I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2015 an application for [TB308 trade name] to be assessed with the aim of including {product name} in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB308 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 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2015	The company's response letter was received.
May 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
March and June 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Sept 2015	The company's response letter was received.
Nov 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Dec 2015	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
April 2016	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
April 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2016	Due to concerns regarding GCP compliance, a new bioequivalence study was submitted. The safety and efficacy data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Jan 2017	The company's response letter were received.
Jan 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2017	The company's response letters were received.
Aug 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Sept 2017	Product dossier accepted (quality assurance).
26 Sept 2017	[TB308 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
Plot No. H-12 & H-13 MIDC,
Waluj Industrial Area
Aurangabad – 431136
Maharashtra State, India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP. Not inspected for GCP/GLP (biowaiver).

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products