FDA
Renewal DTN: 202303171040 58
O.R. No.: 324 20231234 35615
Date Issued: 24 MAR 2023

The validity of this CPR is extended for one year from 09 MARCH 2025 to 08 MARCH 2026 unless earlier cancelled or revoked by this Office.

MARIA CECILIA C. MATIENZO
Director IV
Center for Drug Regulation and Research
18 March 25

Registration Number : DR-XY46280

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.
X	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	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 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 this CPR in accordance with A. O. No. 2013-0022 and FDA Circular No. 2014-016.
	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 compliance to the post-approval commitments detailed in the letter accompanying this CPR.

REMARKS:

FDA
Renewal DTN: 2023031710405 8
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JESUSA JOYCE N. CIRUNAY, RPh
Director IV
Center for Drug Regulation and Research
08 MAR 2024

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JESUSA JOYCE N. CIRUNAY, RPh
Director IV
Center for Drug Regulation and Research
24 MAR 2023