Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2019 an application for [HA751 trade name][*] (HA751) to be assessed with the aim of including [HA751 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA751 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 2018	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
June 2018	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GLP.
April 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January 2020	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional safety and efficacy were reviewed and further information was requested.
February 2020	The quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
March 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2020	The applicant's response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
July 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2020	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
January 2021	Product dossier accepted (quality assurance)
06 January 2021	[HA751 trade name] was included in the list of prequalified medicinal products.

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

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 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