

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB350 trade name]*

Linezolid 600mg film-coated tablets

[TB350 trade name], manufactured at Lupin Limited, Bari Brahmna, India , was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 18 December 2018.

[TB350 trade name] is indicated in combination with other antituberculosis agents 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 (API) of [TB350 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 [TB350 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB350 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB350 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	18 December 2018	Listed
Quality	28 November 2018	MR
Bioequivalence	28 November 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 October 2015	MR
FPP	16 March 2018	MR
GCP (re-)inspection	29 September 2017	MR
GCP/GLP (re-)inspection	29 September 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.