WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB385 trade name]*

Cycloserine 250 mg Capsules

[TB385 trade name], manufactured at Lupin Limited, Aurangabad 431210, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 13 May 2022.

[TB385 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 [TB385 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 [TB385 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB385 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB385 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	13 May 2022	listed
Quality	28 April 2022	MR
Bioequivalence	10 May 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 June 2021	MR*
FPP	28 January 2022	MR
GCP/GLP (re-)inspection	14 April 2022	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.