Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company S Kant Healthcare Ltd. submitted in 2023 an application for [MA193 trade name]* (MA193) to be assessed with the aim of including [MA193 trade name] in the list of prequalified medicinal products for intermittent preventive treatment of malaria in pregnancy and perennial malaria chemoprevention of children.
[MA193 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 2021	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
June 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May 2023	The applicant's response letter was received.
May and June 2023	The quality data were reviewed by the assessment team and further information was requested.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2023	The applicant's response letter was received.
November 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2024	The applicant's response letter was received.
April 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2024	Product dossier accepted (quality assurance)

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

02 May 2024	[MA193 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

S Kant Healthcare Ltd.
Plot No. 1802-1805
G.I.D.C. Phase III,
Vapi 396 195
Gujarat,
India

Inspection status

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

Not inspected for GMP/GLP /GCP. Previous site inspections by WHO or previous inspection by a stringent regulatory authority were acceptable.

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