Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2013 an application for [TB285 trade name]* (TB285) to be assessed with the aim of including [TB285 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB285 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

Sept 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jan 2015	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
April 2015	The applicant's response letters were received.
May 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2015	The applicant's response letters were received.
Sept 2015	In between the meetings of the assessment team the applicant's response letter was received .The additional quality data were reviewed and further information was requested.
Nov 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Dec 2015	The applicant's response letters were received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The applicant's response letters were received.
April 2016	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
May 2016	The applicant's response letters were received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2016	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.

Jan 2017	Due to concerns regarding GCP compliance, a new bioequivalence study was submitted. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Aug 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Sept 2017	Product dossier accepted (quality assurance)
26 Sept 2017	[TB285 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

Mylan Laboratories Limited
Plot No. H-12 & H-13
MIDC, Waluj Industrial Area
Aurangabad 431 136
Maharashtra
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