Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2021 an application for [TB388 trade name]* (TB388) to be assessed with the aim of including [TB388 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB388 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 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
June 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
April 2021	The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP.
August 2021	The assessment team reviewed the safety and efficacy data and further information was requested.
July and September 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
December 2021 and January 2022	The applicant's response letters were received.
January 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2021 and January 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
May 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
July 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

October 2022	The applicant's response letter was received.
October 2022	The additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2022	Product dossier accepted (quality assurance)
24 November 2022	[TB388 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

Mylan Laboratories Limited

F-4 & F-12, MIDC, Malegaon

Sinnar, Nashik-422113

Maharashtra, India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP since a biowaiver applies.

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