Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company PT Sanbe Farma submitted in 2019 an application for [TB373 trade name]* (TB373) to be assessed with the aim of including [TB373 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB373 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

July 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
June and August 2019	The quality data were reviewed and further information was requested.
September 2019	The applicant's response letter was received.
September 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2019	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
November 2019	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP.
March 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November and December 2020	The applicant's response letters were received.
April 2021	The additional quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.

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

May 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2021	Product dossier accepted (quality assurance)
02 November 2021	[TB373 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

PT. Caprifarmindo Laboratories
Jl. Industri Cimareme No. 8
Block H, Desa Cimareme
Kecamatan Padalarang
Kabupaten
Bandung Barat
Indonesia

Inspection status

The 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