

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB375 trade name]*

Isoniazid 300mg tablets

[TB375 trade name], manufactured at Lupin Limited, Kartholi, Bari Brahmana, Jammu & Kashmir, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 21 September 2022.

[TB375 trade name] is indicated for 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 [TB375 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 in tuberculosis, the team of assessors advised that [TB375 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB375 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB375 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	21 September 2022	listed
Quality	06 September 2022	MR
Bioequivalence	12 September 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 November 2018	MR
FPP	14 April 2022	MR
GCP/GLP (re-)inspection		
GCP (re-)inspection	27 May 2022	MR
GLP (re-)inspection	14 April 2022	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 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.