FDA-2020W5WIZPZFY4KERPF6VKKT

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
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	:	**DRP-7513**
Generic Name	:	Cefixime (as trihydrate)
Brand Name	:	Sanix-200
Dosage Strength & Form	:	200 mg Film-Coated Tablet
Pharmacologic Category	:	Antibacterial (Cephalosporin)
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	36 months
Storage Condition	:	Store at temperatures not exceeding 30°C.
Packaging	:	Alu/Alu Blister Pack x 10's (Box of 100's)
Manufacturer	:	Sance Laboratories Pvt. Ltd. VI/51B, P.B. No. 2, Kozhuvanal, Pala, Kottayam, 686 573, Kerala, India
Importer	:	AMB HK Enterprises, Inc. No. 6 Felipe Pike St., Bagong Ilog, Pasig City
Distributor	:	AMB HK Enterprises, Inc. No. 6 Felipe Pike St., Bagong Ilog, Pasig City

The marketing authorization shall be valid until **27 November 2024** 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 **13 March 2020**.

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

RHODA LAINE D. MANALOTO, RPh, MGM
Officer-in-Charge
Center for Drug Regulation and Research

REG. STATUS : **Automatic Renewal (Correction)**
AMOUNT : **Php 10,100.00; Php 510.00**
OR NUMBER : **1212057; 1247765**
DATE : **12 November 2019; 26 February 2020**
BAR CODE / DOC TRACK : 2019102115545 0

FDA-0431077

Registration Number : DRP-7513

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.

X	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	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.
	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.
	H	Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.
X	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.
	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:

- This product has fulfilled the requirement of product interchangeability/ equivalence evidence with the submission of satisfactory Bioequivalence Study Report.
- This Certificate of Product Registration (CPR) is reconstructed to reflect the correct Manufacturer's Address and Approved Shelf-life. This supersedes CPR No. FDA-0446677 issued on 26 December 2019 valid until 27 November 2024.