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 [HP035 trade name][*] (HP035) to be assessed with the aim of including [HP035trade name] in the list of prequalified medicinal products for chronic hepatitis B virus infection.

[HP035 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 2024	During the meeting of the assessment team the safety and efficacy 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	During the meeting of the assessment team the <safety and efficacy data> <quality data> were reviewed and further information was requested.
June 2024	In between the meetings of the assessment team the applicant's response letter was received. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 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.
January 2025	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.
January 2025	The applicant's response letter was received.
January 2025	The additional quality data were reviewed and further information was requested.
January 2025	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
February 2025	The applicant's response letter was received.
February 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2025	Product dossier accepted (quality assurance)
19 February 2025	[HP035 trade name] was included in the list of prequalified medicinal products.

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

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,
Aurangabad 431133,
Maharashtra State,
India

Inspection status

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

Not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

API supported by a CEP. Inspection of the manufacturing site waived based on risk assessment.

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