Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2009 an application for [HA483 trade name]* (HA483) to be assessed with the aim of including [HA483 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA483 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 2009	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Nov 2009	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
Jan 2010	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
Jan 2010	The company's response letter was received.
March 2010	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
March 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2010	The company's response letter was received.
May 2010	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 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.
Aug 2010	During the meeting of the assessment team the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
20 Aug 2010	[HA483 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
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Phase III & Phase IV
Verna Industrial Estate,
Verna, Goa – 403722, India
Phone No.: +91-832- 6686262
Fax No. +91-832- 6686203

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.
BCS-based biowaiver was used.

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