

SECTION VI

SECTION 6

Bioavailability / Bioequivalence

RLD Product Batch No:_____ Exp.____Generic Drug Batch No:_____ Exp.____

COMPARATIVE DISSOLUTION PROFILE

12 Dosage Units

Method SI-00-00 Edition # 00-00	Percentage Assay of the labeled amount dissolved in:-							
	5 min		10 min		15 min		30 min	
Dosage Unit No.	RLD [name]	Generic [name]	RLD [name]	Generic [name]	RLD [name]	Generic [name]	RLD [name]	Generic [name]
Unit 1	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 2	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 3	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 4	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 5	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 6	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 7	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 8	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 9	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 10	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 11	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
Unit 12	00.0	00.0	00.0	00.0	00.0	00.0	00.0	00.0
X (Mean) RSD	42.9 2.4	45.5 1.5	90.2 1.6	84.0 1.3	89.0 1.7	86.0 1.7	101.0 1.7	100.7 1.3

Only Average values and RSD shown..

The innovator's product (Prozac® Dista) and the Generic Fluoxetine capsules were found to give similar dissolution profiles. Both formulas reached 90% dissolved of the labeled at the 10 minute sampling interval.