Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2020 an application for [HA755 trade name]* (HA755) to be assessed with the aim of including [HA755 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA755 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

October 2017	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
November 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2019	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
October 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
March 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May 2020	The applicant's response letter was received.
May 2020	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.
September 2020	A desk review for evaluation of compliance for the bioequivalence study for GCP met WHO requirements.
September 2020	The applicant's response letter was received.
October 2020	The additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
November 2020	During the meeting of the assessment team the additional quality 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 additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.

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

March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 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.
July 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 and February 2022	The additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
April 2022	The additional quality data were reviewed and further information was requested.
April 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
April 2022	The applicant's response letter was received.
April 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2022	Product dossier accepted (quality assurance)
26 April 2022	[HA755 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 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