Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2018 an application for [NT005 trade name]* (NT005) to be assessed with the aim of including [NT005 trade name] in the list of prequalified medicinal products for the treatment of cestode infections, lymphatic filariasis and other nematode infections.

[NT005 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

December 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
April 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2018	The applicant's response letter was received.
July and August 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2018	The applicant's response letter was received.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2019	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
April 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	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2019	The applicant's response letter was received.

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

November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
July 2020	The applicant's response letter was received.
July and September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
December 2020	The additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letters were received.
March 2021	The quality data were reviewed and found to comply with the relevant WHO requirements
March 2021	Product dossier accepted (quality assurance)
31 March 2021	[NT005 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

Cipla Limited Indore (Unit-IV)

Plot No 9, 10 & 15

Indore Special Economic Zone, Phase II

Pithampur, Dhar District

Madhya Pradesh 454 775

India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GLP and GCP.

FPP site not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

The API manufacturer inspected was found to be in compliance with WHO requirements for GMP

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