WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB340 trade name] *

Levofloxacin (as hemihydrate) 750 mg tablets

[TB340 trade name] manufactured at MSN Laboratories Private Limited, Telangana, India, was included in the WHO list of prequalified medicinal products for the prevention and treatment of tuberculosis on 15 May 2019.

[TB340 trade name], in combination with other antituberculosis drugs is indicated for the prevention and treatment of tuberculosis caused by *Mycobacterium 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 [TB340 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 [TB340 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB340 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB340 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	15 May 2019	MR
Quality	26 April 2019	MR
Bioequivalence	10 May 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	09 February 2018	MR
FPP	23 March 2017	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

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.