Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company, Macleods Pharmaceuticals Limited submitted in 2022 an application for [TB397 trade name][*] (TB397) to be assessed with the aim of including [TB397 trade name] in the list of prequalified medicinal products for the treatment of drug-resistant tuberculosis in adults and adolescents at least 14 years old.

[TB397 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

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

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

September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 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 2024	During the meeting of the assessment team 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)
28 October 2024	[TB397 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,
Plot No.50 to 54A,
SEZ, Phase II,
Pithampur, Dist.: Dhar
Madhya Pradesh, 454774,
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GCP/GLP

Not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

API manufacturer inspected for GMP. Site inspected was found to be in compliance with WHO requirements

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