



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**  
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City



## CERTIFICATE OF GMP COMPLIANCE

This is to certify that the foreign manufacturer:

Name : **THEON PHARMACEUTICALS LIMITED**

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

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

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

*\*Primary packaging, Secondary packaging, and Quality Control testing: chemical/physical and microbiological  
\*\*Including Cephalosporin*

made available in the Philippines through **SUHITAS PHARMACEUTICALS INC.**, with valid License to Operate No. CDRR-NCR-DI/W-56620, 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 22 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-10-05  
REG. STATUS : RENEWAL  
TRACK NUMBER : 20211210085931  
AMOUNT : 2020  
OR Number/ DATE : 121421369299 / 14 December 2021

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

