## 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 [CV008 trade name][*] (CV008) to be assessed with the aim of including [CV008 trade name] in the list of prequalified medicinal products for the treatment of COVID-19.

[CV008 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 2020 | A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements. |
| September 2020 | A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements. |
| March 2022 | During the meeting of the assessment team the quality data were reviewed and further information was requested. |
| April 2022 | The safety and efficacy data were reviewed and further information was requested |
| April 2022 | The applicant's response letters were received. |
| April 2022 | The additional quality data were reviewed and further information was requested. |
| May 2022 | The additional safety and efficacy data were reviewed and further information was requested. |
| May 2022 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP. |
| May 2022 | The applicant's response letters were received. |
| May 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. |
| June 2022 | The applicant's response letter was received. |
| June 2022 | The additional quality data were reviewed and further information was requested. |
| July 2022 | The applicant's response letter was received. |
| July 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| August 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. |
| September 2022 | The applicant's response letter was received. |
| September 2022 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| September 2022 | Product dossier accepted (quality assurance) |
| 21 September 2022 | [CV008 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**

Hetero Labs Limited, Unit-V

Survey No. 439, 440, 441 & 458,

TSIIC-Formulation SEZ, Polepally Village,

Jadcherla (Mandal), Mahaboob Nagar District,

Telangana State, 509 301

India

**Inspection status**

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

Not inspected for GMP. Inspection of the manufacturing sites for the API and FPP were based on desk review and 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