

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB315 trade name]*

Moxifloxacin (as hydrochloride) 400 mg Tablets

[TB315 trade name], manufactured at Hetero Labs Ltd, (Unit V), Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 20 July 2017.

[TB315 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 [TB315 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 [TB315 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB315 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB315 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	20 July 2017	listed
Quality	27 June 2017	MR
Bioequivalence	29 June 2017	MR
GMP (re-)inspection		
API	17 Feb 2017	MR
FPP	18 June 2015	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	

Requalification	15/08/2023
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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.