Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Medopharm Private Limited submitted in 2019 an application for [NT008 trade name]* (NT008) to be assessed with the aim of including [NT008 trade name] in the list of prequalified medicinal products for neglected tropical diseases.

[NT008 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

February 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
November 2019 + January 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
March 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
February 2021	The additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
March 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2021	Product dossier accepted (quality assurance)

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

22 April 2021	[NT008 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

Medopharm Private Limited,
Unit II, No. 50, Kayarambedu Village,
Guduvanchery - 603 202,
Tamilnadu,
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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products