Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2024 an application for [HA793 trade name]* (HA793) to be assessed with the aim of including [HA793 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA793 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

December 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
May 2024	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May and June 2024	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2024	The applicant's response letter was received.
June 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2024	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 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.
January 2025	The applicant's response letter was received.
January 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2025	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2025	The applicant's response letter was received.
April 2025	The additional quality data were reviewed and further information was requested.
April 2025	The applicant's response letter was received.

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

May 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 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2025	Product dossier accepted (quality assurance)
17 July 2025	[HA793 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

Micro Labs Limited

Plot No S-155 to S-159 & N1

Phase III & Phase IV,

Verna Industrial Estate,

Verna, Goa, 403 722

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