Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Velvet Med-Healthcare Solutions S.A submitted in 2025 an application for [MA210 trade name]* (MA210) to be assessed with the aim of including [MA210 trade name] in the list of prequalified medicinal products for the treatment of uncomplicated malaria due *to Plasmodium falciparum* in adults and children weighing 35 kg and above.

[MA210 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

June 2022	The manufacturers of both APIs were inspected for compliance with WHO requirements for GMP.
February 2023	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
March 2023	The manufacturers of both APIs were inspected for compliance with WHO requirements for GMP.
April 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2025	During the meeting of the assessment team the safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2025	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2025	A desk review for evaluation of compliance of the manufacturer of both APIs for GMP was conducted and it met WHO requirements.
August 2025	The applicant's response letter was received.
August 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2025	Product dossier accepted (quality assurance)
09 September 2025	[MA210 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

Macleods Pharmaceuticals Limited
At, Oxalis Labs
Village Theda

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

P.O. Lodhimajra, Baddi
Distt. Solan
Himachal Pradesh –174101,
India

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