FDA-2018THIIHVV/UCAXCS/K8XF1

Republic of the Philippines

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

: DR-XY46280

Generic Name **Brand Name**

Glutathione Tationil 600

Dosage Strength & Form

600 mg Lyophilized Powder for Injection (IM/IV)

Pharmacologic Category Classification

Approved Shelf-life

Prescription Drug (Rx)

Storage Condition

36 months

Packaging

Store at temperatures not exceeding 30°C

10 mL USP Type I clear, colorless glass vial sealed with bromo butyl rubber stopper and yellow aluminum seal + USP Type I clear, colorless glass ampoule Water for Injection x 4 mL as diluent (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 City

Distributor

Raquel-Abbas Pharmaceuticals & General Merchandise

No. 17 Madre Isabella di Rocis St., Multinational

Village, Moonwalk, Parañaque City

The marketing authorization shall be valid until 08 March 2023 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 08 March 2018.

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

ATTY. KATHERINE M. AUSTRIA-LOCK

Office-in-Charge Center for Drug Regulation and Research

REG. STATUS AMOUNT OR NUMBER

Monitored Release (MR) Php15,150; Php25,000; Php 557033; 914619; 906622

BAR CODE DOC TRACK



Renewal DTN: 20230317104058 O.R. No.: 324 2023 1234 Date Issued:

Registration Number

DR-XY46280

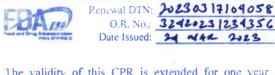
SPECIAL CONDITION:

The validity of this CPR is extended for one year from O9 MARCH 2025 to O8 MARCH 2020, unless earlier cancelled or revoked by this Office.

Provided that nothing in the registration of the product herein grante as an endorsement or representation by FDA, that Registrant has the right or privilege to the dise 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.

A	This is subject to batch notification.	
В	This is subject to lot release certification.	
хс	This is subject to compliance with the requirements under FDA (Release (MR) drug products.	Circular No. 2013-004 for Monitored
X D	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.	
E	For renewal registration, submit a satisfactory Bioequivalence Study Report or Biowaiver (whichever is applicable) within the validity of this CPR in accordance with FDA Circular No. 2016-019.	
F	Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.	
G	Dangerous Drug - To be prescribed by PDEA S-2 licensed preprescription. It is a habit-forming drug.	actitioner in a personalized ordinary
Н	Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.	
I	For renewal registration, submit a Certificate of Good Manufacture Foreign Drug Manufacturer(s) within the validity of this CPR i 0022 and FDA Circular No. 2014-016.	uring Practice (GMP) Compliance of in accordance with A. O. No. 2013-
J	Review of the submitted Bioequivalence Study Report or Biowaiver, whichever is applicable, shall be completed by the FDA within the validity of this CPR; correspondingly, this CPR shall be revoked if product interchangeability has not been established.	
K	Subject to compliance to the post-approval commitments detail CPR.	iled in the letter accompanying this

REMARKS:



O.R. No.: 3242023 |23435C15 Date Issued: 24 NAC 2023 The validity of this CPR is extended for one year from of MAL 2023 to of MAR 2021 unless earlier cancelled or revoked by this Office.

> CRUNAY, RPh JESUSA JOYCE N. Direct Center for Drug Reig dation and Research

Renewal DTN: 2023 0517 10405 8 O.R. No.: 3242023122435115 Date Issued: 24 MAR 223

The validity of this CPR is extended for a year of what 2014 to 05 what 2015 allow the control of revoked by this Office.

CIRUNAY, RE rIV

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