

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB416 trade name]*

Cycloserine 250mg capsules

[TB416 trade name], manufactured at Strides Pharma Science Limited, Periykalapet, Puducherry- 605 014, India , was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 17 September 2025.

[TB416 trade name] is indicated for 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 [TB416 trade name] is Cycloserine.

The efficacy and safety of Cycloserine is well established based on extensive clinical experience in the treatment of drug-resistant 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 treatment of drug-resistant tuberculosis the team of assessors advised that [TB416 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB416 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB416 trade name]:

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

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

Initial acceptance	Date	Outcome
Status on PQ list	17 September 2025	listed
Pharmaceutical quality	04 September 2025	MR
Bioequivalence	08 September 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	27 January 2023	MR
FPP	20 January 2023	MR
GCP/GLP (re-)inspection	20 June 2025	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 NA: not applicable, not available PQ: prequalification	