Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2023 an application for [TB403 trade name]* (TB403) to be assessed with the aim of including [TB403 trade name] in the list of prequalified medicinal products for the treatment tuberculosis.

[TB403 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

April 2023	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
July 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2023	The applicant's response letter was received.
December 2023	The additional quality data were reviewed and further information was requested.
February 2024	The applicant's response letter was received.
March 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2024	The applicant's response letter was received.
May 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2024	The applicant's response letter was received.
July 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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 sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 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.

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

April 2025	The applicant's response letter was received.
April 2025	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
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.
July 2025	The applicant's response letter was received.
August 2025	The additional quality data were reviewed and further information was requested.
August 2025	The applicant's response letter was received.
August 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2025	Product dossier accepted (quality assurance)
09 September 2025	[TB403 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 – 431210

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