Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2017 an application for [TB349 trade name]* (TB349) to be assessed with the aim of including [TB349 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB349 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

October 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and furth information was requested.
June 2017	The company'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	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May and July 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
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.
January 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.
February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 2018	The company's response letter was received.
May 2018	During the meeting of the assessment team 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.
September 2018	The company's response letter was received.
October 2018	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	[TB349 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 – 03)
(Unit – 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, 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/prequal/medicines/prequalified/finished-pharmaceutical-products