WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB326 trade name][1]

Levofloxacin (as hemihydrate) 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 prevention and treatment of tuberculosis on 22 February 2018.

[TB326 trade name] is indicated for the prevention and 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 (API) of [TB326 trade name] is the antibacterial agent levofloxacin.

The efficacy and safety profile of levofloxacin is well established based on extensive clinical experience in the prevention and treatment of tuberculosis.

On the basis of data submitted and public information on the use of levofloxacin in tuberculosis, 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]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 Feb 2018	listed
Quality	09 Feb 2018	MR
Bioequivalence	15 Feb 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	30 Jan 2015	MR
API	18 May 2016	
API	12 Aug 2018	
FPP	17 Jun 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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only

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