Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2023 an application for [TB402 trade name]* (TB402) to be assessed with the aim of including [TB402 trade name] in the list of prequalified medicinal products for treatment and prophylaxis of tuberculosis.

[TB402 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	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
April 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
March 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
July and August 2023	The quality data were reviewed by the assessment team and further information was requested.
August 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
October 2023	The applicant's response letters were received.
November 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2023	The additional 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 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.
May 2024	The applicant's response letter was received.
June 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2024	The applicant's response letter was received.

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

September and October 2024	The additional quality data were reviewed and further information was requested.
October 2024	The applicant's response letter was received.
November 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2024	Product dossier accepted (quality assurance)
21 November 2024	[TB402 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

Aurangabad 431 210

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