Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Ltd submitted in 2007 an application for [MA062 trade name]* (MA062) to be assessed with the aim of including [MA062 trade name] in the list of prequalified medicinal products for treatment of malaria.

[MA062 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

January 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2008	The manufacturer of one API 1 was inspected for compliance with WHO requirements for GMP.
April/May 2008	During the meeting of the assessment team the additional quality, efficacy and safety aspects of the dossier were reviewed and further information was requested.
July 2008	The company's response letter was received.
July 2008	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
August 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
October 2008	The company's response letters were received.
November 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
November 2008	The site responsible for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
January 2009	The company's response letter was received.
March 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
April 2009	The company's response letter was received.
May 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
June 2009	The company's response letter was received.
July 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
September 2009	The company's response letter was received.

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

September 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested
October 2009	The company's response letter was received.
October 2009	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
15 December 2009	[MA062 trade name] was included in the list of prequalified medicines.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Ipca Laboratories Ltd
Plot No. 255/1
Village Athal
396 230 Silvassa
U.T. of Dadra and Nagar Haveli and Daman and Diu,
India

Inspection status

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

3. (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