

DOUBLE-BLIND

Appendix I: Schedule of Activities

Visit #	FORM #	Investigator only						Investigator or Coordinator					ACTIVE TREATMENT			
		Screening -28 days	Baseline	Week 4	Week 8	Week 14	Week 20	Week 26	Week 32	Week 38	Week 44	Week 50	Week 56	Week 62	Week 68	Week 74
		✓														
	L010	✓														
	1100	X														
	1400	I	I													
	1450		X													
	1500	I														
	2000	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I
	2100		X	X	X	X	X	X	X	X	X	X	X	X	X	X
	2200		X													
	2300		X													
	3000	X	X													
	4000	X														
	4200		I	I	I	I	I	I	I	I	I	I	I	I	I	I
	6100	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	6200	I														
	6300															
	6500															
		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	7000															
	7100	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C
	9000															
	L100a															
	L100															
	L200	X														
	L300a	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	L300	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	L400a		X	X	X	X	X	X	X	X	X	X	X	X	X	X
	L400		X	X	X	X	X	X	X	X	X	X	X	X	X	X
	L500															
	L600		X													

I - Investigator only

I/C = Both Investigator/Coordinator

X = Investigator or Coordinator

✓ Required task, not part of the CRF

Visit Windows: Week 4 ± 3 days, all later Visits ± 5 days

Informed Consent

Enrollment Projections/Screening Log (SLOG)

History/Demographic (DEMO)

Inclusion/Exclusion Review<sup>4</sup> (INEX)

Subject Disposition (DISP)

Physical Exam (PHYS)

UPDRS (UPDR)

Timed Motor Tests (MOTR)

Quality of Life (QOL)

Clinical Global Impression (CGI)

Beck (BECK)

Mini Mental (MMSE)

Assess Need for levodopa (LEVO)

Vitals (VITL)

ECG/Chest Xray<sup>2</sup> (ECG)

Pharmacokinetics (PHRM)

AI level (metabolite)

PAI level (drug level)

Lab Tests<sup>3</sup> (LAB)

Chemistry Panel

Blood count, hematology

Urinalysis

Study Termination/Completion:DB (TRM1)

Study Termination/Completion:EXT (TRM2)

Signature Form (SIG)

AE Checklist (AECK)

Adverse Experience Log (AE)

Concomitant Medication Log/PD (MEDP)

Concomitant Medication Checklist (CMCK)

Concomitant Medication Log (CMED)

Medication Labels (LABL)

Drug Dispensing/Compliance (CMPL)

AE Follow-up Log (AEFU)

Pharmacodynamics Log (DYNM)

<sup>1</sup> MAO-B blood samples are drawn on a subset of subjects and sites.

<sup>2</sup> Chest Xray at screening only

<sup>3</sup> Serum pregnancy tests at screening, weeks 26 & 52

<sup>4</sup> Review SCR form 1400 at baselline