Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2021 an application for [TB389 trade name][*] (TB389) to be assessed with the aim of including [TB389 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB389 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

February 2019	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
October 2021	The applicant's response letter was received.
November 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September + November 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
March + May 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
August 2022	The additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
November + December 2022	The additional quality data were reviewed and further information was requested.
January 2023	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
January 2023	The applicant's response letter was received.
February 2023	The additional quality data were reviewed and further information was requested.
February 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 2023	The applicant's response letter was received.
March 2023	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
April 2023	The applicant's response letter was received.

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

May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2023	The applicant's response letter was received.
August 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2023	Product dossier accepted (quality assurance)
02 September 2023	[TB389 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 3]
92 Sipcot Industrial Complex
Hosur-635126
Tamil Nadu
India.

Inspection status

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

A desk review of the FPP site found it to be in compliance with WHO requirements for GMP.

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