WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB222 trade name]*

Cycloserine 250 mg Capsules

[TB222 trade name] manufactured at Biocom JSC, Stavropol, Russian Federation, was accepted for the WHO list of prequalified medicinal products for the treatment of tuberculosis on 20 August 2013.

[TB222 trade name] is indicated for the treatment of 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 (API) of [TB222 trade name] is the antibiotic agent cycloserine.

The efficacy and safety of cycloserine are well established based on extensive clinical experience in the treatment of HIV.

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 [TB222 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB222 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB222 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	20 August 2013	listed
Quality	30 July 2013	MR
Bioequivalence	31 January 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 December 2012	MR
FPP	18 July 2012	MR
GCP/GLP (re-)inspection	NA	NA

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.

Requalification	6 December 2021

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