Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ajanta Pharma Ltd submitted in 2024 an application for [MA198 trade name][*] (MA198) to be assessed with the aim of including [MA198 trade name] in the list of prequalified medicinal products for malaria chemoprophylaxis.

[MA198 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	One manufacturer of one API was inspected for compliance with WHO requirements for GMP.
December 2023	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
January 2024	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
January and February 2024	The quality data were reviewed by the assessment team and further information was requested.
March 2024	The applicant's response letter was received.
March 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2024	The manufacturers of one API were inspected for compliance with WHO requirements for GMP.
April 2024	The applicant's response letter was received.
May 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2024	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
June 2024	The applicant's response letter was received.
June 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2024	The applicant's response letter was received.
September 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	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.

March 2025	The applicant's response letter was received.
March 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2025	The applicant's response letter was received.
May and July 2025	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
July 2025	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
August 2025	The applicant's response letter was received.
August 2025	The additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
September 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2025	Product dossier accepted (quality assurance)
17 September 2025	[MA198 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

Ajanta Pharma Limited

B-4/5/6, MIDC Industrial Area

Paithan, Chhatrapati Sambhajinagar – 431148

Maharashtra, 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