

## Steps before prequalification

### I. BACKGROUND INFORMATION ON THE PROCEDURE

#### 1. Submission of the dossier

The company Guilin Pharmaceutical Co Ltd submitted in 2017 an application for [MA139 trade name]\* (MA139) to be assessed with the aim of including [MA139 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA139 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

September 2017	During the meeting of the assessment team the safety and efficacy and the quality data were reviewed and further information was requested.
October 2017	The applicant's response letter was received.
November 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2018	The applicant's response letter was received.
April 2018	The additional quality data were reviewed and further information was requested.
May 2018	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
July 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2019	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2019	The applicant's response letters were received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2019	The applicant's response letters were received.

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

October 2019	The additional quality data were reviewed and further information was requested.
October 2019	The applicant's response letters were received.
October 2019	Product dossier accepted (quality assurance)
19 November 2019	[MA139 trade name] 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

Guilin Pharmaceutical Co Ltd

Oral Solid Dosage Workshop 1

No. 43, Qilidian Road, Guilin – 541004

Guangxi

China

#### Inspection status

The site inspected were found to be compliant with WHO requirements for GMP, GCP and GLP.

### 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>