

**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

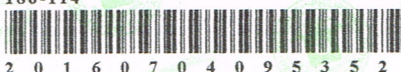
BENJAMIN G. CO, MD, FPPS, FPSECP

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



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ISO 9001:2008
Management
System



www.tuv.com
ID 9105072396

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.

- | | | |
|-------------------------------------|----------|---|
| <input type="checkbox"/> | A | This is subject to batch notification. |
| <input type="checkbox"/> | B | This is subject to lot release certification. |
| <input type="checkbox"/> | C | This is subject to compliance with the requirements under FDA Circular No. 2013-004 for Monitored Release (MR) drug products. |
| <input checked="" type="checkbox"/> | 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. |
| <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | F | Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug. |
| <input type="checkbox"/> | G | Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a personalized ordinary prescription. It is a habit-forming drug. |
| <input type="checkbox"/> | H | Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate. |
| <input type="checkbox"/> | 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. |
| <input checked="" type="checkbox"/> | 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: