Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mepro Pharmaceuticals Pvt. Ltd. submitted in 2021 an application for [NT014 trade name]* (NT014) to be assessed with the aim of including [NT014 trade name] in the list of prequalified medicinal products for neglected tropical diseases.

[NT014 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

July 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
July and September 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
August 2021	The applicant's response letter was received.
September 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2022	The applicant's response letter was received.
January and March 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2022	The applicant's response letter was received.
May 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 manufacturer of the API was inspected for compliance with WHO requirements for GMP.
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.
January 2023	The applicant's response letter was received.

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

January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2023	The applicant's response letter was received.
March 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2023	The applicant's response letter was received.
November 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2024	The applicant's response letter was received.
March and May 2024	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
July 2024	The applicant's response letter was received.
July 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2024	The applicant's response letter was received.
July 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2024	Product dossier accepted (quality assurance)
16 August 2024	[NT014 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-II, Q Road, Phase-IV,
G.I.D.C, Wadhwan
Dist: Surendranagar,
Gujarat 363035,
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