WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB231 trade name]*

Isoniazid/rifampicin 150 mg/300 mg tablets

[TB231 trade name], manufactured at Macleods Pharmaceuticals Limited, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 15 September 2016.

[TB231 trade name] is currently indicated patients weighing 25 kg or over for the treatment of tuberculosis due to *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 ingredients of [TB231 trade name] are 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, the team of assessors advised that [TB231 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB231 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB231 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	15 December 2016	Listed
Pharmaceutical quality	25 August 2016	MR
Bioequivalence	07 September 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	13 June 2014	MR
API	24 June2015	MR
API	22 July 2015	MR
API	13 November 2015	MR
API	23 August 2016	MR
FPP	23 May 2014	MR
GCP/GLP (re-)inspection	25 March 2016	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements

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

GLP: good laboratory practice [quality standard]	MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification

Requalification	20 September 2024