WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB321 trade name]*

Linezolid 600 mg Tablets

[TB321 trade name], manufactured at Cipla Limited, Pithampur, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 07 December 2016.

[TB321 trade name] is indicated for treatment of tuberculosis. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient of [TB321 trade name] is linezolid.

The efficacy and safety of linezolid are well established based on extensive clinical experience in the treatment of tuberculosis.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of linezolid in tuberculosis, the team of assessors advised that [TB321 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB321 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB321 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	07 December 2016	listed
Quality	21 November 2016	MR
Bioequivalence	18 November 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 October 2015	MR
FPP	16 October 2014	MR
GCP/GLP (re-)inspection	NA	NA

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.