WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB349 trade name]*

Moxifloxacin (as hydrochloride) 100 mg dispersible tablets

[TB349 trade name], manufactured at Micro Labs Limited, Tamil Nadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 31 October 2018.

[TB349 trade name] is indicated in combination with other antituberculosis agents for the treatment of drug-resistant 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 of [TB349 trade name] is moxifloxacin.

The efficacy and safety of moxifloxacin 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 moxifloxacin in tuberculosis, the team of assessors advised that [TB349 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB349 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB349 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	31 October 2018	listed
Pharmaceutical quality	15 October 2018	MR
Bioequivalence	19 October 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 October 2015	MR
FPP	14 July 2017	MR
GCP/GLP (re-)inspection	16 February 2018	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	16 July 2024

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