STEPS TAKEN FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2017 an application for [TB352 trade name][*] to be assessed with the aim of including [TB352 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB352 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

July 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
August 2017	The applicant's response letter was received.
September 2017	During the meeting of the assessment team the 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.
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.
February 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	The applicant'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.
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.
July and December 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
February 2019	The applicant's response letter was received.
February 2019	The additional quality data were reviewed and further information was requested.
February 2019	The applicant's response letter was received.
March 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2019	Product dossier accepted (quality assurance)
April 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for

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

	GMP.
23 July 2019	[TB352 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Micro Labs Limited (Unit-03)
92, Sipcot Industrial Complex
Hosur - 635126
Tamil Nadu
India

Commitments for Prequalification

None which have an impact on the benefit-risk profile of the medicinal product.

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/