

## **Pharmasolutions**

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Active Ingredients	АРІ	Dosage Form	Strengths	Tablet Weights	Excipients	Stability Data	Reference Product		Comparison Data	License Available
Tadalafil	Base Ph. Eur	ODT	20mg	200mg	Pharmaburst® 500 Lubripharm® SSF	N/A	Cialis®		Dissolution Similarity Rate	Worldwide except MENA <sup>3</sup>
Ondansetron	Base USP	ODT	4mg 8mg	150mg 300mg	Pharmaburst® C1 Lubripharm® SSF	40/75 - 3 mos	Zofran ODT®		Dissolution Similarity Factor	Worldwide
Carbidopa/ Levodopa	Both USP	ODT	10/100mg 25/100mg 25/250mg	399mg 398mg 998mg	Pharmaburst® C1 Lubripharm® SSF Mannogem® Mannitol	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	Parcopa		Dissolution Similarity Factor	Worldwide except US, Canada, Mexico
Rizatriptan	Benzoate USP	ODT	5mg 10mg	150mg 300mg	Pharmaburst® C1	40/75 - 3 mos	Maxalt-MLT®		Dissolution Similarity Factor	worldwide except US, Canada, Mexico
Acetaminophen	Taste masked IH	ODT	250mg 160mg 125mg 80mg	900mg 576mg 450mg 288mg	Pharmaburst® 500 Lubripharm® SSF Actimask® Acetaminophen	25/60 - 12 mos 30/65 - 12 mos 40/75 - 6 mos	Tylenol®		Dissolution Similarity Factor	Worldwide
Nicotine <sup>1</sup>	Nicotine Polacrilex USP	Lozenge	2mg 4mg	1200mg 1200mg	Mannogem® NL Effer-Soda® 12 Lubripharm® SSF	25/60 - 12 mos 40/75 - 6 mos	Commit® Lozenge		Dissolution Similarity Factor	Worldwide except US, Canada, Mexico, EPO <sup>2</sup>
Loratadine	Base	ODT	5mg 10mg	150mg 300mg	Pharmaburst® C1	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	Claritin® Reditab®		Dissolution Similarity Factor	Worldwide
Phloroglucinol	Dihydrate Ph. Eur	ODT	80mg	400mg	Pharmaburst® B1	25/60 - 3 mos 30/65 - 3 mos 40/75 - 3 mos	Spasfon Lyoc		Dissolution Rate	Worldwide
Domperidone	Ph. Eur	ODT	10mg	300mg	Pharmaburst® B1 Lubripharm® SSF	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	Motilyo® Lyophilisat		Dissolution Rate	Worldwide
Mirtazapine	USP	ODT	15mg	300mg	Pharmaburst® C1 Lubripharm® SSF	25/60 - 3 mos 30/65 - 3 mos 40/75 - 3 mos	Remeron SolTab		Dissolution Rate	Worldwide
Risperidone	Benzoate	ODT	2mg	500mg	Pharmaburst® B1 Lubripharm® SSF	25/60 - 3 mos 40/75 - 3 mos	Resperdal® M-tab®		Dissolution Rate	Worldwide
Loperamide	HCI USP/ EP	ODT	2mg	200mg	Pharmaburst® B1	25/60 - 3 mos 30/65 - 3 mos 40/75 - 3 mos	Imodium® Capsule (Europe)	Imodium® Quick Dissolve (Canada)	Dissolution Similarity Factor	Worldwide except Europe <sup>4</sup>



- 1 Data package includes pilot PK study data and information for facilitating development of a commercial ODT product.
- 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 MENA Territory: Kingdom of Saudi Arabia, Kuwait, Qatar, Bahrain, UAE, Oman, Iraq, Jordan, Lebanon, Palestine, Egypt, Libya, Tunisia, Algeria and Morocco.
- 4 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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