# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [TB008 trade name]*

Ethambutol hydrochloride 400 mg tablets

[TB008 trade name], manufactured at Cadila Pharmaceuticals Limited, Dholka, Ahmedabad, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 13 November 2003.

[TB008 trade name] is indicated in combination with other tuberculosis medicines for the treatment of tuberculosis due to *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 [TB008 trade name] is ethambutol hydrochloride.

The efficacy and safety of ethambutol hydrochloride 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 hydrochloride, the team of assessors advised that [TB008 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB008 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB008 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** | 13 November 2003 | listed |
| Pharmaceutical quality | NA | NA |
| Bioequivalence | NA | NA |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | NA | NA |
| FPP | 02 November 2002 | 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

| | |
|---|---|
| **Requalification** | 29 November 2024 |

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