Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Matrix Laboratories Limited submitted in 2008 an application for [HA467 trade name]* (HA467) to be assessed with the aim of including [HA467 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA467 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

January 2008	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
June 2008	The API manufacturer was inspected for compliance with WHO requirements for GMP.
April 2009	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
August 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2009	CRO site inspected and found to be in compliance with WHO requirements for GCP and GLP.
August 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2010	The data concerning quality aspects were reviewed and found to be in compliance with the relevant WHO requirements.
December 2010	During the meeting of the assessment team data concerning bioequivalence were reviewed and found to be in compliance with WHO requirements.
14 Dec 2010	[HA467 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

Matrix Laboratories Limited

F-4, F-12, Malegaon M.I.D.C

Sinnar

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
** ** Previously known as Matrix Laboratories Limited.

422113 Nashik

Maharashtra

India

Inspection status

The applicant was inspected and found to be in compliance 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/prequal/medicines/prequalified/finished-pharmaceutical-products