WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB226 trade name][*]

Ethambutol Hydrochloride 100 mg tablets

[TB226 trade name], manufactured at Macleods Pharmaceuticals Ltd., Kachigan, Daman, India and Oxalis Labs Lodhimajra , Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 4 November 2013.

[TB226 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 ingredient of [TB226 trade name] isethambutol hydrochloride.

The efficacy and safety of ethambutol hydrochloride 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 ofethambutol hydrochloride in tuberculosis, the team of assessors advised that [TB226 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB226 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB226 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	04 November 2013	listed
Quality	23 October 2013	MR
Bioequivalence	01 March 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 February 2012	MR
FPP	11 June 2012	MR
GCP/GLP (re-)inspection	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.

Requalification	06 May 2020

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