WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB317 trade name][*]

Abstract

[TB317 trade name], manufactured at Shanghai Harvest Pharmaceutical Co. Ltd, Shanghai, China was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 5 February 2020.

[TB317 trade name] is indicated in combination with other antituberculosis agents for the treatment of tuberculosis caused by kanamycin-sensitive strains of *Mycobacterium tuberculosis*. Kanamycin is only indicated as a second-line antimycobacterial drug when first-line drugs cannot be used because of resistance or intolerance.

The active pharmaceutical ingredient (API) of [TB317 trade name] is the antimycobacterial agent kanamycin. The API is well established and documented for the treatment of tuberculosis.

The efficacy and safety profile of kanamycin 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 kanamycin in antituberculosis therapy, the team of assessors advised that [TB317 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB317 trade name] in the list of prequalified medicinal products.

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Summary of Prequalification Status for [TB317 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	05 February 2020	listed
Quality	06 January 2020	MR
Bioequivalence	07 January 2020	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	28 October 2019	MR*
FPP	24 January 2019	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available