

WHO List of Prequalified Medicinal Products

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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

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ
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)	Powder for oral suspension 12mg/ml	Roche Ltd, Switzerland	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging); GP Grenzach Produktions GmbH, Wyhlen, Germany (packaging)	Amber glass bottle 30g	IN003	2009-Sep-21
IN	Oseltamivir (as phosphate)	Capsules 30mg	Roche Ltd, Switzerland	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging)	Blister (PVC/PE/PVDC, sealed with aluminium foil) 10	IN004	2009-Sep-21
IN	Oseltamivir (as phosphate)	Capsules 45mg	Roche Ltd, Switzerland	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging)	Blister (PVC/PE/PVDC, sealed with aluminium foil) 10	IN005	2009-Sep-21

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ
IN	Oseltamivir (as phosphate)	Capsules 75mg	Roche Ltd, Switzerland	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); 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	2009-Sep-21
IN	Zanamivir	Inhalation powder 5mg/dose	GlaxoSmithKline Ltd, United Kingdom	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	2009-Sep-22