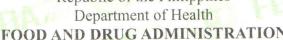
FDA-2018L9OQBUXU2E8QPWMCNBRJ



Republic of the Philippines Department of Health





Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

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

: DR-XY28309

Generic Name

Metoclopramide (as Hydrochloride)

Brand Name

Clomitene

Dosage Strength & Form

5 mg/mL Solution for Injection (I.M./I.V.)

Pharmacologic Category

Gastrokinetic (Prokinetic) : Prescription Drug (Rx)

Classification

: 48 months

Approved Shelf-life Storage Condition

: Store at temperatures not exceeding 30°C.

Packaging

: USP Type I Amber Glass Ampoule x 2 mL

(Box of 50's)

Manufacturer

: L.B.S. Laboratory Limited Partnership

602 Soi Panichanant, Sukhumvit 71 Road, Khlong Tan

Nuea, Watthana, Bangkok 10110, Thailand

Importer

Phil Pharmawealth, Inc.

Suite 3001, East Tower, PSE Center, Exchange Rd.,

Ortigas Center, Pasig City

Distributor

Phil Pharmawealth, Inc.

Suite 3001, East Tower, PSE Center, Exchange Rd.,

Ortigas Center, Pasig City

The marketing authorization shall be valid until 10 February 2023 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 16 April 2018.

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

ATTY. KATHERINE M

Officer-in-Charge

Center for Drug Regulation and Research

REG. STATUS OR NUMBER CODE

Automatic Renewal Php 10,100.00 Trxn. Seq. # 51000 20 March 2018

BAR CODE DOC TRACK







Registration Number

DR-XY28309



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.

NAME AND POST OF THE PERSON OF	A	This is subject to batch notification.
	В	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	Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O No. 2016-0008 for drug products for human use and A.O. No. 105 s. 1991 for veterinary drug products.
	E	Submit a satisfactory Bioequivalence Study Report or Biowaiver (whichever is applicable) within the validity of this CPR in accordance with FDA Circular No. 2016-019.
	F	Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.
Annual Company of the	G	Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a personalized ordinary prescription form. It is a habit-forming drug.
principal and implementation of the second second	н	Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.
Villandramia, drubinabunda jaronda	I	Submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity of this CPR in accordance with A. O. No. 2013-0022 and FDA Circular 2014-016.
Patrician description of the Commission of the C	J	Review of the submitted Bioequivalence Study Report or Biowaiver, whichever is applicable, shall be completed by the FDA within the validity of this CPR; correspondingly, this CPR shall be revoked if product interchangeability has not been established.
-	K	Subject to satisfactory compliance to the post-approval commitments detailed in the letter accompanying this CPR.

REMARKS:

Exhaustion up to retail level of all existing inventory of the previous labeling materials is allowed only until **16 April 2019**. No further extension shall be granted.