

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd. submitted in 2018 an application for [TB362 trade name]* (TB362) to be assessed with the aim of including [TB362 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB362 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

March 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
July 2018	The applicant's response letter was received.
July 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May and July 2018	During the meetings of the assessment team the quality data were reviewed and further information was requested.
October 2018	The applicant's response letter was received.
November 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
July 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
August 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2019	The applicant's response letter was received.
November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.

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

January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
September 2020	The applicant's response letter was received.
September 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2020	Product dossier accepted (quality assurance)
16 September 2020	[TB362 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

G-Block, 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/pqweb/>