World Health Organization | Prequalification of Medical Products
IVDs, Medicines, Vaccines and Immunization Devices, Vector Control

M TB332

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Date: 2023.11.23 09:01:03 EET
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Product Details:

WHO Product ID:	TB332
Status:	Prequalified
INN, dosage form and strength:	Rifampicin Capsules, hard 300mg
Date of prequalification:	17 Jul, 2018
Basis of listing:	Prequalification - Full
Therapeutic area:	Tuberculosis
Type:	Finished Pharmaceutical Product
Dosage form:	Capsules, hard
Applicant organization:	**Macleods Pharmaceuticals Ltd** 304 Atlanta Arcade, Marol Church Road, Andheri (East) Mumbai, 400 059 India

Packaging details and storage conditions:

Packaging Type:	Strip, Alu/Alu
Configuration:	10x10
Shelf life (months):	24
Storage conditions:	Do not store above 25°C, store in dry condition, protect from light
Packaging Type:	Self-sealing bag, LDPE
Configuration:	100x1, LDPE bag packed in Al/PET/LDPE bag, packed in HDPE jar
Shelf life (months):	24
Storage conditions:	Do not store above 25°C, store in dry condition, protect from light
Packaging Type:	Blister, Alu/PVC
Configuration:	10x10
Shelf life (months):	24
Storage conditions:	Do not store above 25°C, store in dry condition, protect from light

API Manufacturing Site(s)

By Organization | By Active Ingredient

Lupin Ltd
T-142, MIDC, Thane District Tarapur, Via Boisar, Maharashtra 401 506 India

Rifampicin

Olon Active Pharmaceutical Ingredients India Private Limited
Plot No: L-1, L-21 to L-28 & L-44, Additional Phase MIDC, Raigad District Mahad, Maharashtra 402 301 India

Rifampicin

Shenyang Antibiotic Manufacturer
Jianshebei 3 Road, Hushitai Town, Xinchengzi District Shenyang, Liaoning 110 122 China

Rifampicin

FPP Manufacturing Site(s)

Macleods Pharmaceuticals Ltd
Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam Daman, 396 210 India

WHO Public Assessment Reports

Part 1 - Abstract
Part 2a - All accepted presentations
Part 2b - Visual appearance of the product
Part 3 - WHO-PQ recommended patient information leaflet*
Part 4 - WHO-PQ recommended summary of product characteristics*
Part 5 - Label
Part 6 - Discussion (status at the time of prequalification)
Part 7 - Steps before Prequalification
Part 8 - Steps following Prequalification (from 01 March 2014, only changes to the published information are included)

** This summary of product characteristics/patient information leaflet focus on uses of the medicine covered by WHO Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from strin regulatory authorities (term to be revised). The medicine may be authorised for additional or different uses by national medici regulatory authorities.*

Samples of the artworks of the SPC/PIL/labelling have not been submitted. Therefore, control of compliance with WHOPAR guidelines (contents and format) has not been possible.

Part 1 , Part 2a , Part 2b , Part 3 , Part 4 , Part 5 , Part 6 , Part 7 , Part 8