

महाराष्ट्र शासन
आयुक्त
अन्न व औषध प्रशासन, महा. राज्य
३४१, वांद्रे - कुर्ला संकुल, रिजर्व बँक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.



GOVERNMENT OF MAHARASHTRA
COMMISSIONER
Food and Drugs Administration (M.S.)
341, Bandra-Kurla Complex,
Opposite of RBI Buildings,
BAndra (E), Mumbai - 400 051
Tel : 022 - 26592362-65
E-Mail : comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/PD/71075/2018/ 2294 /11

दिनांक. ०२/०८/२०१८

प्रति,
PREMIUM SERUMS AND VACCINES PVT. LTD.
PUNE

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजूरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 71075

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ PD/71075 (एकूण प्रमाणपत्रे 1) पाठवीण्यात येत आहेत.

सहआयुक्त, मुख्यालय, मुंबई यांचे मान्यतेने

आपला

(सु सं मोहिते)

सहायक आयुक्त (मुख्यालय) का क्र.११
अन्न व औषध प्रशासन, म. राज्य.





Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 02/08/2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.

(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/PD/71075/2018/11/24333**

On the basis of the inspection carried out on **23/05/2018, 24/05/2018 & 05/07/2018**, we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **PREMIUM SERUMS AND VACCINES PVT. LTD.**
Address : **S. NO. 354-1 & 2A/1, NARAYANGAON, TAL. JUNNAR PUNE 410504 MAHARASHTRA STATE, INDIA**
2. Licence No. : **PDVacc8 In Form 28D**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Injectables	Anti-sera / Anti-Toxin	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 31 Jul 2021 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1ERP6697107520180801

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 01 Aug 2018



01 AUG 2018



Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a licence for the site, this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.
4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

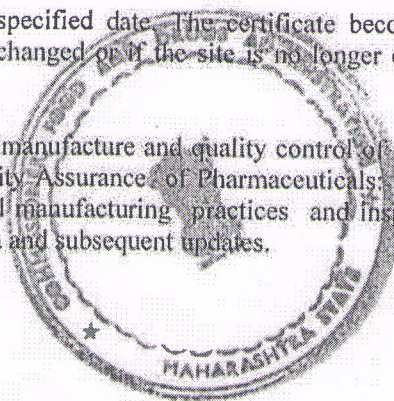
Pharmaceutical Product (s) ¹	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product (s) ¹	Category (ies)	Activity (ies)
Starting material (s) ²		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

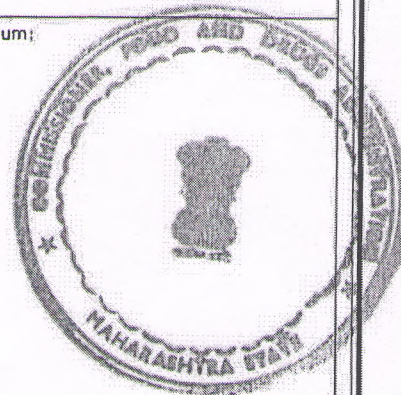
5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/PD/71075/2018/11 VALID UP TO :31 Jul 2021
/24333
Name of Manufacturing Firm : PREMIUM SERUMS AND VACCINES
PVT. LTD.
S. NO. 354-1 & 2A/1, NARAYANGAON, TAL.
JUNNAR PUNE 410504 MAHARASHTRA STATE,
INDIA
Drug License No : PDVacc8 In Form 28D

Sr.No.	Name of the Product	Composition
1	Comblpack of Snake Venom Antiserum with Sterile Water for Injection (Lyophilized, Polyvalent, enzyme refined equine immunoglobulins)	a) Snake Venom Antiserum I.P. (10 ml Vial) After reconstitution, each ml of Polyvalent Snake Venom Antiserum neutralizes not less than Indian Cobra Venom (Naja naja) 0.60 mg Common Krait venom (Bungarus caeruleus) 0.45 mg Russell's Viper Venom (Vipera russelli) 0.60 mg Saw scaled viper venom (Echis carinatus) 0.45 mg Cresol (Preservative) NMT 0.25 % v/v Glycine I.P. : Stabilizer Sodium Chloride I.P.: Excipient b) Diluent: Sterile Water for Injections I.P. (10 ml Ampoule)
2	Diphtheria antitoxin (Bulk)(Enzyme refined equine immunoglobulins). 1L, 5L, 10L, 20L	Each ml of Diphtheria Anti-Toxin neutralizes not less than 1000 IU Preservative: Phenol/Cresol B.P. NMT 0.25% w/v
3	Diphtheria Antitoxin I.P. 10 ml (Liquid, Enzyme refined equine immunoglobulins), 10 ml Vial	Each ml of Diphtheria Antitoxin contains not less than 1000 IU Phenol (Preservative) NMT 0.25 % w/v Glycine I.P. : Stabilizer Sodium Chloride I.P.: Excipient
4	Polyvalent Anti Snake Venom Serum (Bulk) Africa (Central Africa) (Polyvalent enzyme refined equine immunoglobulins). 1 L, 5 L, 10 L, 20 L	Each ml of serum neutralizes not less than: 0.45 mg Black Mamba (Dendroaspis polylepis) venom 0.60 mg Gaboon Viper (Bitis rhinoceros) venom 0.60 mg Russell's viper (Vipera russelli) venom 0.45 mg Saw scaled viper (Echis carinatus) venom Preservative Phenol / Cresol B.P. \leq 0.25 % w/v
5	Polyvalent Antisnake Venom Serum (Bulk) Africa (Pan Africa) (Polyvalent Enzyme refined Equine Immunoglobulins) 1 L, 5 L, 10 L, 20 L	Each ml of serum neutralizes at a minimum: 1) Bitis arietans \geq 25 LD ₅₀ 2) Bitis gabonica \geq 25 LD ₅₀ 3) Bitis nasicornis \geq 20 LD ₅₀ 4) Bitis rhinoceros \geq 25 LD ₅₀ 5) Echis leucogaster \geq 25 LD ₅₀ 6) Echis ocellatus \geq 25 LD ₅₀ 7) Echis carinatus \geq 25 LD ₅₀ 8) Naja haje \geq 25 LD ₅₀ 9) Naja melanoleuca \geq 20 LD ₅₀ 10) Naja nigricollis \geq 20 LD ₅₀ 11) Dendroaspis polylepis \geq 25 LD ₅₀ 12) Dendroaspis viridis \geq 25 LD ₅₀ 13) Dendroaspis jamesoni \geq 25 LD ₅₀ 14) Dendroaspis angusticeps \geq 25 LD ₅₀ Preservative Phenol / Cresol B.P. \leq 0.25 %w/v



A. T. NIKHADE

Joint Commissioner (F.D.)
Food and Drugs Administration
Maharashtra State, Mumbai

01 AUG 2018

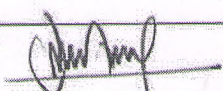


6	Polyvalent Anti-Snake Venom Serum (Bulk) Africa (North Africa) (Polyvalent, Enzyme refined equine immunoglobulins). 1L, 5L, 10L, 20L	Each ml of serum neutralizes at a minimum: Naja haje venom $\geq 75 \text{ LD}_{50}$ Naja nigricollis venom $\geq 25 \text{ LD}_{50}$ Cerastes cerastes venom $\geq 75 \text{ LD}_{50}$ Preservative: Phenol/Cresol B.P. NMT 0.25% w/v
7	Rabies Antiserum (Bulk) (Enzyme refined equine immunoglobulins). 1L, 5L, 10L, 20L	Each ml of Rabies Antiserum neutralizes not less than 300 IU/ml Preservative Phenol / Cresol I.P $\leq 0.25\% \text{ w/v}$
8	Rabies Antiserum (Bulk) (Enzyme refined equine immunoglobulins) 1L, 5L, 10L, 20L	Each ml of Rabies Antiserum contains Not Less Than 200IU Preservative: Phenol/Cresol B.P. NMT 0.25% w/v

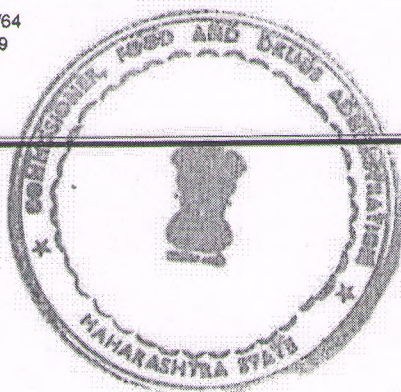
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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai - 400 051,
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1ERP6697107520180801

Name of the Authorised person : A. T. NIKHADE

Signature : 

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 01 Aug 2018



0.1 AUG 2018



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/PD/71075/2018/11 VALID UP TO : 31 Jul 2021
/24333
Name of Manufacturing Firm : PREMIUM SERUMS AND VACCINES
PVT. LTD.
S. NO. 354-1 & 2A/1, NARAYANGAON, TAL.
JUNNAR PUNE 410504 MAHARASHTRA STATE,
INDIA
Drug License No : PDVacc8 In Form 28D

Sr.No.	Name of the Product	Composition
9	Scorpion Venom Antiserum (Bulk) Africa (North Africa) (Polyvalent, enzyme refined equine immunoglobulins). 1L, 5L, 10L, 20L	Each ml of serum neutralizes not less than following quantities of venoms: Androctonus amoerexi 35 LD ₅₀ Leiurus quinqueseratus 50 LD ₅₀ Preservative: Phenol/Cresol B.P. NMT 0.25% w/v
10	Snake Venom Antiserum I.P. (Liquid, Polyvalent, enzyme refined equine immunoglobulins), 10 ml Vial	Each ml of Snake Venom Antiserum neutralizes not less than Indian Cobra Venom (Naja naja) 0.60 mg Common Krait Venom (Bungarus caeruleus) 0.45 mg Russell's Viper Venom (Vipera russelli) 0.60 mg Saw scaled viper venom (Echis carinatus) 0.45 mg Cresol (Preservative) NMT 0.25 % v/v Glycine I.P. : Stabilizer Sodium Chloride I.P. : Excipient
11	Tetanus Antitoxin (Bulk) (Enzyme refined equine immunoglobulins) 1 L, 5 L, 10 L, 20 L	Each ml of Tetanus Anti -Toxin neutralizes not less than 1500 IU Preservative: Phenol/Cresol B.P. ≤ 0.25 % w/v
12	NORAF-Premium Combipack of Snake Venom Antiserum with Sterile Water for Injection (North Africa) (Lyophilized, Polyvalent, enzyme refined equine immunoglobulins)	a) Snake Venom Antiserum (North Africa) (20 ml Vial) After reconstitution, each ml of Snake Venom Antiserum (North Africa) neutralizes not less than following quantities of venoms Naja haje venom ≥ 75 LD ₅₀ Naja nigricollis venom ≥ 25 LD ₅₀ Cerastes cerastes venom ≥ 75 LD ₅₀ Cresol (Preservative) NMT 0.25 % v/v Glycine B.P. Stabilizer Sodium Chloride B.P. : Excipient b) Diluent : Sterilised Water for Injections B.P. (10 ml Ampoule)
13	PANAF-Premium Combipack of Snake Venom Antiserum with Sterile Water for Injection (Pan Africa) (Lyophilized, Polyvalent, enzyme refined equine immunoglobulins)	a) Snake Venom Antiserum (Pan Africa) (20 ml Vial) After reconstitution, each ml of Polyvalent Snake Venom Antiserum (Pan Africa) neutralizes at a minimum- Bitis arietans ≥ 25 LD ₅₀ Bitis gabonica ≥ 25 LD ₅₀ Bitis nasicornis ≥ 20 LD ₅₀ Bitis rhinoceros ≥ 25 LD ₅₀ Echis leucogaster ≥ 25 LD ₅₀ Echis ocellatus ≥ 25 LD ₅₀ Echis carinatus ≥ 25 LD ₅₀ Naja Haje ≥ 25 LD ₅₀ Naja melanoleuca ≥ 20 LD ₅₀ Naja nigricollis ≥ 20 LD ₅₀ Dendroaspis polylepis ≥ 25 LD ₅₀ Dendroaspis viridis ≥ 25 LD ₅₀ Dendroaspis jamesoni ≥ 25 LD ₅₀ Dendroaspis angusticeps ≥ 25 LD ₅₀ Cresol (Preservative) NMT 0.25 % v/v Glycine B.P. : Stabilizer Sodium Chloride B.P. : Excipient b) Diluent: Sterilised Water for Injections B.P. (10 ml Ampoule)

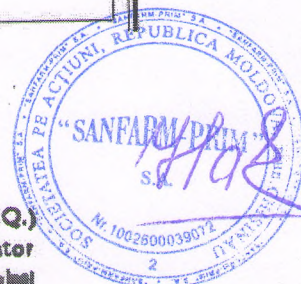


A. T. NIKHADE

(Handwritten Signature)

Joint Commissioner (H.Q.)
Food and Drugs Administrator
Maharashtra State, Mumbai

01 AUG 2018

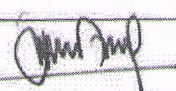


14	Polyvalent Anti-Snake Venom Serum Snake Anti Venom Serum (Bulk). (Polyvalent enzyme refined equine immunoglobulins). 1 L, 5 L, 10 L, 20 L	Each 1 ml of serum neutralizes not less than: 0.60 mg. of Cobra (Naja Naja) Venom 0.45 mg of Krait (Bungarus caeruleus) venom 0.60 mg. of Russell's viper (Vipera russelli) venom 0.45 mg. of Saw scaled viper (Echis carinatus) venom Preservative Phenol / Cresol I.P $\leq 0.25\%$ w/v
15	Premi - RIG Rabies Antiserum 5 ml (Liquid, Enzyme refined equine immunoglobulin), 5 ml Vial	Each ml of Rabies Antiserum contains not less than 200 IU Phenol (Preservative) NMT 0.25 % w/v Glycine B.P. : Stabilizer Sodium Chloride B.P.: Excipient
16	Premi-RAB Rabies Antiserum I.P. 5 ml (Liquid, Enzyme refined equine immunoglobulin), 5 ml Vial	Each ml of Rabies Antiserum contains not less than 300 IU Phenol (Preservative) NMT 0.25 % w/v Glycine I.P.; Stabilizer Sodium Chloride I.P.: Excipient

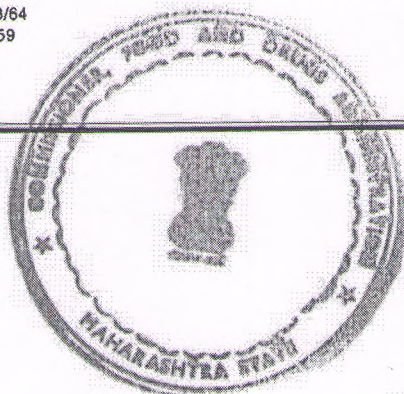
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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai - 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
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Name of the Authorised person : A. T. NIKHADE

Signature : 

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
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PVT. LTD.
S. NO. 354-1 & 2A/1, NARAYANGAON, TAL.
JUNNAR PUNE 410504 MAHARASHTRA STATE,
INDIA
Drug License No : PDVacc8 In Form 28D

Sr.No.	Name of the Product	Composition
17	Premi-TAT 1500 Tetanus Antitoxin B.P. Prophylactic 1.0 ml (Liquid, Enzyme refined equine immunoglobulins), 2 ml Vial	Each ml of Tetanus Antitoxin contains not less than 1500 IU Phenol (Preservative) NMT 0.25 % w/v Glycine B.P. : Stabilizer Sodium Chloride B.P. : Excipient

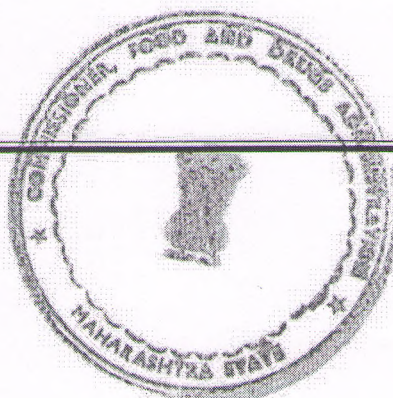
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