Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2013 an application for [TB263 trade name]* (TB263) to be assessed with the aim of including [TB263 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB263 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

Jan 2013	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
March 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2013	The company's response letters were received.
May 2013	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.
July 2013	The company's response letters were received.
July 2013	During the meeting of the assessment team the additional 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.
Sept 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2014	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Nov 2014	The company's response letter was received.
Nov 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2015	The company's response letter was received
March 2015	During the meeting of the assessment team 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.

June 2015	The company's response letter was received
July2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP
Oct / Nov 2015	The company's response letters were received.
Nov 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Dec 2015	Product dossier accepted (quality assurance)
11 July 2016	[TB263 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

Micro Labs Limited
Unit:– 03
92, Sipcot Industrial Complex
Hosur – 635126
Tamilnadu
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