Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cadila Pharmaceuticals Limited submitted in 2023 an application for [TB407 trade name][*] (TB407) to be assessed with the aim of including [TB407 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB407 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

March 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
November and December 2023	The quality data were reviewed by the assessment team 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 safety and efficacy data were reviewed and further information was requested.
February and March 2024	The applicant's response letters were received.
March 2024	During the meeting of the assessment team the additional quality data and the safety and efficacy 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.
April and May 2024	The applicant's response letters were received.
May 2024	During the meeting of the assessment team the additional quality data and the safety and efficacy data were reviewed and further information was requested.
June 2024	The applicant's response letters were received.
June 2024	During the meeting of the assessment team the additional quality data and the safety and efficacy data were reviewed and further information was requested.
August 2024	The applicant's response letter was received.
September 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and October 2024	The additional quality data were reviewed and further information was requested.
October 2024	The applicant's response letter was received.

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

November 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2024	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
November 2024	Product dossier accepted (quality assurance
21 November 2024	[TB407 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

Cadila Pharmaceuticals Limited

1389 Trasad Road,

Dholka- 382 225, District: Ahmedabad,

Gujarat,

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 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