Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laurus Labs Ltd submitted in 2016 an application for [HA679 trade name]* (HA679) to be assessed with the aim of including [HA679 trade name] in the list of prequalified medicinal products for HIV/AIDS and hepatitis B.

[HA679 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

Feb 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Sept 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Oct 2016	The company's response letter was received.
Nov 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept and Nov 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Jan 2017	The company's response letter was received.
Jan 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2017	The company's response letter was received.
March 2017	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.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2017	The company's response letter was received.
Sept 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Sept + Dec 2017	The additional quality data were reviewed and further information was requested.
Dec 2017	The company's response letter was received.
Dec 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2017	Product dossier accepted (quality assurance).
12 Dec 2017	[HA679 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

Laurus Labs Limited

Plot No. 19, 20 & 21, Western Sector

APSEZ, Atchutapuram Mandal,

Visakhapatnam-District-531011

Andhra Pradesh

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