

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd. submitted in 2007 an application for [TB178 trade name]* (TB178) to be assessed with the aim of including [TB178 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB178 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

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| October 2006 | The manufacturer of the API was inspected for compliance with WHO requirements for GMP. |
| January 2007 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested. |
| February 2007 | The applicant's response letters were received. |
| March 2007 | During the meeting of the assessment team, the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements. The quality data were reviewed and further information was requested. |
| June 2007 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| April 2007 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP. |
| May 2007 | The company's response letter was received. |
| May 2007 | During the meetings of the assessment team, the additional quality data were reviewed and further information was requested. |
| September 2007 | The company's response letter was received. |
| October 2007 | During the meeting of the assessment team, the additional quality data were reviewed and further information was requested. |
| November 2007 | The company's response letter was received. |
| November 2007 | During the meeting of the assessment team, the additional quality data were reviewed and further information was requested. |
| February 2008 | The company's response letter was received. |
| March 2008 | During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements. |
| 23 April 2008 | [TB178 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

Macleods Pharmaceuticals Limited

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

Isoniazid 100 mg tablets
(Macleods Pharmaceuticals Ltd.), TB178

WHOPAR Part 7

March 2023

Plot No. 25-27
Survey No. 366
Premier Industrial Estate
Kachigam
396 210 Daman
India

Macleods Pharmaceuticals Limited,
At, Oxalis Labs
G Block
Village Theda,
P.O Lodhimajra, Baddi,
Distt. Solan, Himachal Pradesh, 174101, India

Inspection status

The site inspected was found to be in compliance with WHO requirements for GMP, GLP and GCP.>

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>