

## **I BACKGROUND INFORMATION ON THE PROCEDURE**

### **1. Submission of the dossier**

The company Strides Shasun Ltd submitted in 2012 an application for [HA557 trade name]\* to be assessed with the aim of including [HA557 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA557 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.

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\* 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

Sept 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
Dec 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
April 2012	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Nov 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Dec 2012	The company's response letter was received.
Jan 2013	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
Jan 2013	During the meeting of the assessment team the quality and the additional efficacy data were reviewed and further information was requested.
Feb 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP/GCP.
July 2013	The company's response letter was received.
Oct 2013	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Nov 2013 Jan 2014	The company's response letters were received.
Jan 2014	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
March 2014	The company's response letters were received.
March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2014	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Aug 2014	The company's response letters were received.
Aug 2014	In between the meetings of the assessment team the additional quality were reviewed and further information was requested.
Sept 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2014	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
Sept 2014	The company's response letter was received.
Sept 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2014	Product dossier accepted (quality assurance)
24 Oct 2014	Lamivudine/Nevirapine/Zidovudine 30/50/60mg dispersible tablets was included in the list of prequalified medicinal products.

## II GENERAL CONDITIONS FOR THE PREQUALIFICATION

### 1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Strides Shasun Limited  
36/7, Suragajakkanahalli  
Indlavadi cross  
Anekal Taluk  
Bangalore – 562 106  
India.

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, GLP and GCP.

### 2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

[www.who.int/prequal/](http://www.who.int/prequal/)