WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB406 trade name][*]

Ethambutol hydrochloride 100 mg dispersible tablets

[TB406 trade name], manufactured at Cadila Pharmaceuticals Limited, Ahmedabad, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 21 November 2024.

[TB406 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 [TB406 trade name] is ethambutol hydrochloride.

The efficacy and safety of ethambutol 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 ethambutol in tuberculosis, the team of assessors advised that [TB406 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB406 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB406 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	21 November 2024	listed
Pharmaceutical quality	15 November 2024	MR
Bioequivalence	18 November 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 December 2022	MR*
FPP	15 October 2024	MR*
GCP/GLP (re-)inspection	22 March 2024	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

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