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 [TB134 trade name]* (TB134) to be assessed with the aim of including [TB134 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB134 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 for the assessment of the product

January 2004	During the meeting with the assessment team, the safety and efficacy data were reviewed and further information was requested.
March 2004	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2005	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July/ August 2005	The company's response letters were received.
November 2005	During the meetings of the assessment team, the quality data were reviewed and further information was requested.
November 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
December 2005	During the meeting with the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
January/February 2006	The company's response letters were received.
February 2006	During the meetings of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
May 2006	The sites relevant to the bioequivalence study were inspected for compliance with WHO requirements for GCP.
July 2006	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
September 2006	The company's response letter was received.
September 2006	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
November 2006	The company's response letter was received.
November 2006	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
January 2007	The company's response letter was received.
January 2007	During the meetings of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements
21 December 2007	[TB134 trade name] was accepted to the list for prequalified medicines.

* 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 Ltd
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Premier Industrial Estate,
Kachigam,
Daman – 396210,
Tel: +91-0260 2244337
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Inspection status

The applicant was inspected and found to be in compliance with WHO requirements for GMP 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