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 [MA192 trade name]* (MA192) to be assessed with the aim of including [MA192 trade name] in the list of prequalified medicinal products for malaria prevention.

[MA192 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 March 2023	The quality data were reviewed by the assessment team and further information was requested
March 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
April 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
June 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2023	The applicant's response letters were received.
July 2023	During the meeting of the assessment team the additional 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.
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.
January 2024	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
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.
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	[MA192 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

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.

The site inspected through desk review was found to be in compliance with WHO requirements for 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