Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shijiazhuang Lonzeal Pharmaceuticals Co., Limited submitted in 2021 an application for [HP030 trade name][*] (HP030) to be assessed with the aim of including [HP030 trade name] in the list of prequalified medicinal products for treatment of HIV infection and treatment of chronic hepatitis B.

[HP030 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

September 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and October 2021	During the meeting of the assessment team the quality data were reviewed and further information was requested.
February 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.
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.
May 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
September 2022	The applicant's response letter was received.
September 2022 and January 2023	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
February and March 2023	The applicant's response letters were received.
March 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
March 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.

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

October 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2023	Product dossier accepted (quality assurance)
27 August 2024	[HP030 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/prequal/medicines/prequalified/finished-pharmaceutical-products