WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB319 trade name]*

Amikacin (as sulfate) 500 mg/2 mL solution for injection

[TB319 trade name], manufactured at Qilu Pharmaceutical Co., Ltd., Shandong, China, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 11 May 2018.

[TB319 trade name] is indicated in combination with other antituberculosis agents for the treatment of multi-drug resistant tuberculosis (MDR-TB). 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 [TB319 trade name] is the antibiotic amikacin. The efficacy and safety of amikacin 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 amikacin in tuberculosis, the team of assessors advised that [TB319 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB319 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB319 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	11 May 2018	listed
Quality	19 April 2018	MR
Bioequivalence	25 April 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 Jan 2016	MR
FPP	20 Jan 2017	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.