Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Desano Bio-Pharmaceutical Co Ltd. submitted in 2019 an application for [HA749 trade name]* (HA749) to be assessed with the aim of including [HA749 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS

[HA749 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

January 2019	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
November 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January 2020	The applicant's response letter was received.
January 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2019 and February 2020	The quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.
June 2020	The additional quality data were reviewed and further information was requested.
September 2020	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2020	The applicant's response letter was received.
October 2020	The additional quality data were reviewed and further information was requested.
November 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.
January 2021	The applicant's response letter was received.
January and June 2021	The additional quality data were reviewed and further information was requested.
March 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2022	The applicant's response letters were received.
June 2022	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.

June 2022	The applicant's response letter was received.
July 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2022	The applicant's response letter was received
July 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2022	Product dossier accepted (quality assurance)
08 August 2022	[HA749 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

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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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products