WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB299 trade name]*

Linezolid 600mg film-coated tablets

[TB299 trade name], manufactured at Hetero Labs Ltd, (Unit V), Mahaboob Nagar District, Telangana, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 11 July 2016.

[TB299 trade name] is indicated for the treatment of drug-resistant tuberculosis caused by *Mycobacterium 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 [TB299 trade name] is the antibacterial agent, 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 [TB299 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB299 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB299 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	11 July 2016	Listed
Quality	25 May 2016	MR
Bioequivalence	20 June 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 October 2015	MR
FPP	18 June 2015	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	

The table represents the status of relevant completed activities only.

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