Table 1.2.2
Summary of Subject Randomization by Site
Protocol # 381.201

			Total	Site 1	Site 2	Site 3	Site 4
				Site			
Total Study Participants		N	51	13	12	15	11
Randomization	Yes	N (%)	51 (100.0%)	13 (100.0%)	12 (100.0%)	15 (100.0%)	11 (100.0%)
Assigned Treatment Sequence	ABCDEX	N (%)	12 (23.5%)	3 (23.1%)	3 (25.0%)	3 (20.0%)	3 (27.3%)
	BCDEAX	N (%)	10 (19.6%)	2 (15.4%)	2 (16.7%)	3 (20.0%)	3 (27.3%)
	CDEABX	N (%)	9 (17.6%)	3 (23.1%)	2 (16.7%)	3 (20.0%)	1 (9.1%)
	DEABCX	N (%)	11 (21.6%)	3 (23.1%)	3 (25.0%)	3 (20.0%)	2 (18.2%)
	EABCDX	N (%)	9 (17.6%)	2 (15.4%)	2 (16.7%)	3 (20.0%)	2 (18.2%)

NOTE: A=Placebo B=Adderall 10mg C=SLI381 10mg D=SLI381 20mg E=SLI381 30mg X=Randomized to A,B,C,D, or E

Generation: 04MAY00 t01_2_2.sas/COPPR

Table 1.2.3
Summary of Subject Study Outcome by Site
Protocol # 381.201

			Total	Site 1	Site 2	Site 3	Site 4
				Site			
Total Study Participants		N	51	13	12	15	11
Study Discontinuation	Visit 2	N (%)	1 (2.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Visit 3	N (%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
	Visit 4	N (%)	2 (3.9%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	1 (9.1%)
	Visit 7	N (%)	3 (5.9%)	0 (0.0%)	0 (0.0%)	3 (20.0%)	0 (0.0%)
	Complete Study	N (%)	44 (86.3%)	12 (92.3%)	11 (91.7%)	11 (73.3%)	10 (90.9%)
Reason for Termination	Adverse medical experience	N (%)	2 (3.9%)	1 (7.7%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
	Withdrawal of consent	N (%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
	Lost to follow-up	N (%)	2 (3.9%)	0 (0.0%)	0 (0.0%)	2 (13.3%)	0 (0.0%)
	Other	N (%)	2 (3.9%)	0 (0.0%)	1 (8.3%)	1 (6.7%)	0 (0.0%)

NOTE: A=Placebo B=Adderall 10mg C=SLI381 10mg D=SLI381 20mg E=SLI381 30mg

Generation: 04MAY00 t01_2_3.sas/COPPR

Table 1.2.4
Summary of Subject Study Outcome by Treatment
Protocol # 381.201

Study Phase			Treatment				
			Placebo	Adderall	10mg	20mg	30mg
Practice Week	Enrolled					51	
	Outcome	Complete				51 (100.0%)	
Tmt. Weeks 1-5	Enrolled		49	48	48	50	49
	Outcome	Complete	48 (98.0%)	48 (100.0%)	47 (97.9%)	49 (98.0%)	48 (98.0%)
		Adv. Med. Exp.	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)
		Withdrew consent	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Other	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	1 (2.0%)
Make-up Week	Enrolled		10	11	9	9	8
	Outcome	Complete	9 (90.0%)	10 (90.9%)	8 (88.9%)	9 (100.0%)	8 (100.0%)
		Adv. Med. Exp.	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Lost to Follow-up	0 (0.0%)	1 (9.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)

Practice Week = Visit 2
Make-up Week = Visit 8

Generation: 04MAY00 t01_2_4.sas/COPPR

Table 1.2.5
Listing of Early Terminations by Site
Protocol # 381.201

Patient ID	Age (yr)	Sex	Race	ADHD Subtype	Prior Tx?	Study Outcome	Termination Treatment	Days of Randomized Treatment	Randomized Treatment Week Terminated
1-08	9	Male	White	Combined	RITALIN SR	AME: STOMACH ACHE	SLI381 20mg	1	1
2-17	8	Male	Hispanic	Combined	RITALIN SR	Other: COULD NOT TOLERATE BEING IN STUDY	SLI381 10mg	13	3
3-04	12	Female	White	Combined	RITALIN SR	Other: UCLA IRB EX CRIT: GIRLS WHO HAD MENARCHE	SLI381 30mg	14	2
3-09	11	Male	Hispanic	Combined	RITALIN	Lost to follow-up	Adderall 10mg	33	6
3-10	11	Female	Hispanic	Combined	RITALIN	Lost to follow-up	SLI381 10mg	33	6
3-11	7	Male	Black	Combined	RITALIN	AME: AGITATION	Placebo	28	6
4-08	11	Male	White	Combined	ADDERALL	Withdrawal of consent	Placebo	14	3

Generation: 04MAY00 t01_2_5.sas/COPPR

Table 1.3.1 (Page 1 of 1)
Subject Treatment Compliance During the Core Treatment Weeks - Randomized Subjects
Protocol # 381.201

Parameter			Treatment				
			Placebo	Adderall	10 mg	20 mg	30 mg
Total Randomized		N	49	48	48	50	49
Compliance (%)	0	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	<50	N (%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	50 - 79	N (%)	1 (2.0%)	2 (4.2%)	3 (6.3%)	1 (2.0%)	1 (2.0%)
	80 - 100	N (%)	47 (95.9%)	46 (95.8%)	44 (91.7%)	48 (96.0%)	48 (98.0%)
	>100	N (%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (2.0%)	0 (0.0%)

Generation: 04MAY00 t01_3_1.sas/COPPR

Table 2.1.1
Study-Defined Analysis Populations by Site
Protocol # 381.201

Population		Total	Site			
			Site 1	Site 2	Site 3	Site 4
Study Participants (SP)	N	51	13	12	15	11
Term. Prior to Randomization	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Randomized	N (%)	51 (100.0%)	13 (100.0%)	12 (100.0%)	15 (100.0%)	11 (100.0%)
Intent-to-Treat (ITT)	N	49	12	12	14	11
Per-protocol (PP)	N	47	12	11	14	10
Completed	N	44	12	11	11	10

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_1_1.sas/COPPR

Table 2.1.2
Demographic Characteristics of the Study-Defined Analysis Populations
Protocol # 381.201

Parameter			Population			
			SP	ITT	PP	Completed
Total Subjects		N	51	49	47	44
Gender	Male	N (%)	44 (86.3%)	43 (87.8%)	41 (87.2%)	39 (88.6%)
	Female	N (%)	7 (13.7%)	6 (12.2%)	6 (12.8%)	5 (11.4%)
Race	White	N (%)	25 (49.0%)	23 (46.9%)	22 (46.8%)	22 (50.0%)
	Black	N (%)	8 (15.7%)	8 (16.3%)	8 (17.0%)	7 (15.9%)
	Hispanic	N (%)	12 (23.5%)	12 (24.5%)	11 (23.4%)	9 (20.5%)
	Asian	N (%)	3 (5.9%)	3 (6.1%)	3 (6.4%)	3 (6.8%)
	Other	N (%)	3 (5.9%)	3 (6.1%)	3 (6.4%)	3 (6.8%)
Age	6-8 years	N (%)	18 (35.3%)	18 (36.7%)	17 (36.2%)	16 (36.4%)
	9-12 years	N (%)	33 (64.7%)	31 (63.3%)	30 (63.8%)	28 (63.6%)
Age (yr)		N	51	49	47	44
		Mean (SD)	9.5 (1.9)	9.5 (1.9)	9.5 (1.9)	9.5 (1.9)
		Min - Max	6.0 - 12.0	6.0 - 12.0	6.0 - 12.0	6.0 - 12.0
Weight (lb)		N	51	49	47	44
		Mean (SD)	83.5 (28.9)	82.1 (28.0)	82.5 (28.5)	82.3 (29.2)
		Min - Max	48.0 - 161.0	48.0 - 161.0	48.0 - 161.0	48.0 - 161.0
Height (in)		N	51	49	47	44
		Mean (SD)	54.6 (4.9)	54.4 (4.8)	54.5 (4.8)	54.5 (4.8)
		Min - Max	45.5 - 65.2	45.5 - 63.5	45.5 - 63.5	45.5 - 63.5

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_1_2.sas/COPPR

Table 2.1.3 (Page 1 of 1)
Disease Diagnosis and Treatment Characteristics of the Study-Defined Populations
Protocol # 381.201

Parameter			SP	ITT	PP	Completed
Total Subjects		N	51	49	47	44
Diagnosis	Hyperactive	N (%)	1 (2.0%)	1 (2.0%)	1 (2.1%)	1 (2.3%)
	Combined	N (%)	50 (98.0%)	48 (98.0%)	46 (97.9%)	43 (97.7%)
Duration Tmt. (yr)		N	47	45	43	40
		Mean (SD)	1.7 (1.7)	1.7 (1.7)	1.8 (1.8)	1.6 (1.7)
		Min - Max	0.0 - 5.7	0.0 - 5.7	0.0 - 5.7	0.0 - 5.7
Previous Tmt.	None Listed	N (%)	4 (7.8%)	4 (8.2%)	4 (8.5%)	4 (9.1%)
	Amphetamine only	N (%)	17 (33.3%)	17 (34.7%)	16 (34.0%)	16 (36.4%)
	MPH only	N (%)	30 (58.8%)	28 (57.1%)	27 (57.4%)	24 (54.5%)

NOTE: Missing day or month of date replaced by 01 to compute duration.

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_1_3.sas/COPPR

Table 2.2.1 (Page 1 of 3)
Descriptive Statistics of SKAMP Scores Obtained After Administration of a Single SLI381 20mg Dose
Protocol # 381.201

Factor	Session	Time Post Dose (hr)		Population			
				SP	ITT	PP	Complete
Attention	1	0.0	N	51	49	47	44
			Mean (SD)	1.11 (0.976)	1.13 (0.988)	1.13 (0.975)	1.16 (0.994)
			Min - Max	0.00 - 3.25	0.00 - 3.25	0.00 - 3.25	0.00 - 3.25
	2	1.5	N	51	49	47	44
			Mean (SD)	0.84 (0.862)	0.87 (0.862)	0.79 (0.695)	0.78 (0.683)
			Min - Max	0.00 - 4.50	0.00 - 4.50	0.00 - 3.00	0.00 - 3.00
	3	4.5	N	50	48	46	43
			Mean (SD)	0.65 (0.672)	0.64 (0.680)	0.60 (0.676)	0.61 (0.697)
			Min - Max	0.00 - 2.50	0.00 - 2.50	0.00 - 2.50	0.00 - 2.50
	4	6.0	N	51	49	47	44
			Mean (SD)	0.65 (0.838)	0.67 (0.850)	0.64 (0.845)	0.64 (0.863)
			Min - Max	0.00 - 3.25	0.00 - 3.25	0.00 - 3.25	0.00 - 3.25
	5	7.5	N	50	48	46	43
			Mean (SD)	0.63 (0.824)	0.65 (0.831)	0.61 (0.802)	0.64 (0.821)
			Min - Max	0.00 - 3.00	0.00 - 3.00	0.00 - 3.00	0.00 - 3.00
	6	9.0	N	49	47	45	42
			Mean (SD)	0.76 (0.896)	0.79 (0.904)	0.72 (0.841)	0.74 (0.857)
			Min - Max	0.00 - 3.25	0.00 - 3.25	0.00 - 3.25	0.00 - 3.25
	7	10.5	N	47	45	43	40
			Mean (SD)	0.94 (0.994)	0.94 (1.010)	0.88 (0.953)	0.90 (0.972)

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_2_1.sas/COPPR

Table 2.2.1 (Page 2 of 3)
Descriptive Statistics of SKAMP Scores Obtained After Administration of a Single SLI381 20mg Dose
Protocol # 381.201

Factor	Session	Time Post Dose (hr)		Population			
				SP	ITT	PP	Complete
Attention	7	10.5	Min - Max	0.00 - 4.00	0.00 - 4.00	0.00 - 4.00	0.00 - 4.00
	8	12.0	N	47	45	43	40
			Mean (SD)	0.82 (0.896)	0.84 (0.908)	0.80 (0.892)	0.85 (0.902)
			Min - Max	0.00 - 3.25	0.00 - 3.25	0.00 - 3.25	0.00 - 3.25
Deportment	1	0.0	N	51	49	47	44
			Mean (SD)	0.72 (0.967)	0.74 (0.976)	0.70 (0.885)	0.72 (0.898)
			Min - Max	0.00 - 3.75	0.00 - 3.75	0.00 - 3.25	0.00 - 3.25
	2	1.5	N	51	49	47	44
			Mean (SD)	0.46 (0.649)	0.47 (0.658)	0.47 (0.664)	0.46 (0.673)
			Min - Max	0.00 - 2.50	0.00 - 2.50	0.00 - 2.50	0.00 - 2.50
	3	4.5	N	50	48	46	43
			Mean (SD)	0.53 (0.625)	0.54 (0.632)	0.51 (0.608)	0.52 (0.624)
			Min - Max	0.00 - 2.00	0.00 - 2.00	0.00 - 2.00	0.00 - 2.00
	4	6.0	N	51	49	47	44
			Mean (SD)	0.53 (0.712)	0.54 (0.722)	0.48 (0.655)	0.48 (0.665)
			Min - Max	0.00 - 2.50	0.00 - 2.50	0.00 - 2.50	0.00 - 2.50
	5	7.5	N	50	48	46	43
			Mean (SD)	0.48 (0.679)	0.49 (0.689)	0.47 (0.666)	0.49 (0.680)
			Min - Max	0.00 - 2.75	0.00 - 2.75	0.00 - 2.75	0.00 - 2.75

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_2_1.sas/COPPR

Table 2.2.1 (Page 3 of 3)
Descriptive Statistics of SKAMP Scores Obtained After Administration of a Single SLI381 20mg Dose
Protocol # 381.201

Factor	Session	Time Post Dose (hr)		Population			
				SP	ITT	PP	Complete
Deportment	6	9.0	N	49	47	45	42
			Mean (SD)	0.78 (0.974)	0.81 (0.985)	0.69 (0.837)	0.73 (0.853)
			Min - Max	0.00 - 4.00	0.00 - 4.00	0.00 - 4.00	0.00 - 4.00
	7	10.5	N	47	45	43	40
			Mean (SD)	0.82 (1.069)	0.84 (1.086)	0.77 (1.043)	0.80 (1.067)
			Min - Max	0.00 - 4.75	0.00 - 4.75	0.00 - 4.75	0.00 - 4.75
	8	12.0	N	47	45	43	40
			Mean (SD)	0.74 (0.711)	0.77 (0.709)	0.72 (0.651)	0.75 (0.655)
			Min - Max	0.00 - 2.75	0.00 - 2.75	0.00 - 2.25	0.00 - 2.25

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_2_1.sas/COPPR

Table 2.2.2 (Page 1 of 3)
Descriptive Statistics of PERMP Scores Obtained After Administration of a Single SLI381 20mg Dose
Protocol # 381.201

Factor	Session	Time Post Dose (hr)		Population			
				SP	ITT	PP	Complete
# Attempted	1	0.0	N	50	48	46	44
			Mean (SD)	58.60 (30.881)	59.31 (30.979)	60.22 (31.340)	60.09 (31.480)
			Min - Max	2 - 142	2 - 142	2 - 142	2 - 142
	2	1.5	N	49	48	47	44
			Mean (SD)	99.04 (47.421)	99.79 (47.628)	99.47 (48.089)	99.34 (49.576)
			Min - Max	2 - 246	2 - 246	2 - 246	2 - 246
	3	4.5	N	50	48	46	43
			Mean (SD)	96.16 (47.369)	98.33 (46.578)	98.50 (47.452)	100.74 (46.917)
			Min - Max	2 - 199	2 - 199	2 - 199	2 - 199
	4	6.0	N	51	49	47	44
			Mean (SD)	100.22 (49.206)	102.45 (48.513)	103.32 (49.363)	102.91 (48.511)
			Min - Max	12 - 219	12 - 219	12 - 219	12 - 219
	5	7.5	N	48	47	45	42
			Mean (SD)	101.50 (47.862)	102.04 (48.230)	103.53 (48.642)	101.07 (49.119)
			Min - Max	13 - 246	13 - 246	13 - 246	13 - 246
	6	9.0	N	49	47	45	42
			Mean (SD)	98.71 (59.756)	100.13 (60.574)	101.67 (61.397)	100.79 (61.806)
			Min - Max	7 - 296	7 - 296	7 - 296	7 - 296
	7	10.5	N	47	45	43	40
			Mean (SD)	87.85 (50.827)	88.98 (51.595)	90.56 (51.952)	86.75 (49.802)

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_2_2.sas/COPPR

Table 2.2.2 (Page 2 of 3)
Descriptive Statistics of PERMP Scores Obtained After Administration of a Single SLI381 20mg Dose
Protocol # 381.201

Factor	Session	Time Post Dose (hr)		Population			
				SP	ITT	PP	Complete
# Attempted	7	10.5	Min - Max	11 - 270	11 - 270	11 - 270	11 - 270
	8	12.0	N	47	45	43	40
			Mean (SD)	86.19 (53.837)	87.27 (54.660)	90.12 (54.136)	87.28 (53.685)
			Min - Max	10 - 274	10 - 274	15 - 274	15 - 274
# Correct	1	0.0	N	50	48	46	44
			Mean (SD)	53.20 (30.424)	53.77 (30.610)	54.43 (31.108)	54.23 (31.383)
			Min - Max	0 - 138	0 - 138	0 - 138	0 - 138
	2	1.5	N	49	48	47	44
			Mean (SD)	90.80 (48.349)	91.46 (48.635)	90.98 (49.046)	90.59 (50.508)
			Min - Max	0 - 210	0 - 210	0 - 210	0 - 210
	3	4.5	N	50	48	46	43
			Mean (SD)	84.42 (47.191)	86.13 (46.902)	85.83 (47.791)	87.30 (47.714)
			Min - Max	0 - 184	0 - 184	0 - 184	0 - 184
	4	6.0	N	51	49	47	44
			Mean (SD)	87.69 (49.278)	89.45 (49.090)	89.79 (50.116)	88.80 (49.264)
			Min - Max	0 - 203	0 - 203	0 - 203	0 - 203
	5	7.5	N	48	47	45	42
			Mean (SD)	90.10 (48.030)	90.40 (48.504)	91.42 (49.217)	88.50 (49.437)
			Min - Max	0 - 207	0 - 207	0 - 207	0 - 207

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_2_2.sas/COPPR

Table 2.2.2 (Page 3 of 3)
Descriptive Statistics of PERMP Scores Obtained After Administration of a Single SLI381 20mg Dose
Protocol # 381.201

Factor	Session	Time Post Dose (hr)		Population			
				SP	ITT	PP	Complete
# Correct	6	9.0	N	49	47	45	42
			Mean (SD)	88.98 (54.745)	90.21 (55.534)	91.38 (56.391)	90.02 (56.208)
			Min - Max	2 - 282	2 - 282	2 - 282	2 - 282
	7	10.5	N	47	45	43	40
			Mean (SD)	83.64 (51.217)	84.67 (52.045)	86.07 (52.525)	82.10 (50.237)
			Min - Max	0 - 257	0 - 257	0 - 257	0 - 257
	8	12.0	N	47	45	43	40
			Mean (SD)	81.85 (53.428)	82.84 (54.283)	85.49 (53.979)	82.38 (53.343)
			Min - Max	5 - 265	5 - 265	5 - 265	5 - 265

SP Subjects who presented for the practice visit, Visit 2.
ITT All randomized subjects who have at least one efficacy data point in the first five weeks of blinded treatment.
PP All randomized subjects who have completed the first five weeks of blinded treatment.
Completed Randomized subjects who completed the full duration of blinded treatment with normal termination.

Generation: 04MAY00 t02_2_2.sas/COPPR

Table 2.3.1 (Page 1 of 1)
Descriptive Statistics of SKAMP Attention Scores Obtained During Core Treatment Weeks for the ITT Population (N=49)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Placebo	N	44	44	44	44	44	44	42	42
	Mean	1.18	1.31	1.40	1.74	1.73	1.51	1.74	1.44
	SD	0.977	0.825	0.954	1.006	1.005	0.970	0.869	0.929
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	4.00	2.75	4.00	3.50	3.75	3.75	3.25	4.00
Adderall 10mg	N	44	43	42	42	43	43	42	42
	Mean	1.59	0.88	0.92	1.26	1.22	1.55	1.60	1.59
	SD	1.210	0.828	0.920	1.182	0.872	1.284	1.262	1.211
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	6.00	2.75	3.00	3.75	3.50	6.00	6.00	6.00
SLI381 10mg	N	41	42	42	42	42	41	40	40
	Mean	1.55	1.27	1.13	1.26	1.21	1.40	1.40	1.23
	SD	1.050	0.934	0.982	1.034	0.796	1.022	1.016	0.964
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	3.50	3.50	3.25	3.25	2.75	3.50	3.00	3.25
SLI381 20mg	N	44	45	44	45	45	45	45	44
	Mean	1.27	1.16	1.07	1.14	1.13	1.26	1.27	1.18
	SD	1.152	1.089	1.088	0.986	1.048	1.154	0.876	1.010
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	5.00	5.25	6.00	5.00	5.75	6.00	3.00	5.00
SLI381 30mg	N	41	42	42	42	42	42	41	41
	Mean	1.38	0.98	0.90	0.74	0.74	1.05	1.23	1.15
	SD	1.075	0.987	0.823	0.737	0.809	1.160	1.278	1.208
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	3.50	5.00	3.25	2.50	3.50	6.00	6.00	6.00

Generation: 05JUL00 t02_3_1.sas/COPPR

Table 2.3.2 (Page 1 of 1)
Descriptive Statistics of SKAMP Deportment Scores Obtained During the Core Treatment Weeks for the ITT Population (N=49)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Placebo	N	44	44	44	44	44	44	42	42
	Mean	1.88	2.22	2.28	2.88	2.90	2.82	2.66	1.99
	SD	1.388	1.368	1.314	1.395	1.341	1.162	1.305	1.252
	Min	0.00	0.00	0.00	0.50	0.50	0.25	0.00	0.00
	Max	5.00	6.00	5.25	6.00	5.50	5.50	5.75	4.25
Adderall 10mg	N	44	43	42	42	43	43	42	42
	Mean	2.43	1.08	1.25	1.70	1.94	2.04	2.17	1.91
	SD	1.757	1.272	1.257	1.639	1.414	1.464	1.416	1.445
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	6.00	5.50	6.00	6.00	5.25	6.00	5.25	5.25
SLI381 10mg	N	41	42	42	42	42	41	40	40
	Mean	2.28	1.91	1.80	1.85	2.13	2.35	2.44	2.15
	SD	1.497	1.396	1.277	1.314	1.244	1.414	1.518	1.319
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	6.00	5.25	4.50	4.50	4.75	5.25	6.00	4.75
SLI381 20mg	N	44	45	44	45	45	45	45	44
	Mean	2.26	1.69	1.22	1.84	1.67	1.79	2.15	1.73
	SD	1.367	1.257	1.002	1.491	1.392	1.447	1.686	1.262
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	5.25	4.75	4.50	5.25	4.75	5.00	5.00	5.50
SLI381 30mg	N	41	42	42	42	42	42	41	41
	Mean	1.96	1.58	0.90	1.13	1.29	1.46	1.45	1.59
	SD	1.507	1.579	0.887	1.185	1.338	1.328	1.511	1.571
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	6.00	5.25	3.25	4.00	5.50	4.75	6.00	5.75

Generation: 04MAY00 t02_3_2.sas/COPPR

Table 2.3.3
Mixed-Model ANOVA of SKAMP Attention Scores for the ITT Population (N=49)
Protocol # 381.201

		Time (hr) Post Dose (p-value)								
		0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0	Average (treatment)
Mean Values	Placebo	1.18	1.31	1.40	1.74	1.73	1.51	1.74	1.44	1.51
	Adderall 10mg	1.59	0.88	0.92	1.26	1.22	1.55	1.60	1.59	1.33
	SLI381 10mg	1.55	1.27	1.13	1.26	1.21	1.40	1.40	1.23	1.30
	SLI381 20mg	1.27	1.16	1.07	1.14	1.13	1.26	1.27	1.18	1.18
	SLI381 30mg	1.38	0.98	0.90	0.74	0.74	1.05	1.23	1.15	1.02
Analysis by Session for Treatment Difference	p-value	0.3398	0.1641	0.1062	0.0003	0.0001	0.2378	0.1352	0.2552	

ANOVA Results	Effect	NDF	DDF	F	p
	Treatment	4	1617	41.70	0.0000
	Period	4	1617	13.47	0.0000
	Session	7	1617	7.95	0.0000
	Trt x Sess	28	1617	3.17	0.0000

Generation: 04MAY00 t02_3_3.sas/COPPR

Table 2.3.4 (Page 1 of 1)

Planned Pairwise Mean Comparisons of SKAMP Attention Scores between Active and Reference Drug for the ITT Population (N=49)

Protocol # 381.201

		Time (hr) Post Dose (p-value)							
Active Drug	Reference Drug	0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	Placebo	0.6647	0.0015	0.0000	0.0000	0.0000	0.0001	0.0000	0.0034
	Adderall 10mg	0.0274	0.8716	0.3813	0.0000	0.0001	0.0000	0.0006	0.0001
SLI381 20mg	Placebo	0.8912	0.0513	0.0023	0.0000	0.0000	0.0072	0.0000	0.0077
	Adderall 10mg	0.0048	0.2671	0.6236	0.1067	0.1557	0.0038	0.0012	0.0002
SLI381 10mg	Placebo	0.0152	0.5846	0.0269	0.0003	0.0001	0.2442	0.0062	0.0626
	Adderall 10mg	0.8258	0.0142	0.2033	0.9042	0.8318	0.1699	0.0779	0.0041
Adderall 10mg	Placebo	0.0072	0.0025	0.0005	0.0005	0.0002	0.8264	0.3250	0.3064

Generation: 04MAY00 t02_3_4.sas/COPPR

Table 2.3.5
Mixed-Model ANOVA of SKAMP Deportment Scores for the ITT Population (N=49)
Protocol # 381.201

		Time (hr) Post Dose (p-value)								
		0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0	Average (treatment)
Mean Values	Placebo	1.88	2.22	2.28	2.88	2.90	2.82	2.66	1.99	2.46
	Adderall 10mg	2.43	1.08	1.25	1.70	1.94	2.04	2.17	1.91	1.82
	SLI381 10mg	2.28	1.91	1.80	1.85	2.13	2.35	2.44	2.15	2.11
	SLI381 20mg	2.26	1.69	1.22	1.84	1.67	1.79	2.15	1.73	1.79
	SLI381 30mg	1.96	1.58	0.90	1.13	1.29	1.46	1.45	1.59	1.42
Analysis by Session for Treatment Difference	p-value	0.3999	0.0031	0.0000	0.0000	0.0000	0.0001	0.0047	0.3768	

ANOVA Results	Effect	NDF	DDF	F	p
	Treatment	4	1617	65.98	0.0000
	Period	4	1617	10.51	0.0000
	Session	7	1617	12.98	0.0000
	Trt x Sess	28	1617	4.07	0.0000

Generation: 04MAY00 t02_3_5.sas/COPPR

Table 2.3.6 (Page 1 of 1)
Planned Pairwise Mean Comparisons of SKAMP Deportment Scores between Active and Reference Drug for the ITT Population (N=49)
Protocol # 381.201

		Time (hr) Post Dose (p-value)							
Active Drug	Reference Drug	0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	Placebo	0.7640	0.0002	0.0000	0.0000	0.0000	0.0000	0.0000	0.0062
	Adderall 10mg	0.0023	0.1184	0.0136	0.0005	0.0001	0.0003	0.0000	0.0133
SLI381 20mg	Placebo	0.1205	0.0031	0.0000	0.0000	0.0000	0.0000	0.0021	0.0531
	Adderall 10mg	0.2102	0.0175	0.5576	0.8811	0.0536	0.0664	0.4310	0.0960
SLI381 10mg	Placebo	0.0845	0.0725	0.0090	0.0000	0.0001	0.0083	0.0724	0.9878
	Adderall 10mg	0.3022	0.0006	0.0314	0.8205	0.7011	0.3949	0.6707	0.8045
Adderall 10mg	Placebo	0.0051	0.0000	0.0000	0.0000	0.0000	0.0004	0.0246	0.7901

Generation: 04MAY00 t02_3_6.sas/COPPR

Table 2.3.7 (Page 1 of 1)
Descriptive Statistics of PERMP Number Attempted Obtained During Core Treatment Weeks for the ITT Population (N=49)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Placebo	N	44	44	44	44	44	44	42	42
	Mean	89.43	88.61	85.61	69.16	60.39	60.18	58.05	73.48
	SD	56.222	58.240	64.935	49.278	42.865	46.917	41.789	51.943
	Min	8	6	7	2	2	0	3	4
	Max	231	248	349	219	200	184	184	194
Adderall 10mg	N	41	43	42	42	43	42	42	41
	Mean	59.37	118.86	100.21	95.83	81.16	84.40	62.21	73.37
	SD	38.428	65.036	56.710	61.995	52.505	59.880	51.933	49.482
	Min	4	22	4	0	6	2	0	6
	Max	137	312	246	278	208	287	194	194
SLI381 10mg	N	41	42	42	42	41	41	40	40
	Mean	63.71	102.62	106.12	102.62	87.85	79.80	78.95	72.43
	SD	45.384	58.454	63.856	60.219	57.539	50.216	49.375	44.755
	Min	4	12	8	3	0	1	7	8
	Max	168	228	239	203	236	213	168	192
SLI381 20mg	N	44	45	44	45	45	45	45	44
	Mean	68.36	102.87	111.48	120.87	107.87	89.27	90.07	91.77
	SD	46.393	61.162	62.649	64.498	65.574	55.667	50.611	59.364
	Min	0	0	0	8	0	0	5	1
	Max	176	322	337	368	368	216	208	288
SLI381 30mg	N	41	42	42	42	42	42	41	41
	Mean	80.39	110.98	131.29	127.90	120.12	108.19	100.20	95.63
	SD	53.556	52.277	56.214	61.682	60.736	62.271	54.122	54.893
	Min	7	1	45	35	24	0	0	13
	Max	214	223	271	288	304	284	226	236

Generation: 04MAY00 t02_3_7.sas/COPPR

Table 2.3.8 (Page 1 of 1)
Descriptive Statistics of PERMP Number Correct Obtained During Core Treatment Weeks for the ITT Population (N=49)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Placebo	N	44	44	44	44	44	44	42	42
	Mean	86.77	85.20	77.77	63.23	57.34	54.23	50.17	64.88
	SD	56.094	58.456	51.058	44.314	43.247	46.019	40.023	50.296
	Min	3	2	2	0	0	0	1	3
	Max	231	247	202	186	200	180	183	191
Adderall 10mg	N	41	43	42	42	43	42	42	41
	Mean	56.20	112.72	94.69	90.29	72.58	73.40	60.40	67.78
	SD	38.018	68.891	59.063	63.837	54.465	53.299	51.419	48.002
	Min	4	10	1	0	6	2	0	3
	Max	134	309	246	274	207	182	188	186
SLI381 10mg	N	41	42	42	42	41	41	40	40
	Mean	60.95	97.74	102.12	97.90	82.12	74.44	73.55	68.85
	SD	44.297	59.854	62.336	60.317	57.396	48.904	48.592	45.108
	Min	4	8	8	1	0	1	4	7
	Max	163	225	238	202	234	199	164	187
SLI381 20mg	N	44	45	44	45	45	45	45	44
	Mean	65.39	98.11	107.18	112.49	103.80	85.64	86.16	87.25
	SD	45.957	61.267	61.914	67.941	64.498	55.545	50.856	60.715
	Min	0	0	0	0	0	0	4	1
	Max	169	312	320	361	353	213	204	287
SLI381 30mg	N	41	42	42	42	42	42	41	41
	Mean	77.78	105.52	123.79	124.52	115.55	105.02	97.39	92.54
	SD	52.453	54.723	55.699	61.138	60.621	61.379	53.601	54.302
	Min	5	0	32	34	24	0	0	12
	Max	214	223	268	284	301	282	225	236

Generation: 04MAY00 t02_3_8.sas/COPPR

Table 2.3.9 (Page 1 of 1)
Mixed-Model ANOVA of PERMP Number Attempted for the ITT Population (N=49)
Protocol # 381.201

		Time (hr) Post Dose (p-value)								
		0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0	Average (treatment)
Mean Values	Placebo	89.43	88.61	85.61	69.16	60.39	60.18	58.05	73.48	73.20
	Adderall 10mg	59.37	118.86	100.21	95.83	81.16	84.40	62.21	73.37	84.63
	SLI381 10mg	63.71	102.62	106.12	102.62	87.85	79.80	78.95	72.43	86.98
	SLI381 20mg	68.36	102.87	111.48	120.87	107.87	89.27	90.07	91.77	97.88
	SLI381 30mg	80.39	110.98	131.29	127.90	120.12	108.19	100.20	95.63	109.49
Analysis by Session for Treatment Difference	p-value	0.0279	0.1842	0.0140	0.0001	0.0000	0.0026	0.0003	0.1025	

ANOVA Results	Effect	NDF	DDF	F	p
	Treatment	4	1611	52.71	0.0000
	Period	4	1611	2.83	0.0234
	Session	7	1611	25.60	0.0000
	Trt x Sess	28	1611	3.72	0.0000

Generation: 04MAY00 t02_3_9.sas/COPPR

Table 2.3.10 (Page 1 of 1)

Planned Pairwise Mean Comparisons of PERMP Number Attempted between Active and Reference Drug for the ITT Population (N=49)

Protocol # 381.201

		Time (hr) Post Dose (p-value)							
Active Drug	Reference Drug	0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	Placebo	0.3952	0.0030	0.0000	0.0000	0.0000	0.0000	0.0000	0.0017
	Adderall 10mg	0.0031	0.5724	0.0001	0.0000	0.0000	0.0014	0.0000	0.0006
SLI381 20mg	Placebo	0.0304	0.0283	0.0006	0.0000	0.0000	0.0001	0.0000	0.0053
	Adderall 10mg	0.0816	0.1610	0.0933	0.0005	0.0002	0.2603	0.0001	0.0020
SLI381 10mg	Placebo	0.0019	0.0920	0.0136	0.0001	0.0017	0.0230	0.0101	0.9938
	Adderall 10mg	0.4566	0.0648	0.4614	0.4002	0.4535	0.5999	0.0231	0.7597
Adderall 10mg	Placebo	0.0001	0.0004	0.0850	0.0015	0.0157	0.0048	0.7626	0.7508

Table 2.3.11
Mixed-Model ANOVA of PERMP Number Correct for the ITT Population (N=49)
Protocol # 381.201

		Time (hr) Post Dose (p-value)								
		0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0	Average (treatment)
Mean Values	Placebo	86.77	85.20	77.77	63.23	57.34	54.23	50.17	64.88	67.56
	Adderall 10mg	56.20	112.72	94.69	90.29	72.58	73.40	60.40	67.78	78.69
	SLI381 10mg	60.95	97.74	102.12	97.90	82.12	74.44	73.55	68.85	82.43
	SLI381 20mg	65.39	98.11	107.18	112.49	103.80	85.64	86.16	87.25	93.31
	SLI381 30mg	77.78	105.52	123.79	124.52	115.55	105.02	97.39	92.54	105.41
Analysis by Session for Treatment Difference	p-value	0.0217	0.2985	0.0071	0.0001	0.0000	0.0005	0.0001	0.0466	

ANOVA Results	Effect	NDF	DDF	F	p
	Treatment	4	1611	61.71	0.0000
	Period	4	1611	2.40	0.0483
	Session	7	1611	26.00	0.0000
	Trt x Sess	28	1611	4.07	0.0000

Generation: 04MAY00 t02_3_11.sas/COPPR

Table 2.3.12 (Page 1 of 1)
Planned Pairwise Mean Comparisons of PERMP Number Correct between Active and Reference Drug for the ITT Population (N=49)
Protocol # 381.201

		Time (hr) Post Dose (p-value)							
Active Drug	Reference Drug	0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	Placebo	0.3114	0.0059	0.0000	0.0000	0.0000	0.0000	0.0000	0.0001
	Adderall 10mg	0.0021	0.5321	0.0001	0.0000	0.0000	0.0000	0.0000	0.0001
SLI381 20mg	Placebo	0.0193	0.0333	0.0000	0.0000	0.0000	0.0000	0.0000	0.0007
	Adderall 10mg	0.0638	0.1903	0.0526	0.0008	0.0000	0.0338	0.0001	0.0005
SLI381 10mg	Placebo	0.0009	0.1121	0.0020	0.0000	0.0029	0.0128	0.0025	0.5420
	Adderall 10mg	0.4054	0.0739	0.3287	0.3170	0.2433	0.8687	0.0371	0.4890
Adderall 10mg	Placebo	0.0000	0.0007	0.0353	0.0007	0.0667	0.0195	0.3424	0.9304

Generation: 04MAY00 t02_3_12.sas/COPPR

Table 2.4.1 (Page 1 of 1)
Descriptive Statistics of SKAMP Attention Scores Obtained During Core Treatment Weeks for the PP Population (N=47)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Placebo	N	44	44	44	44	44	44	42	42
	Mean	1.18	1.31	1.40	1.74	1.73	1.51	1.74	1.44
	SD	0.977	0.825	0.954	1.006	1.005	0.970	0.869	0.929
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	4.00	2.75	4.00	3.50	3.75	3.75	3.25	4.00
Adderall 10mg	N	43	43	42	42	43	43	42	42
	Mean	1.56	0.88	0.92	1.26	1.22	1.55	1.60	1.59
	SD	1.211	0.828	0.920	1.182	0.872	1.284	1.262	1.211
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	6.00	2.75	3.00	3.75	3.50	6.00	6.00	6.00
SLI381 10mg	N	41	42	42	42	42	41	40	40
	Mean	1.55	1.27	1.13	1.26	1.21	1.40	1.40	1.23
	SD	1.050	0.934	0.982	1.034	0.796	1.022	1.016	0.964
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	3.50	3.50	3.25	3.25	2.75	3.50	3.00	3.25
SLI381 20mg	N	43	44	43	44	44	44	44	43
	Mean	1.18	1.07	0.95	1.05	1.03	1.15	1.24	1.09
	SD	1.009	0.903	0.787	0.801	0.785	0.911	0.866	0.829
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	3.25	3.25	3.25	3.00	3.25	3.50	3.00	3.25
SLI381 30mg	N	40	41	41	41	41	41	40	40
	Mean	1.33	0.88	0.86	0.70	0.68	0.93	1.11	1.03
	SD	1.046	0.765	0.793	0.690	0.690	0.868	1.038	0.937
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	3.50	2.50	3.25	2.50	3.25	3.25	3.75	3.75

Generation: 04MAY00 t02_4_1.sas/COPPR

Table 2.4.2 (Page 1 of 1)
Descriptive Statistics of SKAMP Deportment Scores Obtained During Core Treatment Weeks for the PP Population (N=47)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Placebo	N	44	44	44	44	44	44	42	42
	Mean	1.88	2.22	2.28	2.88	2.90	2.82	2.66	1.99
	SD	1.388	1.368	1.314	1.395	1.341	1.162	1.305	1.252
	Min	0.00	0.00	0.00	0.50	0.50	0.25	0.00	0.00
	Max	5.00	6.00	5.25	6.00	5.50	5.50	5.75	4.25
Adderall 10mg	N	43	43	42	42	43	43	42	42
	Mean	2.38	1.08	1.25	1.70	1.94	2.04	2.17	1.91
	SD	1.748	1.272	1.257	1.639	1.414	1.464	1.416	1.445
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	6.00	5.50	6.00	6.00	5.25	6.00	5.25	5.25
SLI381 10mg	N	41	42	42	42	42	41	40	40
	Mean	2.28	1.91	1.80	1.85	2.13	2.35	2.44	2.15
	SD	1.497	1.396	1.277	1.314	1.244	1.414	1.518	1.319
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	6.00	5.25	4.50	4.50	4.75	5.25	6.00	4.75
SLI381 20mg	N	43	44	43	44	44	44	44	43
	Mean	2.19	1.63	1.15	1.78	1.60	1.72	2.10	1.64
	SD	1.301	1.181	0.897	1.440	1.326	1.378	1.674	1.133
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	5.25	4.75	4.50	5.25	4.50	4.75	5.00	4.75
SLI381 30mg	N	40	41	41	41	41	41	40	40
	Mean	1.86	1.49	0.85	1.06	1.19	1.38	1.33	1.49
	SD	1.379	1.487	0.833	1.108	1.175	1.238	1.340	1.476
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	5.25	5.25	3.25	3.75	4.00	4.00	4.50	5.75

Generation: 04MAY00 t02_4_2.sas/COPPR

Table 2.4.3
Mixed-Model ANOVA of SKAMP Attention Scores for the PP Population (N=47)
Protocol # 381.201

		Time (hr) Post Dose (p-value)							
		0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Mean Values	Placebo	1.18	1.31	1.40	1.74	1.73	1.51	1.74	1.44
	Adderall 10mg	1.56	0.88	0.92	1.26	1.22	1.55	1.60	1.59
	SLI381 10mg	1.55	1.27	1.13	1.26	1.21	1.40	1.40	1.23
	SLI381 20mg	1.18	1.07	0.95	1.05	1.03	1.15	1.24	1.09
	SLI381 30mg	1.33	0.88	0.86	0.70	0.68	0.93	1.11	1.03
Analysis by Session for Treatment Difference	p-value	0.2473	0.0489	0.0368	0.0000	0.0000	0.0289	0.0340	0.0481

ANOVA Results	Effect	NDF	DDF	F	p
	Treatment	4	1602	43.02	0.0000
	Period	4	1602	14.24	0.0000
	Session	7	1602	8.13	0.0000
	Trt x Sess	28	1602	3.18	0.0000

Generation: 04MAY00 t02_4_3.sas/COPPR

Table 2.4.4 (Page 1 of 1)
Planned Pairwise Mean Comparisons of SKAMP Attention Scores between Active and Reference Drug for the PP Population (N=47)
Protocol # 381.201

		Time (hr) Post Dose (p-value)							
Active Drug	Reference Drug	0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	Placebo	0.4757	0.0010	0.0000	0.0000	0.0000	0.0000	0.0000	0.0014
	Adderall 10mg	0.0612	0.7959	0.5701	0.0001	0.0001	0.0000	0.0002	0.0000
SLI381 20mg	Placebo	0.8565	0.0385	0.0009	0.0000	0.0000	0.0035	0.0001	0.0060
	Adderall 10mg	0.0050	0.3083	0.7960	0.0907	0.1054	0.0018	0.0037	0.0002
SLI381 10mg	Placebo	0.0138	0.5797	0.0248	0.0003	0.0001	0.2383	0.0056	0.0592
	Adderall 10mg	0.8806	0.0129	0.1963	0.9040	0.8302	0.1645	0.0743	0.0037
Adderall 10mg	Placebo	0.0082	0.0021	0.0004	0.0004	0.0002	0.8241	0.3175	0.2999

Generation: 04MAY00 t02_4_4.sas/COPPR

Table 2.4.5
Mixed-Model ANOVA of SKAMP Deportment Scores for the PP Population (N=47)
Protocol # 381.201

		Time (hr) Post Dose (p-value)							
		0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Mean Values	Placebo	1.88	2.22	2.28	2.88	2.90	2.82	2.66	1.99
	Adderall 10mg	2.38	1.08	1.25	1.70	1.94	2.04	2.17	1.91
	SLI381 10mg	2.28	1.91	1.80	1.85	2.13	2.35	2.44	2.15
	SLI381 20mg	2.19	1.63	1.15	1.78	1.60	1.72	2.10	1.64
	SLI381 30mg	1.86	1.49	0.85	1.06	1.19	1.38	1.33	1.49
Analysis by Session for Treatment Difference	p-value	0.3644	0.0017	0.0000	0.0000	0.0000	0.0000	0.0009	0.1685

ANOVA Results	Effect	NDF	DDF	F	p
	Treatment	4	1602	66.50	0.0000
	Period	4	1602	10.61	0.0000
	Session	7	1602	12.49	0.0000
	Trt x Sess	28	1602	4.01	0.0000

Generation: 04MAY00 t02_4_5.sas/COPPR

Table 2.4.6 (Page 1 of 1)
Planned Pairwise Mean Comparisons of SKAMP Deportment Scores between Active and Reference Drug for the PP Population (N=47)
Protocol # 381.201

		Time (hr) Post Dose (p-value)							
Active Drug	Reference Drug	0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	Placebo	0.6852	0.0002	0.0000	0.0000	0.0000	0.0000	0.0000	0.0055
	Adderall 10mg	0.0025	0.1372	0.0197	0.0006	0.0001	0.0003	0.0000	0.0118
SLI381 20mg	Placebo	0.1200	0.0033	0.0000	0.0000	0.0000	0.0000	0.0033	0.0462
	Adderall 10mg	0.2597	0.0182	0.5654	0.8673	0.0554	0.0664	0.5013	0.0840
SLI381 10mg	Placebo	0.0850	0.0733	0.0092	0.0000	0.0001	0.0085	0.0739	0.9921
	Adderall 10mg	0.3533	0.0006	0.0319	0.8222	0.7023	0.3958	0.6689	0.8023
Adderall 10mg	Placebo	0.0072	0.0000	0.0000	0.0000	0.0000	0.0004	0.0250	0.7921

Generation: 04MAY00 t02_4_6.sas/COPPR

Table 2.4.7 (Page 1 of 1)
Descriptive Statistics of PERMP Number Attempted Obtained During Core Treatment Weeks for the PP Population (N=47)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Placebo	N	44	44	44	44	44	44	42	42
	Mean	89.43	88.61	85.61	69.16	60.39	60.18	58.05	73.48
	SD	56.222	58.240	64.935	49.278	42.865	46.917	41.789	51.943
	Min	8	6	7	2	2	0	3	4
	Max	231	248	349	219	200	184	184	194
Adderall 10mg	N	40	43	42	42	43	42	42	41
	Mean	59.40	118.86	100.21	95.83	81.16	84.40	62.21	73.37
	SD	38.917	65.036	56.710	61.995	52.505	59.880	51.933	49.482
	Min	4	22	4	0	6	2	0	6
	Max	137	312	246	278	208	287	194	194
SLI381 10mg	N	41	42	42	42	41	41	40	40
	Mean	63.71	102.62	106.12	102.62	87.85	79.80	78.95	72.43
	SD	45.384	58.454	63.856	60.219	57.539	50.216	49.375	44.755
	Min	4	12	8	3	0	1	7	8
	Max	168	228	239	203	236	213	168	192
SLI381 20mg	N	43	44	43	44	44	44	44	43
	Mean	69.95	105.20	114.07	123.07	110.32	91.30	92.00	93.88
	SD	45.713	59.801	60.956	63.510	64.212	54.602	49.487	58.372
	Min	3	11	1	8	8	11	9	13
	Max	176	322	337	368	368	216	208	288
SLI381 30mg	N	40	41	41	41	41	41	40	40
	Mean	82.05	113.66	132.85	129.76	121.12	110.83	102.70	97.40
	SD	53.160	49.914	55.975	61.255	61.137	60.621	52.349	54.400
	Min	7	33	45	35	24	20	10	13
	Max	214	223	271	288	304	284	226	236

Generation: 04MAY00 t02_4_7.sas/COPPR

Table 2.4.8 (Page 1 of 1)
Descriptive Statistics of PERMP Number Correct Obtained During Core Treatment Weeks for the PP Population (N=47)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Placebo	N	44	44	44	44	44	44	42	42
	Mean	86.77	85.20	77.77	63.23	57.34	54.23	50.17	64.88
	SD	56.094	58.456	51.058	44.314	43.247	46.019	40.023	50.296
	Min	3	2	2	0	0	0	1	3
	Max	231	247	202	186	200	180	183	191
Adderall 10mg	N	40	43	42	42	43	42	42	41
	Mean	56.18	112.72	94.69	90.29	72.58	73.40	60.40	67.78
	SD	38.502	68.891	59.063	63.837	54.465	53.299	51.419	48.002
	Min	4	10	1	0	6	2	0	3
	Max	134	309	246	274	207	182	188	186
SLI381 10mg	N	41	42	42	42	41	41	40	40
	Mean	60.95	97.74	102.12	97.90	82.12	74.44	73.55	68.85
	SD	44.297	59.854	62.336	60.317	57.396	48.904	48.592	45.108
	Min	4	8	8	1	0	1	4	7
	Max	163	225	238	202	234	199	164	187
SLI381 20mg	N	43	44	43	44	44	44	44	43
	Mean	66.91	100.34	109.67	115.05	106.16	87.59	88.00	89.26
	SD	45.367	60.100	60.372	66.501	63.250	54.613	49.898	59.940
	Min	1	2	0	8	7	9	4	6
	Max	169	312	320	361	353	213	204	287
SLI381 30mg	N	40	41	41	41	41	41	40	40
	Mean	79.40	108.10	125.20	126.37	117.34	107.59	99.83	94.33
	SD	52.073	52.766	55.628	60.706	60.235	59.825	51.937	53.757
	Min	5	17	32	34	24	18	9	12
	Max	214	223	268	284	301	282	225	236

Generation: 04MAY00 t02_4_8.sas/COPPR

Table 2.4.9 (Page 1 of 1)
Mixed-Model ANOVA of PERMP Number Attempted for the PP Population (N=47)
Protocol # 381.201

		Time (hr) Post Dose (p-value)							
		0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Mean Values	Placebo	89.43	88.61	85.61	69.16	60.39	60.18	58.05	73.48
	Adderall 10mg	59.40	118.86	100.21	95.83	81.16	84.40	62.21	73.37
	SLI381 10mg	63.71	102.62	106.12	102.62	87.85	79.80	78.95	72.43
	SLI381 20mg	69.95	105.20	114.07	123.07	110.32	91.30	92.00	93.88
	SLI381 30mg	82.05	113.66	132.85	129.76	121.12	110.83	102.70	97.40
Analysis by Session for Treatment Difference	p-value	0.0259	0.1517	0.0086	0.0000	0.0000	0.0010	0.0001	0.0569

ANOVA Results	Effect	NDF	DDF	F	p
	Treatment	4	1596	52.47	0.0000
	Period	4	1596	2.87	0.0220
	Session	7	1596	25.37	0.0000
	Trt x Sess	28	1596	3.66	0.0000

Generation: 04MAY00 t02_4_9.sas/COPPR

Table 2.4.10 (Page 1 of 1)

Planned Pairwise Mean Comparisons of PERMP Number Attempted between Active and Reference Drug for the PP Population (N=47)

Protocol # 381.201

		Time (hr) Post Dose (p-value)							
Active Drug	Reference Drug	0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	Placebo	0.3727	0.0025	0.0000	0.0000	0.0000	0.0000	0.0000	0.0021
	Adderall 10mg	0.0040	0.6303	0.0001	0.0000	0.0000	0.0012	0.0000	0.0007
SLI381 20mg	Placebo	0.0291	0.0254	0.0005	0.0000	0.0000	0.0001	0.0000	0.0051
	Adderall 10mg	0.0917	0.1833	0.0812	0.0004	0.0001	0.2552	0.0001	0.0020
SLI381 10mg	Placebo	0.0019	0.0929	0.0139	0.0001	0.0018	0.0234	0.0104	0.9943
	Adderall 10mg	0.4579	0.0657	0.4634	0.4022	0.4552	0.6011	0.0236	0.7611
Adderall 10mg	Placebo	0.0001	0.0004	0.0858	0.0016	0.0160	0.0049	0.7624	0.7528

Generation: 04MAY00 t02_4_10.sas/COPPR

Table 2.4.11
Mixed-Model ANOVA of PERMP Number Correct for the PP Population (N=47)
Protocol # 381.201

		Time (hr) Post Dose (p-value)							
		0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
Mean Values	Placebo	86.77	85.20	77.77	63.23	57.34	54.23	50.17	64.88
	Adderall 10mg	56.18	112.72	94.69	90.29	72.58	73.40	60.40	67.78
	SLI381 10mg	60.95	97.74	102.12	97.90	82.12	74.44	73.55	68.85
	SLI381 20mg	66.91	100.34	109.67	115.05	106.16	87.59	88.00	89.26
	SLI381 30mg	79.40	108.10	125.20	126.37	117.34	107.59	99.83	94.33
Analysis by Session for Treatment Difference	p-value	0.0200	0.2585	0.0042	0.0000	0.0000	0.0002	0.0000	0.0242

ANOVA Results	Effect	NDF	DDF	F	p
	Treatment	4	1596	61.39	0.0000
	Period	4	1596	2.38	0.0499
	Session	7	1596	25.79	0.0000
	Trt x Sess	28	1596	4.03	0.0000

Table 2.4.12 (Page 1 of 1)

Planned Pairwise Mean Comparisons of PERMP Number Correct between Active and Reference Drug for the PP Population (N=47)

Protocol # 381.201

		Time (hr) Post Dose (p-value)							
Active Drug	Reference Drug	0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	Placebo	0.2887	0.0051	0.0000	0.0000	0.0000	0.0000	0.0000	0.0001
	Adderall 10mg	0.0028	0.5816	0.0002	0.0000	0.0000	0.0000	0.0000	0.0001
SLI381 20mg	Placebo	0.0178	0.0312	0.0000	0.0000	0.0000	0.0000	0.0000	0.0007
	Adderall 10mg	0.0742	0.2100	0.0467	0.0007	0.0000	0.0346	0.0001	0.0006
SLI381 10mg	Placebo	0.0010	0.1132	0.0021	0.0000	0.0030	0.0131	0.0026	0.5431
	Adderall 10mg	0.4056	0.0749	0.3307	0.3190	0.2450	0.8692	0.0378	0.4911
Adderall 10mg	Placebo	0.0000	0.0007	0.0358	0.0007	0.0676	0.0199	0.3435	0.9317

Generation: 04MAY00 t02_4_12.sas/COPPR

Table 2.5.1 (Page 1 of 1)

Descriptive and Inferential Statistics for the Placebo Adjusted SKAMP Attention Scores Obtained During the Core Treatment Weeks for the PP Population (N=47)

Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	N	37	38	38	38	38	38	35	35
	Mean	0.07	-0.44	-0.61	-1.07	-1.14	-0.61	-0.66	-0.46
	SD	0.852	0.699	0.803	0.921	0.949	0.896	0.681	0.924
	t-value	0.53	-3.89	-4.70	-7.18	-7.44	-4.16	-5.71	-2.97
	p	0.599	0.000	0.000	0.000	0.000	0.000	0.000	0.005
SLI381 20mg	N	40	41	41	41	41	41	40	39
	Mean	-0.03	-0.30	-0.48	-0.76	-0.71	-0.38	-0.59	-0.42
	SD	0.953	0.967	0.893	0.800	0.993	1.061	0.796	0.999
	t-value	-0.21	-1.98	-3.45	-6.10	-4.60	-2.32	-4.67	-2.60
	p	0.837	0.055	0.001	0.000	0.000	0.026	0.000	0.013
SLI381 10mg	N	39	40	40	40	40	39	37	37
	Mean	0.37	-0.03	-0.31	-0.49	-0.56	-0.16	-0.26	-0.22
	SD	1.043	1.053	0.903	1.094	0.880	0.899	0.842	0.969
	t-value	2.19	-0.19	-2.14	-2.85	-4.04	-1.11	-1.90	-1.36
	p	0.035	0.852	0.038	0.007	0.000	0.272	0.065	0.183
Adderall 10mg	N	40	40	40	40	40	40	37	37
	Mean	0.33	-0.38	-0.49	-0.45	-0.48	0.06	-0.04	0.28
	SD	1.201	1.013	0.898	1.021	0.839	1.053	1.123	0.974
	t-value	1.74	-2.38	-3.48	-2.79	-3.58	0.38	-0.22	1.77
	p	0.089	0.022	0.001	0.008	0.001	0.709	0.828	0.085

NOTE: Adjustment is treatment minus placebo for each classroom session. Subjects without placebo or treatment during Visits 3-7 were not included.

Generation: 04MAY00 t02_5_1.sas/COPPR

Table 2.5.2 (Page 1 of 1)

Descriptive and Inferential Statistics for the Placebo Adjusted SKAMP Deportment Scores Obtained During the Core Treatment Weeks for the PP Population (N=47)

Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	N	37	38	38	38	38	38	35	35
	Mean	-0.16	-0.80	-1.39	-1.79	-1.74	-1.53	-1.41	-0.59
	SD	1.138	1.297	1.174	1.408	1.495	1.198	1.252	1.259
	t-value	-0.87	-3.78	-7.29	-7.84	-7.19	-7.85	-6.65	-2.75
	p	0.392	0.001	0.000	0.000	0.000	0.000	0.000	0.009
SLI381 20mg	N	40	41	41	41	41	41	40	39
	Mean	0.25	-0.64	-1.09	-1.02	-1.24	-1.12	-0.65	-0.47
	SD	1.208	1.390	1.109	1.594	1.403	1.319	1.773	1.500
	t-value	1.31	-2.95	-6.30	-4.12	-5.65	-5.42	-2.32	-1.98
	p	0.198	0.005	0.000	0.000	0.000	0.000	0.026	0.056
SLI381 10mg	N	39	40	40	40	40	39	37	37
	Mean	0.41	-0.31	-0.56	-1.08	-0.81	-0.39	-0.24	0.05
	SD	1.519	1.488	1.466	1.542	1.234	1.212	1.541	1.289
	t-value	1.69	-1.30	-2.43	-4.41	-4.17	-2.01	-0.93	0.22
	p	0.100	0.201	0.020	0.000	0.000	0.051	0.357	0.825
Adderall 10mg	N	40	40	40	40	40	40	37	37
	Mean	0.51	-1.06	-0.98	-1.18	-0.94	-0.76	-0.35	-0.20
	SD	1.410	1.448	1.347	1.557	1.483	1.324	1.584	1.479
	t-value	2.30	-4.64	-4.61	-4.77	-4.00	-3.64	-1.35	-0.81
	p	0.027	0.000	0.000	0.000	0.000	0.001	0.186	0.426

NOTE: Adjustment is treatment minus placebo for each classroom session. Subjects without placebo or treatment during Visits 3-7 were not included.

Generation: 04MAY00 t02_5_2.sas/COPPR

Table 2.5.3 (Page 1 of 1)
Descriptive and Inferential Statistics for the Placebo Adjusted PERMP Number Attempted Obtained During the Core Treatment Weeks for the PP Population (N=47)
Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	N	37	38	38	38	38	38	35	35
	Mean	-9.81	20.16	43.74	57.34	63.00	52.00	43.29	22.43
	SD	36.352	46.029	68.058	69.396	59.520	55.118	41.940	56.038
	t-value	-1.64	2.70	3.96	5.09	6.52	5.82	6.11	2.37
	p	0.109	0.010	0.000	0.000	0.000	0.000	0.000	0.024
SLI381 20mg	N	40	41	41	41	41	41	40	39
	Mean	-15.48	20.27	28.59	55.29	50.59	35.05	37.73	26.92
	SD	47.276	50.697	56.416	55.921	63.283	63.907	52.777	68.443
	t-value	-2.07	2.56	3.24	6.33	5.12	3.51	4.52	2.46
	p	0.045	0.014	0.002	0.000	0.000	0.001	0.000	0.019
SLI381 10mg	N	39	40	40	40	39	39	37	37
	Mean	-24.54	15.43	18.95	32.25	27.33	16.23	19.81	-5.30
	SD	54.878	64.576	67.788	53.235	56.367	62.808	50.276	55.884
	t-value	-2.79	1.51	1.77	3.83	3.03	1.61	2.40	-0.58
	p	0.008	0.139	0.085	0.000	0.004	0.115	0.022	0.568
Adderall 10mg	N	37	40	40	40	40	39	37	36
	Mean	-35.35	29.70	14.30	25.70	19.48	22.05	-2.59	-3.56
	SD	49.875	74.781	48.986	56.023	58.789	67.652	44.982	65.923
	t-value	-4.31	2.51	1.85	2.90	2.10	2.04	-0.35	-0.32
	p	0.000	0.016	0.072	0.006	0.043	0.049	0.728	0.748

NOTE: Adjustment is treatment minus placebo for each classroom session. Subjects without placebo or treatment during Visits 3-7 were not included.

Generation: 04MAY00 t02_5_3.sas/COPPR

Table 2.5.4 (Page 1 of 1)

Descriptive and Inferential Statistics for the Placebo Adjusted PERMP Number Correct Obtained During the Core Treatment Weeks for the PP Population (N=47)

Protocol # 381.201

Treatment		Time (hr) Post Dose 0.0	1.5	4.5	6.0	7.5	9.0	10.5	12.0
SLI381 30mg	N	37	38	38	38	38	38	35	35
	Mean	-10.11	16.87	44.11	59.11	61.47	54.45	49.26	27.51
	SD	35.925	46.191	54.189	63.043	58.002	55.612	42.555	45.167
	t-value	-1.71	2.25	5.02	5.78	6.53	6.04	6.85	3.60
	p	0.096	0.030	0.000	0.000	0.000	0.000	0.000	0.001
SLI381 20mg	N	40	41	41	41	41	41	40	39
	Mean	-15.95	18.68	32.29	53.00	49.32	37.44	41.68	31.03
	SD	46.568	49.014	49.772	55.087	62.042	57.031	41.468	59.978
	t-value	-2.17	2.44	4.15	6.16	5.09	4.20	6.36	3.23
	p	0.036	0.019	0.000	0.000	0.000	0.000	0.000	0.003
SLI381 10mg	N	39	40	40	40	39	39	37	37
	Mean	-24.69	13.93	23.28	33.90	24.59	17.21	22.89	0.43
	SD	53.350	63.985	61.642	52.756	54.305	56.343	44.543	55.312
	t-value	-2.89	1.38	2.39	4.06	2.83	1.91	3.13	0.05
	p	0.006	0.177	0.022	0.000	0.007	0.064	0.003	0.962
Adderall 10mg	N	37	40	40	40	40	39	37	36
	Mean	-35.27	26.83	17.18	25.95	13.63	16.82	4.03	-1.08
	SD	49.105	74.301	40.715	56.495	57.217	49.662	36.029	60.021
	t-value	-4.37	2.28	2.67	2.91	1.51	2.12	0.68	-0.11
	p	0.000	0.028	0.011	0.006	0.140	0.041	0.501	0.914

NOTE: Adjustment is treatment minus placebo for each classroom session. Subjects without placebo or treatment during Visits 3-7 were not included.

Generation: 04MAY00 t02_5_4.sas/COPPR

Table 3.1.1 (Page 1 of 1)
Descriptive Statistics for the Plasma Drug Concentration Observed after a Single Dose
Administration of SLI381 20mg
Protocol # 381.201

		Time (hr) Sampled Post Dose										
Measure		0	0.5	1.5	3.0	4.5	6.0	7.5	9.0	10.5	12	24
D-amphetamine	N	36	49	51	50	49	48	48	47	48	45	46
	Mean	0.00	2.26	20.78	31.45	38.19	44.67	44.18	41.73	37.88	35.35	16.46
	SD	0.000	5.523	11.237	11.252	13.559	14.209	13.191	12.234	10.810	9.498	8.342
	CV (%)		244.0	54.1	35.8	35.5	31.8	29.9	29.3	28.5	26.9	50.7
L-amphetamine	N	36	49	51	50	49	48	48	47	48	45	46
	Mean	0.00	0.59	5.82	8.94	11.25	13.36	13.27	12.70	11.66	11.03	5.60
	SD	0.000	1.555	3.262	3.271	4.317	4.446	4.161	3.941	3.481	3.139	2.762
	CV (%)		262.7	56.1	36.6	38.4	33.3	31.3	31.0	29.9	28.5	49.3

Generation: 20JUL00 t03_1_1.sas/COPPR

Table 3.1.2 (Page 1 of 1)
Descriptive Statistics for the Plasma PK Parameters Observed after a Single Dose Administration
of SLI381 20mg
Protocol # 381.201

Measure		PK Parameters				
		AUCt	Cmax	Tmax	AUC_{0-inf}	$t_{1/2}$
D-amphetamine	N	48	48	48	40	40
	Mean	703.91	48.81	6.78	936.6	9.53
	SD	190.249	13.521	3.186	319.0	2.35
	CV (%)	27.0	27.7	47.0	34.1	24.6
L-amphetamine	N	48	48	48	40	40
	Mean	216.20	14.80	6.94	309.0	10.85
	SD	59.499	4.282	3.284	115.0	3.12
	CV (%)	27.5	28.9	47.3	37.2	28.7

Generation: 20JUL00 t03_1_2.sas/COPPR

Table 3.2.1 (Page 1 of 1)
Descriptive Statistics for the Plasma D-Amphetamine Concentration Observed at Steady State
During the Make-up Week
Protocol # 381.201

Treatment		Time (hr) Sampled Post Dose										
		0	0.5	1.5	3.0	4.5	6.0	7.5	9.0	10.5	12	24
SLI381 30mg	N	6	6	6	6	6	6	6	6	5	6	7
	Mean	29.94	27.12	57.58	74.52	80.47	79.98	75.56	75.25	66.44	61.78	27.14
	SD	10.474	8.342	21.132	17.102	24.277	12.322	14.271	17.855	18.853	18.459	13.654
	CV (%)	35.0	30.8	36.7	23.0	30.2	15.4	18.9	23.7	28.4	29.9	50.3
SLI381 20mg	N	9	9	9	9	9	9	8	9	9	9	9
	Mean	17.07	17.95	28.69	41.09	43.46	48.85	50.51	43.71	39.82	34.83	15.34
	SD	15.913	13.601	17.851	18.390	20.142	17.454	15.614	16.145	15.952	14.899	9.235
	CV (%)	93.2	75.8	62.2	44.8	46.3	35.7	30.9	36.9	40.1	42.8	60.2
SLI381 10mg	N	8	8	8	8	8	8	8	8	7	8	7
	Mean	7.99	8.54	18.72	24.09	27.28	25.58	23.73	21.94	21.21	20.41	10.49
	SD	3.470	1.751	7.047	3.205	6.503	6.407	7.168	6.309	6.980	6.424	2.227
	CV (%)	43.4	20.5	37.6	13.3	23.8	25.1	30.2	28.8	32.9	31.5	21.2
Adderall 10mg	N	8	8	9	9	9	9	9	9	8	9	9
	Mean	6.16	12.58	26.73	32.05	30.67	27.31	24.78	22.14	18.65	14.78	6.98
	SD	3.889	18.254	16.514	9.706	7.878	7.574	7.380	6.708	6.440	4.686	5.091
	CV (%)	63.2	145.1	61.8	30.3	25.7	27.7	29.8	30.3	34.5	31.7	73.0
Placebo	N	9	9	9	9	9	9	8	8	8	7	9
	Mean	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	SD	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
	CV (%)											

Generation: 20JUL00 t03_2_1.sas/COPPR

Table 3.2.2 (Page 1 of 1)
Descriptive Statistics for the Plasma D-Amphetamine PK Parameters Observed at Steady State
During the Make-up Week
Protocol # 381.201

Treatment		PK Parameters AUCt	Cmax	Tmax
SLI381 30mg	N	6	6	6
	Mean	1364.37	89.04	5.50
	SD	364.305	15.640	2.049
	CV (%)	26.7	17.6	37.3
SLI381 20mg	N	9	9	9
	Mean	777.24	54.63	5.83
	SD	304.319	18.758	1.750
	CV (%)	39.2	34.3	30.0
SLI381 10mg	N	8	8	8
	Mean	431.88	28.82	6.38
	SD	123.010	6.180	3.472
	CV (%)	28.5	21.4	54.5
Adderall 10mg	N	9	9	9
	Mean	422.51	33.80	3.33
	SD	138.272	11.071	1.250
	CV (%)	32.7	32.8	37.5
Placebo	N	0	0	0
	Mean			
	SD			
	CV (%)			

Generation: 20JUL00 t03_2_2.sas/COPPR

Table 3.2.3 (Page 1 of 1)
Descriptive Statistics for the Plasma L-Amphetamine Concentration Observed at Steady State
During the Make-up Week
Protocol # 381.201

Treatment		Time (hr) Sampled Post Dose										
		0	0.5	1.5	3.0	4.5	6.0	7.5	9.0	10.5	12	24
SLI381 30mg	N	6	6	6	6	6	6	6	6	5	6	7
	Mean	10.64	9.70	18.38	23.55	25.59	25.15	24.08	23.95	21.52	20.08	9.69
	SD	4.003	3.306	6.662	6.097	8.701	4.911	5.680	6.526	6.995	6.557	4.866
	CV (%)	37.6	34.1	36.3	25.9	34.0	19.5	23.6	27.3	32.5	32.6	50.2
SLI381 20mg	N	9	9	9	9	9	9	8	9	9	9	9
	Mean	6.88	6.88	9.83	12.88	13.90	15.53	16.49	14.12	13.15	11.86	5.83
	SD	6.731	5.441	6.086	5.547	6.799	6.495	6.126	5.966	5.947	5.722	3.744
	CV (%)	97.8	79.1	61.9	43.1	48.9	41.8	37.1	42.3	45.2	48.2	64.3
SLI381 10mg	N	8	8	8	8	8	8	8	8	7	8	7
	Mean	2.95	3.06	5.82	7.31	8.32	7.85	7.46	6.95	6.88	6.57	3.66
	SD	1.089	0.492	1.946	1.030	1.893	1.917	2.246	2.005	2.237	1.912	0.660
	CV (%)	37.0	16.1	33.4	14.1	22.8	24.4	30.1	28.9	32.5	29.1	18.0
Adderall 10mg	N	8	8	9	9	9	9	9	9	8	9	9
	Mean	2.46	4.35	8.49	10.14	9.80	8.90	8.11	7.46	6.35	5.18	2.71
	SD	1.472	5.673	4.968	3.139	2.666	2.502	2.452	2.204	2.210	1.627	1.636
	CV (%)	59.8	130.6	58.5	30.9	27.2	28.1	30.2	29.5	34.8	31.4	60.4
Placebo	N	9	9	9	9	9	9	8	8	8	7	9
	Mean	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	SD	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
	CV (%)											

Generation: 20JUL00 t03_2_3.sas/COPPR

Table 3.2.4 (Page 1 of 1)
Descriptive Statistics for the Plasma L-Amphetamine PK Parameters Observed at Steady State
During the Make-up Week
Protocol # 381.201

Treatment		PK Parameters AUCt	Cmax	Tmax
SLI381 30mg	N	6	6	6
	Mean	443.53	28.08	5.50
	SD	133.666	6.494	2.049
	CV (%)	30.1	23.1	37.3
SLI381 20mg	N	9	9	9
	Mean	261.63	17.15	5.67
	SD	120.154	6.797	2.222
	CV (%)	45.9	39.6	39.2
SLI381 10mg	N	8	8	8
	Mean	138.34	8.82	6.38
	SD	40.254	1.850	3.472
	CV (%)	29.1	21.0	54.5
Adderall 10mg	N	9	9	9
	Mean	142.82	10.64	3.22
	SD	46.422	3.486	1.460
	CV (%)	32.5	32.8	45.3
Placebo	N	9	9	9
	Mean	na	na	na
	SD			
	CV (%)			

Generation: 20JUL00 t03_2_4.sas/COPPR

Table 3.2.5
Comparative Analysis of the Steady State PK Parameters*
Protocol # 381.201

Measure	Parameter	Source of Variation	SS	df	MS	F	p
D-amphetamine	AUCT	Treatment	3970080.09	3	1323360.03	22.28	0.000
		Error	1663346.32	28	59405.23		
	Cmax	Treatment	15241.62	3	5080.54	26.91	0.000
		Error	5285.84	28	188.78		
	Tmax	Treatment	46.55	3	15.52	3.05	0.045
		Error	142.38	28	5.08		
L-amphetamine	AUCT	Treatment	418128.71	3	139376.24	16.72	0.000
		Error	233411.21	28	8336.11		
	Cmax	Treatment	1541.62	3	513.87	20.51	0.000
		Error	701.62	28	25.06		
	Tmax	Treatment	48.57	3	16.19	2.80	0.058
		Error	161.93	28	5.78		

NOTE: Placebo excluded from the analysis due to all zero data.

Generation: 20JUL00 t03_2_5.sas/COPPR

Table 3.2.6 (Page 1 of 1)
Comparative Analysis of the Steady State Plasma Drug Levels Between SLI381 10mg and Adderall 10mg by Sampling Time
Protocol # 381.201

Metabolite	Time (hr) Sampled Post Dose	Treatment (Mean(SD)) SLI381 10mg	Adderall 10mg	t-value	p
D-amphetamine	0	7.99 (3.470)	6.16 (3.889)	1.00	0.3359
	0.5	8.54 (1.751)	12.58 (18.254)	-0.62	0.5427
	1.5	18.72 (7.047)	26.73 (16.514)	-1.27	0.2238
	3.0	24.09 (3.205)	32.05 (9.706)	-2.21	0.0432
	4.5	27.28 (6.503)	30.67 (7.878)	-0.96	0.3530
	6.0	25.58 (6.407)	27.31 (7.574)	-0.51	0.6206
	7.5	23.73 (7.168)	24.78 (7.380)	-0.29	0.7722
	9.0	21.94 (6.309)	22.14 (6.708)	-0.06	0.9499
	10.5	21.21 (6.980)	18.65 (6.440)	0.74	0.4727
	12.0	20.41 (6.424)	14.78 (4.686)	2.08	0.0552
	24.0	10.49 (2.227)	6.98 (5.091)	1.70	0.1120
L-amphetamine	0	2.95 (1.089)	2.46 (1.472)	0.75	0.4650
	0.5	3.06 (0.492)	4.35 (5.673)	-0.64	0.5324
	1.5	5.82 (1.946)	8.49 (4.968)	-1.42	0.1761
	3.0	7.31 (1.030)	10.14 (3.139)	-2.43	0.0279
	4.5	8.32 (1.893)	9.80 (2.666)	-1.30	0.2131
	6.0	7.85 (1.917)	8.90 (2.502)	-0.96	0.3510
	7.5	7.46 (2.246)	8.11 (2.452)	-0.57	0.5774
	9.0	6.95 (2.005)	7.46 (2.204)	-0.50	0.6228
	10.5	6.88 (2.237)	6.35 (2.210)	0.47	0.6493
	12.0	6.57 (1.912)	5.18 (1.627)	1.62	0.1251
	24.0	3.66 (0.660)	2.71 (1.636)	1.43	0.1733

Generation: 20JUL00 t03_2_6.sas/COPPR

Table 3.3.1
Descriptive Statistics of the Pearson Correlation Coefficients (r) Between the D-Amphetamine Levels and the PD Measures Obtained During the Makeup Week
Protocol # 381.201

Treatment		SKAMP Score		PERMP Measures	
		Attention	Deportment	Number Attempted	Number Correct
SLI381 30mg	N	6	6	6	6
	Mean (SD)	-0.388 (0.3521)	-0.305 (0.4112)	0.456 (0.4714)	0.466 (0.4680)
	95% CI	-0.758, -0.019	-0.737, 0.127	-0.038, 0.951	-0.025, 0.957
SLI381 20mg	N	9	9	9	9
	Mean (SD)	-0.320 (0.4606)	-0.358 (0.3475)	0.463 (0.2724)	0.450 (0.2738)
	95% CI	-0.674, 0.034	-0.625, -0.090	0.254, 0.673	0.239, 0.660
SLI381 10mg	N	8	8	8	8
	Mean (SD)	-0.231 (0.3788)	-0.156 (0.3020)	0.453 (0.3198)	0.448 (0.3264)
	95% CI	-0.548, 0.085	-0.408, 0.097	0.186, 0.721	0.175, 0.721
Adderall 10mg	N	9	9	9	9
	Mean (SD)	-0.150 (0.4103)	-0.074 (0.3054)	0.446 (0.4618)	0.469 (0.4489)
	95% CI	-0.466, 0.165	-0.309, 0.160	0.091, 0.801	0.124, 0.814

Generation: 20JUL00

t03_3_1.sas/COPPR

Table 3.3.2 (Page 1 of 1)
Descriptive Statistics of the Pearson Correlation Coefficients (r) Between the L-Amphetamine Levels and the PD Measures Obtained During the Makeup Week
Protocol # 381.201

Treatment		SKAMP Score		PERMP Measures	
		Attention	Deportment	Number Attempted	Number Correct
SLI381 30mg	N	6	6	6	6
	Mean (SD)	-0.376 (0.3617)	-0.315 (0.3952)	0.462 (0.4672)	0.473 (0.4643)
	95% CI	-0.755, 0.004	-0.730, 0.099	-0.028, 0.953	-0.014, 0.960
SLI381 20mg	N	9	9	9	9
	Mean (SD)	-0.347 (0.4037)	-0.369 (0.3702)	0.426 (0.2640)	0.410 (0.2629)
	95% CI	-0.658, -0.037	-0.653, -0.084	0.223, 0.629	0.208, 0.612
SLI381 10mg	N	8	8	8	8
	Mean (SD)	-0.210 (0.3798)	-0.145 (0.3100)	0.457 (0.3093)	0.451 (0.3169)
	95% CI	-0.527, 0.108	-0.404, 0.114	0.199, 0.716	0.186, 0.716
Adderall 10mg	N	9	9	9	9
	Mean (SD)	-0.130 (0.4002)	-0.067 (0.3178)	0.428 (0.4685)	0.451 (0.4551)
	95% CI	-0.438, 0.178	-0.311, 0.177	0.068, 0.788	0.102, 0.801

Generation: 20JUL00 t03_3_2.sas/COPPR

Table 4.1.1
Patient Drug Exposure During Randomized Treatment Weeks
Protocol # 381.201

Population	Length of Exposure	Treatment (N) Placebo	Adderall 10 mg	SLI381 10 mg	SLI381 20 mg	SLI381 30 mg
Study Participants	0 days	2	3	3	1	2
	1 day	0	0	0	1	0
	2-3 days	1	0	0	0	0
	4-7 days	38	37	39	40	41
	8-14 days	10	11	9	9	8
	Total	51	51	51	51	51
Male	0 days	1	2	2	1	2
	1 day	0	0	0	1	0
	2-3 days	1	0	0	0	0
	4-7 days	33	32	35	33	36
	8-14 days	9	10	7	9	6
	Total	44	44	44	44	44
Female	0 days	1	1	1	0	0
	1 day	0	0	0	0	0
	2-3 days	0	0	0	0	0
	4-7 days	5	5	4	7	5
	8-14 days	1	1	2	0	2
	Total	7	7	7	7	7

NOTE: Exposure calculated as the date of last dose minus first dose plus 1.
Practice visit exposure excluded in this table.

Generation: 24JUL00

t04_1_1.sas/COPPR

Table 5.1.1
Number of Adverse Medical Experiences by Body System and Preferred Term
Protocol # 381.201

Body System	COSTART Term	Total	Pre-Dose	Practice Visit SLI381 20 mg	Treatment				
					Placebo	Adderall 10 mg	SLI381 10 mg	SLI381 20 mg	SLI381 30 mg
Total Events		1031	4	108	161	200	174	200	184
Body as a Whole	ABDOMINAL PAIN	92	1	4	14	21	14	19	19
	HEADACHE	89	3	8	14	17	14	18	15
	ASTHENIA	66	0	6	10	15	9	14	12
	MALAISE	46	0	4	8	13	7	10	4
	ACCIDENTAL INJURY	11	0	1	1	4	0	2	3
	INFECTION	10	0	0	1	2	3	2	2
	FLU SYNDROME	5	0	0	1	0	1	1	2
	CHEST PAIN	2	0	0	0	0	0	2	0
	INFECTION BACTERIAL	2	0	0	0	0	0	1	1
	FACE EDEMA	1	0	0	0	0	0	1	0
	NECK PAIN	1	0	0	0	0	0	0	1
	PAIN	1	0	0	0	0	1	0	0
	VIRAL INFECTION	1	0	0	1	0	0	0	0
Cardiovascular	PALLOR	1	0	1	0	0	0	0	0
Digestive	ANOREXIA	126	0	15	11	27	13	24	36
	NAUSEA	8	0	3	0	2	0	0	3
	VOMITING	8	0	3	0	1	1	2	1
	DIARRHEA	2	0	1	0	1	0	0	0
	DYSPEPSIA	1	0	1	0	0	0	0	0
	LIVER FUNCTION TESTS ABNORMAL	1	0	1	0	0	0	0	0
	TOOTH CARIES	1	0	0	1	0	0	0	0

Generation: 06JUL00 t05_1_1.sas/COPPR

Table 5.1.1 (Page 2 of 3)
Number of Adverse Medical Experiences by Body System and Preferred Term
Protocol # 381.201

Body System	COSTART Term	Total	Pre-Dose	Practice Visit SLI381 20 mg	Treatment				
					Placebo	Adderall 10 mg	SLI381 10 mg	SLI381 20 mg	SLI381 30 mg
Hemalytic & Lymphatic	LYMPHADENOPATHY	2	0	0	0	0	1	0	1
	ECCHYMOSIS	1	0	0	1	0	0	0	0
Musculoskeletal	MYALGIA	1	0	0	0	0	0	1	0
Nervous	NERVOUSNESS	193	0	14	39	33	44	35	28
	INSOMNIA	80	0	9	10	18	8	17	18
	ANXIETY	68	0	9	12	12	15	11	9
	EMOTIONAL LABILITY	65	0	9	6	10	18	13	9
	DEPRESSION	32	0	4	5	4	5	11	3
	PERSONALITY DISORDER	24	0	1	8	7	5	1	2
	MOVEMENT DISORDER	18	0	4	3	2	3	1	5
	TWITCHING	18	0	4	5	1	2	2	4
	HOSTILITY	16	0	0	4	3	4	4	1
	SOMNOLENCE	11	0	2	1	3	2	3	0
	HYPERKINESIA	6	0	1	2	1	1	1	0
	DIZZINESS	3	0	2	0	1	0	0	0
	AGITATION	1	0	0	1	0	0	0	0
	HALLUCINATIONS	1	0	0	0	0	0	0	1
	THINKING ABNORMAL	1	0	0	0	1	0	0	0
	VASODILATATION	1	0	1	0	0	0	0	0
Respiratory	COUGH INCREASED	4	0	0	0	1	1	2	0
	PHARYNGITIS	3	0	0	0	0	1	1	1
	RHINITIS	2	0	0	1	0	1	0	0
	SINUSITIS	1	0	0	0	0	0	0	1

Generation: 06JUL00 t05_1_1.sas/COPPR

Table 5.1.1 (Page 3 of 3)
Number of Adverse Medical Experiences by Body System and Preferred Term
Protocol # 381.201

Body System	COSTART Term	Total	Pre-Dose	Practice Visit SLI381 20 mg	Treatment				
					Placebo	Adderall 10 mg	SLI381 10 mg	SLI381 20 mg	SLI381 30 mg
Skin	ACNE	1	0	0	0	0	0	0	1
	RASH	1	0	0	0	0	0	0	1
	SKIN NODULE	1	0	0	1	0	0	0	0
Special Senses	CONJUNCTIVITIS	1	0	0	0	0	0	1	0

Generation: 06JUL00 t05_1_1.sas/COPPR

Table 5.1.2 (Page 1 of 1)
Number of Adverse Medical Experiences by Body System and Preferred Term - Serious Events
Protocol # 381.201

				Treatment				
Body System	COSTART Term	Total	Pre-Dose	Placebo	Adderall 10 mg	SLI381 10 mg	SLI381 20 mg	SLI381 30 mg
Total Events		0	0	0	0	0	0	0

Generation: 06JUL00 t05_1_2.sas/COPPR

Table 5.1.3 (Page 1 of 3)
Number of Adverse Medical Experiences by Body System and Preferred Term - Non-serious Events
Protocol # 381.201

				Treatment				
Body System	COSTART Term	Total	Pre-Dose	Placebo	Adderall 10 mg	SLI381 10 mg	SLI381 20 mg	SLI381 30 mg
Total Events		1031	4	161	200	174	308	184
Body as a Whole	ABDOMINAL PAIN	92	1	14	21	14	23	19
	HEADACHE	89	3	14	17	14	26	15
	ASTHENIA	66	0	10	15	9	20	12
	MALAISE	46	0	8	13	7	14	4
	ACCIDENTAL INJURY	11	0	1	4	0	3	3
	INFECTION	10	0	1	2	3	2	2
	FLU SYNDROME	5	0	1	0	1	1	2
	CHEST PAIN	2	0	0	0	0	2	0
	INFECTION BACTERIAL	2	0	0	0	0	1	1
	FACE EDEMA	1	0	0	0	0	1	0
	NECK PAIN	1	0	0	0	0	0	1
	PAIN	1	0	0	0	1	0	0
	VIRAL INFECTION	1	0	1	0	0	0	0
Cardiovascular	PALLOR	1	0	0	0	0	1	0
Digestive	ANOREXIA	126	0	11	27	13	39	36
	NAUSEA	8	0	0	2	0	3	3
	VOMITING	8	0	0	1	1	5	1
	DIARRHEA	2	0	0	1	0	1	0
	DYSPEPSIA	1	0	0	0	0	1	0
	LIVER FUNCTION TESTS ABNORMAL	1	0	0	0	0	1	0
	TOOTH CARIES	1	0	1	0	0	0	0
Hemalytic & Lymphatic	LYMPHADENOPATHY	2	0	0	0	1	0	1
	ECCHYMOSIS	1	0	1	0	0	0	0

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Table 5.1.3 (Page 2 of 3)
Number of Adverse Medical Experiences by Body System and Preferred Term - Non-serious Events
Protocol # 381.201

				Treatment				
Body System	COSTART Term	Total	Pre-Dose	Placebo	Adderall 10 mg	SLI381 10 mg	SLI381 20 mg	SLI381 30 mg
Musculoskeletal	MYALGIA	1	0	0	0	0	1	0
Nervous	NERVOUSNESS	193	0	39	33	44	49	28
	INSOMNIA	80	0	10	18	8	26	18
	ANXIETY	68	0	12	12	15	20	9
	EMOTIONAL LABILITY	65	0	6	10	18	22	9
	DEPRESSION	32	0	5	4	5	15	3
	PERSONALITY DISORDER	24	0	8	7	5	2	2
	MOVEMENT DISORDER	18	0	3	2	3	5	5
	TWITCHING	18	0	5	1	2	6	4
	HOSTILITY	16	0	4	3	4	4	1
	SOMNOLENCE	11	0	1	3	2	5	0
	HYPERKINESIA	6	0	2	1	1	2	0
	DIZZINESS	3	0	0	1	0	2	0
	AGITATION	1	0	1	0	0	0	0
	HALLUCINATIONS	1	0	0	0	0	0	1
	THINKING ABNORMAL	1	0	0	1	0	0	0
	VASODILATATION	1	0	0	0	0	1	0
Respiratory	COUGH INCREASED	4	0	0	1	1	2	0
	PHARYNGITIS	3	0	0	0	1	1	1
	RHINITIS	2	0	1	0	1	0	0
	SINUSITIS	1	0	0	0	0	0	1
Skin	ACNE	1	0	0	0	0	0	1
	RASH	1	0	0	0	0	0	1
	SKIN NODULE	1	0	1	0	0	0	0

Generation: 06JUL00 t05_1_3.sas/COPPR

Table 5.1.3 (Page 3 of 3)
Number of Adverse Medical Experiences by Body System and Preferred Term - Non-serious Events
Protocol # 381.201

				Treatment				
Body System	COSTART Term	Total	Pre-Dose	Placebo	Adderall 10 mg	SLI381 10 mg	SLI381 20 mg	SLI381 30 mg
Special Senses	CONJUNCTIVITIS	1	0	0	0	0	1	0

Generation: 06JUL00 t05_1_3.sas/COPPR

Table 5.2.1 (Page 1 of 6)
Number (%) of Patients Reporting Post-Randomization Adverse Medical Experiences by Body System and Preferred Term - All Causality
Protocol # 381.201

Body System	COSTART Term	Patients Reporting	No. of AMEs in the Report Term	Adverse Medical Experience (Reported Term)	No. of AMEs as Reported
Body as a Whole	ABDOMINAL PAIN	38 (74.5%)	92	STOMACH ACHE	74
				STOMACH ACHES	17
				STOMACH PAIN	1
	ACCIDENTAL INJURY	10 (19.6%)	11	ABRASION ON RIGHT HAND	1
				ABRASION TO LEFT KNEE	1
				ABRASION TO RIGHT KNEE	1
				BITE FROM CHILD	1
				BRUISED FINGER RIGHT INDEX FINGER	1
				CUT SKIN ON LEFT EAR	1
				FACIAL SCRATCHES	1
				JAMMED RIGHT THUMB	1
				MILD ABRASION TO (LEFT) HAND	1
				MOUTH INJURY	1
				THUMB INJURY	1
	ASTHENIA	26 (51.0%)	66	TIRED	66
	CHEST PAIN	2 (3.9%)	2	CHEST PAIN	1
				LEFT CHEST PAIN	1
	FACE EDEMA	1 (2.0%)	1	LEFT LOWER EYELID SWELLING	1
	FLU SYNDROME	5 (9.8%)	5	FLU SYMPTOMS	3
				FLU VIRUS	1
				FLU-LIKE SYMPTOMS	1

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Table 5.2.1 (Page 2 of 6)
Number (%) of Patients Reporting Post-Randomization Adverse Medical Experiences by Body System and Preferred Term - All Causality
Protocol # 381.201

Body System	COSTART Term	Patients Reporting	No. of AMEs in the Report Term	Adverse Medical Experience (Reported Term)	No. of AMEs as Reported
Body as a Whole	HEADACHE	32 (62.7%)	89	HEAD ACHE	1
				HEADACHE	70
				HEADACHES	16
				SINUS HEADACHE	2
	INFECTION	8 (15.7%)	10	COLD SYMPTOMS	10
	INFECTION BACTERIAL	2 (3.9%)	2	STREP THROAT	2
	MALAISE	24 (47.1%)	46	LISTLESS	35
				LISTLESSNESS	11
	NECK PAIN	1 (2.0%)	1	NECK PAIN	1
	PAIN	1 (2.0%)	1	PAIN IN SIDE	1
	VIRAL INFECTION	1 (2.0%)	1	STOMACH VIRUS	1
Cardiovascular	PALLOR	1 (2.0%)	1	PALLOR	1
Digestive	ANOREXIA	46 (90.2%)	126	APPETITE LOSS	123
				POOR APPETITE	3
	DIARRHEA	2 (3.9%)	2	DIARRHEA	2
	DYSPEPSIA	1 (2.0%)	1	UPSET STOMACH	1

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Table 5.2.1 (Page 3 of 6)
Number (%) of Patients Reporting Post-Randomization Adverse Medical Experiences by Body System and Preferred Term - All Causality
Protocol # 381.201

Body System	COSTART Term	Patients Reporting	No. of AMEs in the Report Term	Adverse Medical Experience (Reported Term)	No. of AMEs as Reported
Digestive	LIVER FUNCTION TESTS ABNORMAL	1 (2.0%)	1	TRANSIENT HEPATIC DYSFUCTION	1
	NAUSEA	8 (15.7%)	8	FEELING QUEASY	1
				NAUSEA	6
				QUEASINESS	1
	TOOTH CARIES	1 (2.0%)	1	DENTAL CAVITY	1
	VOMITING	7 (13.7%)	8	VOMITING	6
				VOMITTING	2
Hemalytic & Lymphatic	ECCHYMOSIS	1 (2.0%)	1	RIGHT OCCULAR CONTUSION	1
	LYMPHADENOPATHY	2 (3.9%)	2	CERVICAL ADENOPATHY	2
Musculoskeletal	MYALGIA	1 (2.0%)	1	MUSCLE ACHES	1
Nervous	AGITATION	1 (2.0%)	1	AGITATION	1
	ANXIETY	31 (60.8%)	68	ANXIOUS	48
				ANXIOUSNESS	9
				WORRIED	11
	DEPRESSION	21 (41.2%)	32	DEPRESSED	23
				DEPRESSED AFFECT	9

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Table 5.2.1 (Page 4 of 6)
Number (%) of Patients Reporting Post-Randomization Adverse Medical Experiences by Body System and Preferred Term - All Causality
Protocol # 381.201

Body System	COSTART Term	Patients Reporting	No. of AMEs in the Report Term	Adverse Medical Experience (Reported Term)	No. of AMEs as Reported
Nervous	DIZZINESS	3 (5.9%)	3	DIZZINESS	1
				FEELING DIZZY	1
				LIGHTHEADEDNESS	1
	EMOTIONAL LABILITY	25 (49.0%)	65	CRYING	1
				SAD	49
				TEARFUL	15
	HALLUCINATIONS	1 (2.0%)	1	HALLUCINATIONS	1
	HOSTILITY	8 (15.7%)	16	AGGRESSIVE	11
				AGRESSIVE	1
				ANGER	1
				ANGRY	1
				CONFRONTATIONAL	1
				TANTRUM	1
	HYPERKINESIA	5 (9.8%)	6	HYPERACTIVE	3
				HYPERACTIVITY	3
	INSOMNIA	33 (64.7%)	80	(INSOMNIA)	1
				INSOMNIA	45
				TROUBLE SLEEPING	34
	MOVEMENT DISORDER	14 (27.5%)	18	BUCCAL (LINGUAL MOVEMENTS)	1
				BUCCAL - LINGUAL MOVEMENTS	3
				BUCCAL LINGUAL MOVEMENTS	1

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Table 5.2.1 (Page 5 of 6)
Number (%) of Patients Reporting Post-Randomization Adverse Medical Experiences by Body System and Preferred Term - All Causality
Protocol # 381.201

Body System	COSTART Term	Patients Reporting	No. of AMEs in the Report Term	Adverse Medical Experience (Reported Term)	No. of AMEs as Reported
Nervous	MOVEMENT DISORDER	14 (27.5%)	18	BUCCAL MOVEMENTS	2
				BUCCAL-LINGUAL MOVEMENTS	11
	NERVOUSNESS	48 (94.1%)	193	BITES LIPS	1
				BITING LIPS	1
				CRABBY-IRRITABLE	42
				IRRITABILITY	19
				IRRITABLE	95
				NAIL BITING	1
				PICKING AT SKIN	17
				PICKING AT SKIN AND CLOTHING	1
				PICKING-AT SKIN AND CLOTHING	14
				THROAT-CLEARING	2
	PERSONALITY DISORDER	9 (17.6%)	24	"OUT OF CONTROL"	1
				BEHAVIORAL NON-COMPLIANCE	3
				DEFIANT	2
				DISRUPTIVE	1
				IMPULSIVE	2
				INATTENTIVE (POOR BEHAVIOR)	1
				NON-COMPLIANT-PARENTAL INSTRUCTIONS	9
				OPPOSITIONAL-PARENTAL INSTRUCTION	1
				OPPOSITIONAL-PARENTAL INSTRUCTIONS	4
	SOMNOLENCE	7 (13.7%)	11	DULLNESS	11
	THINKING ABNORMAL	1 (2.0%)	1	MENTAL DULLNESS	1

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Table 5.2.1 (Page 6 of 6)
Number (%) of Patients Reporting Post-Randomization Adverse Medical Experiences by Body System and Preferred Term - All Causality
Protocol # 381.201

Body System	COSTART Term	Patients Reporting	No. of AMEs in the Report Term	Adverse Medical Experience (Reported Term)	No. of AMEs as Reported
Nervous	TWITCHING	12 (23.5%)	18	EYE BLINKING	1
				MOTOR TIC	1
				MOTOR TICS	15
				MOTOR TICS (MOUTH)	1
	VASODILATATION	1 (2.0%)	1	ALTERNATE HOT AND COLD FLASHES	1
Respiratory	COUGH INCREASED	3 (5.9%)	4	COUGH	2
				COUGH (VIRAL)	2
	PHARYNGITIS	3 (5.9%)	3	SORE THROAT	1
				UPPER RESPIRATORY INFECTION	2
	RHINITIS	2 (3.9%)	2	NASAL CONGESTION	2
	SINUSITIS	1 (2.0%)	1	SINUS INFECTION	1
Skin	ACNE	1 (2.0%)	1	FACIAL ACNE	1
	RASH	1 (2.0%)	1	RASH	1
	SKIN NODULE	1 (2.0%)	1	SMALL CERVICAL POSTERIOR NODE-CERVICA VE	1
Special Senses	CONJUNCTIVITIS	1 (2.0%)	1	INJECTED CONJUNCTIVA	1

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Table 5.2.2 (Page 1 of 2)
Number (%) of Patients Reporting Post-Randomization Adverse Medical Experiences by Treatment Group, Body System, and Preferred Term
Protocol # 381.201

Body System	COSTART Term	Treatment				
		Placebo (N=49)	Adderall 10mg (N=48)	SLI381 10mg (N=48)	SLI381 20mg (N=50)	SLI381 30mg (N=49)
Any Systems		40 (81.6%)	45 (93.8%)	40 (83.3%)	45 (90.0%)	41 (83.7%)
Body as a Whole	ABDOMINAL PAIN	12 (24.5%)	16 (33.3%)	14 (29.2%)	18 (36.0%)	17 (34.7%)
	HEADACHE	12 (24.5%)	12 (25.0%)	12 (25.0%)	15 (30.0%)	12 (24.5%)
	ASTHENIA	8 (16.3%)	11 (22.9%)	8 (16.7%)	12 (24.0%)	11 (22.4%)
	MALAISE	7 (14.3%)	11 (22.9%)	7 (14.6%)	8 (16.0%)	4 (8.2%)
	INFECTION	1 (2.0%)	2 (4.2%)	3 (6.3%)	2 (4.0%)	2 (4.1%)
	ACCIDENTAL INJURY	1 (2.0%)	4 (8.3%)	0 (0.0%)	2 (4.0%)	2 (4.1%)
	FLU SYNDROME	1 (2.0%)	0 (0.0%)	1 (2.1%)	1 (2.0%)	2 (4.1%)
	CHEST PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.0%)	0 (0.0%)
	INFECTION BACTERIAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)
	FACE EDEMA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)
	NECK PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	PAIN	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
	VIRAL INFECTION	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Digestive	ANOREXIA	11 (22.4%)	22 (45.8%)	13 (27.1%)	20 (40.0%)	27 (55.1%)
	NAUSEA	0 (0.0%)	2 (4.2%)	0 (0.0%)	0 (0.0%)	3 (6.1%)
	VOMITING	0 (0.0%)	1 (2.1%)	1 (2.1%)	2 (4.0%)	1 (2.0%)
	DIARRHEA	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	TOOTH CARIES	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hemalytic & Lymphatic	LYMPHADENOPATHY	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	1 (2.0%)
	ECCHYMOSIS	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Musculoskeletal	MYALGIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)

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Table 5.2.2 (Page 2 of 2)
Number (%) of Patients Reporting Post-Randomization Adverse Medical Experiences by Treatment Group, Body System, and Preferred Term
Protocol # 381.201

		Treatment				
Body System	COSTART Term	Placebo (N=49)	Adderall 10mg (N=48)	SLI381 10mg (N=48)	SLI381 20mg (N=50)	SLI381 30mg (N=49)
Nervous	NERVOUSNESS	29 (59.2%)	22 (45.8%)	26 (54.2%)	28 (56.0%)	21 (42.9%)
	INSOMNIA	10 (20.4%)	17 (35.4%)	6 (12.5%)	16 (32.0%)	14 (28.6%)
	ANXIETY	10 (20.4%)	11 (22.9%)	13 (27.1%)	11 (22.0%)	9 (18.4%)
	EMOTIONAL LABILITY	5 (10.2%)	10 (20.8%)	13 (27.1%)	9 (18.0%)	6 (12.2%)
	DEPRESSION	5 (10.2%)	4 (8.3%)	5 (10.4%)	11 (22.0%)	3 (6.1%)
	PERSONALITY DISORDER	5 (10.2%)	6 (12.5%)	5 (10.4%)	1 (2.0%)	2 (4.1%)
	MOVEMENT DISORDER	3 (6.1%)	2 (4.2%)	3 (6.3%)	1 (2.0%)	5 (10.2%)
	TWITCHING	5 (10.2%)	1 (2.1%)	2 (4.2%)	2 (4.0%)	4 (8.2%)
	HOSTILITY	3 (6.1%)	3 (6.3%)	2 (4.2%)	2 (4.0%)	1 (2.0%)
	SOMNOLENCE	1 (2.0%)	3 (6.3%)	2 (4.2%)	2 (4.0%)	0 (0.0%)
	HYPERKINESIA	2 (4.1%)	1 (2.1%)	1 (2.1%)	1 (2.0%)	0 (0.0%)
	AGITATION	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	DIZZINESS	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	HALLUCINATIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	THINKING ABNORMAL	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory	COUGH INCREASED	0 (0.0%)	1 (2.1%)	1 (2.1%)	2 (4.0%)	0 (0.0%)
	PHARYNGITIS	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (2.0%)	1 (2.0%)
	RHINITIS	1 (2.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
	SINUSITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
Skin	ACNE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	SKIN NODULE	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Special Senses	CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)

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Table 5.2.3 (Page 1 of 2)
Number (%) of Patients Reporting Unrelated Post-Randomization Adverse Medical Experiences by Treatment Group, Body System, and Preferred Term
Protocol # 381.201

Body System	COSTART Term	Treatment				
		Placebo (N=49)	Adderall 10mg (N=48)	SLI381 10mg (N=48)	SLI381 20mg (N=50)	SLI381 30mg (N=49)
Any Systems		15 (30.6%)	15 (31.3%)	16 (33.3%)	17 (34.0%)	13 (26.5%)
Body as a Whole	ASTHENIA	3 (6.1%)	2 (4.2%)	1 (2.1%)	4 (8.0%)	1 (2.0%)
	INFECTION	1 (2.0%)	2 (4.2%)	3 (6.3%)	2 (4.0%)	2 (4.1%)
	ABDOMINAL PAIN	5 (10.2%)	3 (6.3%)	0 (0.0%)	1 (2.0%)	0 (0.0%)
	ACCIDENTAL INJURY	0 (0.0%)	4 (8.3%)	0 (0.0%)	2 (4.0%)	2 (4.1%)
	HEADACHE	2 (4.1%)	0 (0.0%)	1 (2.1%)	2 (4.0%)	0 (0.0%)
	FLU SYNDROME	1 (2.0%)	0 (0.0%)	1 (2.1%)	1 (2.0%)	1 (2.0%)
	CHEST PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.0%)	0 (0.0%)
	INFECTION BACTERIAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)
	FACE EDEMA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)
	NECK PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	PAIN	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
	VIRAL INFECTION	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Digestive	VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.0%)	1 (2.0%)
	NAUSEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	TOOTH CARIES	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hemalytic & Lymphatic	LYMPHADENOPATHY	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	1 (2.0%)
	ECCHYMOSIS	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Musculoskeletal	MYALGIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)
Nervous	NERVOUSNESS	6 (12.2%)	1 (2.1%)	3 (6.3%)	4 (8.0%)	1 (2.0%)
	PERSONALITY DISORDER	4 (8.2%)	6 (12.5%)	3 (6.3%)	1 (2.0%)	1 (2.0%)
	EMOTIONAL LABILITY	2 (4.1%)	2 (4.2%)	2 (4.2%)	1 (2.0%)	2 (4.1%)

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Table 5.2.3 (Page 2 of 2)
Number (%) of Patients Reporting Unrelated Post-Randomization Adverse Medical Experiences by Treatment Group, Body System, and Preferred Term
Protocol # 381.201

		Treatment				
Body System	COSTART Term	Placebo (N=49)	Adderall 10mg (N=48)	SLI381 10mg (N=48)	SLI381 20mg (N=50)	SLI381 30mg (N=49)
Nervous	HOSTILITY	2 (4.1%)	3 (6.3%)	1 (2.1%)	2 (4.0%)	1 (2.0%)
	HYPERKINESIA	2 (4.1%)	1 (2.1%)	1 (2.1%)	1 (2.0%)	0 (0.0%)
	ANXIETY	2 (4.1%)	0 (0.0%)	1 (2.1%)	1 (2.0%)	0 (0.0%)
	MOVEMENT DISORDER	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	DEPRESSION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	TWITCHING	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory	COUGH INCREASED	0 (0.0%)	1 (2.1%)	1 (2.1%)	2 (4.0%)	0 (0.0%)
	PHARYNGITIS	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (2.0%)	1 (2.0%)
	RHINITIS	1 (2.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
	SINUSITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
Skin	ACNE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	SKIN NODULE	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Special Senses	CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)

Generation: 06JUL00 t05_2_3.sas/COPPR

Table 5.2.4 (Page 1 of 2)
Number (%) of Patients Reporting Possibly Related Post-Randomization Adverse Medical Experiences by
Treatment Group, Body System, and Preferred Term
Protocol # 381.201

		Treatment				
Body System	COSTART Term	Placebo (N=49)	Adderall 10mg (N=48)	SLI381 10mg (N=48)	SLI381 20mg (N=50)	SLI381 30mg (N=49)
Any Systems		36 (73.5%)	41 (85.4%)	35 (72.9%)	39 (78.0%)	39 (79.6%)
Body as a Whole	ABDOMINAL PAIN	8 (16.3%)	13 (27.1%)	14 (29.2%)	17 (34.0%)	17 (34.7%)
	HEADACHE	11 (22.4%)	12 (25.0%)	11 (22.9%)	14 (28.0%)	12 (24.5%)
	ASTHENIA	6 (12.2%)	9 (18.8%)	7 (14.6%)	8 (16.0%)	10 (20.4%)
	MALAISE	7 (14.3%)	11 (22.9%)	7 (14.6%)	8 (16.0%)	4 (8.2%)
	ACCIDENTAL INJURY	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	FLU SYNDROME	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
Digestive	ANOREXIA	11 (22.4%)	21 (43.8%)	13 (27.1%)	20 (40.0%)	28 (57.1%)
	NAUSEA	0 (0.0%)	2 (4.2%)	0 (0.0%)	0 (0.0%)	2 (4.1%)
	VOMITING	0 (0.0%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
	DIARRHEA	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nervous	NERVOUSNESS	25 (51.0%)	21 (43.8%)	23 (47.9%)	24 (48.0%)	20 (40.8%)
	INSOMNIA	10 (20.4%)	17 (35.4%)	6 (12.5%)	16 (32.0%)	14 (28.6%)
	ANXIETY	8 (16.3%)	11 (22.9%)	12 (25.0%)	10 (20.0%)	9 (18.4%)
	EMOTIONAL LABILITY	3 (6.1%)	8 (16.7%)	11 (22.9%)	8 (16.0%)	4 (8.2%)
	DEPRESSION	5 (10.2%)	4 (8.3%)	5 (10.4%)	11 (22.0%)	2 (4.1%)
	TWITCHING	4 (8.2%)	1 (2.1%)	2 (4.2%)	2 (4.0%)	4 (8.2%)
	MOVEMENT DISORDER	2 (4.1%)	2 (4.2%)	3 (6.3%)	1 (2.0%)	4 (8.2%)
	SOMNOLENCE	1 (2.0%)	3 (6.3%)	2 (4.2%)	2 (4.0%)	0 (0.0%)
	PERSONALITY DISORDER	1 (2.0%)	1 (2.1%)	2 (4.2%)	0 (0.0%)	1 (2.0%)
	HOSTILITY	1 (2.0%)	0 (0.0%)	2 (4.2%)	1 (2.0%)	0 (0.0%)
	AGITATION	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	DIZZINESS	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	HALLUCINATIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)

Generation: 05JUL00 t05_2_4.sas/COPPR

Table 5.2.4 (Page 2 of 2)
Number (%) of Patients Reporting Possibly Related Post-Randomization Adverse Medical Experiences by
Treatment Group, Body System, and Preferred Term
Protocol # 381.201

		Treatment				
Body System	COSTART Term	Placebo (N=49)	Adderall 10mg (N=48)	SLI381 10mg (N=48)	SLI381 20mg (N=50)	SLI381 30mg (N=49)
Nervous	THINKING ABNORMAL	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin	RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)

Generation: 05JUL00 t05_2_4.sas/COPPR

Table 5.2.5 (Page 1 of 1)
Number (%) of Patients Reporting Related Post-Randomization Adverse Medical Experiences by Treatment Group, Body System, and Preferred Term
Protocol # 381.201

		Treatment				
Body System	COSTART Term	Placebo (N=49)	Adderall 10mg (N=48)	SLI381 10mg (N=48)	SLI381 20mg (N=50)	SLI381 30mg (N=49)
Any Systems		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Generation: 06JUL00 t05_2_5.sas/COPPR

Table 5.2.6 (Page 1 of 1)

Number (%) of Patients Reporting Related or Possibly Related Severe Post-Randomization Adverse Medical Experiences by Treatment Group, Body System, and Preferred Term

Protocol # 381.201

		Treatment				
Body System	COSTART Term	Placebo (N=49)	Adderall 10mg (N=48)	SLI381 10mg (N=48)	SLI381 20mg (N=50)	SLI381 30mg (N=49)
Any Systems		7 (14.3%)	8 (16.7%)	6 (12.5%)	9 (18.0%)	8 (16.3%)
Body as a Whole	HEADACHE	1 (2.0%)	1 (2.1%)	1 (2.1%)	2 (4.0%)	0 (0.0%)
	ABDOMINAL PAIN	0 (0.0%)	1 (2.1%)	0 (0.0%)	2 (4.0%)	0 (0.0%)
	ASTHENIA	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	FLU SYNDROME	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
	MALAISE	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
Digestive	ANOREXIA	1 (2.0%)	1 (2.1%)	1 (2.1%)	1 (2.0%)	3 (6.1%)
Nervous	NERVOUSNESS	3 (6.1%)	5 (10.4%)	4 (8.3%)	5 (10.0%)	1 (2.0%)
	INSOMNIA	1 (2.0%)	2 (4.2%)	1 (2.1%)	2 (4.0%)	2 (4.1%)
	ANXIETY	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	2 (4.1%)
	EMOTIONAL LABILITY	1 (2.0%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
	MOVEMENT DISORDER	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	2 (4.1%)
	TWITCHING	1 (2.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)

Generation: 06JUL00 t05_2_6.sas/COPPR

Table 5.3.1
List of Serious Adverse Events
Protocol # 381.201

Treatment	Patient ID	Age (yr)	Gender	Adv. Med. Exp. Reported Term	Adv. Med. Exp. Preferred Term	Drug Relation	Medwatch Filed
Placebo							
Adderall 10mg							
SLI381 10mg							
SLI381 20mg							
SLI381 30mg							

NOTE: Blank records indicate no reports of serious adverse medical experiences for that treatment.

Generation: 04MAY00 t05_3_1.sas/COPPR

Table 5.3.2
List of Patients Withdrawn Due to Adverse Medical Experiences
Protocol # 381.201

Treatment	Site	Screening Number	Age (yr)	Gender	Diagnosis	Study Outcome	Adv. Med. Exp. Causing Termination
Placebo	Site 3	11	7	Male	Combined	Adverse medical experience	AGITATION
Adderall 10mg							
SLI381 10mg							
SLI381 20mg	Site 1	08	9	Male	Combined	Adverse medical experience	STOMACH ACHE
SLI381 30mg							

NOTE: Blank records denote no patients withdrawn due to AME for that treatment.

Generation: 04MAY00 t05_3_2.sas/COPPR

Table 6.1.1 (Page 1 of 1)
Descriptive Statistics for the Sitting Systolic Blood Pressure (mm Hg)
Protocol # 381.201

Time Post Dose		Practice Visit SLI381 20mg	Randomized Treatment Placebo	Adderall 10mg	SLI381 10mg	SLI381 20mg	SLI381 30mg
Pre-dose	N	51	55	54	50	54	52
	Mean (SD)	112.8 (12.40)	112.6 (13.75)	108.4 (11.50)	108.9 (14.36)	107.9 (11.68)	106.8 (13.56)
	Min - Max	85 - 148	81 - 139	86 - 149	70 - 137	74 - 138	84 - 150
1.5 hours	N		53	54	50	53	50
	Mean (SD)		111.5 (13.13)	112.7 (12.03)	111.6 (13.07)	113.2 (15.56)	113.8 (12.22)
	Min - Max		82 - 139	81 - 135	75 - 162	66 - 147	75 - 148
4.5 hours	N		53	52	50	54	50
	Mean (SD)		111.6 (12.36)	109.9 (13.57)	110.1 (13.86)	110.9 (11.41)	111.3 (11.85)
	Min - Max		73 - 140	86 - 161	82 - 139	76 - 134	93 - 147
7.5 hours	N		52	53	50	54	50
	Mean (SD)		108.8 (13.51)	107.6 (13.13)	111.7 (13.00)	111.3 (13.03)	112.5 (11.23)
	Min - Max		80 - 145	80 - 136	91 - 151	79 - 137	90 - 155

NOTE: The follow-up visit (Visit 8) is included, so subjects may have the same treatment more than once

Generation: 04MAY00 t06_1_1.sas/COPPR

Table 6.1.2
Descriptive Statistics for the Sitting Diastolic Blood Pressure (mm Hg)
Protocol # 381.201

Time Post Dose		Practice Visit SLI381 20mg	Randomized Treatment Placebo	Adderall 10mg	SLI381 10mg	SLI381 20mg	SLI381 30mg
Pre-dose	N	51	55	54	50	54	52
	Mean (SD)	65.9 (7.78)	66.8 (8.83)	64.2 (9.41)	66.4 (8.58)	66.9 (9.60)	65.4 (8.96)
	Min - Max	54 - 93	51 - 93	46 - 92	47 - 81	50 - 96	50 - 92
1.5 hours	N		53	54	50	53	50
	Mean (SD)		66.5 (10.43)	65.2 (8.29)	65.4 (8.84)	66.7 (8.94)	67.9 (8.10)
	Min - Max		36 - 92	40 - 83	49 - 98	51 - 84	41 - 81
4.5 hours	N		53	52	50	54	50
	Mean (SD)		65.1 (8.46)	66.0 (8.31)	65.4 (7.93)	67.6 (6.96)	67.8 (7.25)
	Min - Max		44 - 86	47 - 85	49 - 79	49 - 91	55 - 90
7.5 hours	N		52	53	50	54	50
	Mean (SD)		63.4 (9.28)	63.7 (7.80)	65.4 (8.20)	65.0 (8.97)	68.5 (8.37)
	Min - Max		40 - 102	46 - 93	52 - 93	44 - 85	53 - 97

NOTE: The follow-up visit (Visit 8) is included, so subjects may have the same treatment more than once

Generation: 04MAY00 t06_1_2.sas/COPPR

Table 6.1.3
Descriptive Statistics for the Sitting Pulse Rate (bpm)
Protocol # 381.201

Time Post Dose		Practice Visit SLI381 20mg	Randomized Treatment Placebo	Adderall 10mg	SLI381 10mg	SLI381 20mg	SLI381 30mg
Pre-dose	N	51	55	54	50	54	52
	Mean (SD)	85.5 (9.92)	89.9 (13.46)	84.2 (13.45)	84.4 (12.57)	84.7 (14.68)	87.3 (12.80)
	Min - Max	57 - 108	59 - 119	57 - 125	60 - 119	61 - 123	53 - 119
1.5 hours	N		53	54	50	53	50
	Mean (SD)		98.9 (12.02)	98.7 (15.57)	95.1 (12.05)	97.0 (14.32)	96.9 (14.89)
	Min - Max		68 - 125	70 - 140	70 - 123	69 - 133	44 - 129
4.5 hours	N		53	52	50	54	50
	Mean (SD)		106.6 (15.23)	100.3 (11.78)	102.0 (13.24)	101.5 (16.76)	101.7 (12.38)
	Min - Max		67 - 129	74 - 126	75 - 133	69 - 137	77 - 131
7.5 hours	N		52	53	50	54	50
	Mean (SD)		102.8 (13.24)	97.4 (17.19)	97.4 (15.13)	93.7 (14.25)	99.9 (13.64)
	Min - Max		70 - 133	66 - 166	66 - 140	68 - 129	71 - 140

NOTE: The follow-up visit (Visit 8) is included, so subjects may have the same treatment more than once

Generation: 04MAY00 t06_1_3.sas/COPPR

Table 7.1.1 (Page 1 of 1)
Descriptive Statistics for the Side Effect Rating Scale* Obtained During the Core Randomization Treatment Weeks (Visits 3-7)
Protocol # 381.201

Scale		Treatment				
		Placebo	Adderall 10mg	SLI381 10mg	SLI381 20mg	SLI381 30mg
Parent	N	48	48	46	49	48
	Mean (SD)	0.347 (0.4385)	0.362 (0.3922)	0.342 (0.3524)	0.399 (0.3747)	0.398 (0.3180)
	Min - Max	0.000 - 2.273	0.000 - 1.727	0.000 - 1.273	0.000 - 1.455	0.000 - 1.000
Teacher	N	44	43	42	45	42
	Mean (SD)	0.064 (0.1123)	0.109 (0.1428)	0.079 (0.1279)	0.064 (0.0933)	0.052 (0.0917)
	Min - Max	0.000 - 0.400	0.000 - 0.600	0.000 - 0.500	0.000 - 0.300	0.000 - 0.300

* Individual scores computed as the mean response to the SERS questions at each visit.

Generation: 04MAY00 t07_1_1.sas/COPPR

Table 8.1.1
Descriptive Statistics for the Laboratory Parameters
Protocol # 381.201

Group	Test	Units		Screening	Baseline	Visit 8 (Follow-up) Observed	Visit 8 (Follow-up) Change from Baseline
Chemistry	ALBUMIN	G/DL	N	51	51	48	48
			Mean	4.549	4.478	4.606	0.135
			SD	0.203	0.209	0.276	0.235
	ALKALINE PHOSPHATASE	U/L	N	51	51	48	48
			Mean	273.941	271.608	264.354	0.979
			SD	97.131	99.586	86.185	31.238
	ALT (SGPT)	U/L	N	51	51	48	48
			Mean	16.000	17.078	16.833	-0.333
			SD	12.295	8.899	11.551	6.295
	AST (SGOT)	U/L	N	51	51	48	48
			Mean	23.706	27.529	24.563	-2.979
			SD	6.992	13.484	8.055	13.731
	BILIRUBIN, TOTAL	MG/DL	N	51	51	48	48
			Mean	0.422	0.461	0.438	-0.012
			SD	0.174	0.211	0.232	0.176
	CALCIUM	MG/DL	N	51	51	48	48
			Mean	9.622	9.739	9.642	-0.075
			SD	0.276	0.547	0.334	0.576
	CREATININE	MG/DL	N	51	49	48	46
			Mean	0.500	0.443	0.450	-0.004
			SD	0.111	0.135	0.117	0.123

Generation: 04MAY00 t08_1_1.sas/COPPR

Table 8.1.1
Descriptive Statistics for the Laboratory Parameters
Protocol # 381.201

Group	Test	Units		Screening	Baseline	Visit 8 (Follow-up) Observed	Visit 8 (Follow-up) Change from Baseline
Chemistry	GLUCOSE	MG/DL	N	51	51	48	48
			Mean	90.765	106.196	96.313	-10.500
			SD	10.963	18.596	15.255	21.659
	PHOSPHORUS INORGANIC	MG/DL	N	51	51	48	48
			Mean	4.920	4.784	4.967	0.225
			SD	0.554	0.554	0.764	0.774
	POTASSIUM	MEQ/L	N	51	50	48	47
			Mean	4.296	4.500	4.531	0.034
			SD	0.298	0.501	0.426	0.692
	PROTEIN, TOTAL SERUM	G/DL	N	51	51	48	48
			Mean	7.296	7.214	7.267	0.062
			SD	0.360	0.392	0.330	0.369
	SODIUM	MEQ/L	N	51	51	48	48
			Mean	139.922	138.294	139.813	1.563
			SD	1.683	1.858	2.059	2.782
Hematology	ATYPICAL LYMPHS	%	N	0	0	1	0
			Mean			15.000	
			SD				
	BASOPHILS	%	N	48	46	48	44
			Mean	0.440	0.372	0.415	0.027
			SD	0.275	0.298	0.351	0.476

Generation: 04MAY00 t08_1_1.sas/COPPR

Table 8.1.1
Descriptive Statistics for the Laboratory Parameters
Protocol # 381.201

Group	Test	Units		Screening	Baseline	Visit 8 (Follow-up) Observed	Visit 8 (Follow-up) Change from Baseline
Hematology	EOSINOPHILS	%	N	48	46	48	44
			Mean	4.194	4.583	4.290	-0.291
			SD	3.478	3.467	3.324	3.577
	HEMATOCRIT	%	N	49	49	48	47
			Mean	38.331	37.749	38.900	1.098
			SD	2.464	2.671	2.968	1.807
	HEMOGLOBIN	G/DL	N	49	49	48	47
			Mean	13.139	12.851	13.060	0.209
			SD	0.834	0.942	1.027	0.615
	LYMPHOCYTES	%	N	48	46	48	44
			Mean	40.779	42.620	40.944	-1.350
			SD	10.021	10.106	11.166	14.253
	MONOCYTES	%	N	48	46	48	44
			Mean	5.790	4.663	4.169	-0.391
			SD	2.672	2.737	3.029	2.896
	NEUTROPHIL, BANDS	%	N	0	1	1	0
			Mean		0.000	1.000	
			SD				
	NEUTROPHIL, SEGS	%	N	48	46	48	44
			Mean	48.798	47.763	49.850	1.641
			SD	11.481	11.361	12.078	14.707

Generation: 04MAY00 t08_1_1.sas/COPPR

Table 8.1.1
Descriptive Statistics for the Laboratory Parameters
Protocol # 381.201

Group	Test	Units		Screening	Baseline	Visit 8 (Follow-up) Observed	Visit 8 (Follow-up) Change from Baseline
Hematology	PLATELET COUNT	PER CUMM	N	49	49	47	46
			Mean	307204.082	271612.245	283404.255	14086.957
			SD	61020.823	54750.501	55564.557	48842.070
	RED CELL COUNT	MILL/MCL	N	49	49	48	47
			Mean	4.547	4.451	4.554	0.089
			SD	0.387	0.396	0.384	0.209
	WHITE CELL COUNT	THOU/MCL	N	49	49	48	47
			Mean	6.651	5.659	6.744	1.145
			SD	1.929	1.361	1.956	1.772
Urinalysis	OSMOLALITY, URINE	MOSM/KG	N	50	49	48	46
			Mean	841.260	560.714	803.833	242.391
			SD	295.066	315.319	244.674	374.619
	REACTION PH		N	51	49	48	46
			Mean	5.961	5.673	5.896	0.196
			SD	0.805	0.506	0.472	0.628

Generation: 04MAY00 t08_1_1.sas/COPPR

Table 8.2.1 (Page 1 of 6)
Listing of the End of Study Abnormal Laboratory Parameters
Protocol # 381.201

Group	Test	Units	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Screening Value	Baseline Value	Visit 8 Value	Normal Range
Chemistry	ALBUMIN	G/DL	3-02	11	Male	BCDEAD	4.2	4.6	5.1	3.2-5
			3-06	7	Male	EABCDE	5	4.7	5.2	3.2-5
			3-20	9	Male	ABCDEB	4.8	5	5.3	3.2-5
			4-10	11	Male	CDEABC	4.8	4.9	5.1	3.2-5
	ALKALINE PHOSPHATASE	U/L	2-05	11	Male	DEABCB	429	473	473	60-415
			3-02	11	Male	BCDEAD	433	394	423	60-415
			4-05	11	Male	BCDEAA	416	476	495	60-415
	ALT (SGPT)	U/L	4-05	11	Male	BCDEAA	96	66	87	0-45
	AST (SGOT)	U/L	1-16	7	Male	DEABCD	29	34	56	0-42
			3-06	7	Male	EABCDE	33	32	43	0-42
	CALCIUM	MG/DL	3-06	7	Male	EABCDE	9.7	9.6	10.4	8.5-10.3
			4-10	11	Male	CDEABC	10.3	10.1	10.4	8.5-10.3
	CREATININE	MG/DL	2-06	12	Male	BCDEAD	0.6	0.5	0.4	0.5-1.4
	GLUCOSE	MG/DL	1-01	12	Male	EABCDC	91	109	112	60-110
			2-17	8	Male	ABCDEE	90	102	111	60-110
			4-04	12	Male	BCDEAB	109	105	126	60-110
			4-05	11	Male	BCDEAA	88	91	115	60-110
			4-08	11	Male	DEABCE	76	95	113	60-110
			4-09	11	Male	DEABCE	86	137	175	60-110
	PHOSPHORUS INORGANIC	MG/DL	2-06	12	Male	BCDEAD	5.2	5	6	2.5-4.5
			3-08	12	Male	CDEABD	5.4	5	8.3	2.5-4.5

NOTE: If there were multiple labs at a visit, the last value was used.
No labs were noted as clinically significant at the final visit.

*A=Placebo B=Adderall 10mg C=SLI381 10mg D=SLI381 20mg E=SLI381 30mg

Generation: 04MAY00 t08_2_1.sas/COPPR

Table 8.2.1 (Page 2 of 6)
Listing of the End of Study Abnormal Laboratory Parameters
Protocol # 381.201

Group	Test	Units	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Screening Value	Baseline Value	Visit 8 Value	Normal Range
Chemistry	POTASSIUM	MEQ/L	1-16	7	Male	DEABCD	4.6	4.6	6.1	3.5-5.5
			3-08	12	Male	CDEABD	4.5	4.6	5.4	3.5-5.3
			3-15	11	Male	DEABCB	4.4	4.3	5.6	3.5-5.5
	PROTEIN, TOTAL SERUM	G/DL	3-03	9	Male	EABCDE	8	7.9	8.2	5.5-8
Hematology	ATYPICAL LYMPHS	%	4-10	11	Male	CDEABC			15	0-5
	EOSINOPHILS	%	1-03	8	Male	DEABCB		3.1	13.9	0-5
			1-11	8	Male	CDEABD	7.8		5.3	0-5
			1-12	6	Male	ABCDEB	7.7	2.6	5.9	0-5
			1-16	7	Male	DEABCD	4.8	3.7	6.6	0-5
			2-16	7	Male	DEABCC	0.6		5.2	0-5
			2-21	12	Male	CDEABD	3.6	7.1	7.8	0-5
			3-03	9	Male	EABCDE	1.5	7.6	5.8	0-5
			3-12	10	Male	BCDEAA	6.8	11.5	6.2	0-5
			3-15	11	Male	DEABCB	4.1	9.4	8.4	0-5
			3-18	7	Male	ABCDEC	2.8	4.8	6.2	0-5
			3-19	12	Male	BCDEAD	14.1	13.8	12.9	0-5
			3-20	9	Male	ABCDEB	9.8	7.9	12.9	0-5
			4-01	12	Female	BCDEAC	4.8	3.4	8	0-5
			4-05	11	Male	BCDEAA	5.2	5.1	10.5	0-5
			4-09	11	Male	DEABCE	3.4	3.9	6	0-5
			4-11	11	Male	ABCDEC	3.5	4.3	5.3	0-5
	HEMATOCRIT	%	1-12	6	Male	ABCDEB	35.2	33.5	34.6	35-45
			2-01	11	Male	EABCDE	38.4	42.7	45.8	35-45
			2-13	8	Male	ABCDEB	34	34.2	34.5	35-45

NOTE: If there were multiple labs at a visit, the last value was used.
No labs were noted as clinically significant at the final visit.

*A=Placebo B=Adderall 10mg C=SLI381 10mg D=SLI381 20mg E=SLI381 30mg

Generation: 04MAY00 t08_2_1.sas/COPPR

Table 8.2.1 (Page 3 of 6)
Listing of the End of Study Abnormal Laboratory Parameters
Protocol # 381.201

Group	Test	Units	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Screening Value	Baseline Value	Visit 8 Value	Normal Range
Hematology	HEMATOCRIT	%	3-11	7	Male	CDEABA	35.2	33.2	34.9	35-45
			3-12	10	Male	BCDEAA	37.7	34.9	34.6	35-45
			3-17	8	Male	CDEABA	34.3	32	31.6	35-45
			3-18	7	Male	ABCDEC	33.5	33.1	32	35-45
	HEMOGLOBIN	G/DL	1-12	6	Male	ABCDEB	12.2	11.1	11.4	11.5-15.5
			3-17	8	Male	CDEABA	11.6	10.9	10.8	11.5-15.5
			3-18	7	Male	ABCDEC	11.5	11.5	11.2	11.5-15.5
	LYMPHOCYTES	%	1-04	10	Female	ABCDEB		24.2	66.9	25-55
			1-05	8	Male	ABCDEA	38	34	64.8	25-55
			1-09	12	Male	CDEABC	49.3	54.4	67.6	21-51
			2-02	8	Male	CDEABA			16	25-55
			2-15	6	Male	DEABCA	61	63.8	55.4	25-55
			2-18	9	Male	ABCDED	37	51.5	24	25-55
			3-11	7	Male	CDEABA	47.3	27.4	58	25-55
			4-12	9	Male	ABCDED	59.1	48.2	59.8	25-55
	MONOCYTES	%	4-02	9	Male	ABCDEB	6	6	10.1	0-10
	NEUTROPHIL, BANDS	%	3-08	12	Male	CDEABD			1	4-12
	NEUTROPHIL, SEGS	%	1-04	10	Female	ABCDEB		70	28.5	30-60
			1-05	8	Male	ABCDEA	41.5	51	25.9	30-60
			1-09	12	Male	CDEABC	46.5	33.7	24.2	30-70
			1-16	7	Male	DEABCD	57.1	64.7	63.7	30-60
			2-02	8	Male	CDEABA			79.9	30-60
			2-09	10	Female	EABCDE	49.2	54.6	63.2	30-60

NOTE: If there were multiple labs at a visit, the last value was used.
No labs were noted as clinically significant at the final visit.

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Generation: 04MAY00 t08_2_1.sas/COPPR

Table 8.2.1 (Page 4 of 6)
Listing of the End of Study Abnormal Laboratory Parameters
Protocol # 381.201

Group	Test	Units	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Screening Value	Baseline Value	Visit 8 Value	Normal Range
Hematology	NEUTROPHIL, SEGS	%	2-17	8	Male	ABCDEE	48.9	51.9	64.8	30-60
			2-18	9	Male	ABCDED	53.2	42.9	73.4	30-60
			3-02	11	Male	BCDEAD	40.2	40.5	60.4	30-60
			3-16	8	Male	EABCDC	53.9	41	67.6	30-60
			4-12	9	Male	ABCDED	29	35.3	29	30-60
	PLATELET COUNT	PER CUMM	1-09	12	Male	CDEABC	216000	126000	110000	130000-400000
			2-01	11	Male	EABCDE	422000	316000	402000	130000-400000
			4-01	12	Female	BCDEAC	426000	359000	407000	130000-400000
	RED CELL COUNT	MILL/MCL	2-02	8	Male	CDEABA	5.4	5.6	5.4	4-5.2
			3-17	8	Male	CDEABA	4	3.8	3.8	4-5.2
			3-18	7	Male	ABCDEC	3.8	3.8	3.8	4-5.2
	WHITE CELL COUNT	THOU/MCL	1-01	12	Male	EABCDC	5.2	4.1	4.1	4.5-13
			1-09	12	Male	CDEABC	5.1	4.2	4.4	4.5-13
			2-02	8	Male	CDEABA	4.6	6.7	15.4	4.5-13.5
			2-15	6	Male	DEABCA	3.8	3.2	4.4	4.5-13.5
			3-08	12	Male	CDEABD	3	3	3.3	4.5-13
Urinalysis	AMMONIUM URATES		3-19	12	Male	BCDEAD			MODERATE	
	AMORPHOUS SEDIMENT		2-17	8	Male	ABCDEE	FEW	FEW	MANY	
			3-08	12	Male	CDEABD	FEW		MANY	
			3-15	11	Male	DEABCB	MANY		MANY	
			3-20	9	Male	ABCDEB			MANY	
	BACTERIA		1-01	12	Male	EABCDC			FEW	

NOTE: If there were multiple labs at a visit, the last value was used.
No labs were noted as clinically significant at the final visit.

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Generation: 04MAY00 t08_2_1.sas/COPPR

Table 8.2.1 (Page 5 of 6)
Listing of the End of Study Abnormal Laboratory Parameters
Protocol # 381.201

Group	Test	Units	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Screening Value	Baseline Value	Visit 8 Value	Normal Range
Urinalysis	BACTERIA		1-07	7	Male	CDEABE			OCCASIONAL	
			1-09	12	Male	CDEABC			FEW	
			1-11	8	Male	CDEABD			FEW	
			1-13	7	Female	EABCDE	FEW	MODERATE	FEW	
			1-16	7	Male	DEABCD			FEW	
			3-02	11	Male	BCDEAD		OCCASIONAL	OCCASIONAL	
			3-03	9	Male	EABCDE		OCCASIONAL	OCCASIONAL	
			3-06	7	Male	EABCDE		OCCASIONAL	OCCASIONAL	
			3-08	12	Male	CDEABD		OCCASIONAL	OCCASIONAL	
			3-12	10	Male	BCDEAA		OCCASIONAL	OCCASIONAL	
			3-15	11	Male	DEABCB		OCCASIONAL	FEW	
			3-16	8	Male	EABCDC		OCCASIONAL	OCCASIONAL	
			3-17	8	Male	CDEABA		OCCASIONAL	OCCASIONAL	
			3-18	7	Male	ABCDEC		OCCASIONAL	FEW	
			3-19	12	Male	BCDEAD		OCCASIONAL	FEW	
			3-20	9	Male	ABCDEB		OCCASIONAL	FEW	
	CALCIUM OXALATE CRYS		3-02	11	Male	BCDEAD			MODERATE	
			4-01	12	Female	BCDEAC			MODERATE	
	LEUKOCYTES		1-04	10	Female	ABCDEB	TRACE	NEGATIVE	1+	
	MUCOUS THREADS		1-01	12	Male	EABCDC		FEW	MODERATE	
			1-04	10	Female	ABCDEB	MODERATE	FEW	MODERATE	
			1-05	8	Male	ABCDEA	FEW	FEW	MODERATE	
			1-09	12	Male	CDEABC	MODERATE	FEW	MODERATE	
			1-12	6	Male	ABCDEB	MODERATE	FEW	MODERATE	
			2-01	11	Male	EABCDE	MANY	MODERATE	MANY	

NOTE: If there were multiple labs at a visit, the last value was used.
No labs were noted as clinically significant at the final visit.

*A=Placebo B=Adderall 10mg C=SLI381 10mg D=SLI381 20mg E=SLI381 30mg

Generation: 04MAY00 t08_2_1.sas/COPPR

Table 8.2.1
Listing of the End of Study Abnormal Laboratory Parameters
Protocol # 381.201

Group	Test	Units	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Screening Value	Baseline Value	Visit 8 Value	Normal Range
Urinalysis	MUCOUS THREADS		2-05	11	Male	DEABCB	MODERATE		MODERATE	
			2-17	8	Male	ABCDEE	FEW	FEW	MODERATE	
			2-21	12	Male	CDEABD	FEW	MODERATE	MODERATE	
			3-06	7	Male	EABCDE			MODERATE	
			4-03	11	Male	EABCDE			MODERATE	
	OSMOLALITY, URINE	MOSM/KG	3-08	12	Male	CDEABD	622	377	1209	50-1200
	PROTEIN		1-01	12	Male	EABCDC	TRACE	NEGATIVE	TRACE	
			1-09	12	Male	CDEABC	NEGATIVE	NEGATIVE	TRACE	
			2-21	12	Male	CDEABD	NEGATIVE	NEGATIVE	TRACE	
	RBC/HPF		4-01	12	Female	BCDEAC	NONE SEEN	NONE SEEN	3-5	0-3
	SQUAMOUS EPITH CELLS		2-13	8	Male	ABCDEB			MODERATE (	
			3-06	7	Male	EABCDE		FEW (1-5)	MODERATE (	
	URIC ACID CRYSTALS		3-02	11	Male	BCDEAD			MODERATE	
			3-03	9	Male	EABCDE			MODERATE	
			4-03	11	Male	EABCDE			MANY	
			4-05	11	Male	BCDEAA			MANY	

NOTE: If there were multiple labs at a visit, the last value was used.
No labs were noted as clinically significant at the final visit.

*A=Placebo B=Adderall 10mg C=SLI381 10mg D=SLI381 20mg E=SLI381 30mg

Generation: 04MAY00 t08_2_1.sas/COPPR

Table 9.1.1 (Page 1 of 1)
Number (%) of Patients with Clinically Significant Physical Examination Changes from Screening to Follow-up
Protocol # 381.201

System	Total (N=48)	Site # 01 (N=12)	# 02 (N=12)	# 03 (N=13)	# 04 (N=11)
Dermatological	1 (2.1%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)
HEENT	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
Respiratory	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gastrointestinal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Genitourinary	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Musculoskeletal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lymphatic	2 (4.2%)	0 (0.0%)	0 (0.0%)	2 (15.4%)	0 (0.0%)
Neurological	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Psychological	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

NOTE: Counts represent subjects with normal screening and abnormal follow-up examinations.

Generation: 04MAY00 t09_1_1.sas/COPPR

Table 9.1.2 (Page 1 of 1)
Listing of Clinically Significant Physical Examination Changes from Screening to Follow-up
Protocol # 381.201

System	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Description
Dermatological	3-04	12	Female	DEABCE	MILD FACIAL ACNE
HEENT	4-06	12	Male	EABCDA	SMALL POSTERIOR CERVICAL NODE 1CM X 1CM
Lymphatic	3-03	9	Male	EABCDE	MILD CERVICAL ADENOPATHY SECONDARY TO URI
	3-18	7	Male	ABCDEC	MILD CERVICAL ADENOPATHY SECONDARY TO URI

NOTE: Subjects with normal screening and abnormal follow-up examinations.

*A=Placebo B=Adderall 10mg C=SLI381 10mg D=SLI381 20mg E=SLI381 30mg

Generation: 04MAY00 t09_1_2.sas/COPPR

Table 10.1.1
Number (%) of Patients with Medical Abnormalities at Screening
Protocol # 381.201

System	Total (N=51)	Site # 01 (N=13)	# 02 (N=12)	# 03 (N=15)	# 04 (N=11)
Cardiovascular	1 (2.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)
Respiratory	9 (17.6%)	1 (7.7%)	2 (16.7%)	3 (20.0%)	3 (27.3%)
Gastrointestinal	5 (9.8%)	3 (23.1%)	0 (0.0%)	1 (6.7%)	1 (9.1%)
Genitourinary	2 (3.9%)	1 (7.7%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
Endocrine & Metabolic	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Musculoskeletal	1 (2.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CNS & Sense Organs	10 (19.6%)	2 (15.4%)	3 (25.0%)	2 (13.3%)	3 (27.3%)
Dermatological	1 (2.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)
Hematologic and Lymphatic	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	15 (29.4%)	3 (23.1%)	3 (25.0%)	5 (33.3%)	4 (36.4%)

NOTE: Both ongoing and completed histories are included.

Generation: 04MAY00 t10_1_1.sas/COPPR

Table 10.1.2
Listing of Ongoing Medical Conditions
Protocol # 381.201

System	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Description
Cardiovascular	2-06	12	Male	BCDEAD	BORDERLINE HYPERTENSION
Respiratory	1-16	7	Male	DEABCD	ASTHMA
	2-15	6	Male	DEABCA	ASTHMA
	2-21	12	Male	CDEABD	ASTHMA
	4-01	12	Female	BCDEAC	ALLERGIES
	4-05	11	Male	BCDEAA	ASTHMA
Gastrointestinal	1-05	8	Male	ABCDEA	LACTOSE INTOLERANCE
	1-11	8	Male	CDEABD	LACTOSE INTOLERANT
	1-12	6	Male	ABCDEB	ENCOPRESIS
Genitourinary	1-08	9	Male	DEABCD	ENURESIS
	3-03	9	Male	EABCDE	ENURESIS
Musculoskeletal	1-11	8	Male	CDEABD	CONFIRMED HEARING LOSS
CNS & Sense Organs	1-11	8	Male	CDEABD	RIGHT EAR MINIMAL HEARING LOSS
	1-07	7	Male	CDEABE	HEADACHE
	4-11	11	Male	ABCDEC	RECURRENT EAR INFECTIONS
Other	1-16	7	Male	DEABCD	ALLERGIC TO PEANUTS
		7	Male	DEABCD	ALLERGIC TO TOMATOES
	2-21	12	Male	CDEABD	ALLERGIC TO AUGMENTIN
		12	Male	CDEABD	ALLERGIC TO ENVIRONMENTAL ALLERGIES
	4-05	11	Male	BCDEAA	ALLERGIES
	3-03	9	Male	EABCDE	ALLERGY TO PENICILLIN
	3-04	12	Female	DEABCE	ALLERGIC RHINITIS
		12	Female	DEABCE	ALLERGIC TO PENICILLIN
	3-19	12	Male	BCDEAD	ALLERGIC RHINITIS

Generation: 04MAY00 t10_1_2.sas/COPPR

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
A02	MAALOX	4-03	11	Male	EABCDE	1 TB	10/04/1999	10/06/1999	NAUSEA
A04	EMETROL	3-03	9	Male	EABCDE	2 OT	10/23/1999	10/23/1999	NAUSEA
A07	PEPTO-BISMOL	4-03	11	Male	EABCDE	1 TB	10/05/1999	10/05/1999	NAUSEA
A11	FLINSTONES MULTIPLE VITAMINS	3-17	8	Male	CDEABA	1 TB	09/15/1999		GEN HEALTH
		3-18	7	Male	ABCDEC	1 TB	09/15/1999		GEN HEALTH
	MULTIVITAMINS	2-13	8	Male	ABCDEB	1 TB	10/23/1999		NUTRITIONAL SUPPLEMENT
		2-16	7	Male	DEABCC	1 TB	02/--/1998		NUTRITIONAL SUPPLEMENT
		4-02	9	Male	ABCDEB	1 TB	09/01/1994		NUTRITIONAL SUPPLEMENT
		4-04	12	Male	BCDEAB	1 TB	01/01/1990		DAILY HEALTH
A12	CALCIUM CITRATE	1-05	8	Male	ABCDEA	300 MG	03/--/1999		NUTRITIONAL SUPPLEMENT
	MANGANESE	1-05	8	Male	ABCDEA	5 MG	3/--/1999		NUTRITIONAL SUPPLEMENT
	ZINC	1-05	8	Male	ABCDEA	15 MG	3/--/1999		NUTRITIONAL SUPPLEMENT
B03	VITAMIN B12	1-05	8	Male	ABCDEA	500 MCG	03/--/1999		NUTRITIONAL SUPPLEMENT
B05	MAGNESIUM CITRATE	1-05	8	Male	ABCDEA	.5 TB	03/--/1999		NUTRITIONAL SUPPLEMENT
	SODIUM CHLORIDE	2-16	7	Male	DEABCC	1 GTT	10/30/1999	10/30/1999	NASAL CONGESTION

Generation: 04MAY00 t11_1_1.sas/COPPR

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
D06	TRIPLE ANTIBIOTIC	4-03	11	Male	EABCDE	1 OT	10/09/1999	10/09/1999	RIGHT HAND ABRASION
	TRIPLE ANTIBIOTIC OINTMENT	4-08	11	Male	DEABCE	1 OT	10/16/1999	10/16/1999	ABRASION (LEFT HAND)
						1 OT	10/16/1999	10/16/1999	ABRASION (RIGHT KNEE)
		4-12	9	Male	ABCDED	1 OT	10/16/1999	10/16/1999	ABRASION (LEFT KNEE)
J01	AMOXICILLIN	1-14	7	Male	BCDEAA	1 OT	11/15/1999	11/25/1999	SINUS INFECTION
	AUGMENTIN	3-02	11	Male	BCDEAD	1000 MG	11/30/1999	12/09/1999	STREP THROAT
	PENICILLIN G	1-05	8	Male	ABCDEA	100 MG	11/22/1999	12/01/1999	STREP THROAT
M01	ADVIL	1-14	7	Male	BCDEAA	200 MG	11/08/1999	11/12/1999	HEADACHE
						200 MG	11/20/1999	11/20/1999	HEADACHE
		2-21	12	Male	CDEABD	200 MG	10/13/1999	10/13/1999	HEADACHE
						200 MG	10/22/1999	10/22/1999	MUSCLE ACHES
						200 MG	11/03/1999	11/03/1999	HEADACHE
		3-09	11	Male	DEABCB	1 TB	11/26/1999	11/26/1999	FLU SYMPTOMS
		3-10	11	Female	ABCDEC	100 MG	11/24/1999	11/26/1999	FLU SYMPTOMS
	IBUPROFEN	3-18	7	Male	ABCDEC	2 OT	11/04/1999	11/05/1999	MOUTH INJURY
		1-04	10	Female	ABCDEB	1 TB	10/30/1999	10/30/1999	HEADACHE
		4-01	12	Female	BCDEAC	400 MG	10/09/1999	10/09/1999	HEADACHE
	MOTRIN	3-18	7	Male	ABCDEC	100 MG	11/18/1999	11/20/1999	STOMACH
		4-01	12	Female	BCDEAC	10 ML	10/05/1999	10/06/1999	SINUS HEADACHE

Generation: 04MAY00 t11_1_1.sas/COPPR

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
N01	BENZOCAINE	3-18	7	Male	ABCDEC	1 OT	11/04/1999	11/05/1999	MOUTH INJURY
	EMLA	4-03	11	Male	EABCDE	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
		3-03	9	Male	EABCDE	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		3-17	8	Male	CDEABA	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		3-18	7	Male	ABCDEC	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		2-13	8	Male	ABCDEB	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		2-16	7	Male	DEABCC	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		4-02	9	Male	ABCDEB	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
		4-04	12	Male	BCDEAB	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
		1-05	8	Male	ABCDEA	1 G	10/23/1999	10/24/1999	BLOOD DRAW

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
N01	EMLA	1-05	8	Male	ABCDEA	1 G	12/04/1999	12/05/1999	BLOOD DRAW
		4-08	11	Male	DEABCE	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
		4-12	9	Male	ABCDED	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/13/1999	11/14/1999	BLOOD DRAW
		1-14	7	Male	BCDEAA	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW
		3-02	11	Male	BCDEAD	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		2-21	12	Male	CDEABD	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		3-09	11	Male	DEABCB	1 G	10/23/1999	10/23/1999	BLOOD DRAW
		3-10	11	Female	ABCDEC	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	10/23/1999	10/23/1999	BLOOD DRAW
		1-04	10	Female	ABCDEB	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW
		4-01	12	Female	BCDEAC	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	CATHETER INSERTION
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
		1-01	12	Male	EABCDC	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW
		1-03	8	Male	DEABCB	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/14/1999	12/14/1999	BLOOD DRAW
		1-07	7	Male	CDEABE	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
N01	EMLA	1-09	12	Male	CDEABC	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		1-11	8	Male	CDEABD	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW
		1-12	6	Male	ABCDEB	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW
		1-13	7	Female	EABCDE	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW
		1-15	9	Female	BCDEAA	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW
		1-16	7	Male	DEABCD	1 G	10/23/1999	10/24/1999	BLOOD DRAW
						1 G	12/04/1999	12/05/1999	BLOOD DRAW
		2-01	11	Male	EABCDE	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		2-02	8	Male	CDEABA	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		2-05	11	Male	DEABCB	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		2-06	12	Male	BCDEAD	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
		2-09	10	Female	EABCDE	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
N01	EMLA	2-15	6	Male	DEABCA	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		2-17	8	Male	ABCDEE	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
		2-18	9	Male	ABCDED	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		2-20	10	Male	BCDEAB	1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/10/1999	10/10/1999	BLOOD DRAW
						1 G	11/20/1999	11/20/1999	BLOOD DRAW
						1 G	11/21/1999	11/21/1999	BLOOD DRAW
		3-04	12	Female	DEABCE	1 G	10/23/1999	10/23/1999	BLOOD DRAW
		3-06	7	Male	EABCDE	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		3-08	12	Male	CDEABD	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		3-11	7	Male	CDEABA	1 G	10/23/1999	10/23/1999	BLOOD DRAW
		3-12	10	Male	BCDEAA	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		3-15	11	Male	DEABCB	1 G	10/23/1999	11/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		3-16	8	Male	EABCDC	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		3-19	12	Male	BCDEAD	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW
		3-20	9	Male	ABCDEB	1 G	10/23/1999	10/23/1999	BLOOD DRAW
						1 G	12/04/1999	12/04/1999	BLOOD DRAW

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
N01	EMLA	4-05	11	Male	BCDEAA	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	10/09/1999	10/09/1999	BLOOD DRAW
						1 G	10/16/1999	10/16/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
		4-06	12	Male	EABCDA	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
		4-09	11	Male	DEABCE	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
		4-10	11	Male	CDEABC	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
		4-11	11	Male	ABCDEC	1 G	10/02/1999	10/02/1999	CATHETER INSERTION
						1 G	10/03/1999	10/03/1999	BLOOD DRAW
						1 G	11/13/1999	11/13/1999	CATHETER INSERTION
						1 G	11/14/1999	11/14/1999	BLOOD DRAW
	LIDOCAINE	3-17	8	Male	CDEABA	1 OT	11/01/1999	11/01/1999	PROPHYLAXIS FOR DENTAL PROCEDURE
		3-18	7	Male	ABCDEC	1 OT	11/18/1999	11/18/1999	PROPHYLAXIS FOR DENTAL PROCEDURE
		4-02	9	Male	ABCDEB	1 OT	10/18/1999	10/18/1999	DENTAL PROCEDURE TO FILL CAVITIES

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
N02	COMTREX	3-09	11	Male	DEABCB	1 TB	11/26/1999	11/26/1999	FLU SYMPTOMS
	DAYQUIL	3-09	11	Male	DEABCB	1 TB	11/26/1999	11/26/1999	FLU SYMPTOMS
		3-15	11	Male	DEABCB	1 OT	11/23/1999	11/23/1999	COLD SYMPTOMS
	ECOTRIN	4-01	12	Female	BCDEAC	650 MG	10/06/1999	10/06/1999	SINUS HEADACHE
	SINE-AID	4-01	12	Female	BCDEAC	1 TB	10/06/1999	10/06/1999	SINUS HEADACHE
	TYLENOL	4-03	11	Male	EABCDE	160 MG	10/12/1999	10/12/1999	HEADACHE
		1-14	7	Male	BCDEAA	250 MG	11/06/1999	11/06/1999	HEADACHE
						500 MG	11/13/1999	11/13/1999	HEADACHE
		1-04	10	Female	ABCDEB	250 MG	11/06/1999	11/06/1999	HEADACHE
						500 MG	11/06/1999	11/06/1999	HEADACHE
						500 MG	11/13/1999	11/13/1999	HEADACHE
		4-01	12	Female	BCDEAC	250 MG	10/20/1999	10/20/1999	HEADACHE
		1-03	8	Male	DEABCB	50 MG	11/18/1999	11/18/1999	COLD SYMPTOMS
		3-16	8	Male	EABCDC	100 MG	10/26/1999	10/26/1999	HEADACHE
						100 MG	11/05/1999	11/05/1999	FLU SYMPTOMS
	TYLENOL COLD	3-04	12	Female	DEABCE	1 TB	12/19/1999	12/19/1999	COLD SYMPTOMS
N06	RITALIN	3-11	7	Male	CDEABA	5 MG	02/01/1999		ADHD
R01	DIMETAPP	2-16	7	Male	DEABCC	1 CA	11/04/1999	11/08/1999	COLD SYMPTOMS
		1-04	10	Female	ABCDEB	1 OT	11/15/1999	11/15/1999	COLD SYMPTOMS
	SUDAFED	3-08	12	Male	CDEABD	20 MG	10/28/1999	10/28/1999	NASAL CONGESTION

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
R01	UNKNOWN DECONGESTANT	1-05	8	Male	ABCDEA	1 CA	11/21/1999	11/21/1999	COLD SYMPTOMS
R03	ALBUTEROL SULFATE	3-15	11	Male	DEABCB	90 MCG	11/23/1999	11/23/1999	COLD SYMPTOMS
	PROVENTIL	2-21	12	Male	CDEABD	2 OT	10/02/1995		ASTHMA
R05	CODEINE	1-05	8	Male	ABCDEA	1 TB	11/21/1999	11/21/1999	COLD SYMPTOMS
	DORCOL	2-09	10	Female	EABCDE	1 OT	11/13/1999	11/13/1999	COUGH
	ROBITUSSIN	1-07	7	Male	CDEABE	1 OT	11/01/1999	11/02/1999	COUGH
		2-09	10	Female	EABCDE	1 OT	10/30/1999	10/30/1999	COLD SYMPTOMS
	TUSSIN DM	4-11	11	Male	ABCDEC	5 ML	10/13/1999	10/14/1999	COUGH
						5 ML	10/20/1999	10/22/1999	COUGH
R06	ALLEGRA	4-01	12	Female	BCDEAC	60 MG	11/10/1999	11/12/1999	ALLERGIES
		4-05	11	Male	BCDEAA	60 MG	09/23/1999		ALLERGIES
	BENADRYL	1-04	10	Female	ABCDEB	2 TB	11/09/1999	11/10/1999	COLD SYMPTOMS
						1 OT	11/15/1999	11/15/1999	COLD SYMPTOMS
	CLARITIN	4-01	12	Female	BCDEAC	10 MG	08/25/1999		ALLERGIES
						10 MG	08/25/1999	11/09/1999	ALLERGIES
		3-04	12	Female	DEABCE	10 MG	09/01/1999		ALLERGIC RHINITIS
	UNKNOWN ANTIHISTAMINE	1-05	8	Male	ABCDEA	1 TB	11/18/1999	11/18/1999	COLD SYMPTOMS

Generation: 04MAY00 t11_1_1.sas/COPPR

Table 11.1.1
Listing of Concomitant Medications Received During the Study
Protocol # 381.201

Medication Class	Preferred Term	Sub. ID	Age (yr)	Gender	Treatment Sequence*	Dose	Date Start	Date Stop	Indication
V03	ALL OTHER THERAPEUTIC PRODUCTS	1-05	8	Male	ABCDEA	1 CA	03/--/1999		NUTRITIONAL SUPPLEMENT
						250 MCG	03/--/1999		NUTRITIONAL SUPPLEMENT
						2 CA	03/--/1999		NUTRITIONAL SUPPLEMENT
						1 CA	3/--/1999		NUTRITIONAL SUPPLEMENT
	BORAGE OIL	1-05	8	Male	ABCDEA	1 CA	03/--/1999		NUTRITIONAL SUPPLEMENT
						2 CA	03/--/1999		NUTRITIONAL SUPPLEMENT

Generation: 04MAY00 t11_1_1.sas/COPPR

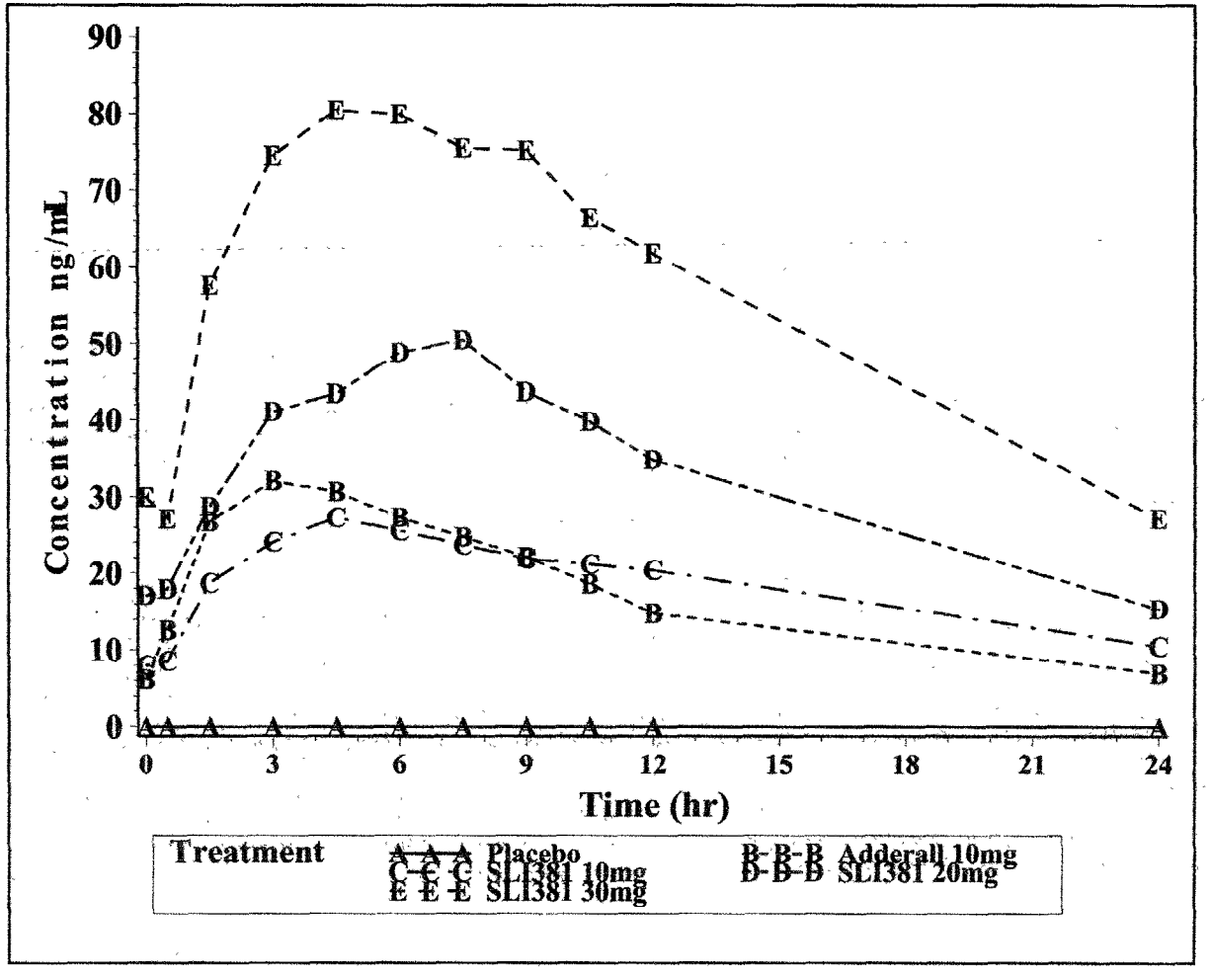


Figure 1.1.1 Plasma Drug Concentration-Time Average at Steady State: D-Amphetamine

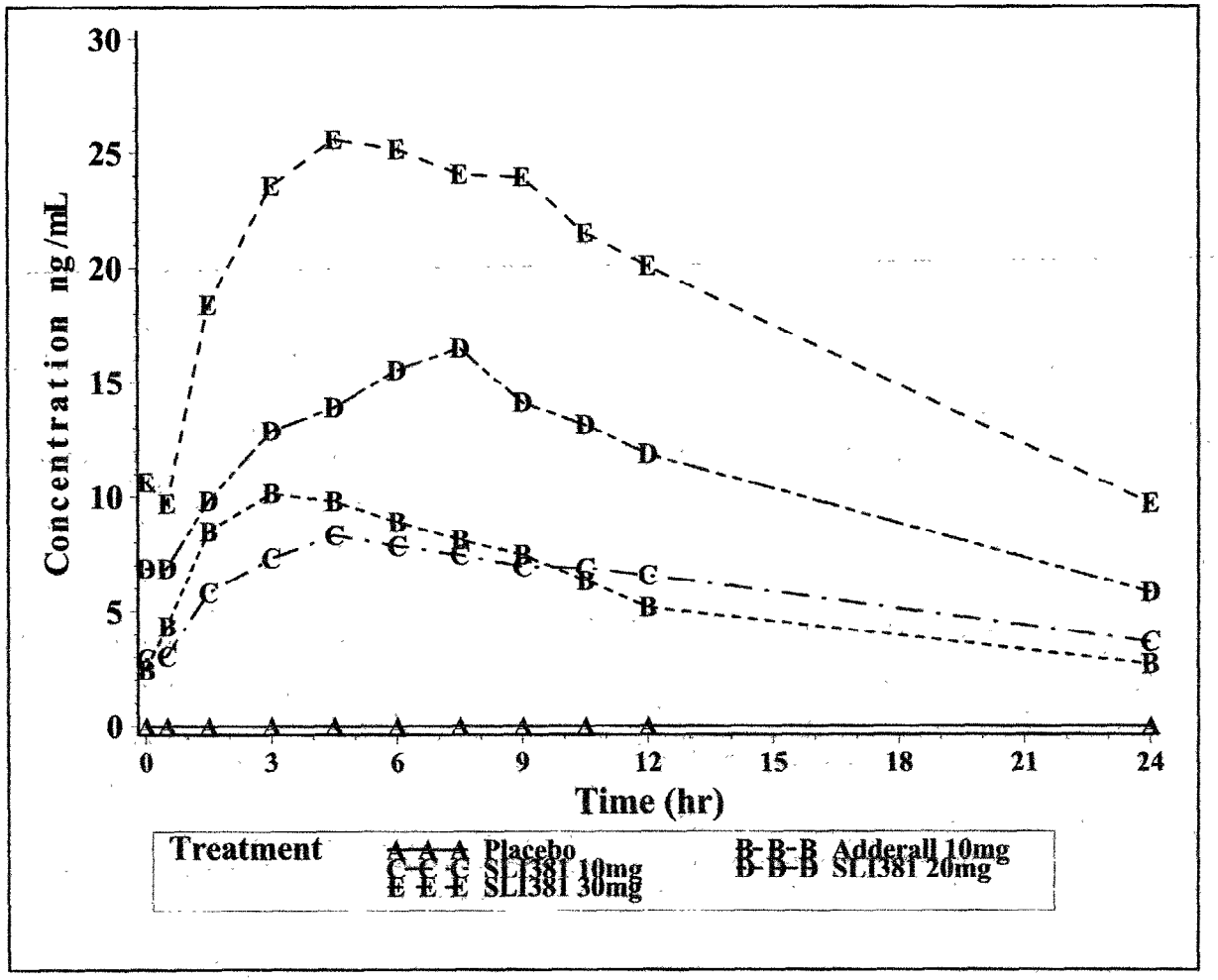


Figure 1.1.2 Plasma Drug Concentration-Time Average at Steady State: L-Amphetamine

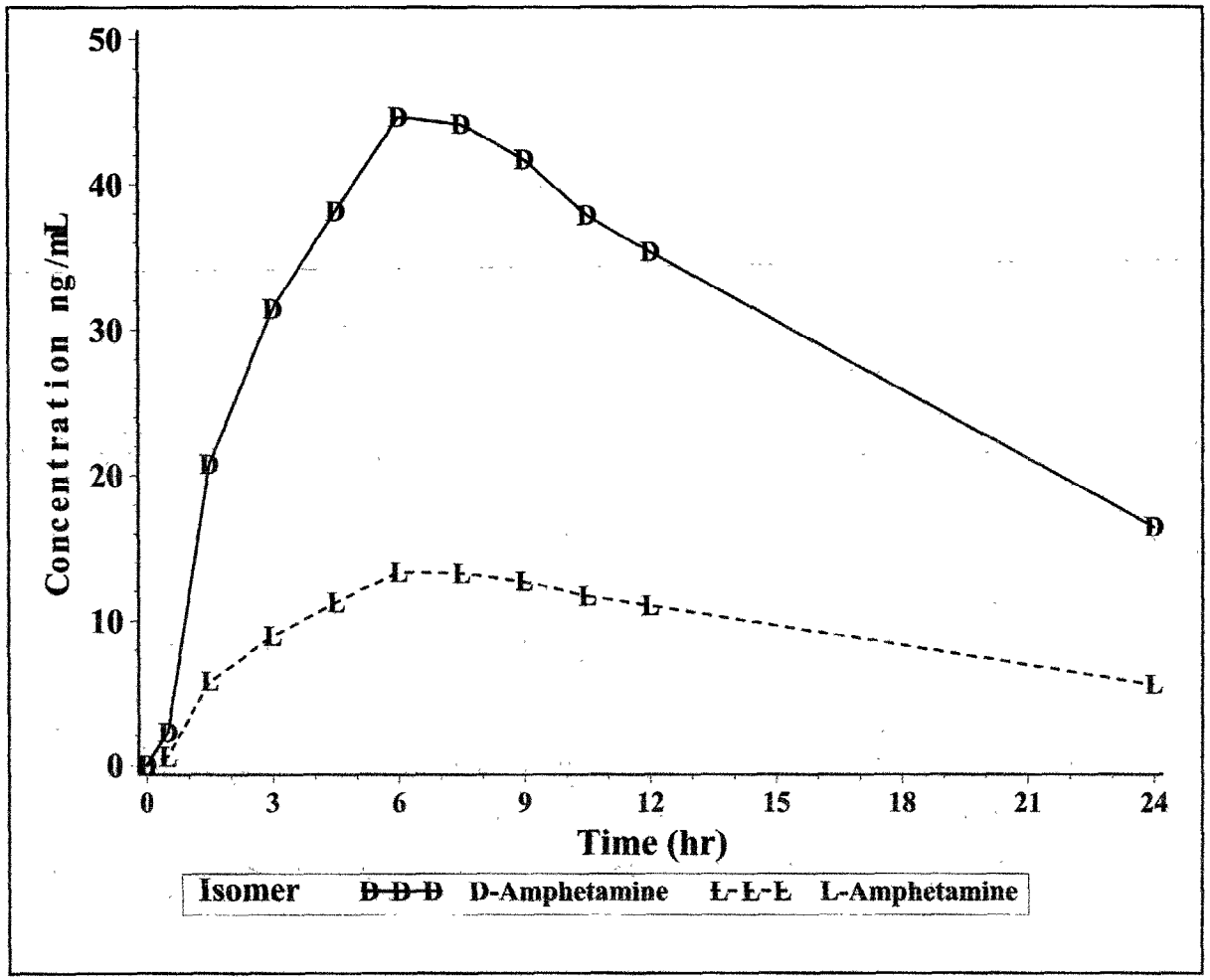
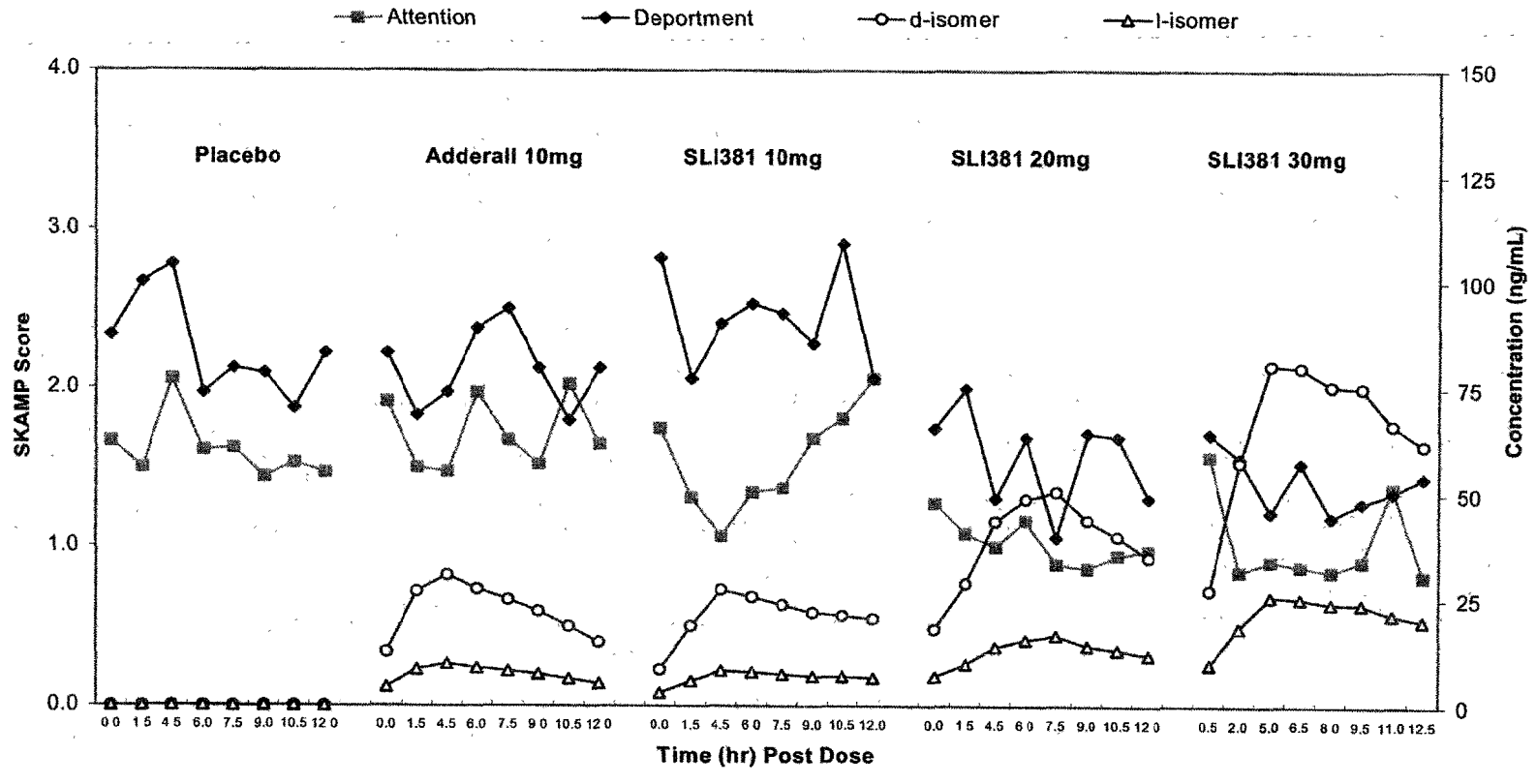


Figure 1.1.3 Plasma Drug Concentration-Time Average Following A Single Dose of SLI381 20 mg

Figure 2.1.1
Mean SKAMP Scores and Plasma Drug Concentration Averages: Make-Up Week



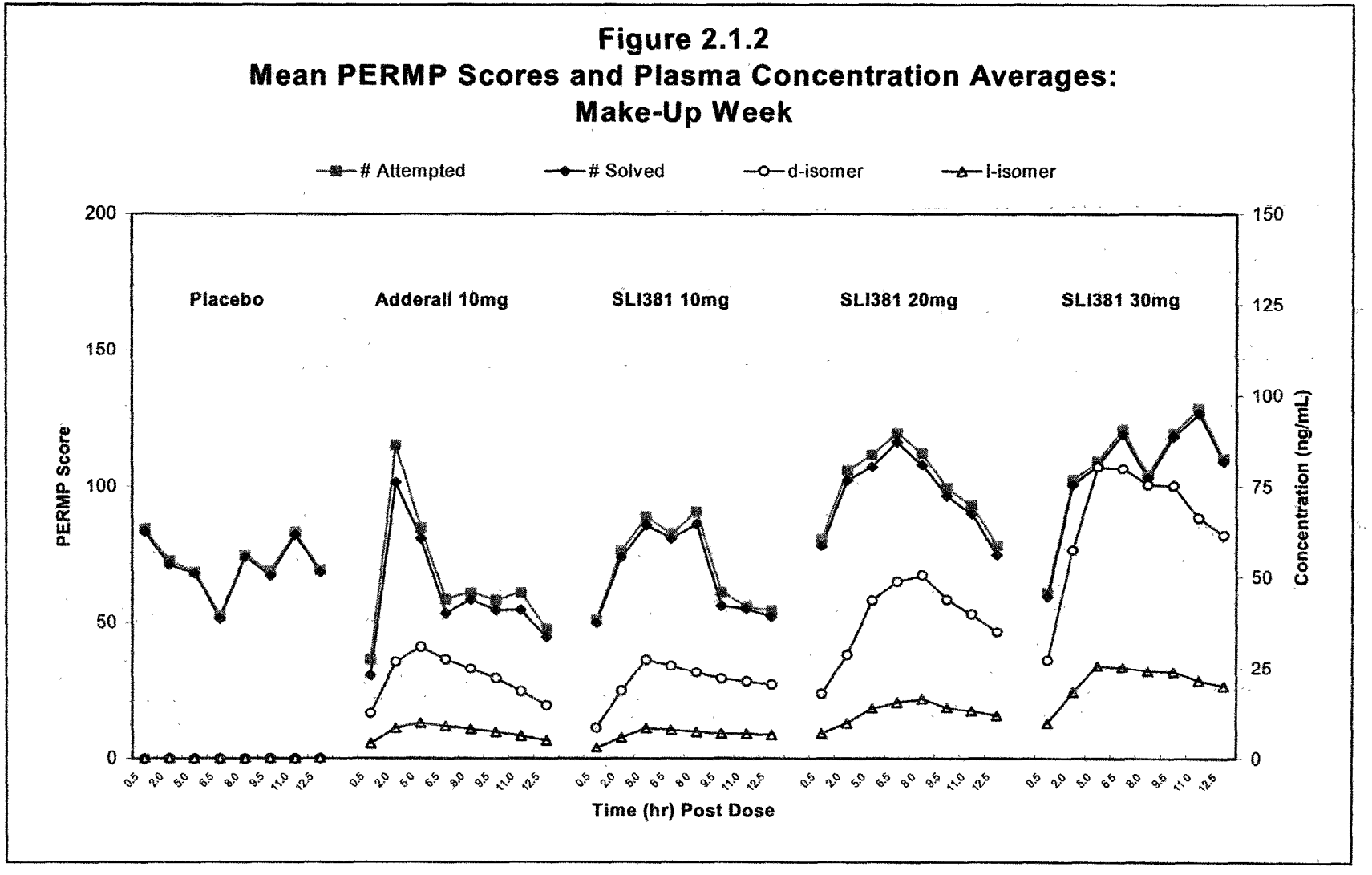


Figure 2.1.2
Mean PERMP Scores and Plasma Concentration Averages:
Make-Up Week
Attempted
Solved
d-isomer
l-isomer
Placebo
Adderall 10mg
SLI381 10mg
SLI381 20mg
SLI381 30mg
PERMP Score
Concentration (ng/mL)
Time (hr) Post Dose
0
50
100
150
200
0
25
50
75
100
125
150
0.5
2.0
5.0
6.5
8.0
9.5
11.0
12.5

15. REFERENCES

Hudziak J, Helzer J, Wetzel M, Kassel K, McGee B, Janca A, Przybeck T. The use of DSM-III-R checklist for initial diagnostic assessments. Compr Psychiatry 1993; 34(6): 375-383.

Schaffer D, Fisher P, Lucas C, eds. The NIMH diagnostic interview schedule for children version 4.0 (DISC-4.0). 1996; Ruane Center for Early Diagnosis, Division of Child Psychiatry, Columbia University: NY.

Swanson JM, Wigal S, Greenhill LL, Browne R, Waslik B, et al. Analog classroom assessment of Adderall® in children with ADHD. J Am Acad Child Adolesc Psychiatry 1998; 37(5):519-526.

Wigal SB, Gupta S; Guinta D; Swanson JM. Reliability and validity of the SKAMP rating scale in a laboratory school setting. Psychopharmacol Bull 1998; 34(1): 47-53.