WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB359 trade name]*

Isoniazid 100 mg dispersible tablets

[TB359 trade name], manufactured at Macleods Pharmaceuticals Limited, Baddi, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 02 March 2021.

[TB359 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 [TB359 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 [TB359 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB359 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB359 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	02 March 2021	listed
Pharmaceutical quality	17 February 2021	MR
Bioequivalence	22 February 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 November 2018	MR
API	01 February 2019	MR
API	March 2019	MR*:
FPP	21 September 2020	MR
GCP/GLP (re-)inspection	01 September 2020	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

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