Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2008 an application for [TB205 trade name]* (TB205) to be assessed with the aim of including [TB205 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB205 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 2009	During the meeting of the assessment team, the safety and efficacy data as well as the quality data were reviewed and further information was requested.
March 2009	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
July 2009	The company's response letters were received.
September 2009	During the meetings of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
November 2009	In between the meetings of the assessment team the company's response letter was received. The additional safety and efficacy data were reviewed and further information was requested.
March 2010	The company's response letter was received.
March 2010	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2010	The company's response letter was received.
May 2010	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
September 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP
September 2010	The company's response letter was received.
November 2010	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
January 2011	The company's response letter was received.
January 2011	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
May 2011	The company's response letter was received.
May 2011	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
June 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP
December 2011	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and found to comply with the relevant WHO requirements.
December 2011	Product dossier accepted (quality assurance)
22 December 2011	[TB205 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

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

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Ltd,
Unit VII, III, IV
Plot No: L-147 to L147-1 & L139 to L-146
Verna Industrial Estate,
Goa – 403722, India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The API and the FPP manufacturers were inspected and found to be in compliance with WHO requirements for GMP.

2. Conditions or restrictions regarding supply and use

To be decided by the national medicines regulatory authority in accordance with national legislation.

Further information is available at:

https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products