

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB395 trade name]*

Bedaquiline (as fumarate) 100 mg tablets

[TB395 trade name], manufactured at MSN Laboratories Private Limited, Rangareddy District, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 19 December 2024.

[TB395 trade name] is indicated in combination with other tuberculosis medicines 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 [TB395 trade name] is bedaquiline fumarate.

The efficacy and safety of bedaquiline are 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 bedaquiline, the team of assessors advised that [TB395 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB395 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB395 trade name]:

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

Initial acceptance	Date	Outcome
Status on PQ list	19 December 2024	listed
Pharmaceutical quality	17 December 2024	MR
Bioequivalence	17 December 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 August 2022	MR
FPP	27 May 2020	MR*
GCP/GLP (re-)inspection	15 March 2024	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		

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