

Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co. Ltd submitted in 2010 an application for [MA084 trade name]* (MA084) to be assessed with the aim of including [MA084 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA084 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

February 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
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.
September 2010	The company's response letter was received.
September 2010	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
September 2010 November 2010	The company's response letters were received.
November 2010	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.
February 2011	The company's response letters were received.
March 2011 May 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 quality data were reviewed and further information was requested.
August 2011	The company's response letter was received.
September 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2011	The company's response letter was received.
November 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2012	The company's response letters were received.
May 2012	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.
June 2012	The company's response letters were received.
July 2012	The safety and efficacy and the quality data were reviewed and found to comply with the relevant WHO requirements.
August 2012	The manufacturer of the API 1 and 2 was inspected for compliance with WHO requirements for GMP.
September 2012	Product dossier accepted (quality assurance)
October 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP/GLP.
16 November 2012	[MA084 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, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Guilin Pharmaceutical Co. Ltd.
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No. 43 Qilidian Road
Guilin, Guangxi
541004 Guilin
China
Tel: +86-773-3675053
Fax: +86-773-3675053

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP/GLP.
Not inspected for GCP (biowaiver).

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

<http://www.who.int/prequal>