Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2022 an application for [TB394 trade name][*] (TB394) to be assessed with the aim of including [TB394 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB394 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.
January 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
March 2022	The applicant's response letter was received.
March 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2022	During the meeting of the assessment team the quality data were reviewed and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November and December 2022	The additional quality data were reviewed and further information was requested.
January 2023	The applicant's response letter was received.
January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2023	The applicant's response letter was received.
March 2023	During the meeting of the assessment team the additional 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 one API for GMP was conducted and it met WHO requirements.
April 2023	The applicant's response letter was received.

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

May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
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.
January 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2024	The applicant's response letter was received.
March and April 2024	The additional quality data were reviewed and further information was requested.
May 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.
June 2024	The additional quality data were reviewed and further information was requested.
September 2024	A new bioequivalence study was submitted. The safety and efficacy data were reviewed and further information was requested.
September 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. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2024	The applicant's response letter was received.
October 2024	The additional quality data were reviewed and further information was requested.
October 2024	The applicant's response letter was received.
October 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2024	Product dossier accepted (quality assurance)
17 October 2024	[TB394 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