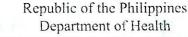


FDA-201945NMPKSEQIFD43FRZVEF









CERTIFICATE OF LISTING OF IDENTICAL DRUG PRODUCT

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-5025-06

Generic Name

: Omeprazole (as sodium)

Brand Name

Gezole IV

Dosage Strength & Form Pharmacologic Category

: 40 mg Powder for Injection (IV) : Proton Pump (H+K+ATPase) Inhibitor

Classification

: Prescription Drug (Rx)

Approved Shelf-life

: 24 months

Storage Condition

: Store at temperatures not exceeding 30°C

Packaging

: 10 mL USP Type III Amber Glass Vial with pink flipoff seal + 10 mL Sterile Water for Injection as diluent

(Box of 1 vial + diluent)

Manufacturer

: Rainbow Life Sciences Pvt. Ltd.

R-914/915, T.T.C. Industrial Area, Rabale, Navi

Mumbai-400 701, India

Importer

: Ambica International Corporation

9 Amsterdam Extension, Merville Park Subd.,

Parañaque, Metro Manila

Distributor

: Pharmasilv Trading

B4 L11 #19 Executive Homes 1, Cainta Greenpark

Vill., San Isidro, Cainta, Rizal

The Certificate of Listing issued to the above Distributor shall be valid until 27 December 2023, which covers the unexpired term of the Principal CPR, subject to the conditions listed on the reverse side. No change in the ownership, registrant's address/location, manufacturer, excipients, formulation, dosage form, strength, therapeutic indication, manufacturing process, labelling and commercial presentation, and packaging of the Principal product covered by the Principal CPR without prior approval of this Office.

This Certificate of Listing 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 16 September 2019.

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

ATTY. KATHERINE M. AUSTRIA-LOCK

Officer-in-Charge Center for Drug Regulation and Research

REG. STATUS OR NUMBER DATE CODE

BAR CODE

DOC TRACK

Automatic Renewal Php 10,100.00 1008183

13 June 2018







