WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB355 trade name][*]

Levofloxacin (as hemihydrate) 750 mg tablets

[TB355 trade name], manufactured at Micro Labs Ltd, Tamil Nadu, India, was included in the WHO list of prequalified medicinal products for the prevention and treatment of tuberculosis on 19 November 2019.

[TB355 trade name] is indicated for the prevention and treatment of 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 [TB355 trade name] is the antibacterial agent levofloxacin.

The efficacy and safety profile of [TB355 trade name] is 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 [TB355 trade name] therapy in antituberculosis therapy, the team of assessors advised that [TB355 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB355 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB355 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 November 2019	listed
Quality	29 October 2019	MR
Bioequivalence	01 November 2019	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	30 January 2015	MR
FPP	12 April 2019	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.