Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2018 an application for [DI011 trade name][*] (DI011 trade name) to be assessed with the aim of including [DI011 trade name] in the list of prequalified medicinal products for the treatment of diarrhoea.

[DI011 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

January 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2019	The applicant's response letter was received.
March 2019	The safety and efficacy data were reviewed and found to comply with the relevant
January and March 2019	During the meetings of the assessment team the quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2019	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
August 2019	The applicant's response letter was received.
December 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
February 2020	The additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.
May 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2020	Product dossier accepted (quality assurance)
25 May 2020	[DI011 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

Ipca Laboratories Limited
Plot No. 255/1. Village Athal
Silvassa 396 230,
Dadra and Nagar Haveli (U.T,)
India.

Inspection status

API manufacturer was not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

A desk review for evaluation of compliance of the manufacturer of the FPP for GMP met WHO requirements.

The CRO (contract research organization) was inspected and found to be in compliance with WHO requirements for 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/