Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co., Limited submitted in 2021 an application for [MA178 trade name][*] (MA178) to be assessed with the aim of including [MA178 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA178 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 2021	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
September 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
October 2021	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP
November and December 2021	The quality data were reviewed and further information was requested.
December 2021	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
February 2022	The applicant's response letter was received.
March 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
May 2022	The applicant's response letter was received.
May 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
July 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
February 2023	The additional quality data were reviewed and further information was requested.
February 2023	The applicant's response letter was received.
March 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.

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

May 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2023	The applicant's response letter was received.
July 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2023	Product dossier accepted (quality assurance)
30 July 2023	[MA178 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 I

No. 43, Qilidian Road, Guilin 541004

Guangxi, China.

Inspection status

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