Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company PT. Kalbe Farma submitted in 2018 an application for [TB354 trade name]* (TB354) to be assessed with the aim of including [TB354 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB354 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 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2018	The applicant's response letter was received.
March 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January and March 2018	During the meetings of the assessment team the quality data were reviewed and further information was requested.
May 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.
May 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2019	The applicant's response letter was received.
February 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2019	Product dossier accepted (quality assurance)
22 February 2019	[TB354 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.
†Formerly PT. Dankos Farma

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

PT. Kalbe Farma
Line 8A
Kawasan Industri Delta Silicon
Jl. M.H. Thamrin Blok A3-1
Lippo Cikarang, Bekasi, 17550
Indonesia

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