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 : **STALLION LABORATORIES PVT. LTD.**

Plant Address : **C-1B, 305/2, 3, 4, & 5 G.I.D.C. KERALA, BAVLA-382 220, DIST: AHMEDABAD, GUJARAT, INDIA**

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

1. Non-sterile, Non-Penicillin*
   1.1. Tablets
   1.2. Capsules
   1.3. Powders
   1.4. Oral liquids

**Primary and Secondary packaging and Quality control testing: 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 **03 November 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 19 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-02-01**
REG. STATUS	:	**RENEWAL**
TRACK NUMBER	:	**20211110095600**
AMOUNT	:	2020
OR Number/ DATE	:	111121356945 / 11 November 2021

This supersedes the Certificate of GMP Compliance issued on 20 May 2016

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