Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2025 an application for [HA809 trade name][*] (HA809) to be assessed with the aim of including [HA809 trade name] in the list of prequalified medicinal products for treatment of HIV infection in infants and children over 4 weeks of age who weigh between 3 kg and 25 kg.

[HA809 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

January 2024	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
June 2024	A desk review for evaluation of compliance of the manufacturers of the APIs for GMP was conducted and it met WHO requirements.
August 2024	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2025	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July and September 2025	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
September 2025	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
October 2025	The applicant's response letter was received.
November 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2025	The applicant's response letter was received.
November 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2026	The applicant's response letter was received.
November and December	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2026	The applicant's response letter was received.
February 2026	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.

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

January and March 2026	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2026	The applicant's response letter was received.
March 2026	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2026	Product dossier accepted (quality assurance)
31 March 2026	[HA809 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 (ML06)
Plot No S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate,
Verna, Goa, 403 722, India

Inspection status

The FPP manufacturer and CRO inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

API manufacturers accepted based on desk assessment.

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