Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2019 an application for [MA160 trade name]* (MA160) to be assessed with the aim of including [MA160 trade name] in the list of prequalified medicinal products for treatment of malaria.

[MA160 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

May 2018	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
November 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January 2020	The applicant's response letter was received.
January 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2019 and January 2020	The quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2020	The applicant's response letter was received.
October 2020	The additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2021	The applicant's response letter was received.

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

September and November 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
December 2021	The applicant's response letter was received.
January 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
January 2022	Product dossier accepted (quality assurance)
01 February 2022	[MA160 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
Dadra and Nagar Haveli (U. T.) India

Inspection status

The manufacturing sites were inspected and found to be in compliance with WHO requirements for GMP.

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products