Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2016 an application for [TB330 trade name][*] (TB330) to be assessed with the aim of including [TB330 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB330 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	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Aug 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2016	The company's response letter was received.
November 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2017	The company's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2017	The company'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.
June 2018	The company's response letter was received.
June 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2018	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
June 2018	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP was conducted and it met WHO requirements.
June 2018	Product dossier accepted (quality assurance)
17 July 2018	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

Macleods Pharmaceuticals Limited,
Phase II/Phase III, Unit 2,
Plot No 25-27, Survey No 366,
Premier Industrial Estate,
Kachigam, Daman, 396 210
India

Inspection status

The API manufacturing site was inspected and found to be in compliance with WHO requirements for GMP.

FPP manufacturing site was not inspected for GMP. Previous inspections by a stringent regulatory authority showed acceptable outcome.

Not inspected for GLP /GCP 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