

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 [TB326 trade name]¹ (TB326) to be assessed with the aim of including [TB326 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB326 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

June 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2014	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Jan 2015	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March & April 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
May 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2016	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2016	The company's response letter was received.
July & Sept 2016	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2016	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Nov 2016	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.
March 2017	The company's response letter was received.
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 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.
June 2017	The company's response letter was received.
July 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 & Nov 2017	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2018	The company's response letter was received.
Jan 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2018	The company's response letter was received.

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Feb 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
Feb 2018	Product dossier accepted (quality assurance)
22 Feb 2018	[TB326 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Macleods Pharmaceuticals Limited
Block-N2
Village Theda
Post Office Lodhimajra
Tehsil Baddi
District Solan
Himachal Pradesh – 174101
India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be in compliance 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>