

# Drug Manufacturing & Analysis

#	Task	Start	End	RStart	REnd	1994		1995				1996				1997				1998				1999	
						Q3 94	Q4 94	Q1 95	Q2 95	Q3 95	Q4 95	Q1 96	Q2 96	Q3 96	Q4 96	Q1 97	Q2 97	Q3 97	Q4 97	Q1 98	Q2 98	Q3 98	Q4 98	Q1 99	
1	<b>Drug Manufacturing &amp; Analysis</b>	9/12/94	1/7/99	9/9/94	5/8/98																				
2	<b>Drug Analysis Process</b>	9/12/94	1/7/99	9/9/94	5/8/98																				
3	<b>Pharmacy &amp; Analytical Science</b>	9/12/94	11/1/95	9/9/94	5/15/95																				
4	<b>Generic Drug Formulation</b>	9/12/94	11/1/95	9/9/94	5/15/95																				
5	Develop Work Order	9/12/94	9/12/94	9/9/94	9/9/94																				
6	Validate manufacturing	7/27/95	11/1/95	2/7/95	5/15/95																				
7	<b>IV Formulation/Concentration</b>	9/12/94	9/12/94	9/9/94	9/9/94																				
8	Support Formulation Dev.	9/12/94	9/12/94	9/9/94	9/9/94																				
9	<b>Pharmacology II</b>	9/26/96	12/18/96	1/26/96	4/18/96																				
10	Autonomic Profile Study	9/26/96	12/18/96	1/26/96	4/18/96																				
11	Renal Function Study	9/26/96	10/23/96	1/26/96	2/22/96																				
12	Cardio Vascular Study	9/26/96	10/23/96	1/26/96	2/22/96																				
13	<b>IND Preparation</b>	12/19/96	12/9/97	4/19/96	4/9/97																				
14	Clinical Pharmacology IND Prep	12/19/96	4/9/97	4/19/96	8/8/96																				
15	Pharmacology IND Prep	12/19/96	4/9/97	4/19/96	8/8/96																				
16	Toxicology IND Prep	12/19/96	4/9/97	4/19/96	8/8/96																				
17	Investigator Brochure	1/2/97	4/16/97	5/3/96	8/15/96																				
18	IND kick off Review Meeting	4/17/97	4/17/97	8/15/96	8/15/96																				
19	Clinical Research	4/17/97	5/22/97	8/16/96	9/20/96																				
20	Chemistry Manufact/Controls	4/17/97	7/7/97	8/16/96	11/5/96																				
21	Metabolism IND Preparation	7/8/97	7/28/97	11/6/96	11/26/96																				
22	IND Complete	7/29/97	9/30/97	11/27/96	1/29/97																				
23	Regulatory Compilation & Rev.	10/1/97	10/14/97	1/30/97	2/12/97																				
24	IND/CTX Submission	10/15/97	10/15/97	2/12/97	2/12/97																				
25	NDA Regulatory Review	10/29/97	12/9/97	2/27/97	4/9/97																				
26	<b>Patient Preclinical</b>	12/10/97	10/30/98	4/10/97	3/2/98																				
27	Assay Methods Development	12/10/97	3/11/98	4/10/97	7/10/97																				
28	Acute Dose Tolerance	3/12/98	7/10/98	7/11/97	11/10/97																				
29	Subchronic Dose Tolerance	3/12/98	6/24/98	7/11/97	10/23/97																				
30	Psychokinesis/Dynamic study	3/12/98	6/24/98	7/11/97	10/23/97																				
31	Metabolism/Mass Balance	7/13/98	10/30/98	11/11/97	3/2/98																				
32	Investigational New Drug (IND)	1/7/99	1/7/99	5/8/98	5/8/98																				