WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB365 trade name]*

Linezolid 600 mg tablets

[TB365 trade name], manufactured at Mylan Laboratories Limited, Madya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 16 March 2020.

[TB365 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 (API) of [TB365 trade name] is the antibacterial agent linezolid. The API is documented for the treatment of tuberculosis and other bacterial infections.

The efficacy and safety profile of linezolid is 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 [TB365 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB365 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB365 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 March 2020	listed
Quality	28 February 2020	MR
Bioequivalence	02 March 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 November 2018	MR*
FPP	25 May 2018	MR
GCP/GLP (re-)inspection	21 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.