Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Ltd submitted in 2010 an application for [MA081 trade name] * (MA081) to be assessed with the aim of including [MA081 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA081 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 2010	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
Aug 2010	The company's response letter was received.
Sept 2010	During the meeting of the assessment team the efficacy data were reviewed and further information was requested.
Nov 2010	The company's response letter was received.
Dec 2010	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
Jan 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Sept 2011	The company's response letter was received.
Nov 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2012	The company's response letters were received.
Jan 2012	During the meeting of the assessment team the additional efficacy data the additional quality data were reviewed and further information was requested.
Feb 2012	The company's response letter was received.
March 2012	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
March 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2012	The company's response letter was received.
March 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2012	The company's response letter was received.
May 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2012	Product dossier accepted (quality assurance).
01 June 2012	[MA081 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture and Inspection status

Manufacture of the finished product and responsible for batch release

Ipca Laboratories Ltd
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Village Athal
396 230 Silvassa
U.T. of Dadra and Nagar Haveli and Daman and Diu,
India
Tel: 0260 6164200/6164203

Inspection status

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

Not inspected for GCP. 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