Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2025 an application for [MA208 trade name]* (MA208) to be assessed with the aim of including [MA208 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA208 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

March 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2025	During the meeting of the assessment team the quality data and the safety and efficacy data were reviewed and further information was requested.
April 2025	The applicant's response letter was received.
May 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2025	The applicant's response letter was received.
September 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2025	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
October 2025	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2026	The applicant's response letter was received.
March 2026	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2026	The applicant's response letter was received.
May and July 2026	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2026	The applicant's response letter was received.
August 2026	The additional quality data were reviewed and further information was requested.
September 2026	The applicant's response letter was received.
September 2026	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2026	Product dossier accepted (quality assurance)
23 September 2026	[MA208 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, 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