Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2019 an application for [HA745 trade name]* (HA745) to be assessed with the aim of including [HA745 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

[HA745 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

September 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP
May 2018	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
February 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
September 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
November 2019	The applicant's response letter was received
November 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2019	The quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
December 2020	The additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
January 2021	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
February 2021	The applicant's response letter was received
February 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

February 2021	Product dossier accepted (quality assurance)
17 February 2021	[HA745 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

Ipca Laboratories Limited
Plot no.255/1, Village Athal
Silvassa 396 230
U.T. of Dadra and Nagar Haveli and Daman and Diu
India

Inspection status

The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.

A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.

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