Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd. submitted in 2006 an application for [HA371 trade name] [*](HA371) to be assessed with the aim for acceptance of [HA371 trade name] on the list of prequalified pharmaceutical products for the treatment of HIV/AIDS.

[HA371 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

May 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP
July 2006	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
September 2006	During the meetings of the assessment team, the quality data were reviewed and further information was requested.
December 2006	The applicant's response letter was received.
January 2007	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
January/March 2007	During the meetings of the assessment team, the quality data were reviewed and further information was requested.
July 2007	The applicant`s response letter was received.
July 2007	During the meetings of the assessment team, the quality data were reviewed and further information was requested.
August 2007	The applicant's response letters were received.
October 2007	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
October 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP
November 2007	The applicant's response letter was received.
November 2007	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
February 2008	The applicant`s response letter was received.
March 2008	The additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
23 April 2008	[HA371 trade name] was was included in the list of prequalified medicinal products.

I. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

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Patalganga Industrial Area,
District – Raigad
410220 Patalganga
Maharashtra, India.
Tel: 91 2192 250811
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E-mail: ciplaptg@cipla.com

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility.

Inspection status

The site inspected were 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