

## STEPS FOR PREQUALIFICATION

### I BACKGROUND INFORMATION ON THE PROCEDURE

#### 1. Submission of the dossier

The company Cipla Ltd submitted in 2008 an application for [HA439 trade name]\* (HA439) to be assessed with the aim of including [HA439 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA439 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

July 2008	During the meeting of the assessment team, the safety, efficacy and quality data were reviewed and further information was requested.
Feb 2009	The company's response letter was received.
March 2009	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
May 2009	The company's response letters were received.
May 2009	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
July 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Sept 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Oct 2010	The company's response letters were received.
Nov 2010	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
Jan 2011	The company's response letter was received.
Jan 2011	During the meeting of the assessment team, the additional safety, efficacy and quality data were reviewed and further information was requested.
Feb 2011	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
March 2011	The company's response letters were received.
March 2011	During the meeting of the assessment team, the additional safety, efficacy and quality data were reviewed and further information was requested.
April 2011	The company's response letter was received.
May 2011	During the meeting of the assessment team the additional safety and efficacy were reviewed and found to comply with the relevant WHO requirements.
July 2011	During the meeting of the assessment team the additional safety and efficacy were reviewed and found to comply with the relevant WHO requirements.
Aug 2011	The company's response letter was received.

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

Aug 2011	The additional quality data were reviewed and found to comply with the relevant WHO requirements.
Sept 2011	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
5 Oct 2011	[HA439 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  
Plot No: L-139 to L-146 and  
L-147 to L147-1  
Verna Industrial Estate  
Goa – 403722, India

Inspection status

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