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 [HA620 trade name]* (HA620) to be assessed with the aim of including [HA620 trade name] in the list of prequalified medicinal products for the treatment HIV/AIDS.

[HA620 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

March 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2014 and August 2014	The quality data were reviewed and further information was requested.
September 2014	The manufacturer of the API 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.
November 2014	The company's response letter was received.
November 2014 and January 2015	During the meetings of the assessment team the additional quality data were reviewed and further information was requested
March 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
May 2015	The company's response letter was received.
May 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2015	Product dossier accepted (quality assurance)
09 July 2015	[HA620 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 compliant with WHO requirements for GMP.

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

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