

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 : BRP-073

Generic Name : Tetanus Antitoxin

Brand Name : Shariyax

Dosage Strength & Form : 1500 IU/0.7 mL Solution for Injection (Equine)

Pharmacologic Category : Immune Sera

Classification : Prescription Drug (Rx)

Approved Shelf-life : 36 months

Storage Condition : Store at temperatures between 2-8°C. Do not freeze.

Packaging : 2 mL Type I Clear Ampoule (Box of 10's)

Manufacturer : Jiangxi Institute of Biological Products

No. 198 Huoju Avenue, Jinggangshan Economic and Technological Development Zone, Ji'an City, Jiangxi

Province, People's Republic of China

Importer/Distributor : Sahar International Trading Inc.

#354 Aguirre Ave., Phase III, BF Homes,

Parañaque City

The marketing authorization shall be valid until <u>04 December 2024</u> 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 19 February 2021.

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

JESUSA JOYCE N. CIRUNAY, RPh

Director IV
Center for Drug Regulation and Research

REG. STATUS AMOUNT OR NUMBER

: Renewal : Php 10,100.00 : 1214277 : 27 November

BAR CODE DOC TRACK 27 November 2019







Registration Number : BRP-073

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.
X 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 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.
Н	Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.
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 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.
X K	Subject to satisfactory compliance to the post-approval commitments detailed in the letter

REMARKS:

Exhaustion up to retail level of all existing inventory of the previous labeling materials is allowed only until 19 February 2022. No further extension shall be granted.



Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



CENTER FOR DRUG REGULATION AND RESEARCH

19 February 2021

Sahar International Trading Inc.

#354 Aguirre Ave., Phase III BF Homes, Parañaque, Metro Manila

Subject: Tetanus Antitoxin 1500 IU/0.7 mL Solution for Injection (Equine)

[Sharjvax] (BRP-073)

Dear Sir/ Madam,

This is to inform you that your application for renewal registration of the subject product has been approved and issued a Certificate of Product Registration (CPR) valid until 04 December 2024.

In line with this, you are advised to provide Periodic Safety Update Report (PSUR) annually to the Pharmacovigilance Unit of the Center for Drug Regulation and Research (CDRR) - Product Research and Standard Development (PRSDD) Division. Likewise, an updated Risk Management Plan (RMP) or any global safety issues/alert from other National Regulatory Agencies (NRAs) should be submitted immediately.

For your guidance and strict compliance.

Very truly yours, (By Authority of the Director General: Per FDA Order No. 2016-005)

JESUSA JOYCE N. CIRUNAY, RPh

Director IV, Center for Drug Regulation and Research

REG. STATUS AMOUNT OR NUMBER

Renewal Php 10,100.00 1214277

27 November 2019

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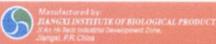


0.7mL

Tetanus Antitoxin

Sharjvax[™] 1500 I.U./0.7 mL Solution for Injection(Equine) (Deep SC/IM) IMMUNE SERUM

Each 0.7mL ampoule contains Tetarus Antitoxin.USP 1500 i.U.NaCl 0.9%, m-Cresol<0.25%. Water for Injection q.s. Modified Globulin Form Antitetanus Caution: Foods, Drugs, Devices and Cosmelics Act Mfg. Date: 10.2019 Exp.Date: 10.2022 prohibits dispensing without prescription. FDA Reg.No.:BRP-073 Mfg.Date:10.20







Reflect storage

condition on the primary