WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB259 trade name][*]

Rifampicin 150mg capsules

[TB259 trade name], manufactured at Macleods Pharmaceuticals Limited, Premier Industrial Estate, Kachigam, Daman – 396210, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis (TB) on 7 September 2016.

[TB259 trade name] is indicated for 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 ingredient(s) of [TB259 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 tuberculosis, the team of assessors advised that [TB259 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB259 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB259 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	07 September 2016	listed
Pharmaceutical quality	07 September 2016	MR
Bioequivalence	24 March 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	13 June 2014	MR
API	22 June 2014	MR
FPP	23 May 2014	MR
GCP/GLP (re-)inspection	12 February 2016	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

Requalification	04 July 2024