Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Ltd submitted in 2023 an application for [CV024 trade name]* (CV024) to be assessed with the aim of including [CV024 trade name] in the list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) in adults.

[CV024 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

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.
May 2023	During the meeting of the assessment team the safety and efficacy data and the 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.
October 2023	The applicant's response letter was received.
October 2023	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.
January 2024	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
February 2024	The applicant's response letter was received.
February 2024	The additional quality data were reviewed and further information was requested.
July 2024	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
August 2024	The applicant's response letter was received.

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

September 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2024	The applicant's response letter was received.
December 2024	The additional quality data were reviewed and further information was requested.
December 2024	The applicant's response letter was received.
December 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2024	Product dossier accepted (quality assurance)
19 December 2024	[CV024 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, FDF-I
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 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