Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Lab Ltd submitted in 2011 an application for [TB237 trade name]* (TB237) to be assessed with the aim of including [TB237 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB237 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

July 2011	During the meeting of the assessment team the safety and efficacy data and the quality data> we reviewed and further information was requested.
Sept 2011	The company's response letter was received.
Sept 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2011	The company's response letter was received.
Jan 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2012	The company's response letter was received.
March 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
April 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2012	The company's response letter was received.
Sept 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
Sept 2012	Product dossier accepted (quality assurance)
3 Oct 2012	[TB237 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

Micro Labs Limited

(Unit: ML-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.

Not inspected for GCP/GLP since a biowaiver applies.

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