FDA-201945NMPKSEQIFD43FRZVEF

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

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	:	40 mg Powder for Injection (IV)
Pharmacologic Category	:	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 flip-off 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 : Automatic Renewal
AMOUNT : Php 10,100.00
OR NUMBER : 1008183
DATE : 13 June 2018
CODE : OPB
BAR CODE / DOC TRACK : 2018060509341 7

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