Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2023 an application for [CV022 trade name]* (CV022) to be assessed with the aim of including [CV022 trade name] in the list of prequalified medicinal products for coronavirus disease 2019 (COVID-19).

[CV022 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

October 2019	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
April 2021	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
March 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
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.
April 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
June 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 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.
September 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2023	The applicant's response letter was received.
November 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2024	The applicant's response letter was received.
March 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2024	The applicant's response letter was received.

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

May 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2024	The applicant's response letter was received.
May 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2024	Product dossier accepted (quality assurance)
23 May 2024	[CV022 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

Mylan Laboratories Limited,

F- 4 & F-12, MIDC, Malegaon,

Sinnar, Nashik - 422 113

Maharashtra

India.

Inspection status

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

The API and FPP manufacturers, inspected through desk assessment were 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