Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2012 an application for [HA555 trade name]* (HA555) to be assessed with the aim of including [HA555 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA555 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

February 2011	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
December 2011	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
November 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
January 2013	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
January 2013	The company's response letter was received.
January 2013	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 2013	The company's response letter was received.
June 2013	The additional quality data were reviewed and further information was requested.
July 2013	The company's response letter was received.
July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2013	The company's response letter was received.
September 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2013	The company's response letter was received.
November 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
April 2014	The manufacturers of the APIs were inspected for compliance with WHO Requirements for GMP.
May 2014	The company's response letter was received.
May 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2014	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
October 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

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

August 2014	Product dossier accepted (quality assurance)
13 January 2015	[HA555 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. No bioequivalence study was required (biowaiver).

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