Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2004 an application for [TB133 trade name]* (TB133) to be assessed with the aim of including [TB133 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB133 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

June 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2004	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
March 2005	The company's response letter was received.
April 2005	During the meetings of the assessment team, the additional safety and efficacy were reviewed and further information was requested.
May 2005	The company's response letter was received.
May 2005	During the meetings of the assessment team, the additional safety and efficacy as well as the quality data were reviewed and further information was requested.
November 2005	The company's response letters were received.
November 2005	During the meetings of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
March 2007	The company's response letters were received.
April 2007	During the meetings of the assessment team, the additional safety and efficacy data as well as the additional quality data were reviewed and further information was requested.
May 2007	The company's response letters were received.
May 2007	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
July 2007	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
September 2007	The company's response letters were received.
September 2007	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
September 2007	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
21 December 2007	[TB133 trade name] was included in the list of prequalified medicinal products.

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

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 2, Plot No. 25 – 27

Survey No. 366

Premier Industrial Estate

Kachigam, Daman 396 210

India

Inspection status

The site inspected was found to be in compliance with WHO requirements for GMP and GLP.

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