Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2015 an application for [TB304 trade name]* (TB304) to be assessed with the aim of including [TB304 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB304 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 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
February 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2016	The company's response letter was 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.
April 2017	The company's response letter was received.
May 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
August 2017	The additional quality data were reviewed and further information was requested.
September 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2017	The company's response letters were received.
November 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2017	Product dossier accepted (quality assurance)
12 December 201	[TB304 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Mylan Laboratories Limited (FDF Unit – 2)
Plot No. H-12 & H-13
MIDC, Waluj
Aurangabad - 431136
Maharashtra
India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GCP/GLP.

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