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	:	**BR-809**
Generic Name	:	Tetanus Antitoxin (Equine)
Brand Name	:	Sharjvax
Dosage Strength & Form	:	3,000 IU/0.95 mL Solution for Injection (IM)
Pharmacologic Category	:	Immune Serum
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	36 months
Storage Condition	:	Store at temperatures between 2-8°C.
Packaging	:	Clear glass ampoules x 0.95 mL (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	:	Sahar International Trading Inc. #354 Aguirre Ave., Phase III, BF Homes, Parañaque City

The marketing authorization shall be valid until **26 May 2026** subject to the conditions listed on the reverse side. No change in the formulation, labeling 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 **18 March 2022**

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 : **Renewal**
AMOUNT : **Php 10,100.00**
OR NUMBER : **SEQ# 111521357897**
DATE : **15 November 2021**
BAR CODE / DOC TRACK : 2 0 2 1 0 4 2 8 0 8 2 6 4 4

Management System ISO 9001:2015

FDA-0568081

Registration Number : BR-809

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. 2018-012 or 2021-020 (whichever is applicable) 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:
Exhaustion up to retail level of all existing inventory of the previous labelling materials is allowed only until 18 March 2023. No further extension shall be granted.

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

18 March 2022

Sahar International Trading Inc.
#354 Aguirre Ave., Phase III,
BF Homes, Parañaque City

Subject: **Tetanus Antitoxin (Equine) 3,000 IU/0.95 mL Solution for Injection (IM) [Sharjvax] (BR-809)**

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 **26 May 2026**.

In line with this, you are required to submit Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) and an updated Risk Management Plan (RMP) or any global safety issues/alert from other National Regulatory Agencies (NRAs) in accordance with the FDA Circular No. 2020-003, Subject: Guidelines for Pharmaceutical Industry on Pharmacovigilance, to the Pharmacovigilance Section of the Product Research and Standard Development (PRSDD) Division - Center for Drug Regulation and Research (CDRR).

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	:	Renewal
AMOUNT	:	Php 10,100.00
OR NUMBER	:	SEQ# 111521357897
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