Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2010, an application for [HA498 trade name]* (HA498) to be assessed with the aim of including [HA498 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA498 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

Nov 2010	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Dec 2010	The company's response letter was received.
Jan 2011	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
Jan 2011	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.
July 2011	The company's response letter was received.
Nov 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Feb 2012	The company's response letter was received.
Feb 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sept 2012	The company's response letter was received.
Sept 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Oct 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Feb 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
April 2013	In between the meetings of the assessment team the company's response letter was received. The quality data were reviewed and further information was requested.
May 2013	The company's response letter was received.
May 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2013	Product dossier accepted (quality assurance)
24 June 2013	[HA498 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

Hetero Labs Limited
Unit – III (Formulations),
22 – 110, IDA
Jeedimetla, Hyderabad – 500 055
Telangana, India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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