

Prequalified Medicinal Products



Reference Number: TB299

Date of prequalification: 11 July 2016

Basis of listing: Prequalified by WHO

Status: Active

INN: Linezolid

Therapeutic area: Tuberculosis

Dosage form & strength: Tablet, Film-coated 600mg

Storage condition: Do not store above 30°C

Shelf life (months): 36

Packaging: Blister Alu/Alu 10x10; Bottle HDPE 20x1, 100x1

Applicant:

Hetero Labs Ltd, Unit 5, Survey No 439, 440, 441 & 458 TSIIIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301, India

FPP Manufacturing Site:

Hetero Labs Ltd, Unit 5, Survey No 439, 440, 441 & 458 TSIIIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301, India

FPP WHO Public Inspection Reports:

M **Hetero Labs, Unit V - (15 - 18 June 2015),**
📍 **Telangana State, India**

API Manufacturing Site:

(Linezolid) Symed Labs Ltd, Survey No 353, Domadugu (Village), Jinnaram (Mandal), Medak (Dist), Telangana, 502 313, India

API WHO Public Inspection Reports:

M **Symed Labs Ltd - Unit I - Desk Review - (26 November 2018),**
📍 **Telangana, India**

WHO Public Assessment Reports

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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