Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2023 an application for [TB408 trade name]* (TB408) to be assessed with the aim of including [TB408 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB408 trade name] was assessed according to the '*Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies*' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

2. Steps taken in the evaluation of the product

November 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
November 2023 and January 2024	During the meetings of the assessment team the quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
January 2024	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2024	The applicant's response letter was received.
March 2024	The applicant's response letter was received.
March 2024	During the meetings of the assessment team the additional safety and efficacy and the quality data were reviewed and further information was requested.
May 2024	The applicant's response letter was received.
June 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2024	The applicant's response letter was received.
September 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2025	The applicant's response letter was received.
January 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2025	The applicant's response letter was received.

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

March 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2025	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2025	The applicant's response letter was received.
July 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2025	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
September 2025	The applicant's response letter was received.
September 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2025	The applicant's response letter was received.
January and March 2026	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2026	The applicant's response letter was received.
March 2026	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2026	Product dossier accepted (quality assurance)
23 March 2026	[TB408 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Mylan Laboratories Limited, (FDF Unit 2)

H-12 & H-13, MIDC, Waluj,

Chhatrapati Sambhajinagar - 431136

Maharashtra State

India.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products