Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Pharma Science Limited submitted in 2006 an application for [HP009 trade name][*] (HP009) to be assessed with the aim of including [HP 009 trade name] in the list of prequalified medicinal products for chronic hepatitis C infection..

[HP009 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

June 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sept 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Sept and Nov 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Nov 2016	The applicant's response letter was received.
Nov 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Feb 2017	The applicant's response letter was received
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2017	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
Oct 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Jan 2018	The applicant's response letter was received
Jan 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Feb 2018	The applicant's response letter was received
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2018	The applicant's response letter was received
Sept 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2018	The applicant's response letter was received
Jan 2019	During the meeting of the assessment team the additional quality data were reviewed and further

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

	information was requested.
June 2019	The applicant's response letter was received
July 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2019	The applicant's response letter was received
Sept 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2019	The applicant's response letter was received
Feb 2020	The additional quality data were reviewed and further information was requested.
Feb 2020	The applicant's response letter was received
Feb 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
Feb 2020	Product dossier accepted (quality assurance)
03 March 2020	[HP009 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

Strides Pharma Science Limited,
KRS Gardens,
Tablet Block,
36/7 Suragajakkanahalli,
Indlavadi Cross,
Anekal Taluk,
Bangalore, Karnataka,
562 106
India

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:
https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products