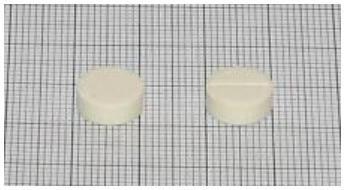
Prequalified Medicinal Products



Reference Number: TB174

Date of prequalification: 01 November 2010

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, store in dry condition, protect from light

Shelf life (months): 60 (bottle pack); 48 (blister pack)

Packaging: Bottle HDPE: 1000x1; Alu/PVC/EVOH/Aclar blister: 28x24; 10 x 10

Applicant:
Micro Labs Ltd, 31 Race Course Road, Bangalore, Karnataka, 560 001, India

FPP Manufacturing Site:
Micro Labs Ltd, Unit 3, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126, India

FPP WHO Public Inspection Reports:

M **Micro Labs Limited - Unit-3 - (07 - 10 December 2015),**
Hosur, India

API Manufacturing Site:
(Isoniazid) Calyx Chemicals & Pharmaceuticals Ltd, Plot No-102/91/90, MIDC Industrial Area, Tarapur, Boisar, Maharashtra, 401 506, India
(Isoniazid) Amsal Chem Pvt Ltd, A-1/401-402-403 GIDC Area, Ankleshwar, Bharuch District, Gujarat, 393 002, 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

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Date: 2021.11.30 15:27:41 EET
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 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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