Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2009 an application for [HA485 trade name]* (HA485) to be assessed with the aim of including [HA485 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA485 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

May 2005	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP
October 2006	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP
May 2009	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP
November 2009	During the meeting of the assessment team, the safety and efficacy data of the dossier were reviewed and further information was requested.
January 2010	The company's response was received
March 2010	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements
April 2010	During the meeting of the assessment team, the quality data of the dossier were reviewed and further information was requested.
October 2009	The company's response was received
March 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP
May 2010	During the meeting of the assessment team, the quality data of the dossier were reviewed and further information was requested
July 2010	The company's response was received
July 2010	During the meeting of the assessment team, the quality data of the dossier were reviewed and further information was requested
5 October 2010	The company's response was received
11 October 2010	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements
25 October 2010	[HA485 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
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 (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