FDA-20172RF2C978Q3I4RGD5MKJC

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

FDA Food and Drug Administration PHILIPPINES

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-4024**
Generic Name	:	Carvedilol
Brand Name	:	Karvil 25
Dosage Strength & Form	:	25mg Tablet
Pharmacologic Category	:	Alpha and Beta Adrenoceptor Blocker
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	24 months
Storage Condition	:	Store at temperatures not exceeding 30°C.
Packaging	:	Alu/Alu Blister Pack x 10's (Box of 30's)
Manufacturer	:	Torrent Pharmaceuticals Ltd. Indrad–382721, Tal: Kadi, City: Indrad, Dist. Mehsana, India
Importer	:	Torrent Pharma Philippines, Inc. Units 3&4, 34th Flr. Zuellig Building, Makati Avenue corner Paseo De Roxas, Makati City
Distributor	:	Torrent Pharma Philippines, Inc. Units 3&4, 34th Flr. Zuellig Building, Makati Avenue corner Paseo De Roxas, Makati City

The marketing authorization shall be valid until **21 September 2021** 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 **8 February 2017**.

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

BENJAMIN G. CO, MD, FPPS, FPSECP
Director IV
Center for Drug Regulation and Research

REG. STATUS : **Renewal**
AMOUNT : **Php11,120**
OR NUMBER : **0755821**
DATE : **12 July 2016**
CODE : **186-114**
BAR CODE / DOC TRACK : 2 0 1 6 0 7 0 4 0 9 5 3 5 2

TÜVRheinland CERTIFIED ISO 9001:2008 Management System www.tuv.com ID 9105073396

FDA-019460

Registration Number : DRP-4024

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.

	A	This is subject to batch notification.
	B	This is subject to lot release certification.
	C	This is subject to compliance with the requirements under FDA Circular No. 2013-004 for Monitored Release (MR) drug products.
x	**D**	Submit commercial sample of the first batch of importation/manufacture/packing/repacking, for all pack sizes, including package insert or patient information leaflet as per approved label.
	E	For renewal registration, submit a satisfactory bioavailability/bioequivalence study report or biowaiver evidence (whichever is applicable) within the validity of the 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 practitioner in a personalized ordinary prescription. It is a habit-forming drug.
	H	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 Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity of the CPR in accordance with A. O. No. 2013-0022 and FDA Circular No. 2014-016.
x	**J**	Review of the submitted Bioequivalence Study Report or Biowaiver, whichever is applicable, shall be completed by this Center within the validity, provided, the CPR shall be revoked if interchangeability is not established.

REMARKS: