Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Pharma Science Ltd. submitted in 2006 an application for [HA390 trade name]* (HA390) to be assessed with the aim of including [HA390 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA390 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	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Nov 2006	During the meeting of the assessment team, safety and efficacy data of the dossier were reviewed and further information was requested.
Jan 2007	The company's response letter was received.
Jan 2007	During the meeting of the assessment team, the additional safety and efficacy data of the dossier were reviewed and further information was requested.
Mar 2007	The company's response letter was received.
Mar 2007	During the meeting of the assessment team, the additional safety and efficacy data of the dossier were reviewed and found to be in compliance with the relevant WHO requirements.
May 2007	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
Nov 2007	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
Apr 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Apr 2008	The company's response letter was received.
May 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested
Jul 2008	The company's response letter was received.
Sep 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Nov 2008	The company's response letter was received.
Jan 2009	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
24 Feb 2009	[HA390 trade name] was included in the list of prequalified medicinal products.

* 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
Strides Pharma Science Limited
36/7, Suragajakkanahalli Indlavadi Cross
Anekal Taluk
Bangalore
Karnataka – 562 106
India.

Universal Corporation Limited.
Club road, past Kikuyu post office,
Plot no.13777
P.O Box: 1748-00902, Kikuyu, Kenya.

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