

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2015 an application for [HA662 trade name]¹ (HA662) to be assessed with the aim of including [HA662 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA662 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 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Feb 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Nov 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2015 Feb 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
April 2016	The company’s response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2016	The company’s response letter was received.
Aug 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Aug 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Sept 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2016	The company’s response letter was received.
Nov 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2016	Product dossier accepted (quality assurance)
21 Dec 2016	[HA662 trade name] was included in the list of prequalified medicinal products

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Limited
Plot No A – 33, A – 2 (Unit – I) MIDC
Patalganga
District Raigad, 410 220 Maharashtra
India

Inspection status

The sites 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>