

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB330 trade name]*

Cycloserine 125 mg capsules

[TB330 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, 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 currently 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 [TB330 trade name] is 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, 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]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	Date	Outcome
Status on PQ list	17 July 2018	listed
Pharmaceutical 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		

Requalification	15 March 2024
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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.