

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB304 trade name]*

Cycloserine 250 mg capsules

[TB304 trade name], manufactured at Mylan Laboratories Limited, Aurangabad, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 12 December 2017.

[TB304 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 [TB304 trade name] is Cycloserine.

The efficacy and safety of Cycloserine is well established based on extensive clinical experience in the treatment of 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 [TB304 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB304 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB304 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	12 December 2017	Listed
Quality	28 November 2017	MR
Bioequivalence	30 November 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	02 May 2017	MR
FPP	15 July 2016	MR
GCP/GLP (re-)inspection	08 September 2017	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.