hematocrit	37.7	. . .	35 - 46	%
				Red Blood Cell Count	4.3	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.5	. . .	30 - 70	%
				Lymphocytes	26.5	. . .	21 - 51	%
				Monocytes	4.1	. . .	0 - 10	%
				Eosinophils	2.6	. . .	0 - 5	%
				Basophils	1.3	. . .	0 - 2	%
				Platelets	218000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	. . .	25 - 35	PG
				Mean Corpuscle Volume	87	. . .	80 - 100	FL
				Blood Urea Nitrogen	14	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.5	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	. . .	44 - 280	U/L
				Aspartate Aminotransferase	10	. . .	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	25JUL96	1	31JUL96	7	7
00288	Oral	2	20 MG	01AUG96	8	08AUG96	15	8
00288	Oral	3	20 MG	09AUG96	16	18AUG96	25	10
00288	Oral	4	20 MG	19AUG96	26	29AUG96	36	11
00288	Oral	4	20 MG	30AUG96	37	05SEP96	43	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	43	20	Lack of Efficacy	PATIENT NO LONGER WANTS TO PARTICIPATE IN STUDY.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1987
PROTEINURIA	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Carbinoxamine Maleate	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH
	Dextromethorphan Hydrobromide	Robitussin-Dm	8, .	01AUG96	.		COUGH
	Ethanol	Robitussin-Dm	8, .	01AUG96	.		COUGH
	Guaifenesin	Robitussin-Dm	8, .	01AUG96	.		COUGH
	Phenylephrine Hydrochloride	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH
	Phenylpropanolamine Hydrochloride	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH
	Phenyltoloxamine Citrate	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory System	Cough Increased	COUGH	2, .	Not Stated	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	01JUL96	-24, .	0	110	70	84	106	70	88	105.50	65.2
BL	18JUL96	-7, .	0	110	68	88	110	70	96	105.50	
1	01AUG96	8, .	20	110	56	70	106	60	76	103.20	
2	09AUG96	16, .	20	110	60	80	100	60	80	103.00	
4	19AUG96	26, .	20	104	70	80	100	70	90	104.20	
5	29AUG96	36, .	20	100	70	80	104	70	80	103.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-7	Hemoglobin	13.9		.	.	13.8 - 17.2	G/DL
				Hematocrit	42.2		.	.	41 - 50	%
				Red Blood Cell Count	4.9		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.7	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.1		.	.	30 - 70	%
				Lymphocytes	37.4		.	.	21 - 51	%
				Monocytes	6.9		.	.	0 - 10	%
				Eosinophils	0.6		.	.	0 - 5	%
				Basophils	1.1		.	.	0 - 2	%
				Platelets	240000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	87		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	230		.	.	44 - 400	U/L
				Aspartate Aminotransferase	18		.	.	0 - 41	U/L
				Alanine Aminotransferase	11		.	.	0 - 48	U/L
				Total Bilirubin	0.9		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	67	L	.	.	70 - 115	MG/DL
				Globulin	3.6		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	2		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	24OCT95	1	30OCT95	7	7
00025	Oral	2	20 MG	31OCT95	8	06NOV95	14	7
00025	Oral	3	20 MG	07NOV95	15	13NOV95	21	7
00025	Oral	4	20 MG	14NOV95	22	20NOV95	28	7
00025	Oral	4	20 MG	21NOV95	29	27NOV95	35	7
00025	Oral	5	30 MG	28NOV95	36	04DEC95	42	7
00025	Oral	6	40 MG	05DEC95	43	11DEC95	49	7
00025	Oral	6	40 MG	12DEC95	50	19DEC95	57	8
	Oral	5	30 MG	20DEC95	58	04JAN96	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	73	30	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES(SKIN)	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Cetirizine Hydrochloride	Reactine	-115, .	01JUL95	.	10MG	SKIN ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	DISCOMFORT ACROSS ALL OF ABDOMEN	14, .	02:00 Hrs	20	1	MOD	NO	PBU	No	No
	Asthenia	FATIGUE	24, .	Not Stated	20	CON	MOD	NO	REL	No	No
Digestive System	Nausea	NAUSEA	14, .	02:00 Hrs	20	1	MOD	NO	PBU	No	No
Nervous System	Insomnia	INITIAL AND MIDDLE INSOMNIA	1, .	Not Stated	20	CON	MOD	NO	PSR	No	No
	Somnolence	DROWSINESS	24, .	20 Days	20	CON	MOD	NO	REL	No	No
	Tremor	SHAKINESS OF WHOLE BODY	1, .	02:00 Hrs	20	CON	MIL	NO	PSR	No	No
Urogenital System	Urinary Tract Infection	[URINARY INFECTION QUESTIONABLE]	57, .	9 Days	40	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	17OCT95	-7,	.	0	114	80	82	118	80	92	114.66	65.0
BL	24OCT95	1,	.	0	110	74	72	114	80	76	114.66	
1	31OCT95	8,	.	20	110	70	94	110	74	100	114.88	
2	07NOV95	15,	.	20	108	90	72	110	92	80	115.10	
3	14NOV95	22,	.	20	100	70	76	90	68	76	114.66	
4	21NOV95	29,	.	20	100	76	70	96	64	74	114.88	
5	28NOV95	36,	.	30	90	60	96	100	70	96	113.56	
6	05DEC95	43,	.	40	98	78	92	102	80	100	113.56	
7	12DEC95	50,	.	40	113	69	74	113	60	85	114.44	
8	19DEC95	57,	.	40	100	62	80	110	70	100	113.34	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	34.7	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	287000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7		.	.	12 - 15.6	G/DL
				Hematocrit	37.2		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3		.	.	30 - 70	%
				Lymphocytes	40.3		.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	4		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	279000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 10/UNSCHEDULED LAB 1	65	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00026 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28NOV95	1	04DEC95	7	7
00026	Oral	2	100 MG	05DEC95	8	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	8	100	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00026 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	09NOV95	-19, .	0	110	70	68	100	72	80	159.20	63.8
BL	28NOV95	1, .	0	110	78	56	90	62	80	161.63	
1	05DEC95	8, .	100	100	66	80	104	80	84	163.17	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00026 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-19	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.3	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	203000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	256	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00026 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-19	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	06DEC95	1	11DEC95	6	6
00027	Oral	2	0 MG	12DEC95	7	18DEC95	13	7
00027	Oral	3	0 MG	19DEC95	14	26DEC95	21	8
00027	Oral	4	0 MG	27DEC95	22	02JAN96	28	7
	Oral	3	0 MG	03JAN96	29	11JAN96	37	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	37	0	Other reason	EARLY WITHDRAWAL-WK 4VISIT PATIENT CHOSE TO WITHDRAW FROM STUDY BECAUSE HE WANTS TO BE TREATED BY PRIMARY THERAPIST AND WANTS TO BE ABLE TO TAKE OTHER MEDICATIONS LIKE LORAZEPAM.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1985
OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
TENSION HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	-8, .	28NOV95	08DEC95	1000MG	OTITIS MEDIA
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Entrophen	19, .	24DEC95	.	2TABS BID	"NECK SPASM"
	Lorazepam	Lorazepam	16, .	21DEC95	26DEC95	0.5MGX1DAY	ANXIETY
	Paracetamol	Tylenol	-1069, .	01JAN93	.	975MG PRN	HEADACHE
			-15, .	21NOV95	07DEC95	975MG PRN	OTITIS MEDIA
DERMATOLOGICALS	Erythromycin	Erythromycin	-8, .	28NOV95	08DEC95	1000MG	OTITIS MEDIA
MUSCULO-SKELETAL	Naproxen Sodium	Anaprox	-25, .	11NOV95	17NOV95#	550MG PRN	HEADACHES
RESPIRATORY	Beclometasone Dipropionate	Becloforte	-127, .	01AUG95	20NOV95#	4MCG/PRN	ASTHMA
			-127, .	01AUG95	20NOV95#	4MCG/PRN	ASTHMA
	Cromoglicate Sodium	Intal	-96, .	01SEP95	.	40MG	ASTHMA
			-96, .	01SEP95	.	40MG	ASTHMA
	Paracetamol	Neo-Citran	10, .	15DEC95	17DEC95	1TAB	COLD
	Pheniramine Maleate	Neo-Citran	10, .	15DEC95	17DEC95	1TAB	COLD
	Phenylephrine Hydrochloride	Neo-Citran	10, .	15DEC95	17DEC95	1TAB	COLD
	Pseudoephedrine Hydrochloride	Sudafed	10, .	15DEC95	17DEC95	1TAB	COLD
	Salbutamol	Ventolin	-461, .	01SEP94	17NOV95#	200MCG/PRN	ASTHMA
			-461, .	01SEP94	17NOV95#	200MCG/PRN	ASTHMA
			10, .	15DEC95	.	200MCG/PRN	ASTHMA
			10, .	15DEC95	.	200MCG/PRN	ASTHMA
SENSORY ORGANS	Betamethasone Sodium Phosphate	Garasone	-9, .	27NOV95	08DEC95	4GTTS 4XDAY	OTITIS MEDIA
	Cromoglicate Sodium	Intal	-96, .	01SEP95	.	40MG	ASTHMA
	Erythromycin	Erythromycin	-8, .	28NOV95	08DEC95	1000MG	OTITIS MEDIA
	Gentamicin Sulfate	Garasone	-9, .	27NOV95	08DEC95	4GTTS 4XDAY	OTITIS MEDIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	NECK SPASM	16, .	Not Stated	0	CON	MOD	NO	PBU	Yes	No
Nervous System	Anxiety	ANXIETY	16, .	Not Stated	0	CON	MOD	NO	PBU	Yes	No
Respiratory System	Respiratory Disorder	COMMON COLD	10, .	13 Days	0	CON	SEV	NO	UNR	Yes	No
Special Senses	Otitis Media	OTITIS MEDIA(EAR INFECTION)	-10, .	12 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	23NOV95	-13,	.	0	110	64	68	104	72	80	154.13	71.7
BL	06DEC95	1,	.	0	110	76	88	120	78	92	158.76	
1	12DEC95	7,	.	0	126	72	96	120	86	70	158.32	
2	19DEC95	14,	.	0	110	70	60	110	80	62	156.33	
3	27DEC95	22,	.	0	100	62	72	110	70	100	159.64	
4	02JAN96	28,	.	0	122	66	60	110	52	64	159.64	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35	.	.	.	30 - 70	%
				Lymphocytes	48.3	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.2		.	.	13.8 - 17.2	G/DL
				Hematocrit	42.6		.	.	41 - 50	%
				Red Blood Cell Count	4.8		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.1		.	.	30 - 70	%
				Lymphocytes	42.2		.	.	21 - 51	%
				Monocytes	6.9		.	.	0 - 10	%
				Eosinophils	9.3	H	.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	314000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	20		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111		.	.	22 - 180	U/L
				Aspartate Aminotransferase	11		.	.	0 - 41	U/L
				Alanine Aminotransferase	8		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	1	Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	92		.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	13.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	39.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	14	L	.	-	30 - 70	%
				Lymphocytes	67	H	.	.	21 - 51	%
				Monocytes	14	H	.	.	0 - 10	%
				Eosinophils	4		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	260000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	17		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	116		.	.	22 - 180	U/L
				Aspartate Aminotransferase	11		.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 6/ACUTE PHASE-WEEK 4	28	Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21MAY96	1	30MAY96	10	10
00217	Oral	2	0 MG	31MAY96	11	06JUN96	17	7
00217	Oral	3	0 MG	07JUN96	18	13JUN96	24	7
00217	Oral	4	0 MG	14JUN96	25	14JUN96	25	1

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	25	0	Adverse event, including intercurrent illness	ABIVALENCE ABOUT MEDICATION,VIRAL ILLNESS,MEDICATION ON IP'S ADVICE,HOSPITALIZATION TO PSYCHIATRY,AND WANTING TO KNOW WHICH MED SHE WAS ON.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1995
INJURY TO LEFT KNEE{PARAGLIDING}	TRAUMA/INJURIES, UNSPEC	INJURY/POISONING	PRV	1993
LIGAMENT TEARS{LEFT FOOT,ANKLE}	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995
MONONUCLEOSIS{(2 EPISODES IN ONE YEAR)}	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	29, .	18JUN96	19JUN96	PRN	FLU
CENTRAL NERVOUS SYSTEM	Paracetamol	Sinutab	16, .	05JUN96	05JUN96	1DOSE	COLD
		Tylenol	-81, .	01MAR96	.	PRN 500MG	HEADACHE
	Phenacetin	Sinutab	16, .	05JUN96	05JUN96	1DOSE	COLD
	Phenylpropanolamine Hydrochloride	Sinutab	16, .	05JUN96	05JUN96	1DOSE	COLD
	Phenyltoloxamine Citrate	Sinutab	16, .	05JUN96	05JUN96	1DOSE	COLD
	Sertraline Hydrochloride	Zoloft	30, .	19JUN96	.	100 MG	DEPRESSION
DERMATOLOGICALS	Budesonide	Pulmicort	29, .	18JUN96	19JUN96	400 MG	ASTHMA
RESPIRATORY	Budesonide	Pulmicort	29, .	18JUN96	19JUN96	400 MG	ASTHMA
			29, .	18JUN96	19JUN96	400 MG	ASTHMA
	Guaifenesin	Robitussin	21, .	10JUN96	12JUN96	2TBSP/DAY	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU	24, .	7 Days	0	CON	MOD	STP	UNR	Yes	No
Nervous System	Depression	DEPRESSION (WORSENING)	30, .	8 Days	0	CON	SEV	NO	UNR	Yes	Yes
Respiratory System	Asthma	RECURRENT ASTHMA	26, .	5 Days	0	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	COMMON COLD	14, .	10 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14MAY96	-7, .	0	92	70	76	100	70	80	110.03	61.4
BL	21MAY96	1, .	0	100	66	60	96	64	84	108.93	
1	31MAY96	11, .	0	110	70	80	108	74	70	110.69	
2	07JUN96	18, .	0	110	70	74	100	76	80	111.35	
3	14JUN96	25, .	0	120	80	70	110	80	76	110.03	
4	19JUN96	30, .	0	100	60	64	100	70	72	108.49	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4	.	.	.	30 - 70	%
				Lymphocytes	22.7	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	4		.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	30	(5)	Hemoglobin	13.1		.	.	12 - 15.6	G/DL
					Hematocrit	38.5		.	.	35 - 46	%
					Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	58.6		.	.	30 - 70	%
					Lymphocytes	26.2		.	.	21 - 51	%
					Monocytes	12.1	H	.	.	0 - 10	%
					Eosinophils	2.8		.	.	0 - 5	%
					Basophils	0.4		.	.	0 - 2	%
					Platelets	233000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31		.	.	25 - 35	PG
					Mean Corpuscle Volume	91		.	.	80 - 100	FL
					Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
					Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
					Uric Acid	2.6		.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	65		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 6/ACUTE PHASE-WEEK 4	30	(5)	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
					Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	98	.	.	.	70 - 115	MG/DL
					Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16JUN96	1	20JUN96	5	5
00218	Oral	2	0 MG	21JUN96	6	27JUN96	12	7
00218	Oral	3	0 MG	28JUN96	13	04JUL96	19	7
00218	Oral	4	0 MG	05JUL96	20	11JUL96	26	7
00218	Oral	4	0 MG	12JUL96	27	18JUL96	33	7
00218	Oral	4	0 MG	19JUL96	34	28JUL96	43	10
00218	Oral	4	0 MG	29JUL96	44	05AUG96	51	8
00218	Oral	4	0 MG	06AUG96	52	12AUG96	58	7
00117	Oral	4	0 MG	13AUG96	59	17SEP96	94	36
00218	Oral	4	0 MG	18SEP96	95	19SEP96	96	2
00218	Oral	3	0 MG	20SEP96	97	21SEP96	98	2
00218	Oral	2	0 MG	22SEP96	99	24SEP96	101	3
00218	Oral	1	0 MG	25SEP96	102	01OCT96	108	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	108	0	Other reason	WISHED TO DISCONTINUE STUDY MEDICATION, FEELS SHE CAN DO WELL WITHOUT "PILLS".

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANXIETY	ANXIETY	MENTAL DISORD	CUR	1996
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1986

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Clonazepam	Clonazepam	-34, -92	13MAY96	16MAY96#	1MG	ANXIETY
	Paracetamol	Tylenol	-8, -66	08JUN96	08JUN96#	500 MG	HEADACHE
			26, -33	11JUL96	11JUL96	500 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE (MODERATE)	-8, -66	02:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			26, -33	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	04JUN96	-12, -70	0	100	68	64	104	70	88	118.63	65.7
BL	14JUN96	-2, -60	0	110	80	80	100	60	100	118.41	
1	21JUN96	6, -53	0	120	80	80	100	70	88	119.95	
2	28JUN96	13, -46	0	118	70	80	112	76	92	122.38	
3	05JUL96	20, -39	0	110	70	76	118	74	80	121.05	
4	12JUL96	27, -32	0	100	70	72	100	72	80	119.29	
5	19JUL96	34, -25	0	110	70	72	120	80	72	119.73	
6	29JUL96	44, -15	0	122	80	76	116	72	82	119.95	
7	06AUG96	52, -7	0	112	70	80	110	70	76	121.05	
8	13AUG96	59, 1	0	110	80	72	110	70	76	121.72	
12	18SEP96	95, 37	0	110	70	72	110	80	80	124.36	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	377000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	99	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-2	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.5	.	.	.	30 - 70	%
				Lymphocytes	28.8	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	12.6	H	.	+	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Basophils	0.9	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	82	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	95	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/CONTINUATION-WEEK 12	95	Segmented Neutrophils	40	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	11	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	366000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	31MAY96	1	06JUN96	7	7
00219	Oral	2	100 MG	07JUN96	8	13JUN96	14	7
00219	Oral	3	150 MG	14JUN96	15	23JUN96	24	10
00219	Oral	4	200 MG	24JUN96	25	01JUL96	32	8
00219	Oral	4	200 MG	02JUL96	33	08JUL96	39	7
00219	Oral	4	200 MG	09JUL96	40	15JUL96	46	7
00219	Oral	4	200 MG	16JUL96	47	22JUL96	53	7
00219	Oral	4	200 MG	23JUL96	54	29JUL96	60	7
00106	Oral	4	200 MG	30JUL96	61	29AUG96	91	31
00106	Oral	4	200 MG	30AUG96	92	25SEP96	118	27
00106	Oral	4	200 MG	26SEP96	119	24OCT96	147	29
00106	Oral	4	200 MG	25OCT96	148	21NOV96	175	28
00106	Oral	4	200 MC	22NOV96	176	19DEC96	203	28
00106	Oral	4	200 MG	20DEC96	204	18JAN97	233	30

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	Yes	233	200		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1985

CUR = Current, PRV = Past

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24MAY96	-7, -67	0	100	70	64	110	70	72	167.36	78.7
BL	31MAY96	1, -60	0	110	80	72	120	90	64	166.92	
1	07JUN96	8, -53	100	110	70	80	100	80	100	165.38	
2	14JUN96	15, -46	150	120	80	68	110	80	60	163.39	
3	24JUN96	25, -36	200	110	70	74	112	76	80	165.38	
5	02JUL96	33, -28	200	104	70	60	102	80	68	167.36	
6	09JUL96	40, -21	200	112	70	60	120	78	68	168.46	
7	16JUL96	47, -14	200	120	80	84	110	80	74	169.12	
8	23JUL96	54, -7	200	110	80	110	100	86	90	168.24	
8	30JUL96	61, 1	200	112	76	74	120	70	84	168.02	
12	30AUG96	92, 32	200	130	78	80	132	80	82	165.82	
16	26SEP96	119, 59	200	118	76	100	120	80	90	170.23	
20	25OCT96	148, 88	200	118	80	86	110	86	80	169.34	
24	22NOV96	176, 116	200	122	80	80	120	70	74	168.24	
28	20DEC96	204, 144	200	110	72	82	112	80	76	168.24	
32	24JAN97	239, 179	200	126	82	64	120	80	72	170.89	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.3		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2		.	.	41 - 50	%
				Red Blood Cell Count	4.7		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7		.	.	30 - 70	%
				Lymphocytes	31.8		.	.	21 - 51	%
				Monocytes	7.9		.	.	0 - 10	%
				Eosinophils	3.1		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	173000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	92		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	176		.	.	44 - 400	U/L
				Aspartate Aminotransferase	22		.	.	0 - 41	U/L
				Alanine Aminotransferase	18		.	.	0 - 48	U/L
				Total Bilirubin	1.8	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7		.	.	6.2 - 8.8	G/DL
				Albumin	4.4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	105		.	.	70 - 115	MG/DL
				Globulin	2.3		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	10		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	181		.	.	44 - 400	U/L
				Aspartate Aminotransferase	20		.	.	0 - 41	U/L
				Alanine Aminotransferase	15		.	.	0 - 48	U/L
				Total Bilirubin	1.3		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1		.	.	6.2 - 8.8	G/DL
				Albumin	4.5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	96		.	.	70 - 115	MG/DL
				Globulin	2.6		.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	15.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	46.2		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.9	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1		.	.	30 - 70	%
				Lymphocytes	37.7		.	.	21 - 51	%
				Monocytes	8.3		.	.	0 - 10	%
				Eosinophils	3.5		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	166	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	92	Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.4	L	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	148	Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	172000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	187	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 14/CONTINUATION-WEEK 24	176	Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	239 (6)	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	34.9	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	163000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	172	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	17JUN96	1	21JUN96	5	5
00220	Oral	2	20 MG	22JUN96	6	27JUN96	11	6
00220	Oral	3	20 MG	28JUN96	12	04JUL96	18	7
00220	Oral	4	20 MG	05JUL96	19	11JUL96	25	7
00220	Oral	5	30 MG	12JUL96	26	18JUL96	32	7
00220	Oral	5	30 MG	19JUL96	33	28JUL96	42	10
00220	Oral	5	30 MG	29JUL96	43	05AUG96	50	8
00220	Oral	5	30 MG	06AUG96	51	15AUG96	60	10
00110	Oral	5	30 MG	16AUG96	61	12SEP96	88	28
00110	Oral	5	30 MG	13SEP96	89	10OCT96	116	28
00110	Oral	5	30 MG	11OCT96	117	07NOV96	144	28
00110	Oral	5	30 MG	08NOV96	145	21NOV96	158	14
00220	Oral	5	30 MG	22NOV96	159	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	159	30	Other reason	WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIC TO SUDAFED	ADVERSE EFF ON AUTONOMIC NS	EXT CAUSES OF INJURY/POISONING	CUR	1984
ATTENTION DEFICIT HYPERACTIVE DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1987
BED-WETTING	INCONTINENCE, URINARY	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1986
BLADDER INFECTIONS	CYSTITIS	GENITOURINARY SYST DIS	PRV	1986
OBSESSIVE COMPULSIVE SYMPTOMS	NEUROSES	MENTAL DISORD	PRV	1994
TOURETTES (TIC DISORDER).	TICS	MENTAL DISORD	PRV	1987

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS
CENTRAL NERVOUS SYSTEM	Methylphenidate Hydrochloride	Ritalin Sr	-148, -208	21JAN96	15MAY96#	20 MG	ADHD
DERMATOLOGICALS	Erythromycin	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS
SENSORY ORGANS	Erythromycin	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	89, 29	04:00 Hrs	30	1	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	9, -52	3 Days	20	CON	MOD	NO	REL	No	No
Respiratory System	Bronchitis	BRONCHITIS	102, 42	37 Days	30	CON	MOD	NO	PBU	Yes	No
Special Senses	Abnormal Vision	BLURRED VISION	9, -52	2 Days	20	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04JUN96	-13, -73	0	122	82	76	128	90	80	179.93	66.9
BL	14JUN96	-3, -63	0	110	80	60	110	70	68	179.49	
1	22JUN96	6, -55	20	112	76	60	110	80	68	182.13	
2	28JUN96	12, -49	20	120	80	68	124	84	64	183.24	
3	05JUL96	19, -42	20	114	80	60	116	78	68	184.34	
4	12JUL96	26, -35	30	110	74	68	120	70	84	186.32	
5	19JUL96	33, -28	30	112	70	70	118	72	72	186.54	
6	29JUL96	43, -18	30	118	78	82	114	74	80	186.54	
7	06AUG96	51, -10	30	126	90	64	128	88	80	186.32	
8	16AUG96	61, 1	30	120	80	80	130	90	86	185.22	
12	13SEP96	89, 29	30	120	70	68	120	80	80	182.79	
16	11OCT96	117, 57	30	120	82	84	122	84	100	180.37	
20	08NOV96	145, 85	30	120	80	68	120	72	70	183.02	
24	06DEC96	173, 113	0	120	80	76	120	70	82	184.12	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	15.5		.	.	13.8 - 17.2	G/DL
				Hematocrit	45.8		.	.	41 - 50	%
				Red Blood Cell Count	5.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8		.	.	30 - 70	%
				Lymphocytes	31.5		.	.	21 - 51	%
				Monocytes	8.2		.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.1		.	.	0 - 2	%
				Platelets	194000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	168		.	.	44 - 400	U/L
				Aspartate Aminotransferase	26		.	.	0 - 41	U/L
				Alanine Aminotransferase	30		.	.	0 - 48	U/L
				Total Bilirubin	0.6		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3		.	.	6.2 - 8.8	G/DL
				Albumin	4.2		.	.	3.1 - 5.3	G/DL
				Glucose - Random	112		.	.	70 - 115	MG/DL
				Globulin	3.1		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	36.3	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	159	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	134	H	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	89	Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	145	Hemoglobin	16.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39.4	.	.	.	30 - 70	%
				Lymphocytes	44.4	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	145		Monocytes	9.5	.	.	.	0 - 10	%
					Eosinophils	5.8	H	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	216000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.4	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	135	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	110	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEC		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	173	(15)	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 14/CONTINUATION-WEEK 24	173	(15)	Hematocrit	44.5		.	.	41 - 50	%
					Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.7		.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	40.1		.	.	30 - 70	%
					Lymphocytes	42.4		.	.	21 - 51	%
					Monocytes	6.7		.	.	0 - 10	%
					Eosinophils	9.1	H	.	.	0 - 5	%
					Basophils	1.8		.	.	0 - 2	%
					Platelets	202000		.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.5		.	.	25 - 35	PG
					Mean Corpuscle Volume	87		.	.	80 - 100	FL
					Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
					Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.5		.	.	4 - 8	MG/DL
					Alkaline Phosphatase	123		.	.	44 - 400	U/L
					Aspartate Aminotransferase	19		.	.	0 - 41	U/L
					Alanine Aminotransferase	23		.	.	0 - 48	U/L
					Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
					Total Protein	7.5		.	.	6.2 - 8.8	G/DL
					Albumin	4.5		.	.	3.1 - 5.3	G/DL
					Glucose - Random	99		.	.	70 - 115	MG/DL
					Globulin	3		.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	25JUN96	1	01JUL96	7	7
00221	Oral	2	100 MG	02JUL96	8	08JUL96	14	7
00221	Oral	3	150 MG	09JUL96	15	15JUL96	21	7
00221	Oral	4	200 MG	16JUL96	22	22JUL96	28	7
00221	Oral	5	250 MG	23JUL96	29	31JUL96	37	9
00221	Oral	4	200 MG	01AUG96	38	08AUG96	45	8
00221	Oral	4	200 MG	09AUG96	46	18AUG96	55	10
00221	Oral	4	200 MG	19AUG96	56	26AUG96	63	8
00112	Oral	4	200 MG	27AUG96	64	22SEP96	90	27
00112	Oral	4	200 MG	23SEP96	91	20OCT96	118	28
00112	Oral	4	200 MG	21OCT96	119	03NOV96	132	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	132	200	Adverse event, including intercurrent illness	MINOR OVERDOSE OF LORAZEPAM AND WITHDREW CONSENT TO STUDY. REFUSED DOWN-TITRATION

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {MODERATE}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1989

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Laxatives, Nos	Laxative (Unknown Name)	112, 49	14OCT96	01NOV96	1-2 TBSP EVERY 2ND DAY	CONSTIPATION
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	78, 15	10SEP96	10SEP96	1950 MG	HEADACHES
	Chloral Hydrate	Chloral Hydrate	56, -8	19AUG96	22SEP96	500 MG PRN	INSOMNIA
	Lorazepam	Lorazepam	132, 69	03NOV96	03NOV96	8 MG	OVERDOSE
	Paracetamol	Tylenol	-906, -969	01JAN94	.	500 MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES (SEVERE)	78, 15	06:00 Hrs	200	1	SEV	NO	PBU	Yes	No
Digestive System	Constipation	CONSTIPATION	112, 49	19 Days	200	CON	MOD	NO	UNR	Yes	No
	Dry Mouth	DRY MOUTH	67, 4	52 Days	200	CON	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	39, -25	8 Days	200	5	MOD	NO	PBU	No	No
	Emotional Lability	OVERDOSE {INTENTIONAL}	132, 69	19:30 Hrs	200	CON	SEV	STP	UNR	No	Yes
	Euphoria	MILD ELATION AND DISINHIBITION	30, -34	13 Days	250	CON	MIL	DCR	PSR	No	No
	Insomnia	INSOMNIA	52, -12	39 Days	200		MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JUN96	-7, -70	0	110	70	80	120	80	80	148.18	69.3
BL	25JUN96	1, -63	0	114	80	64	110	80	80	147.96	
1	02JUL96	8, -56	100	110	70	84	110	80	100	147.29	
2	09JUL96	15, -49	150	110	78	72	118	76	80	144.87	
3	16JUL96	22, -42	200	110	80	104	120	80	100	148.62	
4	23JUL96	29, -35	250	124	80	88	118	90	92	148.18	
5	30JUL96	36, -28	250	110	72	90	120	80	96	148.40	
6	09AUG96	46, -18	200	110	80	96	100	70	100	150.16	
8	19AUG96	56, -8	200	124	78	92	118	78	90	147.74	
8	27AUG96	64, 1	200	120	74	84	118	74	90	147.96	
12	23SEP96	91, 28	200	120	86	88	110	80	80	151.26	
16	21OCT96	119, 56	200	110	80	88	100	80	100	154.35	
20	04NOV96	133, 70	200	120	70	90	124	68	90	157.66	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	26.6	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	235000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	114	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	15.7		.	.	13.8 - 17.2	G/DL
				Hematocrit	46.2		.	.	41 - 50	%
				Red Blood Cell Count	5.1		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7		.	.	30 - 70	%
				Lymphocytes	27.9		.	.	21 - 51	%
				Monocytes	6.1		.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	270000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	90		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	84		.	.	22 - 180	U/L
				Aspartate Aminotransferase	9		.	.	0 - 41	U/L
				Alanine Aminotransferase	10		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	64	Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28JUN96	1	04JUL96	7	7
00222	Oral	2	20 MG	05JUL96	8	11JUL96	14	7
00222	Oral	3	20 MG	12JUL96	15	18JUL96	21	7
00222	Oral	4	20 MG	19JUL96	22	28JUL96	31	10
00222	Oral	4	20 MG	29JUL96	32	05AUG96	39	8
00222	Oral	5	30 MG	06AUG96	40	12AUG96	46	7
00222	Oral	5	30 MG	13AUG96	47	19AUG96	53	7
00222	Oral	5	30 MG	20AUG96	54	29AUG96	63	10
00113	Oral	5	30 MG	30AUG96	64	21SEP96	86	23

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	86	30	Other reason	NON-COMPLIANCE WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HAYFEVER-LATE SPRING,SUMMER MONTHS ONLY	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	21, -43	18JUL96	22JUL96	1500 MG	BLADDER INFECTION
ANTINEOPLASTIC & IMMUNOSUP	Diethylstilbestrol Dipropionate	Cyclen	-119, -182	01MAR96	.	1TAB	CONTRACEPTION
DERMATOLOGICALS	Budesonide	Rhinocort	-36, -99	23MAY96	.	PRN 2SPRAYS OD	HAY FEVER
GU SYSTEM/SEX HORMONES	Diethylstilbestrol Dipropionate	Cyclen	-119, -182	01MAR96	.	1TAB	CONTRACEPTION
RESPIRATORY	Budesonide	Rhinocort	-36, -99	23MAY96	.	PRN 2SPRAYS OD	HAY FEVER
			-36, -99	23MAY96	.	PRN 2SPRAYS OD	HAY FEVER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urogenital System	Cystitis	BLADDER INFECTION	21, -43	4 Days	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JUN96	-10, -73	0	100	66	60	100	70	80	119.51	66.1
BL	28JUN96	1, -63	0	110	70	80	112	76	72	121.05	
1	05JUL96	8, -56	20	100	68	62	112	70	70	119.95	
2	12JUL96	15, -49	20	110	70	72	110	62	68	119.07	
3	19JUL96	22, -42	20	110	62	68	110	70	72	119.29	
4	29JUL96	32, -32	20	114	70	64	110	68	62	119.51	
6	06AUG96	40, -24	30	110	70	68	110	74	60	118.63	
7	13AUG96	47, -17	30	108	76	82	100	80	80	119.51	
8	20AUG96	54, -10	30	100	70	70	110	70	76	119.95	
8	30AUG96	64, 1	30	130	78	68	122	74	70	119.51	
12	27SEP96	92, 29	30	110	80	80	116	76	70	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.2		.	.	12 - 15.6	G/DL
				Hematocrit	39.6		.	.	35 - 46	%
				Red Blood Cell Count	4.5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6		.	.	30 - 70	%
				Lymphocytes	27.1		.	.	21 - 51	%
				Monocytes	6.5		.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.6		.	.	0 - 2	%
				Platelets	296000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	7		.	.	7 - 25	MG/DL
				Creatinine	1.5		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63		.	.	44 - 280	U/L
				Aspartate Aminotransferase	13		.	.	0 - 41	U/L
				Alanine Aminotransferase	8		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5		.	.	6.2 - 8.8	G/DL
				Albumin	4		.	.	3.1 - 5.3	G/DL
				Glucose - Random	87		.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6		.	.		
				Urine Red Blood Cells/HPF	5		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	72	H	.	.	30 - 70	%
				Lymphocytes	21		.	.	21 - 51	%
				Monocytes	5		.	.	0 - 10	%
				Eosinophils	2		.	.	0 - 5	%
				Basophils	0		.	.	0 - 2	%
				Blood Urea Nitrogen	9		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	70	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
		VISIT 10/UNSCHEDULED LAB 1	76	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/UNSCHEDULED LAB 1	76		Platelets	274000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	92	(6)	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.2	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54.6	.	.	.	30 - 70	%
					Lymphocytes	34.6	.	.	.	21 - 51	%
					Monocytes	5.2	.	.	.	0 - 10	%
					Eosinophils	4.4	.	.	.	0 - 5	%
					Basophils	1.1	.	.	.	0 - 2	%
					Platelets	365000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	92	(6)	Alkaline Phosphatase	64	. . .	44 - 280	U/L
					Aspartate Aminotransferase	17	. . .	0 - 41	U/L
					Alanine Aminotransferase	7	. . .	0 - 48	U/L
					Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.7	. . .	6.2 - 8.8	G/DL
					Albumin	4	. . .	3.1 - 5.3	G/DL
					Glucose - Random	83	. . .	70 - 115	MG/DL
					Globulin	3.7	. . .	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	. . .		
					Urine Blood - Dipstick	NEG	. . .		
					Urine Red Blood Cells/HPF	NEG	. . .		
					Urine White Blood Cells/HPF	NEG	. . .		
					Urine Protein - Dipstick	NEG	. . .		
					Serum BHCG pregnancy test	NEGATIVE	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	30AUG96	1	05SEP96	7	7
00223	Oral	2	100 MG	06SEP96	8	15SEP96	17	10
00223	Oral	3	150 MG	16SEP96	18	22SEP96	24	7
00223	Oral	4	200 MG	23SEP96	25	30SEP96	32	8
	Oral	3	150 MG	01OCT96	33	12OCT96	44	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	44	150	Lack of Efficacy	PT WISHED TO WITHDRAW FROM THE STUDY TO BE TREATED OPENLY.

* Relative to Start of Study Medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1996
BENIGN LUMP LEFT FOOT	SWELLING, MASS, LOCALIZED	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
BRONCHOSPASM	RESP DIS, OTHER	RESPIRATORY SYST DIS	CUR	1996
HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
FATTY INFILTRATION OF THE LIVER {CLINICALLY NORMAL}	LIVER DISORD	DIGESTIVE SYST	PRV	1996
HISTORY OF HIGH AVERAGE/BORDERLINE HIGH BLOOD PRESSURE	BLOOD PRESSURE, ELEVATED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1995
PYELONEPHRITIS	KIDNEY INFECT	GENITOURINARY SYST DIS	PRV	1995
RADIAL FRACTURE	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
URINARY TRACT INFECTION'S {FREQUENT}	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	PRV	1984

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-972, .	01JAN94	.	500 MG PRN	HEADACHE
DERMATOLOGICALS	Fluticasone Propionate	Flonase	-107, .	15MAY96	.	1 PUFF PRN	BRONCHOSPASM
RESPIRATORY	Cromoglicate Sodium	Sodium (Cromoglycate)	-107, .	15MAY96	.	2 DROPS PRN	ALLERGIC REACTION
			-107, .	15MAY96	.	2 DROPS PRN	ALLERGIC REACTION
	Fluticasone Propionate	Flonase	-107, .	15MAY96	.	1 PUFF PRN	BRONCHOSPASM
SENSORY ORGANS	Cromoglicate Sodium	Sodium (Cromoglycate)	-107, .	15MAY96	.	2 DROPS PRN	ALLERGIC REACTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Hypertension	HYPERTENSION	32, .	Not Stated	200	CON	MOD	NO	UNR	No	Yes
Nervous System	Depression	MAJOR DEPRESSION	31, .	Not Stated	200	CON	MOD	NO	UNR	No	Yes
	Emotional Lability	SELF MUTILATION	31, .	Not Stated	200	CON	MOD	NO	UNR	No	Yes
		SUICIDAL IDEATION	26, .	10 Days	200	1	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	23AUG96	-7,	.	0	104	70	72	110	70	80	194.04	61.8
BL	30AUG96	1,	.	0	132	86	88	136	88	90	196.25	
1	06SEP96	8,	.	100	136	100	100	130	90	92	196.47	
2	16SEP96	18,	.	150	130	90	108	128	90	100	195.36	
3	23SEP96	25,	.	200	132	84	96	138	86	92	195.14	
5	01OCT96	33,	.	150	140	98	90	140	104	100	195.14	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.1	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	359000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	154	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	44	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	67	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16SEP96	1	23SEP96	8	8
00224	Oral	2	0 MG	24SEP96	9	02OCT96	17	9
00224	Oral	3	0 MG	03OCT96	18	09OCT96	24	7
00224	Oral	4	0 MG	10OCT96	25	16OCT96	31	7
00224	Oral	4	0 MG	17OCT96	32	24OCT96	39	8
00224	Oral	4	0 MG	25OCT96	40	03NOV96	49	10
00224	Oral	4	0 MG	04NOV96	50	11NOV96	57	8
00224	Oral	4	0 MG	12NOV96	58	20NOV96	66	9
00126	Oral	4	0 MG	21NOV96	67	18DEC96	94	28
00126	Oral	4	0 MG	19DEC96	95	19JAN97	126	32
00126	Oral	4	0 MG	20JAN97	127	17FEB97	155	29
00224	Oral	3	0 MG	18FEB97	156	19FEB97	157	2
00224	Oral	2	0 MG	20FEB97	158	22FEB97	160	3
00224	Oral	1	0 MG	23FEB97	161	01MAR97	167	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	167	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	87, 21	11DEC96	18DEC96	750 MG	STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	16, -51	01OCT96	01OCT96	325 MG PRN	TOOTHACHE (ORTHODONTIST APPT)
			25, -42	10OCT96	.	650 MG PRN	MENSTRUAL CRAMPS
RESPIRATORY	Dimenhydrinate	Gravol	108, 42	01JAN97	01JAN97	1 1/2 TAB	DIFFICULTY FALLING ASLEEP

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT	84, 18	11 Days	0	CON	MIL	NO	UNR	Yes	No
Digestive System	Tooth Disorder	TOOTHACHE	16, -51	1 Days	0	CON	MIL	NO	UNR	Yes	No
Musculoskeletal System	Arthralgia	LEFT KNEE PAIN	18, -49	18:00 Hrs	0	CON	MIL	NO	UNR	No	No
Nervous System	Insomnia	DIFFICULTY FALLING TO SLEEP	108, 42	1 Days	0	1	MIL	NO	PBU	Yes	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS	7, -60	11 Days	0	CON	MIL	NO	UNR	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	24, -43	Not Stated	0		MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	30AUG96	-17, -83	0	110	80	70	118	76	74	114.66	63.8
BL	16SEP96	1, -66	0	130	84	86	126	80	82	113.78	
1	24SEP96	9, -58	0	100	70	72	100	70	100	113.56	
2	03OCT96	18, -49	0	120	72	80	108	60	90	114.88	
3	10OCT96	25, -42	0	108	64	68	100	60	84	115.32	
4	17OCT96	32, -35	0	112	68	74	110	70	86	116.42	
6	25OCT96	40, -27	0	100	80	80	100	70	82	117.31	
7	04NOV96	50, -17	0	110	60	72	112	80	72	115.98	
8	12NOV96	58, -9	0	100	70	68	100	70	88	116.42	
8	20NOV96	66, -1	0	117	78	80	120	76	100	116.42	
12	19DEC96	95, 29	0	120	80	80	116	78	84	115.10	
16	20JAN97	127, 61	0	110	70	88	120	70	92	119.07	
24	18FEB97	156, 90	0	108	70	78	100	70	86	119.95	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-19	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	14	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	370000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	248	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/SCREENING (WEEK -1)	-17	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-17	Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-10	Hemoglobin	12.1		.	.	12 - 15.6	G/DL
				Hematocrit	35.5		.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.9		.	.	30 - 70	%
				Lymphocytes	22		.	.	21 - 51	%
				Monocytes	5.1		.	.	0 - 10	%
				Eosinophils	9.2	H	.	.	0 - 5	%
				Basophils	0.8		.	.	0 - 2	%
				Platelets	309000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	92		.	.	80 - 100	FL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEC		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	32	Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	27.2	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	12.9	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	367000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	205	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 13/CONTINUATION-WEEK 20	156	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	15	L	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	12	H	.	+	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	167	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	156	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	26NOV96	1	02DEC96	7	7
00225	Oral	2	0 MG	03DEC96	8	09DEC96	14	7
00225	Oral	3	0 MG	10DEC96	15	19DEC96	24	10
00225	Oral	4	0 MG	20DEC96	25	26DEC96	31	7
00225	Oral	4	0 MG	27DEC96	32	05JAN97	41	10
00225	Oral	4	0 MG	06JAN97	42	12JAN97	48	7
00225	Oral	4	0 MG	13JAN97	49	20JAN97	56	8
00225	Oral	4	0 MG	21JAN97	57	28JAN97	64	8
00129	Oral	4	0 MG	29JAN97	65	23FEB97	90	26
00129	Oral	4	0 MG	24FEB97	91	19MAR97	114	24
00129	Oral	4	0 MG	20MAR97	115	20APR97	146	32
00129	Oral	4	0 MG	21APR97	147	25MAY97	181	35
00129	Oral	4	0 MC	26MAY97	182	29JUN97	216	35
00129	Oral	4	0 MG	30JUN97	217	29JUL97	246	30
00225	Oral	3	0 MG	30JUL97	247	31JUL97	248	2
00225	Oral	2	0 MG	01AUG97	249	03AUG97	251	3
00225	Oral	1	0 MG	04AUG97	252	10AUG97	258	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	Yes	258	0		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin Ethylsuccinate	Pediazole	124, 60	29MAR97	07APR97	40 CC	EAR INFECTION
			124, 60	29MAR97	07APR97	40 CC	EAR INFECTION
	Sulfafurazole Acetyl	Pediazole	124, 60	29MAR97	07APR97	40 CC	EAR INFECTION
			124, 60	29MAR97	07APR97	40 CC	EAR INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	237, 173	20JUL97	23JUL97	300 MG	PREVENT PAIN FROM SPRAINED WRIST
RESPIRATORY	Prednisone	Prednisone	130, 66	04APR97	09APR97	50 MG	BRONCHOSPASM
	Salbutamol	Ventolin	130, 66	04APR97	04APR97	5 MG	BRONCHOSPASM
			130, 66	04APR97	04APR97	5 MG	BRONCHOSPASM
	Terbutaline Sulfate	Bricanyl Inhaler	130, 66	04APR97	08APR97	1 MG Q4H PRN	BRONCHOSPASM
SYSTEMIC HORMONAL	Prednisone	Prednisone	130, 66	04APR97	09APR97	50 MG	BRONCHOSPASM

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Trauma	SPRAINED WRIST LEFT	232, 168	Not Stated	0	CON	MIL	NO	UNR	Yes	No
Hemic and Lymphatic System	Lymphadenopathy	SLIGHTLY ENLARGED NON-TENDER LEFT JUGULO-DIGASTRIC NODE	130, 66	59 Days	0	1	MIL	NO	UNR	No	No
Nervous System	Hypesthesia	NUMB LEFT UPPER LEG	115, 51	1 Days	0	1	MIL	NO	PBU	No	No
Respiratory System	Asthma	BRONCHOSPASM	124, 60	11 Days	0	CON	MOD	NO	UNR	Yes	No
Special Senses	Otitis Media	EAR INFECTION LEFT	124, 60	11 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19NOV96	-7, -71	0	130	78	74	124	76	72	133.40	68.1
BL	26NOV96	1, -64	0	126	60	72	118	70	92	132.30	
1	03DEC96	8, -57	0	120	80	80	118	80	90	133.40	
2	10DEC96	15, -50	0	120	68	64	118	72	68	131.20	
3	20DEC96	25, -40	0	117	68	72	120	68	80	132.30	
4	27DEC96	32, -33	0	120	80	86	117	78	90	134.51	
6	06JAN97	42, -23	0	110	60	80	110	70	76	133.40	
7	13JAN97	49, -16	0	112	70	76	120	70	92	133.40	
8	21JAN97	57, -8	0	110	70	64	120	70	72	136.71	
8	29JAN97	65, 1	0	120	70	64	112	76	96	134.51	
12	24FEB97	91, 27	0	110	70	68	110	68	78	135.61	
16	20MAR97	115, 51	0	120	70	82	110	60	88	132.30	
20	21APR97	147, 83	0	110	64	87	105	62	120	135.61	
24	26MAY97	182, 118	0	106	64	72	114	64	98	137.37	
32	30JUN97	217, 153	0	100	70	80	94	70	100	134.51	
32	30JUL97	247, 183	0	100	62	60	110	64	76	134.95	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	157	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	NEG			.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	36	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	194000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	138	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	65	Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75	H	.	.	30 - 70	%
				Lymphocytes	20.8	L	.	.	21 - 51	%
				Monocytes	3.1	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	147	Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	247	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	113	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	247	Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	03DEC96	1	09DEC96	7	7
00226	Oral	2	20 MG	10DEC96	8	19DEC96	17	10
00226	Oral	3	20 MG	20DEC96	18	20DEC96	18	1

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	18	20	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MILD RECURRENT HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
FRACTURE RIGHT LEG	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1988
SURGERY FOR STRABISMUS	OPERATION, EYE	OPERATIONS	PRV	1983

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Av Block	PR PROLONGATION CARDIAC CONDUCTION DELAY	18, .	4 Days	20	CON	MOD	STP	PSR	No	No
Digestive System	Nausea	NAUSEA	10, .	12 Days	20	CON	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS (SORE THROAT, COUGH)	-3, .	24 Days	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *		Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26NOV96	-7,	.	0	110	70	100	112	80	110	176.40	73.2
BL	03DEC96	1,	.	0	120	82	76	122	80	84	174.20	
1	10DEC96	8,	.	20	132	80	78	128	76	80	174.20	
2	20DEC96	18,	.	20	112	70	86	118	76	100	175.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.1	.	.	.	30 - 70	%
				Lymphocytes	34.8	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	203000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	136	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	18DEC96	1	26DEC96	9	9
00227	Oral	2	100 MG	27DEC96	10	05JAN97	19	10
00227	Oral	3	150 MG	06JAN97	20	14JAN97	28	9
00227	Oral	4	200 MG	15JAN97	29	23JAN97	37	9
00227	Oral	4	200 MG	24JAN97	38	03FEB97	48	11
00227	Oral	4	200 MG	04FEB97	49	13FEB97	58	10
00227	Oral	5	250 MG	14FEB97	59	19FEB97	64	6
00227	Oral	5	250 MG	20FEB97	65	24FEB97	69	5
00114	Oral	6	300 MG	25FEB97	70	26MAR97	99	30
00114	Oral	6	300 MG	27MAR97	100	24APR97	128	29
00114	Oral	6	300 MG	25APR97	129	25MAY97	159	31
00114	Oral	6	300 MG	26MAY97	160	24JUN97	189	30
00114	Oral	6	300 MG	25JUN97	190	20JUL97	215	26
00114	Oral	6	300 MG	21JUL97	216	18AUG97	244	29
00227	Oral	5	250 MG	19AUG97	245	20AUG97	246	2
00227	Oral	4	200 MG	21AUG97	247	22AUG97	248	2
00227	Oral	3	150 MG	23AUG97	249	24AUG97	250	2
00227	Oral	2	100 MG	25AUG97	251	27AUG97	253	3
00227	Oral	1	50 MG	28AUG97	254	03SEP97	260	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	Yes	260	50		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	42, -28	28JAN97	10FEB97	750 MG	PHARYNGITIS
	Phenoxymethylpenicillin Potassium	Penicillin V-K	21, -49	07JAN97	15JAN97	2,400 MG	AC. PHARYNGITIS
CENTRAL NERVOUS SYSTEM	Cannabis	Marijuana	32, -38	18JAN97	18JAN97	0.75 G	PT'S DECISIONS
RESPIRATORY	Chlorphenamine Maleate	Dristan	142, 73	08MAY97	09MAY97	2 TABS.	CONGESTION
	Mepyramine Maleate	Triaminic	142, 73	08MAY97	09MAY97	3 TSP.	COUGH
	Paracetamol	Dristan	142, 73	08MAY97	09MAY97	2 TABS.	CONGESTION
	Pheniramine Maleate	Triaminic	142, 73	08MAY97	09MAY97	3 TSP.	COUGH
	Phenylephrine Hydrochloride	Dristan	142, 73	08MAY97	09MAY97	2 TABS.	CONGESTION
	Phenylpropanolamine Hydrochloride	Triaminic	142, 73	08MAY97	09MAY97	3 TSP.	COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	MODERATE HEADACHE	19, -51	52 Days	100	5	MOD	NO	PSR	No	No
		SEVERE HEADACHES	7, -63	07:00 Hrs	50	2	SEV	NO	PSR	No	No
Carciovascular System	Hypertension	HYPERTENSION	129, 60	117 Days	300		MOD	NO	PBU	No	No
	Syncope	SYNCOPE	96, 27	161 Days	300		MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	31, -39	Not Stated	200	CON	MIL	NO	PBU	No	No
		SEVERE DRY MOUTH	129, 60	128 Days	300	CON	SEV	NO	PSR	No	No
Musculoskeletal System	Myalgia	MUSCLE SPASMS IN RIBS	143, 74	11:00 Hrs	300	CON	MOD	NO	PBU	No	No
Nervous System	Drug Dependence	CANNABIS USE	32, -38	1 Days	200	1	MIL	NO	UNR	No	No
	Insomnia	TERMINAL INSOMNIA	52, -18	Not Stated	200		MIL	INC	PBU	No	No
Respiratory System	Pharyngitis	PHARYNGITIS	20, -50	36 Days	150	CON	MOD	NO	PBU	Yes	No
		SORE THROAT	55, -15	11 Days	200	CON	MIL	NO	PBU	No	No
	Respiratory Disorder	COMMON COLD	139, 70	18 Days	300	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	12DEC96	-6, -75	0	130	70	60	130	76	70	153.25	70.1
BL	18DEC96	1, -69	0	128	82	80	122	76	84	150.38	
1	27DEC96	10, -60	100	128	80	80	126	78	90	150.38	
3	06JAN97	20, -50	150	120	90	100	120	80	95	150.38	
4	15JAN97	29, -41	200	124	80	92	120	78	94	150.38	
5	24JAN97	38, -32	200	130	90	100	124	82	102	150.38	
7	04FEB97	49, -21	200	126	90	90	122	80	92	151.04	
8	14FEB97	59, -11	250	122	82	80	120	78	82	151.04	
8	20FEB97	65, -5	250	130	80	82	120	86	88	152.15	
8	25FEB97	70, 1	300	128	90	78	120	90	90	151.48	
16	27MAR97	100, 31	300	136	90	90	134	90	100	156.56	
20	25APR97	129, 60	300	152	80	96	152	80	105	159.42	
24	26MAY97	160, 91	300	144	90	94	134	80	120	159.86	
28	25JUN97	190, 121	300	130	90	100	120	90	110	157.44	
32	21JUL97	216, 147	300	120	80	88	136	90	100	156.56	
32	19AUG97	245, 176	250	120	70	90	128	70	96	157.66	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG			.		
				Urine Blood - Dipstick	NEG			.		
				Urine Red Blood Cells/HPF	NEG			.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70	Hemoglobin	14.8		.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8		.	.	41 - 50	%
				Red Blood Cell Count	5		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.6	H	.	.	30 - 70	%
				Lymphocytes	15.4	L	.	.	21 - 51	%
				Monocytes	9		.	.	0 - 10	%
				Eosinophils	3.9		.	.	0 - 5	%
				Basophils	1		.	.	0 - 2	%
				Platelets	211000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	1.1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	83		.	.	22 - 180	U/L
				Aspartate Aminotransferase	14		.	.	0 - 41	U/L
				Alanine Aminotransferase	16		.	.	0 - 48	U/L
				Total Bilirubin	0.8		.	.	0.3 - 1.3	MG/DL
				Total Protein	8		.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	70	Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	160	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.9	.	.	.	30 - 70	%
				Lymphocytes	33.5	.	.	.	21 - 51	%
				Monocytes	9.5	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	160	Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	100	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEC			.	.		
				Urine White Blood Cells/HPF NEG			.	.		
				Urine Protein - Dipstick NEG			.	.		
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 16/CONTINUATION-WEEK 32	245	Lymphocytes	24.3	.	.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00228 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	19MAR97	1	22MAR97	4	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	4	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00228 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	2, .	4 Days	20	CON	MIL	NO	PBU	No	No
Nervous System	Insomnia	INITIAL INSOMNIA	2, .	4 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04MAR97	-15, .	0	90	66	68	100	70	70	108.05	63.4
BL	19MAR97	1, .	0	110	70	82	100	70	90	109.15	
1	27MAR97	9, .	20	100	70	66	100	72	70	109.15	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00228 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	12.8		.	.	12 - 15.6	G/DL
				Hematocrit	37.2		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.5		.	.	30 - 70	%
				Lymphocytes	27.3		.	.	21 - 51	%
				Monocytes	6.9		.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.2		.	.	0 - 2	%
				Platelets	260000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6		.	.	25 - 35	PG
				Mean Corpuscle Volume	89		.	.	80 - 100	FL
				Blood Urea Nitrogen	14		.	.	7 - 25	MG/DL
				Creatinine	0.8		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67		.	.	44 - 280	U/L
				Aspartate Aminotransferase	13		.	.	0 - 41	U/L
				Alanine Aminotransferase	5		.	.	0 - 48	U/L
				Total Bilirubin	0.7		.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5		.	.	6.2 - 8.8	G/DL
				Albumin	4.3		.	.	3.1 - 5.3	G/DL
				Glucose - Random	88		.	.	70 - 115	MG/DL
				Globulin	3.2		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00228 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28FEB97	1	06MAR97	7	7
00230	Oral	2	100 MG	07MAR97	8	13MAR97	14	7
00230	Oral	3	150 MG	14MAR97	15	23MAR97	24	10
00230	Oral	4	200 MG	24MAR97	25	02APR97	34	10
00230	Oral	4	200 MG	03APR97	35	10APR97	42	8
00230	Oral	4	200 MG	11APR97	43	20APR97	52	10
00230	Oral	4	200 MG	21APR97	53	01MAY97	63	11
00230	Oral	5	250 MG	02MAY97	64	07MAY97	69	6
00116	Oral	5	250 MG	08MAY97	70	12MAY97	74	5
00230	Oral	4	200 MG	13MAY97	75	13MAY97	75	1
00230	Oral	3	150 MG	14MAY97	76	14MAY97	76	1
00230	Oral	2	100 MG	15MAY97	77	16MAY97	78	2
00230	Oral	1	50 MG	17MAY97	79	26MAY97	88	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	88	50	Other reason	WITHDREW CONSENT.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Calcium Carbonate	Tums	15, -55	14MAR97	.	3-4 TABS	HEARTBURN
			76, 7	14MAY97	26MAY97	3-4 TABS	HEARTBURN
			15, -55	14MAR97	.	3-4 TABS	HEARTBURN
			76, 7	14MAY97	26MAY97	3-4 TABS	HEARTBURN
ANTIINFECTIVES,SYSTEMIC	Clarithromycin	Biaxin	50, -20	18APR97	24APR97	500 MG	PHOPHYLAXIS TEETH EXTRACTION
CENTRAL NERVOUS SYSTEM	Codeine Phosphate	Tylenol With Codeine	50, -20	18APR97	20APR97	14 TSPS.	IMPACTED TEETH EXTRACTION
			53, -17	21APR97	21APR97	10 TSP.	IMPACTED TEETH EXTRACTION
	Paracetamol	Tylenol	32, -38	31MAR97	31MAR97	500 MG	HEADACHE
		Tylenol With Codeine	50, -20	18APR97	20APR97	14 TSPS.	IMPACTED TEETH EXTRACTION
			53, -17	21APR97	21APR97	10 TSP.	IMPACTED TEETH EXTRACTION
DERMATOLOGICALS	Methylprednisolone Sodium Succinate	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION
MUSCULO-SKELETAL	Ibuprofen	Advil	53, -17	21APR97	23APR97	600 MG	IMPACTED TEETH EXTRACTION
RESPIRATORY	Dimenhydrinate	Gravol	69, -1	07MAY97	07MAY97	50 MG	NAUSEA
SENSORY ORGANS	Methylprednisolone Sodium Succinate	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION
SYSTEMIC HORMONAL	Methylprednisolone Sodium Succinate	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	32, -38	1 Days	200	CON	MIL	NO	PBU	Yes	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	50, -20	19 Days	200		MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	12, -58	77 Days	100	CON	MOD	NO	PSR	No	No
	Dyspepsia	HEARTBURN	15, -55	74 Days	150		MIL	NO	PBU	Yes	No
	Nausea	NAUSEA	50, -20	7 Days	200		MOD	NO	UNR	No	No
			69, -1	14:00 Hrs	250	CON	MIL	NO	UNR	Yes	No
	Tooth Disorder	PAIN RE: 4 IMPACTED WISDOM TEETH EXTRACTED UNDER GENERAL ANESTHETIC	50, -20	1 Days	200	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS	13, -57	3 Days	100	2	MIL	NO	PBU	No	No
Urogenital System	Cystitis	FEELING BLADDER FULL AFTER URINATING	63, -7	28 Days	200	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20FEB97	-8, -77	0	120	80	76	120	78	72	121.50	65.4
BL	28FEB97	1, -69	0	120	76	80	120	78	82	121.28	
1	07MAR97	8, -62	100	110	80	84	120	80	96	121.50	
2	14MAR97	15, -55	150	124	70	60	110	70	100	122.38	
3	24MAR97	25, -45	200	120	80	90	114	76	80	122.60	
5	03APR97	35, -35	200	114	76	82	108	80	82	121.72	
6	11APR97	43, -27	200	118	78	90	120	80	96	122.82	
8	23APR97	55, -15	200	106	74	109	90	70	120	119.07	
8	02MAY97	64, -6	250	106	74	100	104	70	116	123.04	
8	08MAY97	70, 1	250	106	68	110	104	60	120	122.16	
12	16MAY97	78, 9	100	106	58	102	100	68	120	122.38	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	48.9	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	186	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	1	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.2	.	.	.	30 - 70	%
				Lymphocytes	35.5	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG			.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	356000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	70	Alkaline Phosphatase	158	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07MAR97	1	16MAR97	10	10
00231	Oral	2	20 MG	17MAR97	11	23MAR97	17	7
00231	Oral	3	20 MG	24MAR97	18	01APR97	26	9
00231	Oral	4	20 MG	02APR97	27	08APR97	33	7
00231	Oral	4	20 MG	09APR97	34	16APR97	41	8
00231	Oral	4	20 MG	17APR97	42	24APR97	49	8
00231	Oral	5	30 MG	25APR97	50	30APR97	55	6
00231	Oral	5	30 MG	01MAY97	56	06MAY97	61	6
00118	Oral	5	30 MG	07MAY97	62	03JUN97	89	28
00118	Oral	5	30 MG	04JUN97	90	29JUN97	115	26
00118	Oral	5	30 MG	30JUN97	116	05AUG97	152	37
00231	Oral	4	20 MG	05AUG97	152	06AUG97	153	2
00231	Oral	3	20 MG	07AUG97	154	08AUG97	155	2
00231	Oral	2	20 MG	09AUG97	156	11AUG97	158	3
00231	Oral	1	20 MG	12AUG97	159	18AUG97	165	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	165	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ECZEMA	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996

CUR = Current, PRV = Past

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Miconazole Nitrate	Micatin	84, 23	29MAY97	.		ECZEMA
CARDIOVASCULAR	Betamethasone	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	49, -13	24APR97	.	650 MG PRN	HEADACHE
			109, 48	23JUN97	.	500 MG PRN	MOD HEADACHES
DERMATOLOGICALS	Betamethasone	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
	Miconazole Nitrate	Micatin	84, 23	29MAY97	.		ECZEMA
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Ortho Tri-Cyclen	32, -30	07APR97	.	1 TAB	CONTRACEPTIVE
	Miconazole Nitrate	Micatin	84, 23	29MAY97	.		ECZEMA
	Norgestimate	Ortho Tri-Cyclen	32, -30	07APR97	.	1 TAB	CONTRACEPTIVE
SENSORY ORGANS	Betamethasone	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
SYSTEMIC HORMONAL	Betamethasone	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	43, -19	2 Days	20	CON	MOD	NO	PBU	No	No
			49, -13	02:00 Hrs	20	CON	MOD	NO	PBU	Yes	No
			53, -9	Not Stated	30		MIL	NO	PBU	Yes	No
		MODERATE HEADACHE	53, -9	Not Stated	30		MOD	NO	PSR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	14, -48	41 Days	20	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	80, 19	10 Days	30	4	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	80, 19	10 Days	30	4	MIL	NO	PBU	No	No
Special Senses	Conjunctivitis	ITCHY EYES	48, -14	4 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26FEB97	-9, -70	0	110	70	68	112	80	72	156.56	63.4
BL	07MAR97	1, -61	0	120	70	82	128	80	90	155.45	
1	17MAR97	11, -51	20	110	80	60	120	80	72	157.88	
2	24MAR97	18, -44	20	118	84	76	108	76	88	158.10	
4	02APR97	27, -35	20	110	90	80	120	80	90	161.63	
5	09APR97	34, -28	20	116	80	76	120	82	80	159.64	
6	17APR97	42, -20	20	122	80	80	126	90	86	161.19	
7	25APR97	50, -12	30	126	70	67	122	74	68	161.41	
8	01MAY97	56, -6	30	116	76	74	114	78	78	162.95	
8	07MAY97	62, 1	30	110	70	64	106	74	62	166.26	
12	04JUN97	90, 29	30	120	80	72	120	86	72	166.92 H	
16	30JUN97	116, 55	30	110	70	80	118	84	84	173.31 H	
20	05AUG97	152, 91	20	128	80	80	120	80	80	176.18 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30; Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	45.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	35.4	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	243000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	4.3	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	100	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	152		Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	116	H	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
					Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 17/DOWN TITRATION	166	(1)	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
					Hematocrit	43.5	.	.	.	35 - 46	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	63	.	.	.	30 - 70	%
					Lymphocytes	29.1	.	.	.	21 - 51	%
					Monocytes	5.9	.	.	.	0 - 10	%
					Eosinophils	1.6	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	232000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	49	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE DAYS *		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 17/DOWN TITRATION	166	(1)	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	82	.	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	+		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable