

Prequalified Medicinal Products



Reference Number: TB158

Date of prequalification: 07 March 2008

Basis of listing: Prequalified by WHO

Status: Active

INN: Isoniazid/Rifampicin

Therapeutic area: Tuberculosis

Dosage form & strength: Tablet, Film-coated 75mg/150mg

Storage condition: Do not store above 30° C, store in a dry condition, protect from light (HDPE Bottle, Alu/PVC/PE/PVdC blister, Alu strip); Do not store above 25° C, store in a dry condition, protect from light (Alu/PVDC/PVC blister)

Shelf life (months): 36 months (HDPE Bottle, Alu/PVC/PE/PVdC blister, Alu strip), 24 months(Alu/PVDC/PVC blister)

Packaging: HDPE/Sachet (PET/Alu/LLDPE) 500x1; 1000x1; Blister Alu/PVC/PE/PVdC 28x3, 28x12, 28x24, 10x10; Blister Alu/PVdC/PVC 28x3, 28x24, 10x10; Strip Alu/Alu 10x10

Applicant:

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

FPP Manufacturing Site:

Oxalis Labs, Vill. Theda, P.O.Iodhimajra, Baddi, Distt. Solan, 174101, India

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 **Oxalis Labs - (13 - 16 March 2018),**
📍 **Solan, India**

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

API Manufacturing Site:

(Isoniazid) Second Pharma Co Ltd, No. 33, Weiwu Road, Hangzhou Gulf Fine Chemical Zone, Shangyu, Zhejiang, 312 369, China (People's Republic of)

(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

(Isoniazid) Amsal Chem Pvt Ltd, A-1/401-402-403 GIDC Area, Ankleshwar, Bharuch District, Gujarat, 393 002, India

(Isoniazid) Calyx Chemicals & Pharmaceuticals Ltd, Plot No-102/91/90, MIDC Industrial Area, Tarapur, Boisar, Maharashtra, 401 506, India

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

(Rifampicin) Shenyang Antibiotic Manufacturer, Jianshebei 3 Road, Hushitai Town, Xinchengzi District, Shenyang, Liaoning, 110 122, China (People's Republic of)

API WHO Public Inspection Reports:

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- M **Amsal Chem Pvt Ltd - (21 - 23 November 2018),**
📍 Ankleshwar, India
 - M **Calyx Chemicals & Pharmaceuticals Ltd - (28 January - 01 February 2019),**
📍 Tarapur, India
 - 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 **Second Pharma Co Ltd - Desk Review - (26 July 2019),**
📍 Shangyu City, China
 - M **Shenyang Antibiotic Manufacturer - (30 July - 02 August 2018),**
📍 Shenyang, China
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WHO Public Assessment Reports

 [Part 1](#),  [Part 2](#),  [Part 3](#),  [Part 4](#),  [Part 5](#),  [Part 6](#),  [Part 7](#),  [Part 8](#)

Part 1 - Abstract

Part 2 - All accepted presentations (including photo)

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.*