Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laurus Labs Limited submitted in 2019 an application for [HP028 trade name][*] (HP028) to be assessed with the aim of including [HP028 trade name] in the list of prequalified medicinal products for the treatment of chronic hepatitis C virus (HCV) infections.

[HP028 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

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

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

November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
December 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2020	Product dossier accepted (quality assurance).
18 December 2020	[HP028 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
Gurajapalem Village, Rambilli
Mandal, Anakapalli - 531011,
Andhra Pradesh 531011
India

Inspection status

The sites underwent desk review and 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/prequal/medicines/prequalified/finished-pharmaceutical-products