Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company S Kant Healthcare Limited submitted in 2023 an application for [TB405 trade name] * (TB405) to be assessed with the aim of including [TB405 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB405 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

June 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2023	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
September 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
September and October 2023	The quality data were reviewed by the assessment team and further information was requested.
October 2023	The applicant's response letter was received.
November 2023	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
January 2024	The applicant's response letters were received.
January 2024	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
January and February 2024	The additional quality data were reviewed by the assessment team and further information was requested.
February 2024	The applicant's response letters were received.
February 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 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.
April 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2024	Product dossier accepted (quality assurance).
17 April 2024	[TB405 trade name] was included in the list of prequalified medicinal products.

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

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, GLP and GCP.

A desk review for evaluation of compliance of the manufacturer of the API 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