

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[TB193trade name]\***

Rifampicin/Isoniazid/Pyrazinamide/Ethambutol

[TB193 trade name], manufactured at Svizera Labs Private Ltd, Navi Mumbai, India was accepted for the WHO list of prequalified products for the treatment of tuberculosis on 19 December 2012.

[TB193 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 [TB193 trade name] are rifampicin, isoniazid, pyrazinamide and ethambutol. The efficacy and safety of rifampicin, isoniazid, pyrazinamide and ethambutol 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 [TB193 trade name] in tuberculosis, the team of assessors advised that [TB193 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB193 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB193 trade name]:**

The table represents the status of relevant completed activities only.

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	19 Dec 2012	listed
Quality	14 Dec 2012	MR
Bioequivalence	4 Dec 2012	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	18 Feb 2011	MR
API	16 Jun 2011	MR
API	4 Feb 2011	MR
FPP	29 Sep 2012	MR
<b>GCP/GLP (re-)inspection</b>	18 Jul 2011	MR
<b>GCP/GLP (re-)inspection</b>	20 Jul 2011	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	

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<b>Requalification</b>	10 June 2022
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\*Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.