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 [MA186 trade name][*] (MA186) to be assessed with the aim of including [MA186 trade name] in the list of prequalified medicinal products for treatment of severe malaria caused by *Plasmodium falciparum*, in adults and children.

[MA186 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 the FPP was inspected for compliance with WHO requirements for GMP.
September 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and November 2022	During the meetings of the assessment team the quality data were reviewed and further information was requested.
November 2022	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
January 2023	The applicant's response letter was received.
January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
March and May 2023	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
June 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2023	Product dossier accepted (quality assurance)
05 September 2023	[MA186 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

P.O. Sejavta, Ratlam 457001

(Madhya Pradesh),

India

Inspection status

The API and FPP manufacturers were inspected and found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP since a bio waiver 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products