Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co., Ltd, Oral Solid Dosage Workshop, Guilin, Guangxi, China submitted in 2019 an application for [MA157 trade name]* (MA157) to be assessed with the aim of including [MA157 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA157 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

May 2018	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
October 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
July 2019	The applicant's response letter was received.
July 2019	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
August 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
May 2019 and September 2019	During the meetings of the assessment team the quality data were reviewed and further information was requested.
November 2019	The applicant's response letter was received.
November 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2019	The applicant's response letter was received.
February 2020	The additional quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2020	The applicant's response letter was received
August 2020	The additional quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received

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

September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received
November 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2020	Product dossier accepted (quality assurance)
25 November 2020	[MA157 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 1
No. 43, Qilidian Road, Guilin 541004
Guangxi, China.

Inspection status

The site was inspected and found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP since a biowaiver applies.

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/