Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd. submitted in 2006 an application for [TB171 trade name] * (TB171) to be assessed with the aim for acceptance of [TB171 trade name] on the list of prequalified pharmaceutical products for the treatment of tuberculosis.

[TB171 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

December 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2006	During the meeting of the assessment team, the safety and efficacy data as well as quality data were reviewed and further information was requested.
May 2008	The company's response letters were received.
May 2008	During the meetings of the assessment team, the additional efficacy and safety data as well as the additional quality data were reviewed and further information was requested.
October 2008	The company's response letters were received.
November 2008	During the meeting of the assessment team, the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements. The additional quality data were reviewed and further information was requested.
January 2009	The company's response letter was received.
March 2009	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
May 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
29 June 2009	[TB171 trade name] was accepted to the list for prequalified medicines

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture, Commitments and Inspection status

Manufacture 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.
Not inspected for GMP/GLP /GCP. Previous site inspections by WHO were acceptable.

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

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