

## 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 TSIC 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 TSIC 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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