# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [TB306 trade name]*

Cycloserine 250 mg capsules

[TB306 trade name], manufactured at Strides Pharma Science Limited, Periyakalapet, Puducherry, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 18 December 2015.

[TB306 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 [TB306 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 [TB306 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB306 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB306 trade name]**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 30 June 2017 | Listed |
| Quality | 26 May 2016 | MR |
| Bioequivalence | 20 June 2016 | MR |
| **GMP (re-)inspection** | | |
| API | NA | NA |
| FPP | 17 June 2016 | MR |
| **GCP/GLP (re-)inspection** | 25 March 2015 | 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.