Republic of the Philippines
Department of Health
Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, and consistent with R.A. No. 6675, known as the Generics Act of 1988 and R.A. No. 9711, otherwise known as the Food and Drug Administration Act of 2009, the product described hereunder has been found to conform with the requirements and standards for marketing authorization of pharmaceutical products per existing regulations in force as of date hereof.

Registration Number:	**DRP-9088**
Generic Name:	Ascorbic Acid
Brand Name:	Tatio-Cee
Dosage Strength & Form:	250 mg/mL (500 mg/2 mL) Solution for Injection (IM/IV/SC)
Pharmacologic Category:	Vitamin
Classification:	Prescription Drug (Rx)
Approved Shelf-life:	36 months
Storage Condition:	Store at temperatures not exceeding 30 °C.
Packaging:	USP Type I Clear Glass Ampoule x 2 mL in a Plastic Tray (Box of 10's)
Manufacturer:	Friends Pharma (Pvt.) Ltd. 31 - Km Ferozepur Road, Lahore, Pakistan
Importer:	Raquel-Abbas Pharmaceuticals & General Merchandise No. 17 Madre Isabella di Rocis St., Multinational Village, Moonwalk, Parañaque, Metro Manila
Distributor:	Raquel-Abbas Pharmaceuticals & General Merchandise No. 17 Madre Isabella di Rocis St., Multinational Village, Moonwalk, Parañaque, Metro Manila

The marketing authorization shall be valid until **02 March 2028** subject to the conditions listed on the reverse side. No change in the formulation, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This marketing authorization is subject to suspension, cancellation or recall should any violation of R.A. No. 3720, R.A. No. 6675 and R.A. No. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this **28 February 2023**

By the Authority of the Director-General Per FDA Order No. 2016-005:

Jesusa Joyce N. Cirunay, RPh

Director IV, Center for Drug Regulation and Research

This electronic-CPR (eCPR) is computer generated and does not require signature

Registration Number: **DRP-9088**

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that registrant has the right or privilege to the use of the name or brand so registered, Registrant hereby agrees and affirms to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property right arising from the registration of the product.

Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O No. 2016-0008 for drug products for human use and A.O. No. 105 s. 1991 for veterinary drug products.

Submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity of this CPR in accordance with A. O. No. 2013-0022 and FDA Circular 2014-016.

REMARKS:

This Certificate of Product Registration (CPR) is revalidated to reflect the full validity until 02 March 2028.

This Certificate of Product Registration (CPR) is granted following Department Circular 2011-0101: The Rules and Regulations Implementing Republic Act No. 9711 - The Food and Drug Administration Act of 2009.

This cancels CPR with control number FDA-0584560 issued on 18 July 2022 and valid until 02 March 2023.

Subject to satisfactory compliance to the following post-approval commitment (for submission within the validity of this CPR before the next renewal application):
To complete the minimum information for Package Insert in accordance with Administrative Order 2016-0008 (Subject: Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use) Section V 3 and Annex A Section E