Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Ltd submitted in 2020 an application for [CV001 trade name]* (CV001) to be assessed with the aim of including [CV001 trade name] in the list of prequalified medicinal products for COVID-19.

[CV001 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

August 2020	The quality data were reviewed by the assessment team and further information was requested.
September 2020	The applicant's response letter was received.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 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 additional quality data were reviewed and further information was requested.
October 2020	The applicant's response letter was received.
November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020 to April 2022	Suspension
April 2022	The applicant's response letter was received.
April 2022	The additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
April 2022	The additional quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
December 2024	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
November 2024 and January 2025	During the meetings 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.

April 2025	The applicant's response letter was received.
April 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2025	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
May 2025	Product dossier accepted (quality assurance)
14 May 2025	[CV001 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

Hetero Labs Limited

Sy.No.321, Biotech Park, Phase - III

C/o M/s. Aspiro Pharma Limited

Karkapatla (V)

Markook (M), Siddipet (D)

Telangana State, India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP. No bioequivalence study was required due to the nature of the pharmaceutical formulation.

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