WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB392 trade name]*

Isoniazid 300 mg Tablets

[TB392 trade name], manufactured at Svizera Labs Pvt. Ltd,Turbhe, Navi Mumbai, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 22 December 2023.

[TB392 trade name] is indicated in combination with other anti-tuberculosis agents for the treatment of multi-drug resistant tuberculosis and prevention of tuberculosis caused by *Mycobacterium 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 [TB392 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 [TB392 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB392 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB392 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	22 December 2023	listed
Pharmaceutical quality	14 December 2023	MR
Bioequivalence	15 December 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	20 April 2023	MR*
FPP	23 March 2023	MR
GCP/GLP (re-)inspection	15 June 2023	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.