WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB227 trade name][*]

Levofloxacin (as hemihydrate) 500 mg tablets

[TB227 trade name], manufactured at Cipla Limited, Verna Industrial Estate, Goa, India, was included in the WHO list of prequalified medicinal products for tuberculosis on 22 December 2011.

[TB227 trade name] is currently indicated for the treatment of drug-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 [TB227 trade name] is levofloxacin.

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 [TB227 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB227 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB227 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	22 Dec 2011	Listed
Pharmaceutical quality	13 Dec 2011	MR
Bioequivalence	14 Dec 2011	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	30 June 2011	MR
FPP	9 Sept 2010	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

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

Requalification	11 February 2020