Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co., Limited submitted in 2024 an application for [MA201 trade name][*] (MA201) to be assessed with the aim of including [MA201 trade name] in the list of prequalified medicinal products for the treatment of severe malaria.

[MA201 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 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2024	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2024	The applicant's response letter was received.
September 2024	During the meeting of the assessment team the additional quality data were reviewed 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 quality data were reviewed and further information was requested.
January 2025	The applicant's response letter was received.
February 2025	The additional quality data were reviewed and further information was requested.
February 2025	The applicant's response letter was received.
March 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2025	Product dossier accepted (quality assurance)
April 2025	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
19 August 2025	[MA201 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 541004

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

Guangxi

China

Inspection status

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

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