Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2019 an application for [TB368 trade name][*] (TB368) to be assessed with the aim of including [TB368 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB368 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

January 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
February 2019	The applicant's response letter was received.
March 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2019 and January 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
November 2020	The applicant's response letter was received.
November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May and July 2021	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.
August 2021	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.

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

August 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
September 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2021	Product dossier accepted (quality assurance)
25 October 2021	[TB368 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 FPP manufacturing site inspected was found to be in compliance with WHO requirements for GMP.

Inspection of API manufacturer waived based on risk assessment.

The CRO inspected was found to be in compliance with WHO requirements for GLP/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