EBAM

Renewal DTN: 202 30 31710 40 58

O.R. No.: 324 2023 1234 35 615

Date Issued: 24 MAR 2023

Registration Number

DR-XY46280

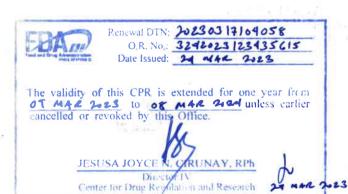
The validity of this CPR is extended for one year from O9 MARCH 2025 to O8 MARCH 2020 unless earlier cancelled or revoked by this Office.

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.			
В	This is subject to lot release certification.			
хс	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	For renewal registration, 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 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 practitione prescription. It is a habit-forming drug.	er in a personalize	d ordinary	
Н	Patient Information Leaflet - Appropriate information for the consumers and/or local dialects, as appropriate.	s shall be written	in Filipino	
I	For renewal registration, submit a Certificate of Good Manufacturing Professional Drug Manufacturer(s) within the validity of this CPR in accordance of the CPR in accordan			
J	Review of the submitted Bioequivalence Study Report or Biowaiver, which completed by the FDA within the validity of this CPR; correspondingly, to product interchangeability has not been established.			
K	Subject to compliance to the post-approval commitments detailed in t CPR.	he letter accompa	mying this	

REMARKS:



Renewal DTN: 2-23 0517 10405 8

O.R. No.: 3242023[224351]5

Date Issued: 24 MAR 2-23

The validity of this CPR is extended for 0 ye on what 2-24 to 05 MAR 2-25 miles of or revoked by this Office.

JESUSA JOYCH N. CIRUNAY, REP. Director IV. Center for Drug Regulation and Research 65 MAR 2-25