

## Steps before prequalification

### I. BACKGROUND INFORMATION ON THE PROCEDURE

#### 1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2007 an application for [TB178 trade name]\* (TB178) to be assessed with the aim of including [TB178 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB178 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

October 2006	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2007	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
February 2007	The applicant's response letters were received.
March 2007	During the meeting of the assessment team, the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements. The quality data were reviewed and further information was requested.
June 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2007	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2007	The company's response letter was received.
May 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 letter was received.
October 2007	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
November 2007	The company's response letter was received.
November 2007	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
February 2008	The company's response letter was received.
March 2008	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
23 April 2008	[TB178 trade name] was included in the list of prequalified medicinal products.

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\* 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  
Plot No. 25-27  
Survey No. 366  
Premier Industrial Estate  
Kachigam  
Daman – 396 210  
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/prequal/medicines/prequalified/finished-pharmaceutical-products>