Prequalified Medicinal Products

Reference Number: TB332

Date of prequalification: 17 July 2018

Basis of listing: Prequalified by WHO

Status: Active

INN: Rifampicin

Therapeutic area: Tuberculosis

Dosage form & strength: Capsules, hard 300mg

Storage condition: Do not store above 25°C, store in dry condition, protect from light

Shelf life (months): 24

Packaging: Blister,Alu/PVC 10x10; Strip,Alu/Alu 10x10; Self-sealing bag,LDPE 100x1, LDPE bag packed in Al/PET/LDPE bag, packed in HDPE jar

---

Applicant:
Macleods Pharmaceuticals Ltd, 304 Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400 059, India

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

FPP WHO Public Inspection Reports:

M **Macleods Pharmaceuticals Ltd (Unit 2) - Desk Review** - (22 October 2018),
Shanti Nagar, India

API Manufacturing Site:
(Rifampicin) Olon Active Pharmaceutical Ingredients India Private Limited, Plot No: L-1, L-21 to L-28 & L-44, Additional Phase MIDC, Mahad, Raigad District, Maharashtra, 402 301, India
(Rifampicin) Shenyang Antibiotic Manufacturer, Jianshebei 3 Road, Hushitai Town, Xinchengzi District, Shenyang, Liaoning, 110 122, China (People's Republic of)
(Rifampicin) Lupin Ltd, T-142, MIDC, Tarapur, Via Boisar, Thane District, Maharashtra, 401 506, India

API WHO Public Inspection Reports:

M **Lupin Ltd - Tarapur** - (21 - 24 August 2017),
Tarapur, India

M **Olon Active Pharmaceutical Ingredient India Pvt Ltd** - (14 - 17 October 2019),
Mahad, India

M **Shenyang Antibiotic Manufacturer** - (30 July - 02 August 2018),
Shenyang, China

Digitally signed by Chirtoacă Iurie
Date: 2021.09.02 10:26:55 MSK
Reason: MoldSign Signature
Location: Moldova

WHO Public Assessment Reports

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

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 stringent regulatory authorities (term to be revised). The medicine may be authorised for additional or different uses by national medicines 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.