Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2020 an application for [TB385 trade name]* (TB385) to be assessed with the aim of including [TB385 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB385 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

May 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May and July 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2020	The applicant's response letter was received.
September 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2021	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
June 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2021	The applicant's response letter was received.
January 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

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

January and April 2022	The additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
April 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2022	Product dossier accepted (quality assurance)
13 May 2022	[TB385 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
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 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products