

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd. submitted in 2013 an application for [MA104 trade name]* (MA104) to be jointly assessed by WHO/EAC with the aim of facilitating the national registration in the EAC countries of [MA104 trade name] once jointly accepted and included in the list of prequalified pharmaceutical products for the treatment of malaria.

[MA104 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

Jan 2011	The manufacturer of one the API's was inspected for compliance with WHO requirements for GMP.
May 2013	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
June + July 2013	The company's response letters were received.
July 2013	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.
Aug 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2013	The company's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2014	The company's response letter was received.
Feb 2014	The manufacturer of one of the API's was inspected for compliance with WHO requirements for GMP.
Feb 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2014	Product dossier accepted (quality assurance)
08 April 2014	[MA104 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. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Limited
Unit II, A-42, MIDC
Patalganga, District: Raigad
Maharashtra state
India

Inspection status

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

Not inspected for GLP/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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products>