Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Ltd submitted in 2012 an application for [TB196 trade name] (TB196) to be assessed with the aim of including [TB196 trade name] in the list of prequalified pharmaceutical products for the treatment of tuberculosis.

[TB196 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

July/Sept 2008	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2009	The company's response letters was received.
March 2009	During the meeting of the assessment team the safety and efficacy data and the additional quality data were reviewed and further information was requested.
May 2009	The company's response letters were received.
May 2009	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2009	The company's response letter was received.
Nov 2009 Jan 2010	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.
Aug 2011	The company's response letter was received.
Aug / Nov 2011	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2011	The company's response letter was received.
Nov 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
Feb 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Oct 2012	The company's response letter was received.
Oct 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2012	Product dossier accepted (quality assurance).
31 Oct 2012	[TB196 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

Lupin Limited
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Chikalthana
431210 Aurangabad
India
Tel: + 91 22 66402370
Fax: + 91 22 26528321
Email: rajeevpatil@lupinpharma.com

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP. The sites were not inspected for GCP and GCP/GLP. Previous site inspections by WHO showed acceptable outcome.

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