WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB278 trade name]*

Levofloxacin (as hemihydrate) 500 mg Tablets

[TB278 trade name], manufactured at Macleods Pharmaceuticals Ltd, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for the treatment and prevention of tuberculosis on 24 October 2014.

[TB278 trade name] is indicated for treatment of 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 ingredients of [TB278 trade name] is levofloxacin.

The efficacy and safety profile of [TB278 trade name] is well established based on extensive clinical experience in the treatment of tuberculosis.

On the basis of data submitted and public information on the use of [TB278 trade name] in tuberculosis, the team of assessors advised that [TB278 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB278 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB278 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	24 Oct 2014	listed
Quality	01 Oct 2014	MR
Bioequivalence	13 Oct 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 March 2012	MR
FPP	24 Feb 2012	MR
GCP/GLP (re-)inspection	12 Feb 2013	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	

The table represents the status of relevant completed activities only.

Requalification	17 May 2021

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