Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cadila Pharmaceuticals Limited submitted in 2002 an application for [TB008 trade name][*] (TB008) to be assessed with the aim of including [TB008 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB008 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

August 2002	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
September 2002	During the meeting of the assessment team the quality data were reviewed and further information was requested.
November 2002	In between the meetings of the assessment team the company's response letter were received. 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.
November 2002	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
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.
May 2003	The company's response letter was received.
May 2003	The quality data were reviewed and found to comply with the relevant WHO requirements.
13 Nov 2003	[TB008] 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

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[*] 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.

Not inspected for GLP /GCP. Previous site inspections by WHO were acceptable.

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/