Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2022 an application for [TB396 trade name]* (TB396) to be assessed with the aim of including [TB396 trade name] in the list of prequalified medicinal products for tuberculosis treatment.

[TB396 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	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
March 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May 2022	The applicant's response letter was received.
May 2022	During the meeting of the assessment team the quality data and the additional safety and efficacy data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
July 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2022	The applicant's response letter was received.
October 2022	The additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
April 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality 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 additional quality data were reviewed and further information was requested.
October 2023	The applicant's response letter was received.
October 2023	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.

October 2023	The applicant's response letter was received.
October 2023	The quality data were reviewed and found to comply with the relevant WHO requirements
November 2023	Product dossier accepted (quality assurance)
16 November 2023	[TB396 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