Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited. submitted in 2006 an application for [TB174 trade name] [*] to be assessed with the aim of including [TB174 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB174 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 2006	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
May 2007	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
May 2008	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
Aug 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sept 2008	The company's response letter was received.
Nov 2008	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
May 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP
July 2009	The company's response letter was received.
Sept 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Nov 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Jan 2010	The company's response letter was received.
Jan 2010	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Feb 2010	The company's response letter was received.
March 2010	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
May 2010	The company's response letter was received.
May 2010	During the meeting of the assessment team, the additional quality and efficacy data were reviewed and further information was requested.
June 2010	The company's response letter was received.
July 2010	During the meeting of the assessment team, the additional quality and efficacy data were reviewed and further information was requested.
July 2010	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.

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

Sept 2010	During the meeting of the assessment team, the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
Sept 2010	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Oct 2010	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
1 Nov 2010	[TB174 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-3]
92, Sipcot Industrial Complex
Hosur 635 126
Tamil Nadu
India

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP and GCP, taking risk/benefit assessment of the API site into account.

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