STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Universal Corporation Ltd submitted in 2010 an application for [HA490 trade name]* (HA490) to be assessed with the aim of including [HA490 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA490 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.

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

2. Steps taken for the assessment of the product

May 2010	During the meeting of the assessment team the quality data were reviewed and further information was requested
May 2010	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
June 2010	The company's response was received
July 2010	During the meeting of the assessment team additional quality, safety and efficacy data were reviewed and further information was requested
February 2011	The company's response was received
March 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested
March 2011	A manufacturer of both APIs was inspected for compliance with WHO requirements for GMP
April 2011	The company's response was received
May 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
May 2011	The company's response was received
May 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
June 2011	The company's response was received
June 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP
June 2011	The CRO was inspected for compliance with WHO requirements for GCP and additional data were requested
July 2011	The quality data were reviewed and found to be in compliance with the relevant WHO requirements
August 2011	The company's response was received
September 2011	During the meeting of the assessment team additional safety and efficacy data were reviewed and further information was requested
October 2011	The company's response was received
October 2011	The safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements
21 October 2011	[HA490 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:

Universal Corporation Limited
Club Road, Plot No.13777
P.O. BOX 1748-00902
Kikuyu
Kenya

Commitments for Prequalification

None which has an impact on the benefit–risk profile of the medicinal product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP. Not inspected for GCP/GLP due to biowaiver being granted.

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/