

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

**[TB308 trade name]\***

Isoniazid 100 mg tablets

[TB308 trade name], manufactured at Mylan Laboratories Limited, Aurangabad, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 31 October 2012.

[TB308 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 [TB308 trade name] is isoniazid. The efficacy and safety of isoniazid 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 isoniazid in the treatment of tuberculosis, the team of assessors advised that [TB308 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB308 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB308 trade name]:**

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	26 Sept 2017	listed
Quality	29 Aug 2017	MR
Bioequivalence	18 Sept 2017	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	13 Nov 2015	MR
FPP	15 July 2016	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 NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

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