Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2015 an application for [TB315 trade name]* (TB315) to be assessed with the aim of including [TB315 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB315 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

May 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May and July 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Aug 2015	The company's response letter was received.
Sept 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Oct 2015	The company's response letter was received.
Nov 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 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.
Feb 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2017	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
June 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2017	Product dossier accepted (quality assurance)
20 July 2017	[TB315 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Hetero Labs Ltd, Unit 5
Survey No 439, 440, 441 & 458 TSIIC Formulation SEZ
Polepally Village
Jadcherla (M)
Mahaboob Nagar District
Telangana – 509301
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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