Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceutical Limited submitted in 2017 an application for [TB312 trade name][*] (TB312) to be assessed with the aim of including [TB312 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB342 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

December 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
April 2017	The company's response letter was received.
May 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March and June 2017	The quality data were reviewed and further information was requested.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2017	The company's response letter was received.
August 2017	The additional quality data were reviewed and further information was requested.
September 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.
January 2018	The company's response letter was received.
January 2018	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.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	The company's response letter was received.
May 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

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

May + October 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2018	The company's response letters were received.
December 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2018	Product dossier accepted (quality assurance)
18 December 2018	Moxifloxacin (as hydrochloride) 100 mg dispersible tablets 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

Macleods Pharmaceutical Limited

Unit-VI, Production Block N2,

Village Theda,

P.O. Lodhimajra,Tehsil Baddi,

District Solan, Himachal Pradesh-174101

India

Inspection status

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

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