Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Pharma Science Limited submitted in 2024 an application for [TB416 trade name][*] (TB416) to be assessed with the aim of including [TB416 trade name] in the list of prequalified medicinal products for treatment of drug-resistant tuberculosis.

[TB416 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

January 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2024 and January 2025	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2025	The applicant's response letter was received.
March 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2025	The applicant's response letter was received.
May 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2025	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
July 2025	The applicant's response letter was received.
July and September 2025	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
September 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2025	Product dossier accepted (quality assurance)
17 September 2025	[TB416 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

Strides Pharma Science Limited
Formulation division unit II
RS. No. 32, 33 & 34,
PIMS Road, Periykalapet,
Puducherry- 605 014,
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