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 currently indicated in combination with other medicines for the treatment and prevention 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, 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]:

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	26 Sept 2017	listed
Pharmaceutical quality	29 Aug 2017	MR
Bioequivalence	18 Sept 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	13 Nov 2015	MR
FPP	15 July 2016	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

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

Requalification	8 April 2024