WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB174 trade name]*

Isoniazid 300 mg tablets

[TB174 trade name], manufactured at Micro Labs Limited, Hosur, Tamil Nadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 1 November 2010.

[TB174 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 [TB174 trade name] is isoniazid. The efficacy and safety of isoniazid is well established based on extensive clinical experience in the treatment 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 [TB174 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB174 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB174 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	1 Nov 2010	Listed
Quality	14 Oct 2010	MR
Bioequivalence	23 Sept 2010	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	15 Sept 2010	Accepted (based on a risk/benefit assessment)
FPP	21 May 2009	MR
GCP/GLP (re-)inspection	16 July 2010	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.

Requalification	6 May 2020	MR

MR: meets requirements

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