Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2016 an application for [TB335 trade name][1] (TB335) to be assessed with the aim of includingTB335 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB335 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

Dec 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sep 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Nov 2016	The company's response letter was received.
Nov 2016	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
Sep and Nov 2016	During the meetings of the assessment team the quality were reviewed and further information was requested.
Jan 2017	The company's response letter was received.
Jan 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Mar 2017	The company's response letter was received.
Mar 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2017	The company's response letter was received.
Jun 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Aug 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Sept 2017	Product dossier accepted (quality assurance)
26 Sep 2017	[TB335 trade name] was included in the list of prequalified medicinal products.

[1] 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-3)
92, Sipcot industrial Complex
Hosur – 635126,
Tamil Nadu,
India

Micro Labs Limited
15/A, 2nd Phase
Kumbalgodu Industrial Area
Bangalore - 560 074
Karnataka
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.
Not inspected for GCP and GLP. Previous site inspections by WHO showed acceptable outcome.

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