Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Rusan Pharma Ltd. submitted in 2024 an application for [NT020 trade name][*] (NT020) to be assessed with the aim of including [NT020 trade name] in the list of prequalified medicinal products for the management of neglected tropical diseases.

[NT020 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.
June 2024	The assessment team reviewed the quality data and further information was requested.
June 2024	The applicant's response letter was received.
June 2024	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
August 2024	The applicant's response letter was received.
September 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2024	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
September 2024	The applicant's response letter was received.
October 2024	The assessment team reviewed the additional quality data 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.
March 2025	The applicant's response letter was received.
April 2025	The assessment team reviewed the additional quality data and further information was requested.
May 2025	The applicant's response letter was received.
February 2025	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
July 2025	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.

July and October 2025	The assessment team reviewed the additional quality data 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 applicant's response letter was received.
November 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2025	Product dossier accepted (quality assurance)
19 December 2025	[NT020 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

Rusan Pharma Ltd.

Khasra No. 122 MI, Central Hope Town,

Selaqui, District: Dehradun - 248197

Uttarakhand

India

Inspection status

The API manufacturer was inspected and found to comply with WHO GMP requirements.

A desk review was conducted to evaluate the FPP manufacturer's compliance with GMP, and it was found to meet WHO requirements.

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