WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB307 trade name]*

Pyrazinamide 150 mg dispersible tablets

[TB307 trade name], manufactured at Macleods Pharmaceuticals Limited, Tehsil Baddi, District Solan, Himachal Pradesh, India was accepted for the WHO list of prequalified products for the treatment of tuberculosis on 07 December 2016.

[TB307 trade name] is indicated for treatment of 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 of [TB307 trade name] pyrazinamide. The efficacy and safety of pyrazinamide 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 [TB307 trade name] in tuberculosis, the team of assessors advised that [TB307 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB307 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB307 trade name]:

The table represents the status of relevant completed activities only.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	07 Dec 2016	listed
Quality	03 Nov 2016	MR
Bioequivalence	03 Nov 2016	NA
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	25 June 2015	MR
FPP	17 July 2014	MR
GCP/GLP (re-)inspection	14 March 2016	NA

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.

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