Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Celltrion, Inc. submitted in 2022 an application for [CV017 trade name][*] (CV017) to be assessed with the aim of including [CV017 trade name] in the list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19).

[CV017 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

October 2020	A desk review for evaluation of compliance of the manufacturer of one FPP for GMP was conducted and it met WHO requirements.
August 2021	A desk review for evaluation of compliance of the manufacturer of one FPP for GMP was conducted and it met WHO requirements.
December 2022 and January 2023	During the meeting of the assessment team the safety and efficacy and the quality data were reviewed, and further information was requested.
January 2023	The applicant's response letter was received.
February 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2023	The applicant's response letter was received.
February 2023	The quality data were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
March 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.
April 2023	The applicant's response letter was received.
April 2023	The quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
June 2023	The quality data were reviewed and further information was requested.
July 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
August 2023	The applicant's response letter was received.
August 2023	The quality data were reviewed and further information was requested.
September 2023	The applicant's response letter was received.

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

September 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2023	Product dossier accepted (quality assurance)
10 October 2023	[CV017 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

Celltrion Pharm, Inc.
82, 2 Sandan-ro, Ochang-eup,
Cheongwon-gu, Cheongju-si,
Chungcheongbuk-do, 28117,
Republic of Korea

Inspection status

The manufacturer of the API was found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of compliance of the manufacturers of FPPs for GMP was conducted and it met WHO requirements.

The site relevant for the bioequivalence study was 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/prequalification-reports/whopars