WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB070 trade name]*

Ethambutol hydrochloride/isoniazid/pyrazinamide/ rifampicin 275mg/ 75mg/ 400mg/ 150mg tablets

[TB070 trade name], manufactured at Lupin Limited, Chikaltana, Aurangabad, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 13 November 2003.

[TB070 trade name] is indicated for treatment of 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(s) of [TB070 trade name] Ethambutol hydrochloride, isoniazid, pyrazinamide and rifampicin. The efficacy and safety of Ethambutol hydrochloride, isoniazid, pyrazinamide and rifampicin 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 [TB070 trade name] in tuberculosis, the team of assessors advised that [TB070 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB070 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB070 trade name]:

The table represents the status of relevant completed activities only.

Summary of prequalification status for [TB070 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	13 November 2003	listed
Requalification	27 January 2021	MR
Quality	January 2021	MR
Bioequivalence	NA	NA
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 August 2017	MR
API	01 September 2017	MR
API	23 November 2018	MR
API	01 February 2019	MR
API	26 July 2019	MR
API	17 October 2019	MR
API	12 June 2020	MR

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

FPP	10 November 2017	MR
FPP	16 March 2018	MR
GCP/GLP (re-)inspection	19 April 2018	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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification	27 January 2021