Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Universal Corporation Limited submitted in 2020 an application for [MA172 trade name]* (MA172) to be assessed with the aim of including [MA172 trade name] in the list of prequalified medicinal products for malaria prevention.

[MA172 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

July 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
July and September 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
September 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2021	The applicant's response letter was received.
January and March 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2021	The applicant's response letter was received.
June 2021	The additional quality data were reviewed and further information was requested.
June 2021	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2021	The applicant's response letter was received.
September and October 2021	The additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
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 meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
May 2022	During the meetings 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.

June 2022	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
July 2022	The applicant's response letter was received.
July and August 2022	The additional quality data were reviewed and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
December 2022	The additional quality data were reviewed and further information was requested.
January 2023	The applicant's response letters were received.
January 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. The analytical facilities, relevant for the acceptability of one biowaiver were inspected for compliance with WHO requirements for GMP
January 2023	Product dossier accepted (quality assurance)
30 July 2023	[MA172 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

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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