

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB431 trade name]*

Moxifloxacin (as hydrochloride) 400 mg tablets

[TB341 trade name], manufactured at MSN Laboratories Private Limited, Rangareddy, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 19 June 2018.

[TB341 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 of [TB341 trade name] is 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 [TB341 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB341 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB341 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	19 June 2018	Listed
Pharmaceutical quality	09 May 2018	MR
Bioequivalence	29 May 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 October 2015	MR
FPP	23 March 2017	MR
GCP/GLP (re-)inspection	06 October 2017	MR
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.