

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB389 trade name]*

Linezolid 150 mg Dispersible Tablets

[TB389 trade name], manufactured at Micro Labs Ltd, Hosur, Tamilnadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 02 September 2023.

[TB389 trade name] is indicated for 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(s) of [TB389 trade name] is linezolid.

The efficacy and safety 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 [TB389 trade name] is of acceptable quality, efficacy and safety to allow the inclusion of [TB389 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB389 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	02 September 2023	listed
Quality	03 August 2023	MR
Bioequivalence	11 August 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 February 2019	MR
FPP	18 January 2023	MR*
GCP/GLP (re-)inspection	03 February 2023	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.