Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd submitted in 2023 an application for [CV020 trade name][*] (CV020) to be assessed with the aim of including [CV020 trade name] in the list of prequalified medicinal products for coronavirus disease 2019 (COVID-19).

[CV020 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

February 2023	The safety and efficacy data were reviewed by the assessment team and further information was requested
February and March 2023	The quality data were reviewed by the assessment team and further information was requested
March 2023	The applicant's response letter was received.
March 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 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 sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2023	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
August 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.
December 2023	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
December 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2024	The applicant's response letter was received.
February 2024	The additional quality data were reviewed by the assessment team and further information was requested

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

March 2024	The applicant's response letter was received.
March 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2024	The applicant's response letter was received.
May and July 2024	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
July 2024	The applicant's response letter was received.
August 2024	The quality data were reviewed by the assessment team and further information was requested
August 2024	The applicant's response letter was received.
August 2024	The quality data were reviewed and found to comply with the relevant WHO requirements
September 2024	Product dossier accepted (quality assurance)
04 September 2024	[CV020 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

Yaopharma Co., Ltd.

100 Xingguang Avenue, Renhe Town,

Yubei District,

Factory Bldg. No. 2, Oral solid line I

Chongqing 401121,

People's Republic of China

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