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 [MA205 trade name][*] (MA205) to be assessed with the aim of including [MA205 trade name] in the list of prequalified medicinal products for treatment of malaria.

[MA205 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 the APIs were inspected for compliance with WHO requirements for GMP.
March 2023	The manufacturers of the 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.
June 2023	The manufacturers of one API were inspected for compliance with WHO requirements for GMP.
May 2024	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
January 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2025	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2025	The applicant's response letter was received.
April 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2025	A desk review for evaluation of compliance of the manufacturers of the APIs for GMP was conducted and it met WHO requirements.
June 2025	Product dossier accepted (quality assurance)
05 July 2025	[MA205 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

Phase II/Phase III, Unit II
Plot No. 25 – 27,

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

Survey No. 366,
Premier Industrial Estate,
Kachigam,
Daman – 396210,
India

Oxalis Labs
Village Theda,
P.O. Lodhimajra, Baddi,
Distt. Solan, Himachal Pradesh, 174101, India
Tel: +91-1795 661400
Fax: +91-1795 661452

Inspection status

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

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