

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

**[TB408 trade name]\***

Bedaquiline (as fumarate) 100 mg tablet

[TB408 trade name], manufactured at Mylan Laboratories Limited, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 23 March 2026.

[TB408 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 [TB408 trade name] is bedaquiline.

The efficacy and safety of bedaquiline 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 bedaquiline in the treatment of tuberculosis, the team of assessors advised that [TB408 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB408 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB408 trade name]:**

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

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

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	23 March 2026	listed
Pharmaceutical quality	12 March 2026	MR
Bioequivalence	16 March 2026	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	26 January 2024	MR
FPP	02 May 2025	MR
<b>GCP/GLP (re-)inspection</b>	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	