WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB378 trade name]*

Levofloxacin 500 mg film-coated tablets

[TB378 trade name], manufactured at Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd, Dongyang, Zhejiang province, China, was included in the WHO list of prequalified medicinal products for the treatment and prevention of drug-resistant tuberculosis on 04 April 2022.

[TB378 trade name] is currently indicated for the treatment and prevention 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 [TB378 trade name] is levofloxacin.

The efficacy and safety of levofloxacin are well established based on extensive clinical experience in the treatment of drug-resistant 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 [TB378 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB378 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB378 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	04 April 2022	listed
Pharmaceutical quality	28 March 2022	MR
Bioequivalence	31 March 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	10 September 2020	MR*
FPP	17 January 2020	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.