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 [TB338 trade name]* (TB338) to be assessed with the aim of including [TB338 trade name] in the list of prequalified medicinal products for the prevention and treatment of tuberculosis.

[TB338 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

Nov 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Jan 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jan 2017	The applicant's response letter was received.
Mar 2017	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Mar 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Apr 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.
Jun 2017	The additional quality data were reviewed and further information was requested.
Jul 2017	The applicant's response letters were received.
Sep 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.
Feb 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Feb 2018	The applicant's response letter was received.
Mar 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Apr 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.
Jul 2018	The applicant's response letter was received.
Sep 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2018	The applicant's response letter was received.
Feb 2019	The additional quality data were reviewed and further information was requested.
Apr 2019	The applicant's response letter was received.
Apr 2019	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.

Apr 2019	The applicant's response letter was received.
Apr 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	[TB338 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 active pharmaceutical ingredient and finished pharmaceutical product manufacturing sites 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products