WHO List of Prequalified Medicinal Products

Printed from WHO prequalification web site (http://www.who.int/prequal/) on 2015-May-23 00:03 GMT.

For information about the listing of prequalified products and the alternative approval procedure, please see "General information" at http://www.who.int/prequal/info_general/notes_registry.htm.

Legend:

"+" means combination product, both fixed-dose combination (co-formulated) and co-packaged product (i.e. co-blister)
[A+B] + C means A and B are in a fixed-dose formulation and C is co-packaged
"*" refers to products approved by both WHO Prequalification Programme and US FDA
USFDA1 - approved by USFDA; USFDA2 - tentatively approved by USFDA; EMEA Art 58 - approved by EMEA according to Article 58

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
IN	Oseltamivir (as phosphate)	Capsules 75mg	Cipla Ltd	Goa, India	HDPE bottle 30; PVC/PE/PVdC Aluminum blister 10	IN001	2009-May-13	
IN	Oseltamivir (as phosphate)	Capsules 75mg	Strides Arcolab Limited	Anekal Taluk, Bangalore, India	PVDC/PVC/Alu blister	IN002	2010-Oct-25	
IN	Oseltamivir (as phosphate)	Powder for oral suspension 12mg/ml	Roche Ltd	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Rottendorf Pharma GmbH, Ennigerloh, Germany (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging); GP Grenzach Produktions GmbH, Wyhlen, Germany (packaging)	Amber glass bottle 30g	IN003 (a)	2009-Sep-21	
IN	Oseltamivir (as phosphate)	Capsules 30mg	Roche Ltd	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging)	Blister (PVC/PE/PVDC, sealed with aluminium foil) 10	IN004 (a)	2009-Sep-21	
IN	Oseltamivir (as phosphate)	Capsules 45mg	Roche Ltd	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging)	Blister (PVC/PE/PVDC, sealed with aluminium foil) 10	IN005 (a)	2009-Sep-21	
IN	Oseltamivir (as phosphate)	Capsules 75mg	Roche Ltd	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Catalent Germany Schorndorf GmbH, Schorndorf, Germany (Galenic bulk production); CENEXI SAS, Fontenay-sous-Bois, France (Galenic bulk production); Hoffmann-La Roche Inc., New Jersey, USA (Galenic bulk production); Patheon Inc., Cincinnati, OH, USA (Galenic bulk production); DSM Pharmaceuticals Inc, Greenville, USA (Galenic bulk production); Catalent Germany Schorndorf GmbH, Schorndorf, Germany (packaging); GP Grenzach Produktions GmbH, Grenzach-Wyhlen, Germany (packaging); Wurmisweg, Kaiseraugst, Switzerland (packaging)	Blister (PVC/PE/PVDC, sealed with aluminium foil) 10	IN006 (a)	2009-Sep-21	
IN	Oseltamivir (as phosphate)	Capsule 30mg	Mylan Laboratories Ltd	Waluj, Aurangabad, Maharashtra, India	Alu/PVC blister 10; Alu/PVC/PE/PVDC blister 10; HDPE bottle 30	IN009	2014-Jun-13	
IN	Oseltamivir (as phosphate)	Capsule 45mg	Mylan Laboratories Ltd	Waluj, Aurangabad, Maharashtra, India	Alu/PVC blister 10; Alu/PVC/PE/PVDC blister 10; HDPE bottle 30	IN010	2014-Jun-13	
IN	Oseltamivir (as phosphate)	Capsule 75mg	Mylan Laboratories Ltd	Waluj, Aurangabad, Maharashtra, India	Alu/PVC blister 10; Alu/PVC/PE/PVDC blister 10; HDPE bottle 30	IN011	2014-Jun-13	
IN	Zanamivir	Inhalation powder 5mg/dose	GlaxoSmithKline	GlaxoSmithKline Australia Pty Ltd, Boronia, Australia; Glaxo Wellcome Production, Evreux, France	Alu/Alu blister, 4 blisters per disk (a pack contains 1 or 5 Alu foil disks)	IN007 (a)	2009-Sep-22	