Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2011 an application for [TB239 trade name]* (TB239) to be assessed with the aim of including [TB239 trade name] in the list of prequalified medicinal products for the treatment of TB.

[TB239 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 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Nov 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Oct 2011	The company's response letter was received.
Nov 2011	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
March 2012	The company's response letters were received.
March 2012	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.
April 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
July 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Nov 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Nov 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan 2013	The company's response letters were received.
Jan 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
Feb 2013	Product dossier accepted (quality assurance)

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

25 Feb 2013	[TB239 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
Tamil Nadu
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