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 [MA196 trade name]* (MA196) to be assessed with the aim of including [MA196 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA196 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 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2024	During the meeting of the assessment team the safety and efficacy were reviewed and further information was requested.
February 2024	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2024	The applicant's response letter was received.
January and March 2024	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2024	The applicant's response letter was received.
June 2024	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2024	The applicant's response letter was received.
September 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2025	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2025	The applicant's response letter was received.
February 2025	The additional quality data were reviewed and further information was requested.
June 2025	The applicant's response letter was received.

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

June 2025	The additional quality data were reviewed and further information was requested.
June 2025	The applicant's response letter was received.
June 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2025	Product dossier accepted (quality assurance)
17 July 2025	[MA196 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, 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