Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Dr. Reddy's Laboratories Limited submitted in 2022 an application for [CV009 trade name]* (CV009) to be assessed with the aim of including [CV009 trade name] in the list of prequalified medicinal products for treatment of COVID-19.

[CV009 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 2022	The assessment team reviewed the safety and efficacy data and the quality data and further information was requested.
May 2022	The applicant's response letter was received.
May 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
June 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2022	The applicant's response letters were received.
June 2022	The additional safety and efficacy and quality data were reviewed and further information was requested.
July 2022	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
July 2022	The applicant's response letters were received.
July 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2022	The additional quality data were reviewed and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
October 2022	The additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
October 2022	The additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letters were received.
October 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

October 2022	Product dossier accepted (quality assurance)
March 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
17 April 2023	[CV099 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

Dr. Reddy's Laboratories Ltd
Formulation Tech Ops – II
Survey No 42p,43,44p,45p,46p,53,54&83,
Bachupally Village
Qutubullapur Mandal
Ranga Reddy District
Telangana
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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products