

Prequalified Medicinal Products



Reference Number: TB179

Date of prequalification: 23 April 2008

Basis of listing: Prequalified by WHO

Status: Active

INN: Isoniazid

Therapeutic area: Tuberculosis

Dosage form & strength: Tablet 300mg

Storage condition: Do not store above 30°C

Shelf life (months): 48

Packaging: Blister Al/PVC/PVdC: 10x3, 10x9, 10x10, 28x3, 28x24, 7x6; Strip Alu/Alu 10x3, 10x9, 10x10, 28x3, 28x24, 7x6; Bottle, HDPE, 1000x1 in LDPE bag

Applicant:

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

FPP Manufacturing Site:

Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India

Oxalis Labs, Vill. Theda, P.O. Iodhimajra, Baddi, Distt. Solan, 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
- M **Macleods (N2 (Unit VI) - Desk Review - (27 August 2018),**
📍 Village Theda Baddi, 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)

(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

API WHO Public Inspection Reports:

- M **Amsal Chem Pvt Ltd - (21 - 23 November 2018),**
📍 Ankleshwar, India

▼ **Alkermes India, India**

M **Calyx Chemicals & Pharmaceuticals Ltd - (28 January - 01 February 2019),**
📍 **Tarapur, India**

M **Second Pharma Co Ltd - Desk Review - (26 July 2019),**
📍 **Shangyu City, China**

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.*

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