Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Celltrion, Inc. submitted in 2020 an application for [HA756 trade name]* (HA756) to be assessed with the aim of including [HA756 trade name] in the list of prequalified medicinal products for is indicated for the treatment of human immunodeficiency virus type1 (HIV-1) infection. [HA756 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 one API was inspected for compliance with WHO requirements for GMP.
May 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
June 2020	Desk reviews for evaluation of compliance of the manufacturers for two APIs for GMP were conducted and they met WHO requirements.
May and August 2020	The assessment team reviewed the quality data and further information was requested.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
August 2020	The applicant's response letter was received.
September 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2020	The applicant's response letter was received.
January and March 2021	During the meetings of the assessment team 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.
April 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2021	The applicant's response letter was received.
September (and October) 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.
November 2021 and March 2022	During the meetings 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.

June 2022	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
July 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.
November 2022	The applicant's response letter was received.
November 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2022	The applicant's response letter was received.
December 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2022	Product dossier accepted (quality assurance)
28 December 2022	[HA756 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
Block No. B,
Survey No. 172 &173,
Apparel Park Road, Dulapally Village,
Dundigal Gandimaisamma Mandal,
Medchal-Malkhajgiri District,
Hyderabad, Telangana 500100,
India.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GCP

Final Product manufacturer was not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

Of the API manufacturers some were not inspected for GMP as previous inspections by a stringent regulatory authority were acceptable, whilst other API manufacturers were inspected and were found to be compliant for GMP

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