Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Medopharm Private Limited submitted in 2021 an application for [NT012 trade name][*] (NT012) to be assessed with the aim of including [NT012 trade name] in the list of prequalified medicinal products for neglected tropical diseases.

[NT012 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.
September 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.
November 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2021	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2022	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
March 2022	During the meeting 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.

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

September 2022	The applicant's response letter was received.
September and November 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
December 2022	The applicant's response letter was received.
December 2022	The additional quality data were reviewed and further information was requested.
December 2022	The applicant's response letter was received.
December 2022	The additional quality data were reviewed and further information was requested.
January 2024	A desk review for evaluation of compliance for the bioequivalence study for GCP/GLP met WHO requirements.
October 2024	The applicant's response letters were received.
October 2024	The additional quality data were reviewed and further information was requested.
November 2024	Due to concerns regarding GCP compliance, a new bioequivalence study was submitted. The safety and efficacy data were reviewed and further information was requested.
December 2024	The applicant's response letters were received.
December 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2024	Product dossier accepted (quality assurance).
25 December 2024	[NT012 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

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Inspection status

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

A desk review for evaluation of compliance for the bioequivalence study for GCP/GLP met WHO requirements.

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