WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB302 trade name]*

Isoniazid/rifampicin 50 mg/75mg dispersible tablets

[TB302 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 31 August 2017.

[TB302 trade name] is currently indicated for the treatment of tuberculosis due to *Mycobacterium tuberculosis* in children weighing less than 25 kg. It is also indicated for the prevention of tuberculosis in children at risk. 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 [TB302 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 and prevent 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 [TB302 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB302 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB302 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	31 August 2017	Listed
Pharmaceutical quality	18 July 2017	MR
Bioequivalence	14 November 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	19 March 2014	MR
API	22 July 2015	MR
API	13 November 2015	MR
API	25 June 2016	MR
API	23 August 2016	MR
FPP	23 May 2014	MR
GCP/GLP (re-)inspection	14 July 2017	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.