Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Desano Bio-Pharmaceutical Co., Ltd., submitted in 2023 an application for [CV026 trade name][*] (CV026) to be assessed with the aim of including [CV026 trade name] in the list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) in adults.

[CV026 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

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

July 2024	The applicant's response letter was received.
July 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2024	Product dossier accepted (quality assurance)
27 September 2024	[CV026 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

Shanghai Desano Bio-Pharmaceutical Co., Ltd.
Block No. 2
1479 Zhangheng Road
China (Shanghai) Pilot Free Trade Zone
Shanghai 201203
P.R. 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