WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB276 trade name]*

Isoniazid 300mg tablets

[TB276 trade name], manufactured at Cadila Pharmaceuticals Limited, Dholka, Ahmedabad, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 29 October 2015.

[TB276 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 [TB276 trade name] 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 [TB276 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB276 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB276 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	29 October 2015	Listed
Quality	20 January 2015	MR
Bioequivalence	25 January 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	25 June 2015	MR
FPP	13 June 2014	MR
GCP/GLP (re-)inspection	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 NoC: Notice of concern PQ: prequalification NA**: Previous inspection by WHO showed accepted outcome

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.

Requalification	February 2022