

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Reyoung Pharmaceutical Co., Ltd submitted in 2023 an application for [HA782 trade name]* (HA782) to be assessed with the aim of including [HA782 trade name] in the list of prequalified medicinal products for treatment and prevention of infections in HIV/AIDS patients.

[HA782 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 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
March and May 2023	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
July 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2023	The applicant's response letter was received.
November 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2024	The applicant's response letter was received.
March and May 2024	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2024	The applicant's response letter was received.
May 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.

June 2024	The applicant's response letter was received.
June 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2024	Product dossier accepted (quality assurance)
02 July 2024	[HA782 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

Reyoung Pharmaceutical Co., Ltd.
Solid Preparation Workshop (316)
First Floor of Building B2
Plant B Reyoung Pharmaceutical Co., Ltd.
No. 1, Ruiyang Road, Yiyuan County
Shandong Province, 256100
China

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

APIs were supported by CEPs. Inspection of the manufacturing site waived based on previous satisfactory inspection by a stringent regulatory authority.

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>