WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB381 trade name]*

Levofloxacin (as hemihydrate) 250 mg Tablets

[TB381 trade name], manufactured at Remington Pharmaceutical Industries (Pvt) Ltd, Lahore, Pakistan, was included in the WHO list of prequalified medicinal products for tuberculosis on 30 August 2021.

[TB381 trade name] is indicated for treatment or 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 [TB381 trade name] is levofloxacin (as hemihydrate).

The efficacy and safety of levofloxacin are well established based on extensive clinical experience in the treatment or prevention 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 in tuberculosis, the team of assessors advised that [TB381 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB381 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB381 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	30 August 2021	listed
Pharmaceutical quality	10 February 2021	MR
Bioequivalence	12 February 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 November 2019	MR*
FPP	23 April 2021	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