

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2018 an application for [HP021 trade name]* (HP021) to be assessed with the aim of including [HP021 trade name] in the list of prequalified medicinal products for chronic hepatitis C infections.

[HP021 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 manufacturer of the API was inspected for compliance with WHO requirements for GMP.
December 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2018	The applicant’s response letter was received.
July 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2018	The quality data were reviewed and further information was requested.
November 2018	The applicant’s response letter was received.
November 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2019	The applicant’s response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 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.
October 2019	The applicant’s response letter was received.
December 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2019	Product dossier accepted (quality assurance)
17 December 2019	[HP021 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

Cipla Limited,
Plot A-42 (Unit 2),
MIDC, Patalganga,
Raigad District,
Maharashtra 410 220,
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/prequal/medicines/prequalified/finished-pharmaceutical-products>