Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2021 an application for [TB390 trade name][*] (TB390) to be assessed with the aim of including [TB390 trade name] in the list of prequalified medicinal products for the treatment tuberculosis.

[TB390 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

September 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2021 and February 2022	The assessment team reviewed the quality data and further information was requested.
May 2022	The applicant's response letter was received.
May and July 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
November 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November and December 2022	The additional quality data were reviewed and further information was requested.
January 2023	The applicant's response letter was received.
January 2023	During the meeting of the assessment team 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.
March 2023	The applicant's response letter was received.
March 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
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.
June 2024	The applicant's response letter was received.

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

June 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2024	The applicant's response letter was received.
September and October 2024	The additional quality data were reviewed and further information was requested.
October 2024	The applicant's response letter was received.
October 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2024	Product dossier accepted (quality assurance)
04 November 2024	[TB390 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

Block N2, Village Theda

Post Office 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