WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB354 trade name]*

Levofloxacin 500 mg tablets

[TB354 trade name], manufactured at PT. Kalbe Farma, Lippo Cikarang, Bekasi, Indonesia, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 22 February 2019.

[TB354 trade name] is currently indicated for the treatment of drug-resistant tuberculosis and the 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 [TB354 trade name] is levofloxacin hemihydrate.

The efficacy and safety of levofloxacin 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 levofloxacin in tuberculosis, the team of assessors advised that [TB354 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB354 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB354 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 February 2019	listed
Pharmaceutical quality	06 February 2019	MR
Bioequivalence	07 February 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 May 2016	MR
FPP	28 May 2018	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.