Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2022 an application for [MA189 trade name]* (MA189) to be assessed with the aim of including [MA189 trade name] in the list of prequalified medicinal products for malaria prevention.

[MA189 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 manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
February 2023	The safety and efficacy 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.
February and April 2023	The quality data were reviewed by the assessment team and further information was requested.
May 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 one API was inspected for compliance with WHO requirements for GMP.
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 safety and efficacy data were reviewed and further information was requested.
July 2023	The applicant's response letters were received.
September 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and October 2023	The additional quality data were reviewed and further information was requested.
November 2023	The applicant's response letter was received.

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

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.
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	[MA189 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 GMP. Previous inspections by a stringent regulatory authority were acceptable.

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