

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[TB297 trade name]\***

Linezolid 600mg film-coated tablets

[TB297 trade name], manufactured at Macleods Pharmaceuticals Limited, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 12 December 2017.

[TB297 trade name] is indicated in combination with other antituberculosis agents for the treatment of 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 [TB297 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 [TB297 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB297 trade name] in the list of prequalified medicinal products.

**Summary of Prequalification Status for [TB297 trade name]:**

Initial acceptance	Date	Outcome
Status on PQ list	12 December 2017	listed
Quality	12 December 2017	MR
Bioequivalence	27 January 2015	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	12 August 2016	MR
FPP	17 July 2014	MR
<b>GCP/GLP (re-)inspection</b>	14 July 2017	MR
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.