Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd, Bangalore, Karnataka, India submitted in 2017 an application for [TB348 trade name][*] to be assessed with the aim of including [TB348 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB348 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

May 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
June 2017	The applicant's response letter was received.
July 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
September 2017	The applicant'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 applicant'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.
December 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2018	The applicant's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2018	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
November 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2019	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

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

April + June 2019	The applicant's response letters were received.
May and July 2019	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
August 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2019	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2020	The applicant's response letter was received.
February 2020	The additional quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
March 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2020	Product dossier accepted (quality assurance)
16 March 2020	[TB348 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-03)
92, Sipcot Industrial Complex
Hosur
Tamil Nadu, 635126
India.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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