WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB285 trade name]*

Isoniazid BP 300 mg Tablets

Abstract

[TB285 trade name], manufactured at Mylan Laboratories Limited, Aurangabad, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 26 September 2017.

[TB285 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 [TB285 trade name] is the antimycobacterial agent 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 antituberculosis, the team of assessors advised that [TB285 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB285 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB285 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	26 Sept 2017	listed
Quality	29 Aug 2017	MR
Bioequivalence	18 Sept 2017	MR
GMP (re-)inspection		
API	13 Nov 2015	MR
FPP	15 July 2015	MR
GCP/GLP (re-)inspection	21 July 2017	MR

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.

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