Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2024 an application for [TB411 trade name][*] (TB411) to be assessed with the aim of including [TB411 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB411 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

January 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP / GCP.
January 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 were reviewed and further information was requested.
May and June 2024	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 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.
October 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 and February 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 20245	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.
March 2025	The applicant's response letter was received.
March 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

March 2025	Product dossier accepted (quality assurance)
14 March 2025	[TB411 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 Industrial Area

Chikalthana,

Chhatrapati Sambhajinagar -431 210

Maharashtra, India

Inspection status

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

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