WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB377 trade name]*

Levofloxacin 250 mg film-coated tablets

[TB377 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 of drug-resistant tuberculosis on 04 April 2022.

[TB377 trade name] is indicated in combination with other tuberculosis medicines for the treatment of drug-resistant tuberculosis due to *Mycobacterium 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 [TB377 trade name] is levofloxacin.

The efficacy and safety of levofloxacin is 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 in drug-resistant tuberculosis, the team of assessors advised that [TB377 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB377 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB377 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	04 April 2022	listed
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	

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.