WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB405 trade name]*

Isoniazid 100 mg dispersible tablets

[TB405 trade name], manufactured at S Kant Healthcare Limited, Vapi, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 17 April 2024.

[TB405 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 [TB405 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 [TB405 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB405 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB405 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	17 April 2024	listed
Pharmaceutical quality	04 April 2024	MR
Bioequivalence	11 April 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	20 April 2023	MR*
FPP	16 June 2022	MR
GCP/GLP (re-)inspection	09 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.