

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 [MA163 trade name]* (MA163) to be assessed with the aim of including [MA163 trade name] in the list of prequalified medicinal products for malaria prophylaxis.

[MA163 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 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March and May 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
September 2020	The applicant’s response letter was received.
November 2020 and January 2021	The additional quality data were reviewed and further information was requested.
March 2021	The applicant’s response letter was received.
April 2021	The additional quality data were reviewed and further information was requested.
June 2021	A desk review for evaluation of compliance of one manufacturer of one API for GMP was conducted and it met WHO requirements.
September 2021	The applicant’s response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2021	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2021	The applicant’s response letter was received.
November 2021	During the meeting of the assessment team 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.
March 2022	The applicant’s response letter was received.

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

March 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
June 2022	Three manufacturers of two APIs were inspected for compliance with WHO requirements for GMP.
May and July 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
July 2022	The applicant's response letter was received.
August 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2022	Product dossier accepted (quality assurance)
22 August 2022	[MA163 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

Universal Corporation Limited
Club Road, Plot No. 13777
P.O.Box 1748-00902
Kikuyu
Kenya

Inspection status

The sites inspected and desk-reviewed were found to be in compliance with WHO requirements for GMP and GCP/GLP.

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>