WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB277 trade name]*

Levofloxacin 250 mg Tablets

[TB277 trade name], manufactured at Macleods Pharmaceuticals Ltd, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment tuberculosis on 24 October 2014.

[TB277 trade name] is currently indicated for treatment of drug-resistant tuberculosis and prevention of multidrug-resistant 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 [TB277 trade name] is levofloxacin hemihydrate.

The efficacy and safety of levofloxacin 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 levofloxacin, the team of assessors advised that [TB277 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB277 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB277 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	24 Oct 2014	listed
Pharmaceutical quality	01 Oct 2014	MR
Bioequivalence	13 Oct 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 March 2012	MR
FPP	24 Feb 2012	MR
GCP/GLP (re-)inspection	NA	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
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.

Requalification	17 May 2021