

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2016 an application for [HA678 trade name]* (HA678) to be assessed with the aim of including [HA678 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA678 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

April 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
September 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
September and November 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
November 2016	In between the meetings of the assessment team the company's response letter was received. The additional safety and efficacy data were reviewed and further information was requested.
January 2017	The company's response letter was received.
January 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
August 2017	The company's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The company's response letter was received.

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

March 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.
May 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2018	The additional quality data were reviewed and further information was requested.
September 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
September 2018	The company's response letter was received.
September 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2018	Product dossier accepted (quality assurance).
31 October 2018	[HA678 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: 11-12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III

Pithampur –454775

Dist. Dhar, Madhya Pradesh

India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GCP/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>