

Prequalified Medicinal Products



Reference Number: TB168

Date of prequalification: 07 March 2008

Basis of listing: Prequalified by WHO

Status: Active

INN: Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin

Therapeutic area: Tuberculosis

Dosage form & strength: Tablet, Film-coated 275mg/75mg/400mg/150mg

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

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

Packaging: Bottle HDPE: 500x1, 1000x1; Blister Alu/PVC/PE/PVdC: 10x10,28x3, 28x24; Blister Alu/PVC/PVdC: 10x10,28x3, 28x24;Strip Al/Al: 10x10, 28x3, 28x24

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

Linaria Chemicals (Thailand) Ltd, 309, Soi6C, Sukhumvit Rd, Bangpoo Industrial Estate, Moo4, Tumbol Phraska, Ampur Muang Samutprakan, Samutprakan, 10280, Thailand

(Rifampicin) Novartis India Ltd, Sandoz Business Unit, Plot No L-1, Additional Phase, MIDC, Mahad, District - Raigad, Maharashtra, 402 301, India

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

(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

India

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

(Ethambutol hydrochloride) Lupin Ltd, Plot No. 09, 123, 123/1, 124 & 125 -Ethambutol (ETB) Plant, GIDC Estate, Ankleshwar 393 002, Gujarat, India

(Pyrazinamide) Anuh Pharma Ltd, E17/3 & 17/4 MIDC, Boisar, Tarapur, Thane District, Maharashtra, 401 506, India

(Pyrazinamide) Macleods Pharmaceuticals Ltd, Plot No 2209 GIDC Industrial Area, At and Post Sarigam, Taluka: Umbergaon, Valsad District, Gujarat, 396 155, India

API WHO Public Inspection Reports:

- 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 - (30 August - 01 September 2017),**
📍 Gujarat, India
- M **Lupin Ltd - Tarapur - (21 - 24 August 2017),**
📍 Tarapur, India
- M **Macleods Pharmaceuticals Ltd - (08 - 12 August 2016),**
📍 Gujarat, 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

WHO Public Assessment Reports

 [Part 1](#),  [Part 2a](#),  [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.

