

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB189 trade name]*

Isoniazid/rifampicin 75mg/150mg film-coated tablets

[TB189 trade name], manufactured at Svizera Labs Private Ltd, Navi Mumbai, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 19 December 2012.

[TB189 trade name] is indicated for 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 ingredients of [TB189 trade name] are the antimycobacterial agents isoniazid and rifampicin.

The efficacy and safety of isoniazid and rifampicin 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 and rifampicin in tuberculosis, the team of assessors advised that [TB189 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB189 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB189 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	19 December 2012	listed
Quality	05 December 2012	MR
Bioequivalence	04 December 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 February 2011	MR
API	16 June 2011	MR
FPP	29 September 2011	MR
GCP/GLP (re-)inspection	15 October 2010	MR

MR: meets requirements

NA: not applicable, not available

The table represents the status of relevant completed activities only.

Requalification	03 August 2021
------------------------	----------------

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