

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

**[TB263 trade name]\***

Moxifloxacin (hydrochloride) 400mg film coated tablets

[TB263 trade name], manufactured at Micro Labs Limited, Hosur, Tamilnadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 11 July 2016.

[TB263 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 [TB263 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 bacterial infections.

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 [TB263 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB263 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB263 trade name]:**

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	11 July 2016	listed
Pharmaceutical quality	26 Nov 2015	MR
Bioequivalence	04 Dec 2015	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	16 Oct 2015	MR
FPP	10 Dec 2015	MR
GCP (re-)inspection	22 Jan 2014	MR
<b>GCP/GLP (re-)inspection</b>	24 Jan 2014	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		

<b>Requalification</b>	24 April 2023
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