## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Hetero Labs Limited submitted in 2022 an application for [CV012 trade name][*] (CV012) to be assessed with the aim of including [CV012 trade name] in the list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) in adults.

[CV012 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

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| August 2019 | A desk review for evaluation of compliance of the manufacturer for two FPPs for GMP was conducted and it met WHO requirements. |
| August 2019 | A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements. |
| August 2020 | A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements. |
| October 2020 | A desk review for evaluation of compliance of the manufacturer of one FPP for GMP was conducted and it met WHO requirements. |
| August 2022 | The quality data and the safety and efficacy data were reviewed by the assessment team and further information was requested |
| August 2022 | The applicant's response letter was received. |
| August 2022 | The additional safety and efficacy data were reviewed and further information was requested. |
| August 2022 | The applicant's response letters were received. |
| September 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested.<br>The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| 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. |
| November 2022 | The applicant's response letter was received. |
| November 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| November 2022 | The applicant's response letter was received. |
| December 2022 | The additional quality data were reviewed and further information was requested. |
| December 2022 | The applicant's response letter was received. |

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

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| December 2022 | The additional quality data were reviewed and further information was requested. |
| December 2022 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP. |
| December 2022 | The applicant's response letter was received. |
| December 2022 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| December 2022 | Product dossier accepted (quality assurance) |
| 25 December 2022 | [CV012 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**

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**Inspection status**

API and FPP manufacturers were inspected through desk assessment and found to be in compliance with WHO requirements for GMP.

The site inspected was found to be in compliance with WHO requirements for 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