WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB178 trade name]*

Isoniazid 100 mg tablets

[TB178 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 23 April 2008.

[TB178 trade name] is currently indicated in combination with other tuberculosis medicines for the treatment of tuberculosis due to *Mycobacterium tuberculosis*, including in regimens for drug-resistant 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 [TB178 trade name] is isoniazid.

The efficacy and safety of isoniazid 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 isoniazid, the team of assessors advised that [TB178 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB178 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB178 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	23 April 2008	listed
Pharmaceutical quality	14 March 2008	MR
Bioequivalence	29 March 2007	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	14 October 2006	Waived (only source)
FPP	20 June 2007	MR
GCP/GLP (re-)inspection	28 April 2007	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

Requalification	18 July 2025

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