Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2005 an application for [TB158 trade name]* (TB158) to be assessed with the aim of including [TB158 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB158 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

Nov 2005	During the meeting of the assessment team, safety and efficacy data of the dossier were reviewed andfurther information was requested.
Jan 2006	The company's response letters were received.
Feb 2006	During the meeting of the assessment team, the additional safety and efficacy data were reviewed andfound to be in compliance with the relevant WHO requirements.
Apr 2006	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
May 2006	During the meeting of the assessment team, the quality data were reviewed andand further information was requested.
Oct 2006	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Mar 2007	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Jun 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sep 2007	The company's response letters were received.
Sep/ Nov 2007	During the meeting of the assessment team, the additional quality data of the dossier were reviewed andfurther information was requested.
Jan 2008	The company's response letters were received.
Feb 2008	The additional quality data were reviewed and found to be in compliance with the relevant WHOrequirements.
7 Mar 2008	[TB158 trade name] was accepted, in principle, to the list for 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 Ltd.
Plot No. 25- 27,
Survey no. 366,
Premier Industrial Estate
Kachigam,
396 210 Daman,
India

Oxalis Labs
Village Theda,
P.O Lodhimajra, Baddi,
Distt. Solan,
Himachal Pradesh, 174101,
India

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