



CERTIFICATE OF GMP COMPLIANCE

This is to certify that the foreign manufacturer:

Name : **THEON PHARMACEUTICALS LIMITED**

Plant Address : **VILLAGE & P.O. SAINI MAJIRA, TEHSIL
NALAGARH 174 101, HIMACHAL PRADESH, INDIA**

engaged in the manufacture of the following pharmaceutical dosage form/s:

- | | |
|-------------------------------|---------------------------------|
| 1. Sterile, Cephalosporin* | 2. Non-sterile, Non-penicillin* |
| 1.1. Dry powder for injection | 2.1. Tablets |
| | 2.2. Hard capsules |

**Primary and Secondary packaging, Quality Control: chemical/physical and microbiological*

made available in the Philippines through **AMBICA INTERNATIONAL CORPORATION**, with valid License to Operate No. CDRR-NCR-DI/E/W-61582, has complied with the requirements of **current Good Manufacturing Practice (cGMP)** after **desktop evaluation of the submitted GMP documentary evidence**, consistent with Administrative Order No. 2012-008, "Adoption and Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guides for the Good Manufacturing Practice (GMP) for Medicinal Products" and Administrative Order No. 2013-0022, "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers."

This Certificate is valid until **17 December 2024**. Notwithstanding this certification, the foreign manufacturer shall be subject to inspection at any time to validate its continuous compliance with relevant FDA laws, rules, and regulations. Any violation thereof, this Office reserves the right to suspend, cancel or revoke this certificate.

Issued this 25 August 2022 at Alabang, Muntinlupa City, Philippines.

BY AUTHORITY OF THE DIRECTOR GENERAL
Per FDA Order No. 2016-005

JESUSA JOYCE N. CIRUNAY, RPh
Director IV
Center for Drug Regulation & Research

CERTIFICATE NO. : CDRR-CGMP-FA-10-03
REG. STATUS : RENEWAL
TRACK NUMBER : 20211217150257
AMOUNT : 2020
OR Number/ DATE : 122121372281 / 21 December 2021

This supersedes the Certificate of GMP Compliance issued on 12 August 2016

