Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2002 an application for [TB068 trade name]* (TB068) to be assessed with the aim of including [TB068 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB068 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

September 2002	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
October 2002	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2002	In between the meetings of the assessment team the company's response letter was received. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2002	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2002	The company's response letter was received.
January 2002	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2003	The company's response letter was received.
January 2003	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2003	The company's response letter was received.
March 2003	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2003	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.
November 2003	In between the meetings of the assessment team the company's response letter was received. The quality data were reviewed and found to comply with the relevant WHO requirements.
19 December 2003	[TB068 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture, Commitments and Inspection status

Manufacture of the finished product and responsible for batch release

Lupin Limited
A-28/1, M.I.D.C. Industrial Area
Chikalthana
Chhatrapati sambhajinagar,431 210
India

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

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

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