Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2016 an application for [TB334 trade name][*] (TB334) to be assessed with the aim of including [TB334 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB334 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 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
October 2016	The company's response letter was received.
November 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September & December 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
September 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2017	The company's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2018	The company's response letter was received.
January /February 2018	The additional quality data were reviewed and further information was requested.
February 2018	The company's response letter was received.
March 2018	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.

March 2018	Product dossier accepted (quality assurance).
14 March 2018	[TB334 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
Unit II
Plot No 25-27, Survey No 366
Premier Industrial Estate
Kachigam, Daman, 369 210
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/medicines/prequalified/finished-pharmaceutical-products