WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB154 trade name]*

Cycloserine 250 mg capsules

[TB154 trade name], manufactured at Macleods Pharmaceutical Limited, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 23 March 2007.

[TB154 trade name] is indicated in combination with other antituberculosis agents for the treatment of drug-resistant tuberculosis due to *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 [TB154 trade name] is the antimycobacterial agent cycloserine. The efficacy and safety of cycloserine 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 of cycloserine in tuberculosis, the team of assessors advised that [TB154 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB154 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB154 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	23 March 2007	listed
Quality	14 Feb 2007	MR
Bioequivalence	29 Nov 2005	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	23 March 2005	MR
GCP/GLP (re-)inspection	28 Jan 2006	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

The table represents the status of relevant completed activities only.

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

Requalification	25 October 2017