Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2014 an application for [HA633 trade name]* (HA633) to be assessed with the aim of including [HA633 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA633 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

September 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2014	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
November 2014	The company's response letter was received.
November 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and December 2014	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2015	The company's response letter was received.
July2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2017	The company's response letter was received.
January 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2017	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
May 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2017	The company's response letter was received.
September 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2017	Product dossier accepted (quality assurance)

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

24 October 2017	[HA633 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–403722
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP. Previous site inspections by WHO showed acceptable outcome.

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