Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2024 an application for [TB412 trade name][*] (TB412) to be assessed with the aim of including [TB412 trade name] in the list of prequalified medicinal products for treatment and prevention of tuberculosis.

[TB412 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 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
April 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2024	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2024	The applicant's response letter was received.
June and August 2024	The quality data were reviewed by the assessment team and further information was requested.
September 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2024	The applicant's response letter was received.
November and December 2024	The additional quality data were reviewed by the assessment team and further information was requested.
January 2025	The applicant's response letter was received.
January 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2025	The applicant's response letter was received.
March and April 2025	The additional quality data were reviewed by the assessment team and further information was requested.
May 2025	The applicant's response letter was received.
May 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2025	The applicant's response letter was received.
June 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

June 2025	Product dossier accepted (quality assurance).
05 July 2025	[TB412 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

Macleods Pharmaceuticals Limited
At Oxalis Labs,
Village Theda
P.O. Lodhimajra
Tehsil Baddi, Dist. Solan
Himachal Pradesh, 174101, 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