Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Quality Chemical Industries Limited submitted in 2025 an application for [MA211 trade name][*] (MA211) to be assessed with the aim of including [MA211 trade name] in the list of prequalified medicinal products for malaria.

[MA211 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 2023	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
April 2025	A desk review for evaluation of compliance of the manufacturers of the APIs for GMP was conducted and it met WHO requirements.
May 2025	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July and August 2025	The assessment team reviewed the quality data and further information was requested.
September 2025	The applicant's response letter was received.
September 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2025	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
November 2025	The applicant's response letter was received.
November 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2025	The applicant's response letter was received.
February 2026	The assessment team reviewed the additional quality data and further information was requested.
March 2026	The applicant's response letter was received.
March and May 2026	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
June 2026	The applicant's response letter was received.
July 2026	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.

July 2026	The applicant's response letter was received.
July 2026	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2026	Product dossier accepted (quality assurance)
27 August 2026	[MA211 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

Quality Chemical Industries Limited
Plot 1-7, 1st Ring Road,
Luzira Industrial Park,
P.O. Box 34871,
Kampala-Uganda.
Email: contactus@qcil.com

Inspection status

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

API manufacturer inspected for GMP.

Not inspected for GLP /GCP. Previous site inspections by WHO were acceptable under previous applicant.

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/prequal/medicines/prequalified/finished-pharmaceutical-products