Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ranbaxy Research Laboratories submitted in May 2005 an application for [HA306 trade name]* (HA 306) to be assessed with the aim for acceptance, in principle, of [HA306 trade name] on the list of prequalified pharmaceutical products for the treatment of HIV/AIDS.

[HA306 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	During the meeting of the assessment team the bioequivalence aspects of the dossier was reviewed and further information was requested.
May 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June and October 2005	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2005	During the meeting of the assessment team the bioequivalence aspects and the quality part of the dossier were reviewed and further information was requested.
July 2005	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
August 2005	The applicant submitted response on the bioequivalence issue.
September 2005	The assessors team reviewed the submitted bioequivalence data and the bioequivalence part of the dossier was accepted.
October 2005	The applicant's response on quality issue was received.
November 2005	During the meeting of the assessment team quality data were reviewed and further information was requested
January 2006	The applicant's response was received.
January 2006	During the meeting of the assessment team quality data were reviewed and further information was requested
March 2006	The applicant's response was received.
March 2006	The assessors team reviewed the submitted quality data. The quality part of the dossier was accepted with commitments as detailed below.
23 May 2006	[HA306 trade name] was included in the list of prequalified medicinal products with commitments as stated below.

* 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

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Commitments for Prequalification

The applicant committed to continue long-term testing of the API, efavirenz, for a period of time sufficient to cover the whole proposed retest date (NLT 24 months) and to report any out-of-specification results immediately to WHO;

The applicant committed to continue long-term testing of the FPP, [HA306 trade name], for a period of time sufficient to cover the whole proposed shelf life (NLT 24 months) and to report any out-of-specification results immediately to WHO.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

2. 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