WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB330 trade name]*

Cycloserine 125 mg Capsules

[TB330 trade name], manufactured at Macleods Pharmaceuticals Limited, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 17 July 2018.

[TB330 trade name] is indicated for 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 [TB330 trade name] is cycloserine.

The efficacy and safety of cycloserine is 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 [TB330 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB330 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB330 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 July 2018	listed
Quality	20 June 2018	MR
Bioequivalence	25 June 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 August 2016	MR
FPP	28 June 2018	MR*
GCP/GLP (re-)inspection	28 June 2018	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	17 July 2023