WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB326 trade name]*

Levofloxacin 100 mg Dispersible Tablets

[TB326 trade name], manufactured at Macleods Pharmaceuticals Ltd Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 2 February 2018.

[TB326 trade name] is currently indicated for the 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 [TB326 trade name] is levofloxacin hemihydrate.

The efficacy and safety of levofloxacin are 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 [TB326 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB326 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB326 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	22 February 2018	listed
Pharmaceutical quality	09 February 2018	MR
Bioequivalence	15 February 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	30 January 2015	MR
API	18 May 2016	MR
API	12 August 2018	MR
FPP	17 June 2014	MR
GCP/GLP (re-)inspection	14 July 2014	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	29 January 2024