Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Qilu Pharmaceutical Co., Ltd. submitted in 2015 an application for [TB319 trade name][*] (TB319) to be assessed with the aim of including [TB319 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB319 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 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jan 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2017	The company's response letter was received.
Jan 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 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.
Aug 2017	The company's response letter was received.
Sept 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2017	The company's response letter was received.
Nov/Dec 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2018	The company's response letter was received.
April 2018	The additional quality data were reviewed and further information was requested.
April 2018	The company's response letter was received.
April 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2018	Product dossier accepted (quality assurance)

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

11 May 2018	[TB319 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

Qilu Pharmaceutical Co., Ltd.

No. 317, Xinluo Road

High-Tech Zone

Jinan, Shandong

P.R. China

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