Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Aurobindo Pharma Ltd, submitted in 2022 an application for [CV014 trade name]* (CV014) to be assessed with the aim of including [CV014 trade name] in the list of prequalified medicinal products for Covid-19.

[CV014 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

September 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
Oktober 2022	The assessment team reviewed the quality data and further information was requested.
October 2022	The applicant's response letter was received.
November 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2022	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
February 2023	The applicant's response letter was received.
February 2023	The additional quality data were reviewed and further information was requested.
February 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
April 2023	The applicant's response letter was received.
April 2023	The additional quality data were reviewed and further information was requested.
April 2023	The applicant's response letter was received.
April 2023	The additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
June and July 2023	The additional quality data were reviewed and further information was requested.
July 2023	The applicant's response letter was received.
August 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2023	Product dossier accepted (quality assurance)
December 2023	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
18 December 2023	[CV014 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

Aurobindo Pharma Limited (Unit III),
Survey No. 313 & 314,
Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District,
Telangana State, Zip Code: 500090,
India

Inspection status

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

Not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

API supported by a CEP. Inspection of the manufacturing site waived based on previous satisfactory inspection by a stringent regulatory authority.

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

<Not inspected for GCP/GLP since a biowaiver applies.>

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