

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: TIRUPATI MEDICARE LIMITED

Plant Address : NAHAN ROAD, TEHSIL PAONTA SAHIB, DISTRICT

SIRMOUR-173025, HIMACHAL PRADESH, INDIA

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

1. Non-sterile*

1.1. Tablets

1.2. Hard capsules

1.3. Liquids for internal use

1.4. Powders

*Primary and Secondary packaging and Quality control testing: Chemical/Physical and Microbiological

made available in the Philippines through FIRMLINK PHARMA PHILS., CO., with valid License to Operate No. CDRR-NCR-DI-96909, 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 12 October 2023. 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 JOYCI . CIRUNAY, RPh

Center for Drug/Regulation & Research

CERTIFICATE NO

CDRR-CGMP-FA-77-03

110221352282 / 02 November 2021