Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2020 an application for [HA758 trade name]* (HA758) to be assessed with the aim of including [HA758 trade name] in the list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection.

[HA758 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

May 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
June 2020	The applicant's response letter was received.
July 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May and September 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
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.
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.
June 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 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.

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

March 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	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.
April 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.
May 2024	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2024	The applicant's response letter was received.
June 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2024	The applicant's response letter was received.
September 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
September 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2025	The applicant's response letter was received.
November 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2025	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
January 2026	The applicant's response letter was received.
January and April 2026	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2026	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2026	The applicant's response letter was received.
May 2026	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2026	The applicant's response letter was received.

May 2026	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2026	The applicant's response letter was received.
June 2026	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2026	Product dossier accepted (quality assurance)
15 June 2026	[HA758 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

Hetero Labs Limited
Unit - III (Formulations),
Plot no 22 - 110, I.D.A
Jeedimetla, Hyderabad,
Telangana, India

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