Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co Ltd submitted in 2024 an application for [MA202 trade name]* (MA202) to be assessed with the aim of including [MA202 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA202 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

June 2022	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2024	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
September 2024	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
September and October 2024	The quality data were reviewed by the assessment team and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
December 2024	The applicant's response letter was received.
January 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2025	The applicant's response letter was received.
January and February 2025	The additional quality data were reviewed and further information was requested.
March 2025	The applicant's response letter was received.
March 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2025	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2025	The applicant's response letter was received.
May 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2025	The applicant's response letter was received.
July 2025	A desk review for evaluation of compliance of one manufacturer of the API for GMP was conducted and it met WHO requirements.

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

July and September 2025	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
October 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2025	Product dossier accepted (quality assurance)
06 November 2025	[MA202 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

No. 43, Qilidian Road

Guilin

Guangxi – 541 004

China

Inspection status

A desk review for evaluation of compliance of one of the manufacturers of the APIs for GMP was conducted and it met WHO requirements.

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/prequal/medicines/prequalified/finished-pharmaceutical-products