Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company MSN Laboratories Private Limited submitted in 2022 an application for [TB395 trade name]* (TB395) to be assessed with the aim of including [TB395 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB395 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 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
January 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January and April 2022	The quality data were reviewed by the assessment team and further information was requested.
March 2022	The applicant's response letter was received.
March 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2022	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
August 2022	The applicant's response letter was received.
September and October 2022	The 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.
January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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 applicant's response letter was received.

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

July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 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 sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2024	The applicant's response letter was received.
March and June 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.
September and November 2024	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
December 2024	The applicant's response letter was received.
December 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2024	Product dossier accepted (quality assurance)
19 December 2024	[TB395 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

MSN Laboratories Private Limited

Formulations Division (Block-D), Unit-II,

Survey Nos. 1277, 1319 to 1324,

Nandigama (Village & Mandal),

Ranga Reddy (District),

Telangana 509228,

India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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