Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd. submitted in 2011 an application for [TB243 trade name][*] (TB243) to be assessed with the aim for acceptance of [TB243 trade name] on the list of prequalified pharmaceutical products for the treatment of tuberculosis.

[TB243 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 for the assessment of the product

June 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP (wi conditions)
June 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2012	The company's response letter was received.
September 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
November 2012	The company's response letter was received.
November 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2012	Product dossier accepted (quality assurance)
09 January 2013	Pyrazinamide 500 mg Tablets 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

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Daman – 396210,
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[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Commitments for Prequalification

None

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP. Not inspected for GCP/GLP. Previous site inspections by WHO showed acceptable outcome.

2. Conditions or restrictions regarding supply and use

Condition COMPLIANT status on Macleods Daman relates to limited space in the final packing area and restrictions on utilization for contemporaneous packing of multiple different products. Extensions in progress.

Medicinal product subject to medical prescription.

Further information is available at:
https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products