Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2010 an application for [HA500 trade name]* (HA500) to be assessed with the aim of including [HA500 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA500 trade name] was assessed according to *SOP 20 of the Prequalification programme* 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

Sept 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP
Jan 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Feb 2011	The manufacturer of two of the APIs was inspected for compliance with WHO requirements for GMP.
March 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2011	The company's response letter was received.
May 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2011	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
July 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Aug 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
Oct 2011	The company's response letter was received.
Nov 2011	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2011	Product dossier accepted (quality assurance)
08 Dec 2011	[HA500 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

Cipla Ltd.
Unit VII, III, IV
L-147 to L147-1 and L-139 to L-146
Verna Industrial Estate,

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

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Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP 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