WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB388 trade name]*

Delamanid 50 mg tablets

[TB388 trade name], manufactured at Mylan Laboratories Limited, Nashik, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 24 November 2022.

[TB388 trade name] is indicated in combination with other tuberculosis medicines for the treatment of drug-resistant 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 [TB388 trade name] is the antibiotic delamanid. The efficacy and safety of delamanid are well established based on 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 delamanid in tuberculosis, the team of assessors advised that [TB388 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB388 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB388 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	24 November 2022	listed
Quality	7 November 2022	MR
Bioequivalence	17 November 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	8 June 2020	MR*
FPP	9 April 2021	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.