Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Desano Pharmaceuticals Private Limited submitted in 2020 an application for [HA766 trade name]* (HA766) to be assessed with the aim of including [HA766 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA766 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 2020 and January 2021	During the meetings of the assessment team the safety and efficacy data were reviewed and further information was requested
November 2020 and March 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
May 2021	The applicant's response letters were received.
May 2021	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.
August 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2022	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
March 2022	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.

March 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2022	The applicant's response letter was received.
June 2022	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
May and September 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
October 2022	The additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2022	Product dossier accepted (quality assurance)
24 November 2022	[HA766 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

Aizant Drug Research Solutions Pvt. Ltd.
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Dundigal- Gandimaisamma Mandal,
Medchal-Malkhajgiri District
Hyderabad-500 100
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Inspection status

The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.

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

The sites relevant for the bioequivalence study were inspected for 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products