

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB158 trade name]*

Rifampicin/Isoniazid 150 mg/75 mg Tablets

[TB158 trade name] manufactured at Macleods Pharmaceuticals Ltd, Kachigam, Daman, India, were accepted for the WHO list of prequalified products for the treatment of tuberculosis on 7 March 2008.

[TB158 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 (SPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients of [TB158 trade name] are the antimycobacterial agents rifampicin and isoniazid.

The efficacy and safety profile of Rifampicin and 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 rifampicin/isoniazid in tuberculosis the team of assessors advised that [TB158 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB158 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB158 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	7 March 08	listed
Quality	06 Feb 08	MR
Bioequivalence	02 Feb 06	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	17 March 07	MR
FPP	14 October 06	MR
GCP/GLP (re-)inspection	20 February 07	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	

The table represents the status of relevant completed activities only.

Requalification	17 May 2021
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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.