Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2015 an application for [TB307 trade name] * (TB307) to be assessed with the aim for acceptance of [TB307 trade name] on the list of prequalified pharmaceutical products for the treatment of tuberculosis.

[TB307 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

July 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
April 2015	The company's response letter was received.
May 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Aug 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2015	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2016	The company's response letter was received.
Sept 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
Oct 2016	The company's response letter was received.
Nov 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2016	Product dossier accepted (quality assurance)

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

7 December 2016	[TB307 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture, Commitments and Inspection status

Manufacture of the finished product and responsible for batch release

Macleods Pharmaceuticals Limited
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Tehsil Baddi, District Solan
Himachal Pradesh – 174101
India
Phone: +91 1795 661400
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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-lists/finished-pharmaceutical-products