WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB367 trade name]*

Ethambutol hydrochloride 50 mg dispersible tablets

[TB367 trade name], manufactured at Micro Labs, Tamil Nadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 25 October 2021.

[TB367 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 of [TB367 trade name] is ethambutol.

The efficacy and safety of ethambutol 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 ethambutol in tuberculosis, the team of assessors advised that [TB367 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB367 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB367 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	25 October 2021	listed
Pharmaceutical quality	23 September 2021	MR
Bioequivalence	07 October 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	03 August 2021	MR*
FPP	10 April 2019	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.