# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [TB354 trade name] *

## Levofloxacin 500mg film-coated tablets

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

[TB354 trade name] is indicated for 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(s) of [TB354 trade name] is the fluoroquinolone, levofloxacin.

The efficacy and safety profile of levofloxacin is well established based on the 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 [TB354 trade name] 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]**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| Status on PQ list | 22 February 2019 | listed |
| 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

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.