FDA-20219472TAFMQIDXZJGUG4U5

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-6356-01

Generic Name

: Co-Amoxiclay

Brand Name

Faxiclay

Dosage Strength & Form Pharmacologic Category

: 250 mg/62.5 mg per 5mL Powder for Suspension

: Antibacterial (Penicillin - Beta-Lactamase Inhibitor Combination)

Classification

Prescription Drug (Rx)

Approved Shelf-life

: 24 months

Storage Condition

: Store at temperatures not exceeding 30°C

Packaging

Amber bottle x 60mL (Box of 1's)

Manufacturer

: Pil Pharmaceuticals Pvt. Ltd.

Plot No. 71-72, Sector 6A, IIE, SIDCUL, Ranipur,

Haridwar-249403 (Uttarakhand), India

Importer

: JF Draf Pharmaceuticals Corp.

Suite 407, Greenhills Mansion, 37 Annapolis St., North

East Greenhills, San Juan City

Distributor

Health Alliance Pharma, Inc.

162 3rd St., 11th Ave, Grace Park, Brgy. 90, Zone 8,

Dist. II, Caloocan City

The Certificate of Listing issued to the above Distributor shall be valid until <u>02 October 2025</u>, 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, labeling 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 19 February 2021.

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

JESUSA JOYCE N. CIRUNAY, RPh

Director IV
Center for Drug Regulation and Research

REG. STATUS AMOUNT OR NUMBER DATE Automatic Renewa Php10,100.00 092520178641

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