Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company RV Lifesciences Limited submitted in 2024 an application for [HA794 trade name]* (HA794) to be assessed with the aim of including [HA794 trade name] in the list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection.

[HA794 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

March 2024	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
September 2024	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
October 2024	The applicant's response letter was received.
November 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2024	During the meeting of the assessment team the quality data were reviewed and further information was requested.
December 2024	The applicant's response letter was received.
January 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2025	The applicant's response letter was received.
March and April 2025	The additional quality data were reviewed and further information was requested.
May 2025	The applicant's response letter was received.
June 2025	The additional quality data were reviewed and further information was requested.
July 2025	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
August 2025	The applicant's response letter was received.
August 2025	The additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
October 2025	The additional quality data were reviewed and further information was requested.
April 2026	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
May 2026	The applicant's response letter was received.
May 2026	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2026	The applicant's response letter was received.
June 2026	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 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)
19 June 2026	[HA794 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

RV Lifesciences Limited

Plot No. H-19, MIDC, Waluj

Chhatrapati Sambhajinagar– 431133

Maharashtra State

India

Inspection status

Desk review of the sites was found to be in compliance with WHO requirements for GMP.

The sites inspected were found to be in 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/prequal/medicines/prequalified/finished-pharmaceutical-products