Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2012 an application for [HA565 trade name]* (HA565) to be assessed with the aim of including [HA565 trade name] in the list of prequalified medicinal products for treatment of HIV.

[HA565 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

January 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January and March 2013	During the meetings of the assessment team 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.
September 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2014	The company's response letter was received.
November 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2015	The company's response letter was received.
July 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2017	The company's response letter was received.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

April 2017	The additional quality data were reviewed and further information was requested.
July 2017	The company's response letter was received.
July 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2017	Product dossier accepted (quality assurance)
20 July 2017	[HA565 trade name] was included in the list of prequalified medicinal products.

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),
22-110, I.D.A, Jeedimetla,
Hyderabad-500055, 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