

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

**[TB177 trade name]\***

Ethambutol hydrochloride 400mg tablets

[TB177 trade name], manufactured at Lupin Ltd, Aurangabad, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 8 April 2010.

[TB177 trade name] is indicated for the 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 of [TB177 trade name] is the antimycobacterial agent ethambutol.

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 [TB177 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB177 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB177 trade name]:**

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

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

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	8 April 2010	listed
Pharmaceutical quality	21 May 2008	MR
Bioequivalence	28 Jan 2010	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	30 Nov 2005	MR
FPP	2 Oct 2009	MR
<b>GCP/GLP (re-)inspection</b>	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.

<b>Requalification</b>	06 May 2020
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