Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Zydus Lifesciences Limited submitted in 2022 an application for [HP034 trade name]* (HP034) to be assessed with the aim of including [HP034 trade name] in the list of prequalified medicinal products for treatment of chronic hepatitis C virus (HCV) infection in adults and children.

[HP034 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 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
July 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July and September 2022	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2022	The applicant's response letter was received.
January and March 2023	During the meetings of the assessment team the quality data were reviewed and further information was requested.
April 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 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 and December 2023	The additional quality data were reviewed and further information was requested.
December 2023	The applicant's response letter was received.
December 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2023	Product dossier accepted (quality assurance)
22 December 2023	[HP034 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

Zydus Lifesciences Limited

Kundaim Industrial Estate,

Plot No.203-213, Kundaim,

Goa-403 115,

India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

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