

WHO Prequalification Programme  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

[TB230 trade name]\*

Moxicifloxacin (as hydrochloride) 400mg Tablet

[TB230 trade name] manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman (U.T.), India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 16 November 2012.

[TB230 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 [TB230 trade name] is the antibacterial agent, moxifloxacin. The API is documented for the treatment of tuberculosis and other bacterial infections.

The efficacy and safety profile of [TB230 trade name] is well established based on extensive clinical experience in the treatment of bacterial infections.

On the basis of data submitted and public information on the use of [TB230 trade name] in tuberculosis, the team of assessors advised that [TB230 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB230 trade name] in the list of prequalified medicinal products.

**Summary of Prequalification Status for [TB230 trade name]:**

Initial Acceptance	Date	Outcome
Status on PQ list	16 Nov 2012	listed
Quality	08 Nov 2012	MR
Bioequivalence	09 Nov 2012	MR
Safety, Efficacy	NA	NA
<b>GMP(re-)inspection</b>		
API	19 April 2012	MR
FPP	11 June 2012	MR
<b>GCP (re-)inspection</b>	NA	NA
Batch Analysis	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 NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

<b>Requalification</b>	18 December 2019
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\* Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.