Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2020 an application for [HA767 trade name]* (HA767) to be assessed with the aim of including [HA767 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA767 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

April 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
October 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
November 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2021	The applicant's response letter was received.
April 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January and May 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2022	The applicant's response letter was received.
June 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

June 2022	Product dossier accepted (quality assurance)
28 June 2022	[HA767 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products