Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company MSN Laboratories Private Limited submitted in 2016 an application for [TB339 trade name]* (TB339) to be assessed with the aim of including [TB339 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB339 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

November 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
January 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2017	The applicant's response letter was received.
March 2017	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
March 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2017	The applicant's response letters were received.
May 2017	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
June 2017	The additional quality data were reviewed and further information was requested.
July 2017	The applicant's response letters were received.
September 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.
February 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2018	The applicant's response letter was received.
February 2019	The additional quality data were reviewed and further information was requested.
April 2019	The applicant's response letter was received.
April 2019	The additional quality data were reviewed and further information was requested.
April 2019	The applicant's response letter was received.

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

April 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2019	Product dossier accepted (quality assurance)
15 May 2019	[TB339 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

MSN Laboratories Private Limited
Formulations Division, Unit-II
Survey Nos. 1277, 1319 to 1324
Nandigama (Village & Mandal)
Rangareddy District
Telangana 509228
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