Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2023 an application for [MA191 trade name]* (MA191) to be assessed with the aim of including [MA191 trade name] in the list of prequalified medicinal products for malaria chemoprevention.

[MA191 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	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
January and February 2023	The safety and efficacy data were reviewed by the assessment team and further information was requested
January and March 2023	The quality data were reviewed by the assessment team and further information was requested
March 2023	The applicant's response letter was received.
March 2023	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
May 2023	The applicant's response letter was received.
May 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2023	The applicant's response letter was received.
November 2023 and January 2024	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
February 2024	The applicant's response letter was received.
March 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

April 2024	The applicant's response letter was received.
April 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2024	Product dossier accepted (quality assurance)
25 April 2024	[MA191 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

Ipca Laboratories Limited

Plot no. 255/1, Village Athal

Silvassa 396 230

U.T. of Dadra and Nagar Haveli and Daman and Diu

India

Inspection status

The sites inspected were 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/medicines/prequalified/finished-pharmaceutical-products