WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB253 trade name]*

Moxifloxacin (as hydrochloride 400mg) film-coated tablets

[TB253 trade name], manufactured at MSN Laboratories Limited, Bollaram, Medak District, Andhra Pradesh, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 4 November 2013.

[TB253 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 [TB253 trade name] is the antibacterial agent, moxifloxacin. The API is documented for the treatment of tuberculosis and other bacterial infections.

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 [TB253 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB253 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB253 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	04 Nov 2013	Listed
Quality	30 Sept 2013	MR
Bioequivalence	04 Oct 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	19 April 2012	MR
FPP	15 May 2013	MR
GCP/GLP (re-)inspection	09 Sept 2013	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 NA: not applicable, not available PQ: prequalification

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NA: not applicable, not available

The table represents the status of relevant completed activities only.

Requalification	18 December 2019

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