Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd submitted in 2022 an application for [CV018 trade name]* (CV018) to be assessed with the aim of including [CV018 trade name] in the list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) in adults.

[CV018 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.
January 2023	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
February 2023	The applicant's response letters were received
February 2023	The additional quality, safety and efficacy 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.
April 2023	The applicant's response letter was received.
April 2023	The additional quality data were reviewed and further information was requested.
April 2023	The applicant's response letter was received.
April 2023	The additional quality data were reviewed and further information was requested.
May 2023	The applicant's response letter was received.
May 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
August 2023	The applicant's response letter was received.
August 2023	The additional quality data were reviewed and further information was requested.
September 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2023	The applicant's response letter was received.

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

October 2023	The quality data were reviewed and found to comply with the relevant WHO requirements
November 2023	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
November 2023	A desk review for evaluation of compliance of the manufacturer of one FPP for GMP was conducted and it met WHO requirements.
October 2023	Product dossier accepted (quality assurance)
08 November 2023	[CV018 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

Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd.
Building # 27 (FPP Workshop #7, FPP Quality Unit and Warehouse)
333 Second Jiangnan Road,
Hengdian，
Dongyang,
Zhejiang 322118,
P.R. China

Inspection status

API and FPP manufacturers were inspected through desk assessment and found to be in compliance with WHO requirements for GMP.
The sites inspected were 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/prequalified/finished-pharmaceutical-products