Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2012 an application for [HA536 trade name][*] (HA536) to be assessed with the aim of including [HA536 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA536 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

Jan 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2012	The company's response letter was received.
July 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Aug 2012	The company's response letter was received.
Sept 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2013	The company's response letter was received.
Jan 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan/Feb 2013	The company's response letters were received.
Feb 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
Feb 2013	Product dossier accepted (quality assurance)
18 Feb 2013	[HA536 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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Verna Industrial Estate, Verna, Goa 403 722,
India.
Tel: + 91 832 6686262
Fax: +91 832 6686203

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GLP. Not inspected for GCP. 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