Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Ltd submitted in 2013 an application for [HA572 trade name]* (HA572) to be assessed with the aim of including [HA572 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA572 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

Feb 2011	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Aug 2011	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Dec 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan 2013	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Jan 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Feb 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2013	The company's response letter was received.
July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2013	The company's response letter was received.
Jan 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2014	The company's response letter was received.
Feb 2014	The additional quality data were reviewed and further information was requested.
March 2014	The company's response letter was received.

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

March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2014	The company's response letter was received.
March 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2014	Product dossier accepted (quality assurance)
10 April 2014	[HA572 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

Mylan Laboratories Limited

Plot No. H-12 & H-13
MIDC, Waluj
Industrial Area
Aurangabad 431136
Maharashtra State
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GLP /GCP. Previous site inspections by WHO were acceptable.

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