Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mepro Pharmaceuticals Pvt. Ltd submitted in 2025 an application for [NT022 trade name][*] (NT022) to be assessed with the aim of including [NT022 trade name] in the list of prequalified medicinal products for the treatment of neglected tropical disease.

[NT022 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 2025	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
July 2025	The applicant's response letters were received.
July 2025	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
September 2025	The applicant's response letters were received.
September 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2025	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
September 2025	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2025	The applicant's response letter was received.
December 2025	The additional quality data were reviewed and further information was requested.
January 2026	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
January 2026	The applicant's response letter was received.
February 2026	The additional quality data were reviewed and further information was requested.
March 2026	The applicant's response letter was received.
March and May 2026	During the meetings 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	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2026	Product dossier accepted (quality assurance)

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

19 June 2026	[NT022 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

Mepro Pharmaceuticals Pvt. Ltd.

Unit-III, Plot No. 141/2 & 227, Haripura,

Ta. Savli, Jarod, Samlaya road,

Vadodara, Gujarat 391520,

India

Inspection status

A desk review for evaluation of compliance of the manufacturer of the API and FPP for GMP was conducted and it met 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