Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2023 an application for [TB400 trade name]* (TB400) to be assessed with the aim of including [TB400 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB400 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

June 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
January 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January and March 2023	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2023	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
April 2023	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
April 2023	The applicant's response letter was received.
May 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2023	The applicant's response letter was received.
November 2023	During the meeting of the assessment team 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.

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

January 2024	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
April 2024	The applicant's response letter was received.
May and June 2024	The additional quality data were reviewed and further information was requested.
July 2024	The applicant's response letter was received.
July 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2024	Product dossier accepted (quality assurance)
16 August 2024	[TB400 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 431210

Maharashtra State

India

Inspection status

A desk review for evaluation of compliance of two of the manufacturers of the APIs for GMP was conducted and it met WHO requirements.

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