Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laurus Labs Limited submitted in 2021 an application for [HA772 trade name][*] (HA772) to be assessed with the aim of including [HA772 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA772 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

June 2020	A desk review for evaluation of compliance of the manufacturer of the APIs for GMP was conducted and it met WHO requirements.
January 2021	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
November 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
December 2021	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
December 2021 and January 2022	The quality data were reviewed and further information was requested.
February 2022	The applicant's response letter was received.
March 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2022	The applicant's response letter was received.
July 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2022	The applicant's response letter was received.
January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

July 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2023	The applicant's response letter was received.
August 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2023	Product dossier accepted (quality assurance)
02 September 2023	[HA772 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

Laurus Labs Limited, (Unit-II)
Plot No:19, 20 & 21
Western Sector, APSEZ
Atchutapuram Mandal
Visakhapatnam-District-531011
Andhra Pradesh
India

Inspection status

A desk review for evaluation of the manufacturers of the APIs was conducted and found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of the manufacturer of the FPP was conducted and found to be in compliance with WHO requirements for GMP.

The sites inspected were found to be in compliance with WHO requirements for 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/prequal/medicines/prequalified/finished-pharmaceutical-products