WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB332 trade name][*]

Rifampicin 300 mg Capsules

[TB332 trade name], manufactured at Macleods Pharmaceuticals Ltd, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 13 July 2018.

[TB332 trade name] is indicated for in combination with other antituberculosis agents, for the treatment of tuberculosis caused by drug-susceptible *Mycobacterium tuberculosis* and in combination with other medicines for the treatment of leprosy. It is also indicated for post-exposure prophylaxis (PEP) in persons who have been in contact with a leprosy patient. 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 [TB332 trade name] is the antimycobacterial agent rifampicin.

The efficacy and safety of rifampicin 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 rifampicin in antituberculosis therapy, the team of assessors advised that [TB332 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB332 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB332 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 July 2018	listed
Pharmaceutical quality	11 June 2018	MR
Bioequivalence	19 June 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 July 2015	MR
API	24 August 2017	MR
FPP	05 January 2018	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