



PRODUCT PROSPECTUS

Data packages include information for facilitating development of a commercial ODT product. SPI will be pleased to provide our know-how and laboratory capabilities to assist your development on a fee for service basis. SPI acknowledges that manufacturing in your equipment may yield different results.

ACTIVE INGREDIENTS	mirtazapine	ondansetron	carbidopa levodopa	rizatriptan	risperidone	nicotine ¹	loratadine	phloroglucinol	domperidone	loperamide	
API	USP	base USP	both USP	benzoate USP	benzoate	nicotine polacrilex USP	base	dihydrate Ph. Eur.	Ph. Eur.	HCl USP/EP	
DOSAGE FORM	ODT	ODT	ODT	ODT	ODT	lozenge	ODT	ODT	ODT	ODT	
STRENGTHS	15mg	4mg 8mg	10/100mg 25/100mg 25/250mg	5mg 10mg	2mg	2mg 4mg	5mg 10mg	80mg	10mg	2mg	
TABLET WEIGHTS	300mg	150mg 300mg	399mg 398mg 998mg	150mg 300mg	500mg	1200mg 1200mg	150mg 300mg	400mg	300mg	200mg	
SPI Pharma EXCIPIENTS	Pharmaburst® C1 Lubripharm® SSF	Pharmaburst® C1 Lubripharm® SSF	Pharmaburst® C1 Lubripharm® Mannogem®	Pharmaburst® C1	Pharmaburst® B1 Lubripharm® SSF	Mannogem® NL Effer-soda® 12 Lubripharm® SSF	Pharmaburst® C1	Pharmaburst® B1	Pharmaburst® B1 Lubripharm® SSF	Pharmaburst® B1	
STABILITY DATA	25/60 - 3 mos 30/65 - 3 mos 40/75 - 3 mos	40/75 - 3 mos	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	40/75 - 3 mos	25/60 - 3 mos 40/75 - 3 mos	25/60 - 12 mos 40/75 - 6 mos	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	25/60 - 3 mos 30/65 - 3 mos 40/75 - 3 mos	
REFERENCE PRODUCT	Remeron SolTab	Zofran ODT®	Parcopa	Maxalt-MLT®	Risperdal® M-tab®	Commit® Lozenge	Claritin® Reditab®	Spasfon Lyoc	Motilyo® Lyophilisat	Imodium® capsule (Europe)	Imodium® Quick Dissolve (Canada)
COMPARISON DATA	dissolution rate	dissolution Similarity Factor	dissolution Similarity Factor	dissolution Similarity Factor	dissolution rate	dissolution Similarity Factor T _{max} , C _{max} , AUC	dissolution Similarity Factor	dissolution rate	dissolution rate	dissolution Similarity Factor	
LICENSE AVAILABLE	worldwide	worldwide	worldwide except US, Canada, Mexico	worldwide except US, Canada, Mexico	worldwide	worldwide except US, Canada, Mexico, EP0 ²	worldwide	worldwide	worldwide	worldwide except Europe ³	

1 - data package includes pilot PK study data

2 - European Patent Organization as of July 2012: Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, Turkey

3 - European Union as of Dec 2006: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom



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