Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co Ltd submitted in 2025 an application for [MA209 trade name]* (MA209) to be assessed with the aim of including [MA209 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA209 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.
April 2025	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May and June 2025	The quality data were reviewed by the assessment team and further information was requested.
July 2025	A desk review for evaluation of compliance of one manufacturer of the API for GMP was conducted and it met WHO requirements.
July 2025	The applicant's response letter was received.
July 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
September and October 2025	The additional quality data were reviewed and further information was requested.
October 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	[MA209 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

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

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