WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB311 trade name]*

Moxifloxacin (as hydrochloride) 400 mg Tablets

[TB311 trade name], manufactured at Getz Pharma (Pvt) Limited, Karachi, Pakistan, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 22 February 2019.

[TB311 trade name] is indicated in combination with other antituberculosis agents for the treatment of tuberculosis caused by *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 (API) of [TB311 trade name] is the antibacterial agent, moxifloxacin.

The efficacy and safety of moxifloxacin are 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 moxifloxacin in tuberculosis, the team of assessors advised that [TB311 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB311 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB311 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	22 February 2019	Listed
Pharmaceutical quality	11 February 2019	MR
Bioequivalence	06 February 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	17 February 2017	MR
FPP	24 August 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

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