



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-9864
Generic Name:	Vancomycin (as hydrochloride)
Brand Name:	Vancotan 500
Dosage Strength & Form:	500 mg Lyophilized Powder for IV Infusion
Pharmacologic Category:	Antibacterial (Glycopeptide)
Classification:	Prescription Drug (Rx)
Approved Shelf-life:	24 months
Storage Condition:	Store at temperatures not exceeding 30°C.
Packaging:	USP Type I Glass Vial x 10 mL + USP Type III Flint Glass Ampoule (Sterilized Water for Injection as diluent) x 10 mL Box of 1's
Manufacturer:	Gufic Biosciences Ltd. National Highway No. 8, Near Grid, Kabilpore City: Navsari - 396424, Dist: Navsari, Gujarat State, India
Importer:	SRS Life Sciences Inc. Unit 810 One Park Drive 9th St. cor. 11th Ave., Bonifacio Global City, Fort Bonifacio, Taguig, Metro Manila
Distributor:	SRS Life Sciences Inc. Unit 810 One Park Drive 9th St. cor. 11th Ave., Bonifacio Global City, Fort Bonifacio, Taguig, Metro Manila

The marketing authorization shall be valid until **21 June 2027** 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 **30 October 2021**

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

Jesusa Joyce N. Cirunay, RPh

Director IV, Center for Drug Regulation and Research

This electronic-CPR (eCPR) is computer generated and does not require signature



Registration Number:

DRP-9864

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.

This is subject to batch notification.

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.

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.

REMARKS:

This Certificate of Product Registration (CPR) is revalidated to reflect the full validity until 21 June 2027.