Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2023 an application for [CV021 trade name]* (CV021) to be assessed with the aim of including [CV021 trade name] in the list of prequalified medicinal products for coronavirus disease 2019 (COVID-19).

[CV021 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

March 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
March 2023	During the meeting of the assessment team the safety and efficacy data and the quality data> were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
March 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2023	The applicant's response letter was received.
August 2023	The additional quality data were reviewed and further information was requested.
September 2023	The applicant's response letter was received.
October and November 2023	The additional quality data were reviewed and further information was requested.
November 2023	The applicant's response letter was received.
November 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2023	Product dossier accepted (quality assurance)
18 December 2023	[CV021 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

Cipla Limited, Goa (Unit-VII)
Plot No. S- 103 to S- 105, S-107 to S-112
& L-147, L-147/1 to L-147/3, L-147/A & L-138,
Verna Industrial Estate, Verna,
Salcette, Goa – 403 722,
India

Inspection status

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

Inspection of API manufacturer waived based on risk assessment.

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