WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB334 trade name]*

Ethambutol hydrochloride 100 mg dispersible tablets

[TB334 trade name], manufactured at Macleods Pharmaceuticals Ltd (Kachigan Daman, India) and Macleods Pharmaceuticals Ltd at Oxalis Labs Lodhimajra (Himachal Pradesh, India), was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 14 March 2018.

[TB334 trade name]is indicated in combination with other anti-tuberculosis agents for the treatment of multi-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 of [TB334 trade name] is the antibacterial agent 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 antituberculosis therapy, the team of assessors advised that [TB334 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB334 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB334 trade name]:

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

*Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 March 2018	listed
Pharmaceutical quality	2 March 2018	MR
Bioequivalence	5 March 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	1 September 2017	MR
FPP	11 December 2017	MR
GCP/GLP (re-)inspection	14 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

Requalification	06 November 2023