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 [MA200 trade name][*] (MA200) to be assessed with the aim of including [MA200 trade name] in the list of prequalified medicinal products for treatment of severe malaria.

[MA200 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.
September 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2024	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 2024	The applicant's response letter was received.
May 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2024	The applicant's response letter was received.
June 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2024	The applicant's response letter was received.
September and November 2024	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
December 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2024	Product dossier accepted (quality assurance)
12 December 2024	[MA200 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Guilin Pharmaceutical Co., Limited

No. 43, Qilidian Road, Guilin 541004

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