Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co., Ltd submitted in 2020 an application for [MA165 trade name]* (MA165) to be assessed with the aim of including [MA165 trade name] in the list of prequalified medicinal products for treatment of malaria.

[MA165 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 2017	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2020	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May 2020	The applicant's response letter was received.
May 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March and June 2020	The quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
October 2020	The additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January and March 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letters were received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May and October 2021	The additional quality data were reviewed and further information was requested.

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

October 2021	The applicant's response letter was received.
October 2021	The additional quality data were reviewed and further information was requested.
December 2021	The applicant's response letter was received.
January 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
January 2022	Product dossier accepted (quality assurance)
26 January 2022	[MA165 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

API manufacturers not inspected for GMP. Previous site inspections by WHO were acceptable.

FPP manufacturer was found to be in compliance with WHO requirements for GMP in a previous inspection.

The inspected CRO was found to be in compliance with WHO requirements for GLP and GCP.

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