Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited 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 drug-resistant tuberculosis due to *Mycobacterium tuberculosis* in combination with other tuberculosis medicines.

[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 were reviewed and further information was requested.
September 2011	The applicant's response letters were received.
September 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2011	The applicant's response letters were received.
January 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2012	The applicant'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.
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 applicant's response letters were received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2012	The applicant's response letters were received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2012	The applicant's response letters were received.
September 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2012	Product dossier accepted (quality assurance)
03 October 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

Tamil Nadu

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/prequal/medicines/prequalified/finished-pharmaceutical-products