WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB237 trade name]*

Levofloxacin 250 mg tablets

[TB237 trade name], manufactured at Micro Labs Ltd, Tamilnadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 3 October 2012.

[TB237 trade name] is indicated in combination with other tuberculosis medicines for the treatment of drug-resistant tuberculosis due to *Mycobacterium tuberculosis*. It is also indicated as monotherapy for the prevention of multidrug-resistant tuberculosis in persons at risk.

The active pharmaceutical ingredient of [TB237 trade name] is the antibacterial agent 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 in tuberculosis, the team of assessors advised that [TB237 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB237 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB237 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	03 Oct 2012	listed
Quality	28 Sept 2012	MR
Bioequivalence	10 Aug 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 March 2012	MR
FPP	20 April 2012	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.

Requalification	30 Sept 2019

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