Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laboratórios Basi - Indústria Farmacêutica, S.A. submitted in 2019 an application for [MA167 trade name]* (MA167) to be assessed with the aim of including [MA167 trade name] in the list of prequalified [MA167 trade name] medicinal products for treatment of malaria.

[MA167 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

February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2018	Two manufacturers of three APIs were inspected for compliance with WHO requirements for GMP.
February 2019	One manufacturer of one API was inspected for compliance with WHO requirements for GMP.
July 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June and August 2020	The quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
November 2020	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.
February 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
July 2021	The applicant's response letter was received.
October and December 2021	The additional quality data were reviewed and further information was requested.
January 2022	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

February 2022	The applicant's response letter was received.
February 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2022	Product dossier accepted (quality assurance)
9 February 2022	[MA167 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

Additional Testing and Release site

Laboratórios Basi - Indústria Farmacêutica, S.A.

Parque Industrial Manuel Lourenço Ferreira,

lotes 8, 15 e 16 3450-232

Mortágua, Portugal.

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