Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2015 an application for [TB323 trade name]* (TB323) to be assessed with the aim of including [TB323 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB323 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 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
January & March 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
April 2016	The company's response letters were received.
May 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2016	The company's response letter was received.
September 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2017	The company's response letter was received.
January 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2017	The company's response letter was received.

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

May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2017	The company's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2018	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
June 2018	The company's response letter was received.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2018	The company's response letter was received.
October 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2018	Product dossier accepted (quality assurance).
31 October 2018	[TB323 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

Plot No. 15/A 2nd Phase

Kumbalgodu Industrial Area

560074 Bangalore

Karnataka

India

Inspection status

The site inspected was 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