## **Steps before prequalification**

#### I. BACKGROUND INFORMATION ON THE PROCEDURE

#### 1. Submission of the dossier

The company Micro Labs Limited. submitted in 2006 an application for [TB174 trade name] \* to be assessed with the aim of including [TB174 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB174 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

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<sup>\*</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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Sept 2010	During the meeting of the assessment team, the additional efficacy data were reviewed
	and found to be in compliance with the relevant WHO requirements.
Sept 2010	The manufacturer of the API was inspected for compliance with WHO requirements for
	GMP.
Oct 2010	During the meeting of the assessment team, the additional quality data were reviewed
	and found to be in compliance with the relevant WHO requirements.
1 Nov 2010	[TB174 trade name] was included in the list of prequalified medicinal products

## II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

# 1. Manufacturer and Inspection status

## Manufacturer of the finished product and responsible for batch release

Micro Labs Limited–[ Unit-3] 92, Sipcot Industrial Complex Hosur 635 126 Tamil Nadu India

#### **Inspection status**

The sites inspected were found to be compliant with WHO requirements for GMP and GCP, taking risk/benefit assessment of the API site into account.

## 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