

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2024 an application for [TB410 trade name]* (TB410) to be assessed with the aim of including [TB410 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB410 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

March 2023	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
May 2024	During the meeting of the assessment team the safety and efficacy data 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.
December 2024	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.
January 2025	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
March 2025	The applicant’s response letter was received.
March 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2025	The applicant’s response letter was received.
May 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.

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

August 2025	The applicant's response letter was received.
September and October	The additional quality data were reviewed and further information was requested.
November 2025	The applicant's response letter was received.
November 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.
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	[TB410 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

Lupin Limited

A-28/1, MIDC Area, Chikalthana

Chhatrapati sambhajinagar

Aurangabad 431210

Maharashtra State

India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.

A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.

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>