

Office of The Commissioner. Food & Drugs Administration M.S. Bandra - Kurla Complex, Bandra (E), Mumbai - 400 051 Date :-04 Jul 2022

### 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/KD/107921/2022/11/39826

On the basis of the inspection carried out on 23.12.2021 & 24.12.2021 ,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.

Name of the Firm

**BHARAT SERUMS AND VACCINES LIMITED** 

Address

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE,

ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506 MAHARASHTRA STATE, INDIA

2. Licence No. KD360 In Form 28, KD4 In Form 28D,

KD5 in Form 28E

#### Table 1

Dosage Form(s)	Categor(ies)	Activity(ies)	
Active Pharmaceutical Ingredients ( Bulk Drugs)	Anti-sera / Anti-Toxin	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
Active Pharmaceutical Ingredients ( Bulk Drugs)	Blood Products	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance	
Active Pharmaceutical Ingredients ( Bulk Drugs)	General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones )	Production, Filling, Packing, labelling, Quality Control, Quality Assurance Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
Active Pharmaceutical Ingredients ( Bulk Drugs)	Hormones		
Active Pharmaceutical Ingredients ( Bulk Drugs)	Recombinant Vaccines / Drugs	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
Dry Powder Injections	Blood Products	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
	Active Pharmaceutical Ingredients (Bulk Drugs)  Active Pharmaceutical Ingredients (Bulk Drugs)	Active Pharmaceutical Ingredients ( Bulk Drugs)  Recombinant Vaccines / Drugs	

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 29 Mar 2025 . 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 auth Food & Drug Administration

Bandra-kurla Com

Maharashtra, IMMA Tel: +91-22-24592363/ Fax: +91-2 363/64 25591959

BHARAT SERUM D VACCINES LIMITED NEW-WHO-GM /39826

ame of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

#### 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 a food manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



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ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506 MAHARASHTRA STATE, INDIA

2. Licence No.

KD360 In Form 28,

KD4 In Form 28D, KD5 In Form 28E

#### Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
7	Dry Powder Injections Hormones		Production, Filling, Packing, labelling, Quality Control, Quality Assurance
8	Injectables	Anti-sera / Anti-Toxin	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
9	Injectables	Blood Products	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
10	Injectables	General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones )	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
11	Injectables	Hormones	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
12	Injectables	Recombinant Vaccines / Drugs	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

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Address of certifying authority
Food & Drug Administration, M.S.
Bandra-kurla Complete
Bandra (E), Mumbel 400 051.

Bandra (E), Mumba 400 051 Maharashtra, INDIA: Tel: +91-22-2659236364 Fax: +91-22-26591950 BHABAT SEPLINS AND ACCIONS LIMITI

Fax: +91-22-26591959
BHARAT SERUMS AND VICCINES LIMITED NEW-WHO-GMP/CERT/IN/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature :

np and Date : Joint Commissioner (HQ) & Control ing

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

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## Example -1

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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.	

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Licence No.

KD360 In Form 28, KD4 In Form 28D,

KD5 In Form 28E

#### Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
13	Liquid Injection ( SVP )	General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones )	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
14	Lyophilised / Powder injectable	Anti-sera / Anti-Toxin	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
15	Lyophilised / Powder injectable	Blood Products	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
16	Lyophilised / Powder injectable	General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones )	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
17	Lyophilised / Powder injectable	Hormones	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
18	Powder for Solution for Infusion	General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones )	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
<u>1 2</u> 3	*	A Co	

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26591959 Fax: +91-22

MID VACCINES LIMITED GERT/KD/107921/2022/ BHARAT SERUM NEW-WHO-GMP /39826

of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

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## Example -1

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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.

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No. of certificate

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4

In Form 28D, KD5 In

Form 28E

Name of the Product	Composition   F	
AMPHOTERICIN B EMULSION	Each ml contains: Amphotericin USP 5 mg	
ANTI RHO - D IMMUNOGLOBULIN (MONOCLONAL)- BULK	Animo Accuracy STATE	
ANTI RHO D IMMUNOGLOBULIN INJECTION (MONOCLONAL) 1500 IU (FREEZE DRIED)	Each vial contains: Monoclonal Anti Rho D Immunoglobulin IHS 1500 IU To be reconstituted with 2 ml of Sterile Water for Injection USP provided with this pack.	
ANTI RHO D IMMUNOGLOBULIN INJECTION (MONOCLONAL) 1500 IU (LIQUID INJECTION)	Each ml contains: Monoclonal Anti Rho D Immunoglobulin IHS 1500 IU Water for Injection USP , qs	
Cetrorelix Acetate for Injection 0.25 mg (Lyophilized)	Each Vial Contains: Cetrorelix (as acetate) (Lyophilized) 0.25 mg To be reconstituted with 1.0 ml of Sterile Water for Injection IP provided with the pack. For Subcutaneous use only. For Single Use only.	
FOLLICLE STIMULATING HORMONE INJECTION (HUMAN RECOMBINANT) (FOLLITROPIN INJECTION) IP 900 IU (66.0 µg) / 1.5 ML Dosage form :Solution for Injection in Prefilled pen-Multidose)	Each Prefilled pen containing one 3 ml Cartridge contains: Follicle Stimulating Hormone concentrated solution (Follitropin concentrated solution) (Human Recombinant) IP 900 IU (66.0 μg)	
FOLLICLE STIMULATING HORMONE INJECTION (HUMAN RECOMBINANT)(FOLLITROPIN INJECTION) IP 450 IU (33.0 µg) / 0.75 ML (Dosage form : Solution for Injection in Prefilled pen-Multidose)	Fach Prefilled pen containing one 3 ml Cartridge contains Follicle Stimulating Hormone concentrated solution (Follitropin concentrated solution) (Human Recombinant) IP 450 IU (33.0 μg) )  r	
LIPOSOMAL AMPHOTERICIN B POWDER FOR SOLUTION FOR INFUSION 50 MG (LYOPHILIZED)	Each Vial Contains: Amphotericin B (Intercalated into liposomal membrane) Ph.Eur 50 mg	
	AMPHOTERICIN B EMULSION  ANTI RHO - D IMMUNOGLOBULIN (MONOCLONAL) - BULK  ANTI RHO D IMMUNOGLOBULIN INJECTION (MONOCLONAL) 1500 IU (FREEZE DRIED)  ANTI RHO D IMMUNOGLOBULIN INJECTION (MONOCLONAL) 1500 IU (LIQUID INJECTION)  Cetrorelix Acetate for Injection 0.25 mg (Lyophilized)  FOLLICLE STIMULATING HORMONE INJECTION (HUMAN RECOMBINANT) (FOLLITROPIN INJECTION) IP 900 IU (66.0 µg) / 1.5 ML Dosage form : Solution for Injection in Prefilled pen-Multidose)  FOLLICLE STIMULATING HORMONE INJECTION (HUMAN RECOMBINANT) (FOLLITROPIN INJECTION) IP 450 IU (33.0 µg) / 0.75 ML (Dosage form : Solution for Injection in Prefilled pen-Multidose)  LIPOSOMAL AMPHOTERICIN B POWDER FOR SOLUTION FOR	

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Bandra-kurla Complex,

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Maharashtra, INDIA.

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Fax: +91-22-26591959

BHARAT SERUMS AND VACCINES LIMITED -NEW-WHO-GMP/CERT/KD/107921/2022/11 /39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India

# LIST OF PRODUCT APPROVED UNDER WHO $\mbox{\rm GMP}^1$

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

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Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4

In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
9	MENOTROPHIN FOR INJECTION B.P. 150 I.U. (Freeze Dried) (Highly Purified)	Each vial contains:  Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 150 IU  Luteinizing Hormone 150 IU
		Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
10	MENOTROPHIN FOR INJECTION B.P. 75 I.U. (Freeze Dried) (Highly	Each vial contains:  Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 75 IU  Luteinizing Hormone 75 IU
	Purified)	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack.  To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
11	POLYMYXIN B FOR INJECTION U.S.P. (Lyophilized)	Each vial contains: Polymyxin B Sulphate U.S.P. Equivalent to Polymyxin B 50 mg To be reconstituted with 5 ml of Sterile water for Injection U.S.P For Intrathecal / I.M. / I.V. Infusion .
12	POLYMYXIN B INJECTION U.S.P. 25 MG (LYOPHILISED)	Each vial contains: Polymyxin B Sulphate U.S.P. Equivalent to Polymyxin B 25 mg For Intrathecal/I.M./I.V. Infusion .
13	Recombinant - Human Follicle Stimulating Hormone - Purified Liquid Bulk	COMMIS
14	RECOMBINANT ANTI RHO-D IMMUNOGLOBULIN (r-ANTI-D; IgG1) Purified Liquid bulk drug: 5.00 mg/mL to 10.00 mg/mL	13 11 A W A S
15	RECOMBINANT ANTI RHO-D IMMUNOGLOBULIN INJECTION 300 MCG (LIQUID INJECTION)	Each Vial Contains: Recombinant Anti Rho-D Immunoglobulin (Purified Liquid Bulk) IHS 300 mcg Pack Size : 2 ml vial .
16	RECOMBINANT FOLITROPIN CONCENTRATED SOLUTION Ph. Eur	

<u>1</u> 2 3 4 <u>5</u> <u>6</u> <u>7</u> <u>8</u> <u>9</u> <u>10</u> ...

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Maharashtra, INDIA. Tel: +91-22-26592363/64 Fax: +91-22-26591959

BHARAT SERUMS AND VACCINES LIMITED -NEW-WHO-GMP/CERT/KD/107921/2022/11 /39826

Name of the Authorised person: D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

LIST OF PRODUCT APPROVED UNDER WHO  $\mbox{\rm GMP}^1$ 

No. of certificate

/39826

Name of Manufacturing Firm BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA KD360 In Form 28, KD4

Drug License No

In Form 28D, KD5 In

r.No. Name of the Product		Composition	
17	SNAKE VENOM ANTISERUM	After reconstitution each ml neutralizes the following quantities of standard venoms of:	
	(LYOPHILIZED)	Cobra 0.6 mg	
	(LIOTHELES)	Common Krait 0.45 mg	
		Russel's Viper 0.6 mg	
		Saw-scaled viper 0.45 mg	
		Preservative : Cresol BP NMT 0.25 % v/v .	
		Stabilizer : Glycine BP .	
		Excipients : Mannitol B.P. and Sodium Chloride B.P.	
		Reconstitute with 10 ml Sterile Water for Injections BP provided in this pac	
18	SNAKE VENOM ANTISERUM I.P.	After an experience of the property of the following grantities of the day	
	(LYOPHILIZED)	After reconstitution each ml neutralizes the following quantities of standar venoms of: .	
		Cobra 0.6 mg	
		Common Krait 0.45 mg	
		Russel's Viper 0.6 mg	
		Saw-scaled viper 0.45 mg	
		Preservative: Cresol BP . NMT 0.25 % v/v, Stabilizer: Glycine BP, Excipients:	
		Mannitol BP & Sodium Chloride BP .	
19	LIPOTOLLITPODIN FOR INJECTION	Each vial contains:	
	UROFOLLITROPIN FOR INJECTION B.P. 150 i.U. (Freeze Dried) (Highly	Urofollitropin BP 150 IU	
	Purified)	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pa	
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P	
20		Each vial contains:	
	UROFOLLITROPIN FOR INJECTION B.P. 75 I.U. (Freeze Dried) (Highly	Urofollitropin BP 75 IU	
	Purified)	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pa	
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P	
21	ALDOUGH AGE FOR INVESTIGATION	Each vial contains:	
	UROKINASE FOR INJECTION	Urokinase BP 500000 IU	
	Lyophilized	Excipients and Stabilizers:	
		Human Albumin B.P 20 mg, Sodium Citrate B.P. 24 mg, Disodium Hydroger	
		Phosphate B.P 7.8 mg, Sodium Dihydrogen Phosphate Dihydrate B.P 2	
		Img . For I.V. Use .	
22	AMBUOLD /C		
22	AMPHOLIP (Combipack) [Amphotericin B Lipid Complex	Each ml Contains	
	mirculos I.V.]	Amphotericin B USP 5 mg Sodium chloride BP 9 mg	
A	NO DRUG	Water for Injection USP . gs	
-	- Contraction		
	7.3	Lipids: Dimyristoylphosphatidylcholine [DMPC] 3.4 mg Lipids: Dimyristophosphatidylglycerol [DMPG as sodium salt] 1.5 mg	
	_ ) [	Pack Size: 2 ml, 10 ml, 20 ml.	
-	15	This product will be manufactured by M/s. Bharat Serums and Vaccines Ltd	
		and will be combipacked along with Pre-Sterilized filter needle (Pre-Sterilized)	
		filter needle is not covered under the scope of WHO GMP)	

Joint Commissioner (H.Q.) Foot and Drugs Administrator

23	AMPHOMUL	Each ml Contains
	(Amphotericin B Emulsion)	Amphotericin B USP 5 mg
		In a vehicle containing Soybean oil USP .
		Glycerin USP .
		Purified Egg Lechithin IH
		Sodium Hydroxide USP .
		water for Injection USP .
24	BHARGLOB 16.5 %	COMPOSITION:
	[Human Normal Immunoglobulin	Protein Content 16.5 % w/v
	B.P.]	Pack Size: 1ml, 2ml and 5ml .
	<u> </u>	

12345678910...

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MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4

In Form 28D, KD5 In

Sr.No.	Name of the Product	Composition
	POLY-MxB	
	Polymyxin B for Injection U.S.P	Each vial Contains
	Lyophilized	Polymyxin B Sulphate U.S.P. Equivalent to Polymyxin B 500000 Units
		For Intrathecal / IM / IV Infusion .
		To be reconstituted with 5ml of Sterile water for Injection U.S.P
26	THYMOGAM	Each 5ml vial Contains
	[Antithymocyte Globulin - Equine]	Antithymocyte Globulin (Equine) 250 mg
		Water for Injection USP . qs
		For Intravenous Use only .
27	AMPHO	Each vial contains:
	Amphotericin B for Injection U.S.P	Amphotericin B USP 50 mg
	(Lyophilized)	Sodium Deoxycholate . qs
28	AMPHOLIP CF	Each ml contains
	Amphotericin B Lipid Complex	Amphotericin B USP 5 mg
	Injection I.V. (Combipack)	Sodium Chloride BP 9 mg
		Water for Injection USP . qs
		Lipids:Dimyristoylphosphatidylcholine (DMPC) 3.4 mg,
		Dimyristoylphosphatidylglycerol (DMPG as Sodium salt)1.5 mg .
		Pack Size: 2 ml, 10 ml and 20 ml .
		This product will be manufactured by M/s. Bharat Serums and Vaccines Ltd. will be combipacked along with a Pre-Sterilized filter needle .
29	AMPHOMED	Each vial contains:
	[Amphotericin B for Injection U.S.P.] (Lyophilized)	Amphotericin B USP 50 mg
		To be reconstituted with 10ml of Sterile Water for Injection U.S.P.
	AMPHOMILL	Each vial contains
	Amphotericin B for Injection USP (Lyophilized)	Amphotericin B USP 50 mg
		Sodium Deoxycholate . qs
	AMPHONEX	Each vial contains:
	Liposomal Amphotericin B Injection	Amphotericin B Ph.Eur 50 mg
	(Lyophilized)	Intercalated into liposomal membrane .
		Excipients . qs
32	AMPHONEX	Each vial contains:
	Liposomal Amphotericin B Powder for Solution for Infusion 50 mg	Amphotericin B (Intercalated into liposomal membrane) Ph.Eur 50 mg

(Lyophilized) 12345678910...

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Tel: +91-22-26592363/64

Fax: +91-22-26591959

BHARAT SERUMS AND VACCINES LIMITED NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date: Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

No. of certificate

/39826

:

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4

In Form 28D, KD5 In

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Form 28E

r.No.	Name of the Product	Composition
33	AMPHONEX Powder for Concentrate for Solution for Infusion 50 mg Liposomal Amphotericin B Injection	Each vial contains Amphotericin B (Intercalated into liposomal membrane) Ph.Eur 50 mg
34	AMPHOSOME [Amphotericin B Lipid Complex Injection I.V.]	Each ml contains: Amphotericin B USP 5 mg Water for Injection USP . qs Lipids: Dimyristoylphosphatidylcholine [DMPC] 3.4 mg Lipids: Dimyristoylphosphatidylglycerol [DMPG as Sodium salt] 1.5 mg Pack Size: 2 ml, 10 ml and 20 ml
35	AMPHOTERICIN B FOR INJECTION U.S.P. (Lyophilized)	Each vial contains: Amphotericin B USP 50 mg Sodium Deoxycholate . qs
36	AMPHOTERICIN B LIPID COMPLEX INJECTION I.V. (Lyophilized) (Combipack)	Each ml contains: Amphotericin B USP 5 mg Water for Injection USP. qs Lipids: Dimyristoylphosphatidylcholine [DMPC] 3.4 mg Lipids: Dimyristoylphosphatidylglycerol [DMPG as Sodium salt] 1.5 mg
37	AMPHOTERICIN B LIPID POWDER (An Intermediate for Liposomal Amphotericin B for Injection)	Each gram of Lipid powder contains  Amphotericin B Ph.Eur 12.51 % w/w
38	AMPHOTRET Amphotericin B for Injection USP- Lyophilized (Dosage form: Lyophilized Injection)	Each vial Contains Amphotericin B USP 50 mg Sodium Deoxycholate . qs
	ANFOCIN (Amphotericin B for Injection U.S.P.) (Lyophilized)	Each vial contains:
	ANFOTERICINA OMICRON [Amphotericin B for Injection U.S.P.] (Lyophilized)	Each vial contains: Amphotericin B USP 50 mg sodium deoxycholate . qs

<u>1 2 3 4 5 6 7 8 9 10 ...</u>

Address of certifying authority: Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai - 400 051. Maharashtra, INDIA.

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Stamp and Date: Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

No. of certificate : NE

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
41	ANTI D-COX 1500 IU (300 MCG) Anti Rho-D Immunoglobulin Injection (Monoclonal)(Freeze Dried)	Each Vial Contains Monoclonal Anti Rho-D Immunoglobulin 300 mcg Stabiliser: Glycine BP and Human Albumin BP. To be reconstituted with 2 ml of Sterile Water for Injection USP provided with this pack.
42	Anti D 300 mcg Recombinant Anti Rho-D Immunoglobulin Injection 300 mcg (Liquid Injection)	Each Vial Contains: Recombinant Anti Rho-D Immunoglobulin (Purified Liquid Bulk) IH 300 mcg Pack Size: 2 ml vial.
43	ASPORELIX 0.25 [Cetrorelix Acetate for Injection 0.25 mg] (Lyophilized)	Each Vial Contains: Cetrorelix (as acetate) (Lyophilized) 0.25 mg To be reconstituted with 1.0 ml of Sterile Water for Injection U.S.P provided with the pack. For Subcutaneous use only. For Single Use only.
44	ASPORELIX 0.25 mg [Cetrorelix Acetate 0.25 mg Powder and Solvent for Solution for Injection]	Each Vial Contains: Cetrorelix (as acetate) (Lyophilized) IH 0.25 mg To be reconstituted with 1.0 ml of Sterile Water for Injection U.S.P. provided with the pack. For Subcutaneous use only. For Single Use only.
	ASPOREX 0.25 Cetrorelix Acetate for Injection 0.25 mg (Lyophilized)	Each Vial Contains: Cetrorelix (as acetate) (Lyophilized) IHS 0.25 mg To be reconstituted with 1.0 ml of Sterile Water for Injection U.S.P. provided with the pack . For Subcutaneous use only . For Single Use only .
	BSV LUPRODEX 3.75 MG [Leuprolide Acetate for Injection 3.75 MG (DEPOT)]	Each Vial contains (As lyophilized powder) Leuprorelin B.P. (As Acetate) 3.75 mg To be reconstituted with 1mL of Diluents [(Diluent for Leuprolide Acetate for Injection) (DEPOT)] provided with the pack
47	BSV-FOLICULIN 150 HP Urofollitropin for Injection B.P Freeze Dried (Highly Purified)	Each vial contains: Urofollitropin BP 150 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
	BSV-FOLICULIN 75 HP Urofollitropin for Injection B.P Freeze Dried (Highly Purified)	Each vial contains: Urofollitropin BP 75 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack

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Address of certifying authority: Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai – 400 051. Maharashtra,INDIA.

Manarashita, INDIA.
Tel: +91-22-26592363/64
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BHARAT SERUMS AND VACCINES LIMITED NEW-WHO-GMP/CERT/KD/107921/2022/11
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Name of the Authorised person : D. R. GAHANE

Signature
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.



No. of certificate

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
49	BSV-HUMOG 150 HP	Each vial contains:
	Menotrophin for Injection B.P (Freeze Dried) (Highly Purified)	Menotrophin B.P. Equivalent to activity of Follicle-stimulating Hormone 150 IU
		Luteinizing Hormone 150 IU
		Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack. To be packed as combi pack with 1 ml of Sodium Chloride Injection BP
50	BSV-HUMOG 75 HP	Each vial contains:
	Menotrophin for Injection B.P (Freeze Dried) (Highly Purified)	Menotrophin B.P. Equivalent to activity of Follicle-stimulating Hormone 75 IU Luteinizing Hormone 75 IU
		Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack. To be packed as combi pack with 1 ml of Sodium Chloride Injection BP
51	CHORIONIC GONADOTROPHIN	Each Vial contains:
	INJECTION B.P. 5000 I.U.	Chorionic Gonadotrophin BP [Human] 5000 IU
	Human Chorionic Gonadotrophin Injection (Freeze Dried)	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in this pack .
52	CLIMACT 75	Each vial contains:
	Menotrophin for Injection BP -	Menotrophin BP equivalent to activity of .
	Freeze Dried (Highly Purified) (Powder for Injection)	Follicle Stimulating Hormone 75 IU
	, , , , , , , , , , , , , , , , , , , ,	Luteinizing Hormone 75 IU  Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
53	CLOSTET	Each vial contains:
	Tetanus Immunoglobulin B.P (Human) 250 I.U./vial (Dosage Form : Injectable Solution)	Human Tetanus Immunoglobulin BP 250 IU
54	CORGON	Each vial contains:
	Chorionic Gonadotrophin Injection B.P.] [Human Chorionic Gonadotrophin Injection] 5000 I.U. Freeze Dried	Chorionic Gonadotrophin BP (Human) 5000 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in this pack .
55	CORGON – 5000 HP	Each Vial contains:
	(Chorionic Gonadotrophin for Injection B.P.) (Highly Purified) (Freeze Dried)	Chorionic Gonadotrophin BP 5000 IU  Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
56	DIULENT FOR LEUPROLIDE ACETATE	
	FOR INJECTION (DEPOT)	D- Mannitol BP 50 mg
		Water for Injection USP . qs

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Address of pertifying authority:
Food & Drus Administration, M.S.
Bandra Amila Complex,

d A3E) Mumbai – 400 051. d A3E) Mumbai – 400 051. d A3E) Mumbai – 400 051. d A3E) Mumbai – 400 051.

Tel:

991-22-26591959 SERUMS AND VACCINES WHO GMP/CERT/KD/107 Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, MS.

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4

In Form 28D, KD5 In

Form 28E

r.No.	Name of the Product	Composition
57	ELYCRAN	Each ml contains:
	[Amphotericin B Lipid Complex	Amphotericin B USP 5 mg
	Injection I.V.]	Water for Injection USP . qs
		Excipients: Sodium Chloride B.P 9 mg .
		Lipids: Dimyristoylphosphatidylcholine [DMPC]. 3.4 mg,
		Dimyristoylphosphatidylglycerol [DMPG as Sodium salts] 1.5 mg .
		Pack Size: 10 ml
5 <b>8</b>	ENDOPROST - 125 mcg	Each 0.5 ml contains:
	(Carboprost Tromethamine	Carboprost Tromethamine U.S.P equivalent to Carboprost 125 mcg
	Injection U.S.P.)(Liquid Injection)	Water for Injection USP . qs
59	ENDOPROST - 250 mcg	Each ml contains:
	(Carboprost Tromethamine	Carboprost Tromethamine U.S.P equivalent to Carboprost 250 mcg
	Injection U.S.P.)(Liquid Injection)	Water for Injection USP . qs
60	ENDOPROST - 250 mcg	Each ml Contains:
	Carboprost Tromethamine Injection	Carboprost 250 mcg equivalent to Carboprost Tromethamine USP
	U.S.P. 250 mcg	332.18 mcg .
		Water for Injection USP .
61	EQUIRAB	Each vial contains:
	[Rabies Antiserum - Equine]	Equine antirables immunoglobulin fragments not less than 300 I.U./ml
		Water for Injection USP . qs
		For Intramuscular use .
		Pack size: 4 ml & 5 ml.
62	EQUIRAB	Each 5 ml vial Contains
	Rabies Antiserum - Equine	Equine antirables immunoglobulin fragments not less than 1000 iv
		Water for injection USP . gs
		For Intramuscular use .
		1 3
63	FARMAKINASE 7,50,000 I.U.	Each Vial contains:
	[Streptokinase for Injection B.P.]	Streptokinase BP 7,50,000 IU
	Lyophilized	Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
64	FARMAKINASE 15,00,000 I.U.	Each Vial contains:
	[Streptokinase for injection B.P.]	Streptokinase BP 15,00,000 IU
	Lyophilized	Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
1027	15670010	

<u>1 2 3 4 5 6 7 8 9 10 ...</u>

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 BHARAT SERUMS AND VACCINES LIMITED -NEW-WHO-GMP/CERT/KD/107921/2022/11 /39826 Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India Date:04 Jul 2022



THE STATE

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/I, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
65	FOLICULIN - 150 HP Urofollitropin for Injection B.P. — Freeze Dried (Highly Purified)	Each vial contains: Urofollitropin BP 150 IU Reconstitute with 1 ml of Sodium Chloride Injection BP provided in the pack. To be packed as combi pack with 1 ml of Sodium Chloride Injection BP.
66	FOLICULIN – 150 I.U. (Urofollitropin for Injection B.P.) (Freeze Dried) (FOR MALAYSIA ONLY)	Each vial contains: Urofollitropin BP 150 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P.,
67	FOLICULIN – 75 I.U. (Urofollitropin for Injection B.P.) (Freeze Dried) (FOR MALAYSIA ONLY)	Each mI contains: Urofollitropin BP 75 IU Reconstitute with 1 mI of Sodium Chloride Injection B.P. provided in the pack . To be packed as combi pack with 1 mI of Sodium Chloride Injection B.P. IP/US .
68	FOLICULIN 150 [Urofollitropin for Injection B.P.] [FSH] Freeze Dried	Each Vial contains: Urofollitropin equivalent to activity of Follicle Stimulating Hormone BP 150 IV Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in this pack
69	FOLICULIN 75 [Urofollitropin for Injection B.P.] [FSH] Freeze Dried	Each Vial contains: Urofollitropin equivalent to activity of Follicle Stimulating Hormone BP 75 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in this pack
70	FOLICULIN -75 HP (Urofollitropin for Injection B.P.) (Highly Purified) – Freeze Dried	Each vial contains: Urofollitropin BP 75 IU Reconstitute with 1ml of Sodium Chloride Injection B.P. provided in the pack. To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
71	FOLICULIN BSV 150 HP Urofollitropin for Injection BP (Freeze Dried)(Highly Purified)	Each vial contains Urofollitropin BP 150 IU Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack To be packed as combi pack with 1 ml of Sodium Chloride Injection BP.
72	FOLICULIN BSV 75 HP Urofollitropin for Injection BP (Freeze Dried)(Highly Purified)	Each vial contains Urofollitropin BP 75 IU Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack To be packed as combi pack with 1 ml of Sodium Chloride Injection BP.
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Address of certaining authority
Food & Dung Addression, M.S.
Bandrastria Complex,
Bandrastria Complex,
Bandrastria (D), Mumbai – 400 051.
Maharahtra,INDIA.
Tel 1483 - 22-26592363/64

91-22-26591950

SERUMS AND VACCIN

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

No. of certificate

Drug License No

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506 MAHARASHTRA STATE, INDIA KD360 In Form 28, KD4

KD360 In Form 28. KD4

In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
73	FOLIFORM 150 IU Recombinant - Human Follicle Stimulating Hormone for Injection – Freeze Dried	Each vial contains  Recombinant - Human Follicle Stimulating Hormone IHS 150 IU  For Subcutaneous use only .  Reconstitute with 0.5 ml of sterile water for injection B.P. provided in this pack  To be packed as combi pack with 0.5 ml of sterile water for injection BP .
74	FOLIFORM-150 IU (PFS) Recombinant - Human Follicle Stimulating Hormone Injection 150 IU (Pre-filled Syringe)	Each Pre-filled syringe contains Recombinant - Human Follicle Stimulating Hormone IHS 150 IU Water for Injection USP . qs Pack : 0.5 ml in 1 ml Pre-Filled Syringe .
	FOLIFORM-75 IU Recombinant - Human Follicle Stimulating Hormone for Injection – Freeze Dried	Each vial contains  Recombinant - Human Follicle Stimulating Hormone IHS 75 IU  For Subcutaneous use only .  Reconstitute with 0.5 ml of sterile water for injection B.P. provided in this pack  To be packed as combi pack with 0.5 ml of sterile water for injection BP .
	FOLIGRAF - 150 IU (Recombinant-Follicle Stimulating Hormone Injection 150 IU] (Pre Filled Syringe)	Each Pre-filled Syringe contains Recombinant-Human Follicle Stimulating Hormone Ph.Eur 150 IU Water for Injection USP . qs Pack : 0.5 ml in 1 ml Pre Filled Syringe .
	FOLIGRAF - 75 IU [Recombinant -Human Follicle Stimulating Hormone Injection 75 IU (Pre Filled Syringe)	Each Pre-filled Syringe contains Recombinant-Human Follicle Stimulating Hormone Ph.Eur 75 IU Water for Injection USP . qs Pack : 0.5 ml in 1 ml Pre Filled Syringe .
	FOLIGRAF - MD 1200 IU [Recombinant Human Follicle Stimulating Hormone for Injection 1200 IU (Lyophilized) (Multidose)]	Each Vial Contains:  Recombinant Human Follicle Stimulating Hormone IH 1200 IU  Reconstitute with Pre-filled Syringe of Diluent contains: m-Cresol BP 6.0 m and Water for Injection BP 2.0 ml provided with this pack .  (15 disposable syringe for administration graduated in FSH units provided with this pack (15 disposable syringes are not covered under the scope of WHO GMP certificate) .
	FOLIGRAF 150 I.U. [Recombinant - Human Follicle Stimulating Hormone for Injection - Freeze Dried]	Each Vial Contains:  Recombinant - Follitropin Concentrated Solution Ph.Eur 150 IU  For Subcutaneous Use only .  Reconstitute with 0.5 ml of Sterilised water for injections B.P. provided in th pack .  To be packed as combi pack with 0.5 ml of Sterilised water for injections B.P.
	FOLIGRAF 150 I.U. Recombinant - Human Follicle Stimulating Hormone for Injection- Freeze Dried (Dosage form: Lyophilized Injection)	Each vial Contains  Recombinant - Human Follicle Stimulating Hormone 150 IU  For Subcutaneous use only  Reconstitute with 0.5ml of sterile water for injection B.P. provided in this pa
		To be packed as combi pack with 0.5 ml of sterile water for injection B.P

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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
BHARAT SERUMS AND VACCINES LIMITED - NEW-WHO-GMP/CERT/KD/107921/2022/11 /39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date: Joint Commissioner (HQ) & Controlling Authority Food & Drug Administration, M.S.



LIST OF PRODUCT APPROVED UNDER WHO  $\mathsf{GMP}^1$ 

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

/39826
BHARAT SERUMS AND VACCINES
LIMITED
PLOT NO K-27, K-27 PART AND K-27/1, ANAND
NAGAR, JAMBIVILI VILLAGE, ADDITIONAL
MIDC, AMBERNATH (EAST), THANE 421506
MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4 In Form 28D, KD5 In Form 28E

r.No.	Name of the Product	Composition
	FOLIGRAF 150 IU Follitropin Alpha For Injection(Recombinant Human Follicle Stimulating Hormone For Injection — Freeze Dried)	Each vial contains: Follitropin Alpha (Recombinant Human Follicle Stimulating Hormone) 150 IU Reconstitute with 0.5 ml of Sterilised water for Injections BP provided in this pack .  To be packed as a combi pack with 0.5 ml of Sterilised Water for Injections BI . For Subcutaneous use only .
	FOLIGRAF 225 IU (PFS) [Recombinant-Human Follicle Stimulating Hormone Injection 225 IU (PFS)]	Each Pre Filled Syringe contains: Folitropin Concentrated Solution (Recombinant) Ph.Eur 225 IU Water for Injection USP . Pack: 0.5 ml in 1ml Pre-Filled Syringe .
	FOLIGRAF 300 IU (PFS) Recombinant – Human Follicle Stimulating Hormone Injection 300 IU (PFS)	Each Pre Filled Syringe contains: Follitropin Concentrated Solution (Recombinant) Ph.Eur 300 IU Water for injection USP . Pack: 0.S ml in 1ml Pre-Filled Syringe .
	FOLIGRAF 450 IU (MULTIDOSE) Pre Filled Pen Recombinant Human Follicle Stimulating Hormone Injection IH 450 IU (33.0 µg)/ 0.75 ml (Dosage Form: Solution for Injection in Prefilled pen-Multidose)	Each Prefilled pen containing one 3 ml Cartridge contains: Recombinant-Follitropin Concentrated Solution Ph.Eur 450 IU (33.0 μg)
	FOLIGRAF 75 I.U. [Recombinant - Human Follicle Stimulating Hormone for Injection - Freeze Dried]	Each Vial Contains: Recombinant - Follitropin Concentrated Solution Ph.Eur 75 IU For Subcutaneous Use only . Reconstitute with 0.5 ml of Sterilised water for injections B.P. provided in thi pack To be packed as combi pack with 0.5 ml of Sterilised water for injections B.P.
	FOLIGRAF 75 I.U. Recombinant-Human Follicle Stimulating Hormone for Injection- Freeze Dried (Dosage form: Lyophilized Injection)	Each vial Contains Recombinant - Human Follicle Stimulating Hormone 75 IU For Subcutaneous use only Reconstitute with 0.5ml of sterile water for injection B.P. provided in this pac. To be packed as combi pack with 0.5 ml of sterile water for injection BP.
	FOLIGRAF 75 IU Follitropin Alpha For Injection(Recombinant Human Follicle Stimulating Hormone For Injection – Freeze Dried)	Each vial contains: Follitropin Alpha (Recombinant Human Follicle Stimulating Hormone) 75 IU Reconstitute with 0.5 ml of Sterilised water for Injections BP provided in this pack. To be packed as a combi pack with 0.5 ml of Sterilised Water for Injections BI. For Subcutaneous use only.
	FOLIGRAF 900 IU (MULTIDOSE) Pre Filled Pen Recombinant Human Follicle Stimulating Hormone Injection IH 900 IU (66.0 µg)/ 1.5 ml (Dosage Form: Solution for Injection in Prefilled pen-Multidose)	Each Prefilled pen containing one 3 ml Cartridge contains Recombinant-Follitropin Concentrated Solution Ph.Eur 900 IU (66.0 μg)

<u>...</u> 11 <u>12 13 14 15 16 17 18 19 20 ...</u>

Address of certifying authority : Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai – 400 051. Maharashtra, INDIA. Manarashtra, INVIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
BHARAT SERUMS AND VACCINES LIMITED NEW-WHO-GMP/CERT/XD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature 🧹

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai.



No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/I, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

r.No.	Name of the Product	Composition
	FOLIGRAF-MD 1200 IU Recombinant Human Follicle Stimulating Hormone for Injection 1200 IU (Lyophilized) (Multidose)	Each vial contains Recombinant Human Follicle Stimulating Hormone Ph.Eur 1200 IU Reconstitute with Pre-filled Syringe of Diluent Contains: m-Cresol BP 6.0 m and Water for Injection BP 2.0 ml provided with this pack .  15 disposable Syringe for administration graduated in FSH units provided with this pack .
	FOLISAN 75 IU (Recombinant - Human Follicle Stimulating Hormone for Injection) - Freeze Dried	Each Vial Contains:  Recombinant - Human Follicle Stimulating Hormone 75 IU  Reconstitute with 0.5ml of sterilised water for injections B.P. provided in this pack.  To be packed as combi pack with 0.5 ml of sterilised water for injections B.P. For Subcutaneous use only.
	FORMONE — 150 HP Urofollitropin for Injection B.P Freeze Dried (Highly Purified)	Each Vial contains: Urofollitropin BP 150 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pac . To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
	FORMONE – 75 HP Urofollitropin for Injection B.P Freeze Dried (Highly Purified)	Each Vial contains: Urofollitropin BP 75 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pac To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
	FORMONE 150 [Urofollitropin for Injection B.P.] [FSH] Freeze Dried	Each Vial contains: Urofollitropin equivalent to activity of Follicle Stimulating hormone BP 150 I Reconstitute with 1ml of Sodium Chloride Injection B.P. provided with this pack.
	FORMONE 75 [Urofollitropin for Injection B.P.][FSH] Freeze Dried	Each Vial contains: Urofollitropin equivalent to activity of Follicle Stimulating Hormone BP 75 IL Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in this page.
	FSH-R.B.A-75 HP Urofollitropin for Injection B.P Freeze Dried (Highly Purified)	Each vial contains: Urofollitropin BP 75 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pac To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
	FUNGIPLUS 50 mg (Amphotericin B for Injection U.S.P.) (Lyophilized)	Each Vial contains: Amphotericin B USP 50 mg Sodium Deoxycholate . qs

Address of certifying authority:
Food & Drug Administration, M.S.
Bangra-kurla Complex
Bangra (E), Mumbai 400 51.
Illaharashtra,INDIA.
Tel 2-91-22-26592363/64

91-22-26591958 SERUMS AND VACCIMES LIMITED -HO-GMP/CERT/KD/117-217, 022/11 Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.J

Bandra (E), Mumbai. Maharashtra State, India Date:04 Jul 2022

AWAR AS HTRA STA

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In Form 28E

No.	Name of the Product	Composition
97	GAMMA IV – 0.5	Each ml contains:
	[Normal Immunoglobulin for	Immunoglobulin G 0.05 gm
	Intravenous use B.P.]	Excipients & Stabilizer : Maltose .
		Pack Size: 10 ml .
98	GAMMA IV – 5	Each ml contains:
	(Normal Immunoglobulin for	Immunoglobulin G 0.05 gm
	Intravenous use B.P.] (Dosage form:	Excipients & Stabilizer : Maltose
	Injectable Solution)	Pack Size : 100 ml .
99	GAMMA IV	Each ml contains:
	Normal immunoglobulin for	Immunoglobulin G 0.05 gm
	intravenous use BP 0.05 g/ml	Stabilizer : Maltose 100 mg/ml
i		[Pack Size: 10 ml (Protein: 0.5 g)], [Pack Size: 50 ml (Protein: 2.5 g)] [Pack Size: 50 ml (Protein: 5.0 g)] .
.00	Ganimet	Each 5 ml vial contains:
	Antithymocyte Globulin - Equine	Antithymocyte Globulin (Equine) 250 mg
		Water for Injection USP . qs
		Excipients and stabilizers: Glycine BP , Sodium Chloride BP .
		For Intravenous use only .
.01	GOSELIN 3.6	Each Implant contains:
	Goserelin Implant BP 3.6 mg (1	Goserelin BP (as acetate) 3.6 mg
	Month Depot Injection)	Lactide / Glycolide Copolymer IH .
		For Subcutaneous Injection .
	HCG-COX 5000 1.U.	Each vial contains:
	(Chorionic Gonadotrophin Injection	Chorionic Gonadotrophin BP 5000 IU
	B.P.) (Highly Purified) (Freeze Dried)	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pa
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P. ,
	HCG-R.B.A. – 5000 HP	Each vial contains:
	Chorionic Gonadotrophin Injection	Chorionic Gonadotrophin BP 5000 IU
	B.P Freeze Dried (Highly Purified)	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pa
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P.
04	HISTOGLOB	Each rnl contains:
		Human Normal Immunoglobulin 12 mg
		Histamine Dihydrochloride BP 0.15 mcg
		Sodium Thiosulphate BP 32 mg
		Water for Injection USP . qs
		Excipients & Stabiliser: Maltose 7 %, Benzyl Alcohol BP 1 %.
		Pack size: 1 ml & 2 ml .

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
BHARAT SERUMS AND VACCINES LIMITED NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature : <

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority Food & Drug Administration, M.S.



No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
	HMG Menotrophin for Injection BP (Freeze Dried) (Highly Purified) 75 IU	Each vial contains  Menotrophin B.P. equivalent to activity of Follicle stimulating Hormone 75 IU  Luteinizing Hormone 75 IU  Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack.  To be packed as combi pack with 1 ml of Sodium Chloride Injection BP.
106	HMG-COX 75 I.U. Menotrophin for Injection B.P Freeze Dried (Highly Purified)	Each vial contains:  Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 75 IU  Luteinizing Hormone 75 IU  Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack.  To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P.
107	HMG-R.B.A- 75 HP Menatraphin for injection B.P Freeze Dried (Highly purified)	Each vial contains:  Menotrophin B.P. equivalent to activity of .  Follicle Stimulating Hormone 75 IU  Luteinizing Hormone 75 IU  Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack  To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
108	HuCoG Chorionic Gonadotrophin Injection B.P. (Human Chorionic Gonadotrophin Injection)(Freeze Dried) 5000 I.U.	Each Vial contains: Chorionic Gonadotrophin BP [Human] 5000 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in this pack
	HuCoG – 10000 HP Highly Purified Chorionic Gonadotrophin Injection 10000 I.U.	Each ml contains: Chorionic Gonadotrophin highly purified IH 10000 IU Water for Injection USP . qs
	HuCoG – 10000 I.U. Chorionic Gonadotrophin Injection 10000 I.U.	Each ml contains: Chorionic Gonadotrophin highly purified IH 10000 IU Water for Injection USP . qs
	HuCoG – 2000 HP (Highly Purified Chorionic Gonadotropin Injection 2000 I.U.)	Each ml contains: Charionic Gonadotropin highly purified IH 2000 IU Water for Injection USP . qs
112	HuCoG – 2000 I.U.	Each ml contains:

... <u>11 12 13 14 15 16 17 18 19 20 ...</u>

Chorionic Gonadotropin Injection

Address of certifying authority: Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai – 400 051.

Maharashtra,INDIA.

2000 I.U.

Tel: +91-22-26592363/64
Fax: +91-22-26591959
8HAART SERUMS AND VACCINES LIMITED NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Water for Injection USP . qs

Signature 5

Chorionic Gonadotropin highly purified IH 2000 IU

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S. -

Bandra (E), Mumbai. Maharashtra State, India Date:04 Jul 2022 SELES LOMMANST

ASUTA TIME

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
113	HUCOG – 5000	
	(Chorionic Gonadotrophin Injection	Each vial contains: Chorionic Gonadotrophin BP 5000 IU
	B.P.) (Freeze Dried) (FOR MALAYSIA	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack.
	ONLY)	
		For Subcutaneous & Intramuscular use
114	HuCoG – 5000 HP	Each vial contains:
	(Chorionic Gonadotrophin Injection	Chorionic Gonadotrophin BP 5000 IU
	B.P Freeze Dried) (Highly Purified)	Reconstitute with 1ml of Sodium Chloride Injection B.P. provided in the pack.
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P.
115	U. C. C. T000 U.S.	
	HuCoG — 5000 HP Highly Purified Charianic	Each ml contains:
	Gonadotrophin Injection 5000 I.U.	Chorionic Gonadotrophin highly purified IH 5000 IU
	donado doprim injection 3000 i.o.	Water for Injection USP . qs
116	HuCoG – 5000 I.U.	Each ml contains:
	Chorionic Gonadotrophin Injection	Chorionic Gonadotrophin highly purified IH 5000 IU
	5000 I.U.	Water for Injection USP . gs
	HUCOG 5000 IU	Each Vial Contains
		Chorionic Gonadotrophin BP 5000 IU
	B.P. (Highly Purified) (Freeze Dried)]	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the park
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P.
118	HuMoG – 150 I.U.	Each vial contains:
	(Menotrophin for injection B.P.)	Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 150
	(Freeze Dried) (FOR MALAYSIA	IU
	ONLY)	Luteinizing Hormone 150 IU
		Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack.
		, The state of the
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
119	HuMoG – 75 I.U.	Each vial contains:
	(Menotrophin for injection B.P.)	Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 75 IU
İ	(Freeze Dried) (FOR MALAYSIA	Luteinizing Hormone 75 IU
	ONLY)	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack.
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
120	HUMOG 150	Each vial contains
	Menotrophin for Injection BP	Each vial contains  Menotrophin BP equivalent to Activity of Follicle Stimulating Hormone 150 IL
	(Freeze Dried)(Highly Purified) (For	Luteinizing Hormone 150 IU
	Export only in Philippines)	Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection BP .
		To be passed as contact pack that I may be solded an emotion injection of
	<u> </u>	

<u>... 11 12 13 14 15 16 17 18 19 20 ...</u>

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

BHARAT SERUMS AND VACCINES LIMITED - NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/I, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
121	HUMOG 150 IU	Each Vial Contains
ļ	[Menotrophin for Injection B.P (Highly Purified) (Freeze Dried)]	Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 150 IU
		Luteinizing Hormone 150 IU
- 1		Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack.
		To be packed as combi pack with 1 ml of Sodium Chloride Injection BP .
	HUMOG 150 IU	Each vial contains:
	Menotrophin for injection B.P Freeze Dried (For Russia Export	Menotrophin B.P. equivalent to activity of .
	Only)	Follicle Stimulating Hormone 150 IU Luteinizing Hormone 150 IU
- 1		Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
123	HUMOG 75	Each vial contains
i	Menotrophin for Injection BP (Freeze Dried) (Highly Purified) (For	Menotrophin BP equivalent to Activity of Follicle Stimulating Hormone 75 IU Luteinizing Hormone 75 IU
	Export only in Philippines)	Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection BP .
- 1	HuMoG -75 HP	Each vial contains:
	(Menotrophin for Injection B.P.	Menotrophin B.P. equivalent to activity of Follicle-stimulating Hormone 75 IU
	(Highly Purified) -Freeze Dried	Luteinizing Hormone 75 IU
		Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
	HUMOG 75 IU [Menotrophin for Injection B.P (Highly Purified) (Freeze Dried)]	Each Vial Contains:
		Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 75 IU
1		Luteinizing Hormone 75 IU Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection BP .
126	HUMOG 75 IU	Each vial contains:
1	Menotrophin for injection B.P	Menotrophin B.P. equivalent to activity of .
l l	Freeze Dried (For Russia Export Only)	Follicle Stimulating Hormone 75 1U
ľ		Luteinizing Hormone 75 IU
		Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack  .
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P.,
- 1	HUMOG BSV 150 HP	Each vial contains
1	Menotrophin for Injection BP	Menotrophin BP equivalent to activity of Follicle stimulating Hormone 150 IU
	(Freeze Dried) (Highly Purified)	Luteinizing Hormone 150 IU
		Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack To be packed as combi pack with 1 ml of Sodium Chloride Injection BP .
128	HUMOG BSV 75 HP	Each vial contains
ľ	Menotrophin for Injection BP	Each vial contains  Menotrophin BP equivalent to activity of Follicle stimulating Hormone 75 IU
	(Freeze Dried) (Highly Purified)	Luteinizing Hormone 75 IU
		Reconstitute with 1 ml of Sodium Chloride Injection BP provided in this pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection BP

<u>... 11 12 13 14 15</u> 16 <u>17 18 19 20 ...</u>

Address of certifying authority:
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26591959
BHARAT SERUMS AND VACCINES LIMITED-NEW-WHO-GMP/CERT/ND/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature: 🕢

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.



No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/I, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506 MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In Form 28E

Sr.No.	Name of the Product	Composition
129	HuMoG-150 HP (Menotrophin for Injection B.P. (Highly Purified) -Freeze Dried	Each vial contains:  Menotrophin B.P. equivalent to Activity of Follicle stimulating Hormone 150 IU  Luteinizing Hormone 150 IU  Reconstitute with 1ml of Sodium Chloride Injection B.P. provided in the pack.  To be packed as combi pack with 1 ml of Sodium Chloride injection B.P
130	IMMUNEX – 2.5 (Normal Immunoglobulin for Intravenous use B.P.)	Each ml contains: Immunoglobulin G 0.05 gm Excipients & Stabilizer : Maltose 。 Pack Size : 50 ml .
131	IMMUNEX – 5 (Normal Immunoglobulin for Intravenous use B.P.)	Each ml contains: Immunoglobulin G 0.05 gm Excipients & Stabilizer : Maltose , Pack Size : 100 ml .
132	INMUKORP I.V. – 5 (Normal Immunoglobulin for Intravenous use B.P.)	Each ml contains: Immunoglobulin G 0.05 gm Excipients & Stabilizer: Maltose , Pack Size: 100 ml .
133	INMUKORP I.V. – 2.5 (Normal Immunoglobulin for Intravenous use B.P.)	Each ml contains: Immunoglobulin G 0.05 gm Excipients & Stabilizer: Maltose . Pack Size: 50 ml .
134	INMUKORP Rho-D Anti Rho-D Immunoglobulin Injection (Monoclonal)300 mcg (Freeze Dried)	Each vial contains  Monoclonal Anti Rho-D Immunoglobulin IHS 300 mcg  To be reconstituted with 2 ml of Sterile Water for Injection USP provided with this pack.
135	INMUKORP TET Tetanus Immunoglobulin B.P. (Human) 250 I.U.	Each Vial Contains Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 250 IU Stabiliser: Glycine BP 0.3 M reservative: Thiomersal BP 0.1 % w/v Pack Size: 1 ml vial.
136	KARMA – FSH 75 [Urofollitropin for Injection B.P.] [FSH] Freeze Dried	Each Vial contains: Urofollitropin equivalent to activity of Follicle Stimulating Hormone BP 75 U

... 11 12 13 14 15 16 17 18 19 20 ...

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
BHARAT SERUMS AND VACCINES LIMITED NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India



No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
137	KARMA – HCG 5000 [Chorionic Gonadotrophin for Injection B.P.(Human)] Freeze Dried	Each Vial contains: Chorionic Gonadotrophin [Human] BP 5000 IU
138	KARMA – KINASE (Lyophilized) Streptokinase for Injection B.P.	Each Vial contains: Streptokinase BP 7,50,000 IU Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
139	KARMA – KINASE (Lyophilized) Streptokinase for Injection B.P.	Each Vial contains: Streptokinase BP 15,00,000 IU Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
140	KARMA FSH 150 HP (Urofollitropin for Injection B.P.) (Freeze Dried) (Highly Purified)	Each vial contains: Urofollitropin BP 150 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
141	KARMA FSH 75 HP (Urofollitropin for Injection B.P.) (Freeze Dried) (Highly Purified)	Each vial contains: Urofollitropin BP 75 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
142	KARMA HCG 5000 HP (Chorionic Gonadotrophin Injection B.P.) (Freeze Dried)(Highly Purified)	Each vial contains: Chorionic Gonadotrophin BP 5000 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack. To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P.
	KARMA HMG 150 HP {Menotrophin for Injection B.P.) (Freeze Dried) (Highly Purified)	Each vial contains: Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 150 IU Luteinizing Hormone 150 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack. To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
	KARMA HMG 75 HP (Menotrophin for Injection B.P.) (Freeze Dried) (Highly Purified)	Each vial contains: Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 75 IU Luteinizing Hormone 75 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
11 3	21309 15 NE 1018 19.20	N

Address of pertifying authority
Fords Drug Administration, M.S.
Fardra-kurla Complex,
Fandra (E), Mumbai - 400 051.
Mainerashtra,INDIA
Pel: +91-22-265923 sign
Fax: +91-22-26591951
Pelahart SERUMS AND V. 2015 LIMITEDNEW WHO-GMP/CERT/RD, V. 2015 LIMITEDNEW WHO-GMP/CERT/RD, V. 2017

SALVASUTE STATE

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S. Bandra (E), Mumbai.

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/I, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
145	L-AMPHO	Each ml contains:
	(Amphotericin B Lipid Complex Injection I.V.)	Amphotericin B USP 5 mg
		Sodium Chloride BP 9 mg
		Water for Injection USP . gs
		Lipids: Dimyristoylphosphatidylcholine [DMPC] 3.4 mg
		Lipids: Dimyristoylphosphatidylglycerol [DMPG as Sodium salt] 1.5 mg
		Pack Size: 2 ml, 10 ml and 20 ml.
		This product will be manufactured by M/s. Bharat Serums and Vaccines Ltd.
		will be combipacked alongwith a Pre-Sterilized Filter needle.
	LEUPROLIDE ACETATE FOR	Each Vial contains
	INJECTION 3.75 MG (DEPOT)	(As lyophilized powder) .
		Leuprorelin (As Acetate) BP 3.75 mg
	LIFOCIN - B	Each ml contains:
	[Amphotericin B Lipid complex	Amphotericin B USP 5 mg
	Injection I.V.]	Water for Injection USP . qs
- 1		Lipids: Dimyristoylphosphatidylcholine [DMPC] 3.4 mg
		Lipids: Dimyristoylphosphatidylglycerol [DMPG as Sodium salt] 1.5 mg
	LIPO AMPHOTERICIN B BHARAT	Each vial contains
	Liposomal Amphotericin B Powder for Solution for Infusion 50 mg	Amphotericin B (Intercalated into liposomal membrane) Ph.Eur 50 mg
149	LIPOTERICIN	Each vial contains:
ļ	[Amphotericin B for injection	Amphotericin B USP 50 mg
İ	U.S.P.]Lyophilized	Sodium Deoxycholate . qs
	L-THYMO (Injection)	Each 5ml vial contains:
	(Antithymocyte Globulin - Equine)	Antithymocyte Globulin (Equine) 250 mg
		Water for Injection USP . qs
		For Intravenous Use only .
151	LUPRODEX 3.75 MG ( DEPOT)	Each vial Contains (as Lyophilized Powder)
	(Leuprolide Acetate for Injection	Leuprorelin (As acetate) BP 3.75 mg
	3.75 mg) (DEPOT)	To be reconstituted with 1 ml of the Diluent [ ( Diluent for Leuprolide Aceta
		for Injection) (DEPOT)] Provide with the pack .
	LUPRODEX DEPOT 11.25 MG	Each vial contains (As Lyophilized Powder)
1	(Depot)	Leuprorelin (As Acetate) BP 11.25 mg
	Leuprolide Acetate for Injection 11.25 mg (Depot)-Lyophilized - 3	To be reconstituted with Diluent (Diluent for Luprodex 11.25 mg Depot) provided with the pack.
ŀ	Month Depot	For Intramuscular use/ Subcutaneous use .
		For Single use only .

<u>... 11 12 13 14 15 16 17 18 19 20 ...</u>

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
BHARAT SERUMS AND VACCINES LIMITED –
NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India Date:04 Jul 2022 AND DRUGE TOWN

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED
PLOT NO K-27 K-27 PART AND K-27/1

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	. Name of the Product	Composition
153	MENACT 75	Each vial contains:
	Menatrophin for Injection BP -	Menotrophin B.P. equivalent to activity of .
	Freeze Dried (Highly Purified)	Follicle stimulating Hormone 75 IU
	(Powder for Injection)	Luteinizing Hormone 75 IU
		Reconstitute with 1ml of Sodium Chloride Injection B.P. provided in the pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
154	MENOFER 75 HP	Each vial contains:
	Menotrophin for Injection B.P Freeze Dried (Highly Purified)	Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 75 IU Lutelnizing Hormone 7S IU
		Reconstitute with 1ml of Sodium Chloride Injection B.P. provided in the pack To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
155	NORMAL IMMUNOGLOBULIN FOR	Each ml contains:
	INTRAVENOUS USE B.P.	Immunoglobulin G 0.05 gm Pack Size: 50 ml .
156	NORMAL IMMUNOGLOBULIN FOR	Each ml contains:
	INTRAVENOUS USE B.P.	Immunoglobulin G 0.05 gm
		Pack Size: 100 ml .
157	ORMOLON FSH 150	Each vial contains
	Recombinant - Human Follicle	Recombinant - Human Follicle Stimulating Hormone IHS 150 IU
	Stimulating Hormone for Injection- Freeze Dried	For Subcutaneous use only .
	Freeze Direct	Reconstitute with 0.5ml of sterile water for injection B.P. provided in this page
		To be packed as combi pack with 0.5 ml of sterile water for injection B.P
		To be packed as combi pack with 0.5 fm of sterile water for injection b.r.
158	ORMOLON FSH 75	Each vial contains
	Recombinant-Human Follicle	Recombinant - Human Follicle Stimulating Hormone IHS 75 IU
	Stimulating Hormone for Injection-	For Subcutaneous use only .
	Freeze Dried	Reconstitute with 0.5ml of sterile water for injection B.P. provided in this page
		To be packed as combi pack with 0.5 ml of sterile water for injection BP .
159	ORMOLON HCG 5000 IU	Each Vial Contains
	Chorionic Gonadotrophin Injection	Chorionic Gonadotrophin BP 5000 IU
	B.P. 5000 IU - Freeze Dried (Highly	Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack
	Purified)	To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P
160	ORMOLON HMG 150 IU	Each Vial Contains
	Menotrophin for injection B.P. 150 IU - Freeze Dried (Highly Purified)	Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 150 IU
		Luteinizing Hormone 150 IU
		Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pact
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P

<u>... 11 12 13 14 15 16 17 18 19</u> 20 <u>...</u>

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 BHARAT SERUMS AND VACCINES LIMITED -NEW-WHO-GMP/CERT/KD/107921/2022/11 /39826 Name of the Authorised person : D. R. GAHANE
Signature

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S. Bandra (E), Mumbai.



No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506 MAHARASHTRA STATE, INDIA KD360 In Form 28, KD4

Drug License No

In Form 28D, KD5 In

Form 28E

r.No.	Name of the Product	Composition
161	ORMOLON HMG 75 IU	Each Vial Contains
		Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 75 IU
ŀ	- Freeze Dried (Highly Purified)	Luteinizing Hormone 75 IU
		Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P. ,
162	Ovifol – R 150 I.U.	Each vial contains:
	(Recombinant - Human Follicle	Recombinant - Human Follicle Stimulating Hormone 150 IU
1	Stimulating Hormone for Injection)	For Subcutaneous use only .
	- Freeze Dried	Reconstitute with 0.5ml of sterilised water for injections B.P. provided in this pack
		To be packed as combi pack with 0.5 ml of sterilised water for injections B.P
163	Ovifol – R 75 1.U.	Each vial contains:
	(Recombinant - Human Follicle	Recombinant - Human Follicle Stimulating Hormone 75 IU
	Stimulating Hormone for Injection)	For Subcutaneous use only .
1	- Freeze Dried	Reconstitute with 0.5ml of sterilised water for injections B.P. provided in this
		pack
		To be packed as combi pack with 0.5 ml of sterilised water for injections B.P.
164	PEGNEL [Chorionic gonadotrophin for Injection B.P. (Human)] 5000 I.U. Freeze Dried	Each vial contains:
		Chorionic Gonadotrophin BP (Human) 5000 IU
		Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack
		To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P.
165	POLAXIN B	Each vial contains
	Polymyxin B for Injection U.S.P	Polymyxin B Sulphate U.S.P. Equivalent to Polymyxin B 500000 Units
	Lyophilized	For intrathecal / IM / IV Infusion .
		To be reconstituted with 5ml of Sterile water for Injection U.S.P
166	POLYMxB 25 mg	Each Vial Contains:
	Polymyxin B for Injection USP 25	Polymyxin B Sulphate USP equivalent to sum of Polymyxin B1, B2, B3, B1-I 25
	mg (Lyophilized)	mg
		For Intrathecal / I.M / I.V. Infusion .
167	POLYMxB 50 mg	Each Vial Contains:
	Polymyxin B for Injection USP 50	Polymyxin B Sulphate USP equivalent to sum of Polymyxin B1, B2, B3, B1-I 50
	mg (Lyophilized)	mg
		For Intrathecal / I.M / I.V. Infusion
168	POLYMX-E 1	Each vial contains
	Colistimethate Sodium for Injection	Colistimethate Sodium BP 1000000 IU
	BP 1 MIU (Lyophilized)	To be reconstituted using Sodium Chloride Injection BP or Water for Injection BP.
		For I.V. use only . Single dose vial .

... 18 19 20 21 22 23 24 25 26 27

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/39826

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Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
169	POLYMX-E 2	Each vial contains
	Colistimethate Sodium for Injection	Colistimethate Sodium BP 2000000 IU
	BP 2 MIU (Lyophilized)	To be reconstituted using Sodium Chloride Injection BP or Water for Injection BP .
		For I.V. use only .
		Single dose vial .
170	POLYMYXIN B FOR INJECTION U.S.P.	Each vial contains:
		Polymyxin B Sulphate equivalent to Polymyxin B USP 5,00,000 Units
		To be reconstitute with 5 ml Sterile Water for Injection I.P.
		For Intrathecal/ IM/ IV Infusion .
171	R- FORMONE 75 I.U.	Each vial contains:
	[Recombinant - Human Follicle	Recombinant - Human Follicle Stimulating Hormone 75 IU
	Stimulating Hormone for Injection]  -Freeze Dried	Reconstitute with 0.5 ml of Sterilised water for injections B.P. provided in this pack
		To be packed as combi pack with 0.5ml of Sterilised water for injections B.P
		For Subcutaneous Use only .
172	RABIES ANTISERUM EQUINE	
	(Antirabies immunoglobulin Bulk) NLT 200 IU/ ml	
173	R-FORMONE 150 I.U.	Each vial contains:
	Recombinant-Human Follicle	Recombinant-Human Follicle Stimulating Hormone IHS 150 IU
	Stimulating Hormone for Injection- Freeze Dried	Reconstitute with 0.5 ml of Sterillised water for Injections BP provided in this Pack.
		To be packed as combi pack with 0.5ml of Sterilised water for injections B.P.
		For Subcutaneous Use only .
174	R-FORMONE 75 IU	Each Vial Contains:
	[Recombinant-Human Follicle	Recombinant - Follitropin Concentrated Solution Ph.Eur 75 IU
	Stimulating Hormone for Injection -	For Subcutaneous use only .
	Freeze Dried]	Reconstitute with 0.5 ml of Sterilised water for injections B.P. provided in this pack.
		To be packed as combi pack with 0.5 ml of Sterilised water for injections B.P.
175	r-FSH-COX 75 I.U.	Each vial contains:
	[Recombinant - Human Follicle	Recombinant - Human Follicle Stimulating Hormone 75 IU
	Stimulating Hormone for Injection]  —Freeze Dried	Reconstitute with $0.5 \mathrm{ml}$ of sterilised water for injections B.P. provided in this pack
		To be packed as combi pack with 0.5 ml of sterilised water for injections B.P.
		qs
176	r-FSH-COX 75 I.U.	Each Vial Contains
	Recombinant - Human Follicle	Follitropin Concentrated Solution (Recombinant) Ph.Eur 75 IU
	Stimulating Hormone for Injection	For Subcutaneous and Intramuscular use only .
	–Freeze Dried	Reconstitute with 0.5 ml of Sterilised water for injections B.P. provided in this pack
		To be packed as combi pack with 0.5ml of Sterilised water for injections B.P
	10 20 21 22 22 24 25 27 27	

<u>... 18 19 20 21 22 23 24 25 26 27</u>

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BHARAT SERUMS AND VACCINES LIMITED NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S. Bandra (E), Mumbal.



No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

Drug License No

MAHARASHTRA STATE, INDIA KD360 In Form 28, KD4 In Form 28D, KD5 In Form 28E

r.No.	Name of the Product	Composition
177	RHOCLONE 150 mcg	Each vial contains:
	(Anti Rho-D Immunoglobulin	Monoclonal Anti Rho-D Immunoglobulin 150 mcg
1	Injection) (Monoclonal) (Freeze	To be reconstituted with 1 ml of sterile water for Injection U.S.P. provided
	Dried)	with this pack .
	RHOCLONE 150 mcg	Each ml contains:
	[Anti – D (Rho) Immunoglobulin]	Anti Rho - D Immunoglobulin 150 mcg
	(Monoclonal) (Liquid Injection)	Water for Injection USP , qs
	RHOCLONE 300mcg	Each vial contains:
	(Anti Rho-D Immunogiobulin	Monoclonal Anti Rho-D Immunoglobulin 300 mcg
- 1	Injection) (Monoclonal) (Freeze Dried)	To be reconstituted with 2ml of sterile water for Injection U.S.P. provided with a poly
		this pack .
	RHOCLONE 300mcg (Anti Rho-D Immunoglobulin	Each ml contains:
	Injection) (Monoclonal) (Liquid	Anti Rho-D Immunoglobulin 300 mcg
ì	Injection)	Water for Injection USP , qs
- 1	r-HUCOG	Each Pre-filled Syringe contain
- 1	RECOMBINANT HUMAN	Recombinant Human Chorionic Gonadotropin IH 6500 IU
Į	CHORIONIC GONADOTROPIN FOR INJECTION (r-HCG) 6500 IU	Water for Injection BP . qs
	SNAKE VENOM ANTISERUM	Each ml neutralizes the following quantities of standard venoms of:
		Cobra 0.6 mg
		Common Krait 0.45 mg
		Russell's viper 0.6 mg
		Saw-scaled Viper 0.45 mg
		Preservative: Cresol BP NMT 0.25 % v/v
ŀ		Stabilizer: Glycine B.P Excipient: Mannitol B.P. & Sodium chloride B.P
		Pack size: 10ml, 20ml, 50ml .
183	SNAKE VENOM ANTISERUM	After reconstitution each ml neutralizes the following quantities of standard
- 1	(Lyophilized)	venoms of:
1		Cobra 0.6 mg
		Common Krait 0.45 mg
		Russell's Viper 0.6 mg
		Saw-scaled Viper 0.45 mg
		Preservative: Cresol BP NMT 0.25 % v/v
		Stabilizer: Glycine BP .
184	SNAKE VENOM ANTISERUM IP	Each ml neutralizes the following quantities of standard venoms of:
		Cobra 0.6 mg
		Common Krait 0.45 mg
		Russel's Viper 0.6 mg
		Saw-scaled viper 0.45 mg
		Preservative : Cresol IP NMT 0.25 % v/v

Address of certifying authority : Food & Drug Administration, M.S. Bandra-kurla Complex,

Bandra (E), Mumbai - 400 051. Maharashtra, INDIA.

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BHARAT SERUM SAND VACCINES LIMITED - NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India



No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4

In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
185	SODIUM CHLORIDE INJECTION B.P.	Each pack contains:
	(Small Volume parenterals)	Sodium Chloride BP 0.9 % w/v
		Water for Injection BP . qs
		Pack Size: 2 ml .
186	STERILE WATER FOR INJECTION	
	U.S.P. (Small Volume Parenterals)	Pack Size: 2 ml .
	STERILISED WATER FOR INJECTIONS	
	B.P. (Small Volume parenterals)	Pack Size: 1.0 ml .
	STREPTOKINASE FOR INJECTION B.P.	Each Vial contains:
	(Lyophilized)	Streptokinase BP 7,50,000 IU
		Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
	STREPTOKINASE FOR INJECTION B.P.	Each Vial contains:
İ	[Lyophilized]	Streptokinase BP 15,00,000 IU
		Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
I	STREPTOLASE 15,00,000 I.U.	Each Vial contains:
	[Streptokinase for Injection B.P.] -	Streptokinase BP 1500000 IU
	Lyophilized	Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
	ı	For I.V. Use .
l l	STROKINASE	Each Vial contains:
	Streptokinase for Injection B.P.	Streptokinase BP 15,00,000 IU
	(Lyophilized)	Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
	Tetanus immunoglobulin B.P 1000	Each vial contains:
	I.U. (Human)	Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 1000 IU

... 18 19 20 21 22 23 24 25 26 27

Address of certifying authority:

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Bandra-kurla Complex,

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BHARAT SERUMS AND VACCINES LIMITED NEW-WHO-GMP/CERT/KD/107921/2022/11
/39826

Name of the Authorised person: D. R. GAHANE

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Maharashtra State, India



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/39826

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BHARAT SERUMS AND VACCINES

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PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

Drug License No

KD360 In Form 28, KD4

In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
193	Tetanus Immunoglobulin B.P 250	Each vial contains:
	I.U. (Human)	Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 250 IU
	Tetanus Immunoglobulin B.P 500	Each vial contains:
	I.ປ. (Human)	Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 500 IU
195	TETGLOB 250 I.U.	Each vial contains:
	[Tetanus Immunoglobulin B.P.] {Human)	Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 250 IU
196	TETGLOB 500 I.U.	Each vial contains:
	[Tetanus Immunoglobulin B.P.] (Human)	Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 500 IU
197	TETGLOB 1000 I.U.	Each vial contains:
	Tetanus Immunoglobulin B.P (Human)	Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 1000 IU
198	THROMBOFLUX	Each vial contains:
	(Streptokinase for Injection B.P.)	Streptokinase BP 750000 IU
	Lyophilized	Excipients and stabilizers: .
		Human Albumin B.P 0.17mg/ 1 lac I.U
		Polygeline / Gelofusin 2.67mg/ 1 lac I.U
		For I.V. Use .
199	THROMBOFLUX	Each vial contains:
	[Streptokinase for injection	Streptokinase BP 1500000 IU
	B.P.](LYOPHILIZED)	Excipients: Human Albumin BP 0.17 mg/1 lac I.U., Polygeline / Gelofusin
		2.67 mg / 1 lac I.U
		For I.V. use
200	THROMBOFLUX 7,50,000 IU	Each Vial Contains:
	[Streptokinase for Injection BP	Streptokinase BP 7,50,000 IU
	7,50,000 IU - Lyophilized]	Excipients and Stabilizers : Human Albumin BP 0.17 mg/1 lac IU, Gelofusii
		2.67 mg/1 lac IU .

<u>... 18 19 20 21 22 23 24 25 26 27</u>

Address of certifying authority:

Food & Drug Administration, M.S

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Name of the Authorised person : D. R. GAHANE

Signature :

Stamp and Date: Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India

No. of certificate

NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

BHARAT SERUMS AND VACCINES

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
	THROMBOFLUX 15,00,000 IU Streptokinase for Injection BP 15,00,000 IU	Each Vial Contains::  Streptokinase BP 1500000 IU  Excipients and Stabilizer: Human Albumin BP 0.17 mg/1 lac I.U., Gelofusin  2.67 mg / 1 lac I.U  For I.V. use.
	THYMOGAM (Antithymocyte Globulin- Equine) (Injectable Solution)	Each 5 ml vial contains Antithymocyte Globulin (Equine) 250 mg Water for Injection USP . qs For Intravenous use only
	THYMOGAM-250 Anti-T Lymphocyte Immunoglobulin for Human use, Animal 250 mg Ph.Eur	Each 5 ml vial contains Antithymocyte Globulin (Equine) 250 mg Water for Injection USP . qs For intravenous use only .
	U – FRAG Urokinase for Injection (Lyophilized)	Each Vial contains: Urokinase BP 5,00,000 IU Excipients and stabilizers: Human Albumin B.P., Sodium citrate B.P., Disodiun hydrogen phosphate Dihydrate B.P., Sodium dihydrogen phosphate Dihydrate B.P B.P For J.V. use
	U-Frag Urokinase for Injection 5000 IU (Lyophilized)	Each vial contains: Urokinase IP 5000 IU Excipients and Stabilizer added: Human Albumin I.P., Mannitol I.P., Disodium Hydrogen Phosphate Dihydrate B.P., Sodium Dihydrogen Phosphate Dihydrate I.P., Phosphoric acid I.P.
	U-TRYP - 100,000 I.U. Ulinastatin for Injection 100,000 I.U. (Lyophilized)	Each vial contains: Ulinastatin JP 100000 IU For I.V. use in Infusion . Reconstitute with 5 ml 0.9 % normal saline or Dextrose 5 % . Pack Size : 5 ml vial .
	U-TRYP 100000 IU [Ulinastatin for Injection 100000 IU] (Liquid) (Dosage Form : Injectable Solution)	Each 4 ml contains Ulinastatin JP 100000 IU For I.V. Infusion .
	WELLOBACTIN- B 25 Polymyxin B for Injection U.S.P. 25 MG (Lyophilised)	Each vial contains Polymyxin B Sulphate U.S.P. equivalent to sum of Polymyxin B1, B2, B3, B1-I 25 mg For Intrathecal / I.M. / I.V. Infusion .

<u>... 18 19 20 21 22 23 24 25 26 27</u>

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NEW-WHO-GMP/CERT/KD/107921/2022/11 VALID UP TO :29 Mar 2025

/39826

Name of Manufacturing Firm

**BHARAT SERUMS AND VACCINES** 

LIMITED

PLOT NO K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506

MAHARASHTRA STATE, INDIA

**Drug License No** 

KD360 In Form 28, KD4 In Form 28D, KD5 In

Form 28E

Sr.No.	Name of the Product	Composition
	WELLOBACTIN- B 50 Polymyxin B for Injection U.S.P. 50 MG (Lyophilised)	Each vial contains Polymyxin B Sulphate U.S.P. equivalent to sum of Polymyxin B1, B2, B3, B1-I 50 mg For Intrathecal / I.M. / I.V. Infusion .
	ZIKINAZ 1500000 I.U. Streptokinase for Injection B.P. (Lyophilized)	Each vial contains: Streptokinase BP 1500000 IU Excipients: Human Albumin BP 0.17 mg/1 lac I.U., Polygeline / Gelofusin 2.67 mg / 1 lac I.U For I.V. use

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

BHARAT SERUMS AND VACCINES LIMITED -NEW-WHO-GMP/CERT/KD/107921/2022/11

/39826

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration/M.S.

Bandra (E), Mumbai. Maharashtra State, India

