



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.

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

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients ( Bulk Drugs)	Anti-sera / Anti-Toxin	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	Active Pharmaceutical Ingredients ( Bulk Drugs)	Blood Products	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
3	Active Pharmaceutical Ingredients ( Bulk Drugs)	General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones )	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Active Pharmaceutical Ingredients ( Bulk Drugs)	Hormones	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Active Pharmaceutical Ingredients ( Bulk Drugs)	Recombinant Vaccines / Drugs	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
6	Dry Powder Injections	Blood Products	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

1 2 3

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 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  
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## 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.

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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.





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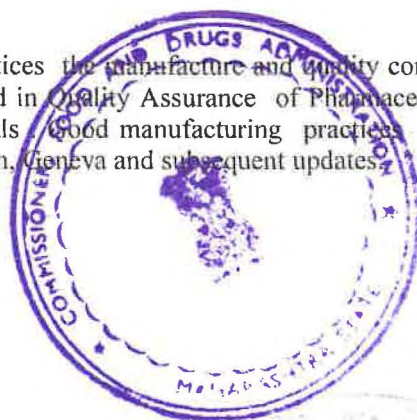
Pharmaceutical Product (s) <sup>1</sup>	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

#### Example - 2.

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

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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

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Signature :   
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Dosage form (s)		
Tablets	Cytotoxic	Packaging
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	Cefalosporin	Aseptic preparation, Packaging, Labelling.

### Example - 2.

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

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**Drug License No** : KD360 In Form 28, KD4 In Form 28D, KD5 In Form 28E



Sr.No.	Name of the Product	Composition
1	AMPHOTERICIN B EMULSION	Each ml contains: Amphotericin USP 5 mg
2	ANTI RHO - D IMMUNOGLOBULIN (MONOCLONAL)- BULK	
3	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 .
4	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
5	Cetorelix Acetate for Injection 0.25 mg (Lyophilized)	Each Vial Contains: Cetorelix (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 .
6	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)
7	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)	Each Prefilled pen containing one 3 ml Cartridge contains Follicle Stimulating Hormone concentrated solution (Follitropin concentrated solution) (Human Recombinant) IP 450 IU (33.0 µg )
8	LIPOSOMAL AMPHOTERICIN B POWDER FOR SOLUTION FOR INFUSION 50 MG (LYOPHILIZED)	Each Vial Contains: Amphotericin B (Intercalated into liposomal membrane) Ph.Eur 50 mg

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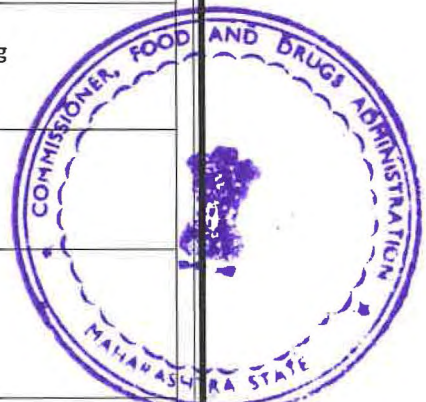
**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

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**Drug License No** : KD360 In Form 28, KD4 In Form 28D, KD5 In Form 28E

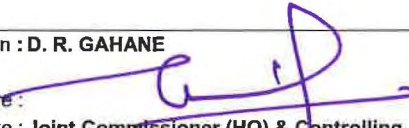
Sr.No.	Name of the Product	Composition
9	MENOTROPHIN FOR INJECTION B.P. 150 I.U. (Freeze Dried) (Highly Purified)	Each vial contains: Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone 150 IU Luteinizing Hormone 150 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided 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 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	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	
14	RECOMBINANT ANTI RHO-D IMMUNOGLOBULIN (r-ANTI-D; IgG1) Purified Liquid bulk drug: 5.00 mg/mL to 10.00 mg/mL	
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	



1 2 3 4 5 6 7 8 9 10 ...

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Sr.No.	Name of the Product	Composition
17	SNAKE VENOM ANTISERUM (LYOPHILIZED)	After reconstitution 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 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 pack .
18	SNAKE VENOM ANTISERUM I.P. (LYOPHILIZED)	After reconstitution 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 BP . NMT 0.25 % v/v, Stabilizer: Glycine BP, Excipients: Mannitol BP & Sodium Chloride BP .
19	UROFOLLITROPIN FOR INJECTION B.P. 150 I.U. (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. .
20	UROFOLLITROPIN FOR INJECTION B.P. 75 I.U. (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. .
21	UROKINASE FOR INJECTION Lyophilized	Each vial contains: Urokinase BP 500000 IU Excipients and Stabilizers : Human Albumin B.P 20 mg, Sodium Citrate B.P. 24 mg, Disodium Hydrogen Phosphate B.P. ... 7.8 mg, Sodium Dihydrogen Phosphate Dihydrate B.P. ... 20 mg . For I.V. Use .
22	AMPHOLIP (Combipack) [Amphotericin B Lipid Complex Injection I.V.]	Each ml Contains Amphotericin B USP 5 mg Sodium chloride BP 9 mg Water for Injection USP . qs Lipids: Dimyristoylphosphatidylcholine [DMPC] 3.4 mg Lipids: Dimyristophosphatidylglycerol [DMPG as sodium salt] 1.5 mg Pack Size : 2 ml, 10 ml, 20 ml . 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) .



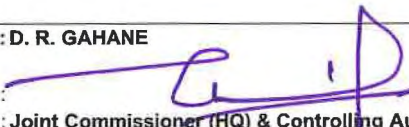
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23	<b>AMPHOMUL</b> (Amphotericin B Emulsion)	Each ml Contains Amphotericin B USP 5 mg In a vehicle containing Soybean oil USP . Glycerin USP . Purified Egg Lecithin IH Sodium Hydroxide USP . water for injection USP .
24	<b>BHARGLOB 16.5 %</b> [Human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

1 2 3 4 5 6 7 8 9 10 ...

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Sr.No.	Name of the Product	Composition
25	POLY-MxB Polymyxin B for Injection U.S.P.- Lyophilized	Each vial Contains 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 [Antithymocyte Globulin - Equine]	Each 5ml vial Contains Antithymocyte Globulin (Equine) 250 mg Water for Injection USP . qs For Intravenous Use only .
27	AMPHO Amphotericin B for Injection U.S.P. - (Lyophilized)	Each vial contains: Amphotericin B USP 50 mg Sodium Deoxycholate . qs
28	AMPHOLIP CF Amphotericin B Lipid Complex Injection I.V. (Combi-pack)	Each ml contains Amphotericin B USP 5 mg 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 combi-packed along with a Pre-Sterilized filter needle .
29	AMPHOMED [Amphotericin B for Injection U.S.P.] (Lyophilized)	Each vial contains: Amphotericin B USP 50 mg To be reconstituted with 10ml of Sterile Water for Injection U.S.P. .
30	AMPHOMILL Amphotericin B for Injection USP (Lyophilized)	Each vial contains Amphotericin B USP 50 mg Sodium Deoxycholate . qs
31	AMPHONEX Liposomal Amphotericin B Injection (Lyophilized)	Each vial contains: Amphotericin B Ph.Eur 50 mg Intercalated into liposomal membrane . Excipients . qs
32	AMPHONEX Liposomal Amphotericin B Powder for Solution for Infusion 50 mg (Lyophilized)	Each vial contains: Amphotericin B (Intercalated into liposomal membrane) Ph.Eur 50 mg

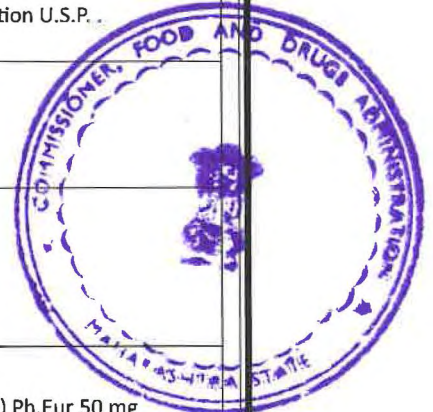
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Address of certifying authority :  
Food & Drug Administration, M.S.  
Bandra-kurla Complex,  
Bandra (E), Mumbai - 400 051.  
Maharashtra, INDIA.  
Tel: +91-22-26592363/64  
Fax: +91-22-26591959  
BHARAT SERUMS AND VACCINES LIMITED -  
NEW-WHO-GMP/CERT/KD/107921/2022/11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

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**  
**Food & Drug Administration, M.S.**  
**Bandra (E), Mumbai.**  
**Maharashtra State, India**  
Date:04 Jul 2022



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**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
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
39	ANFOCIN (Amphotericin B for Injection U.S.P.) (Lyophilized)	Each vial contains: Amphotericin B USP 50 mg sodium deoxycholate . qs
40	ANFOTERICINA OMICRON [Amphotericin B for Injection U.S.P.] (Lyophilized)	Each vial contains: Amphotericin B USP 50 mg sodium deoxycholate . qs

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Name of the Authorised person : D. R. GAHANE

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**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**No. of certificate** : NEW-WHO-GMP/CERT/KD/107921/2022/11 /39826 **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

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 .
45	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 .
46	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. .
48	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 . To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P. .

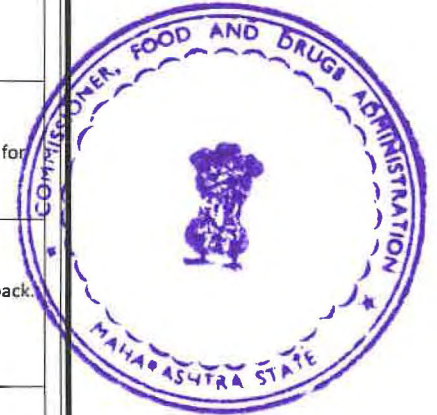
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Name of the Authorised person : D. R. GAHANE

Signature: 

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**  
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**Bandra (E), Mumbai.**  
**Maharashtra State, India**  
Date:04 Jul 2022



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**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
49	BSV-HUMOG 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 BP provided in this pack. . To be packed as combi pack with 1 ml of Sodium Chloride Injection BP. .
50	BSV-HUMOG 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 BP provided in this pack. . To be packed as combi pack with 1 ml of Sodium Chloride Injection BP. .
51	CHORIONIC GONADOTROPHIN INJECTION B.P. 5000 I.U. Human Chorionic Gonadotrophin Injection (Freeze Dried)	Each Vial contains: Chorionic Gonadotrophin BP [Human] 5000 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in this pack.
52	CLIMACT 75 Menotrophin for Injection BP - Freeze Dried (Highly Purified) (Powder for Injection)	Each vial contains: Menotrophin BP 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 B.P. .
53	CLOSTET Tetanus Immunoglobulin B.P (Human) 250 I.U./vial (Dosage Form : Injectable Solution)	Each vial contains: Human Tetanus Immunoglobulin BP 250 IU
54	CORGON Chorionic Gonadotrophin Injection B.P.] [Human Chorionic Gonadotrophin Injection] 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 this pack.
55	CORGON – 5000 HP (Chorionic Gonadotrophin for Injection B.P.) (Highly Purified) (Freeze Dried)	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. .
56	DIULENT FOR LEUPROLIDE ACETATE FOR INJECTION (DEPOT)	Each Vial contains: D- Mannitol BP 50 mg Water for Injection USP . qs

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Name of the Authorised person : **D. R. GAHANE**

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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
57	ELYCRAN [Amphotericin B Lipid Complex Injection I.V.]	Each ml contains: Amphotericin B USP 5 mg 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 .
58	ENDOPROST - 125 mcg (Carboprost Tromethamine Injection U.S.P.)(Liquid Injection)	Each 0.5 ml contains: Carboprost Tromethamine U.S.P equivalent to Carboprost 125 mcg Water for Injection USP . qs
59	ENDOPROST - 250 mcg (Carboprost Tromethamine Injection U.S.P.)(Liquid Injection)	Each ml contains: Carboprost Tromethamine U.S.P equivalent to Carboprost 250 mcg Water for Injection USP . qs
60	ENDOPROST - 250 mcg Carboprost Tromethamine Injection U.S.P. 250 mcg	Each ml Contains: Carboprost ... 250 mcg equivalent to Carboprost Tromethamine ... USP.. 332.18 mcg . Water for Injection USP .
61	EQUIRAB [Rabies Antiserum - Equine]	Each vial contains: Equine antirabies 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 Rabies Antiserum - Equine	Each 5 ml vial Contains Equine antirabies immunoglobulin fragments not less than 1000 IU Water for injection USP . qs For Intramuscular use .
63	FARMAKINASE 7,50,000 I.U. [Streptokinase for Injection B.P.] Lyophilized	Each Vial contains: Streptokinase BP 7,50,000 IU Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
64	FARMAKINASE 15,00,000 I.U. [Streptokinase for injection B.P.] Lyophilized	Each Vial contains: Streptokinase BP 15,00,000 IU Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .

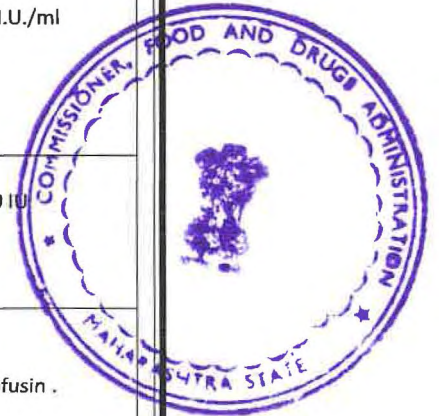
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BHARAT SERUMS AND VACCINES LIMITED -  
NEW-WHO-GMP/CERT/KD/107921/2022/11  
/39826

Name of the Authorised person : **D. R. GAHANE**

Signature: 

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**  
**Food & Drug Administration, M.S.**  
**Bandra (E), Mumbai.**  
**Maharashtra State, India**  
**Date:04 Jul 2022**



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**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 ml 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. IP/USP
68	FOLICULIN 150 [Urofollitropin for Injection B.P.] [FSH] Freeze Dried	Each Vial contains: Urofollitropin equivalent to activity of Follicle Stimulating Hormone BP 150 IU 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 .

1 2 3 4 5 6 7 8 9 10 ...

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**Drug License No** : KD360 In Form 28, KD4 in Form 28D, KD5 In Form 28E

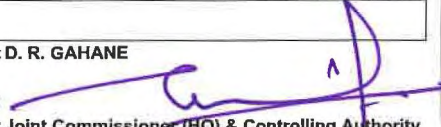
Sr.No.	Name of the Product	Composition
73	FOLIFORM 150 IU Recombinant - Human Follicle Stimulating Hormone for Injection - Freeze Dried	Each vial contains Recombinant - Human Follicle Stimulating Hormone IHS 150 IU For Subcutaneous use only . Reconstitute with 0.5 ml of sterile water for injection B.P. 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 .
75	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 .
76	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 .
77	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 .
78	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 mg 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) .
79	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 this pack . To be packed as combi pack with 0.5 ml of Sterilised water for injections B.P. .
80	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 pack . To be packed as combi pack with 0.5 ml of sterile water for injection B.P. .



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**Drug License No** : KD360 In Form 28, KD4 In Form 28D, KD5 In Form 28E

Sr.No.	Name of the Product	Composition
81	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 BP . For Subcutaneous use only .
82	FOLIGRAF 225 IU (PFS) [Recombinant-Human Follicle Stimulating Hormone Injection 225 IU (PFS)]	Each Pre Filled Syringe contains: Follitropin Concentrated Solution (Recombinant) Ph.Eur 225 IU Water for Injection USP . Pack: 0.5 ml in 1ml Pre-Filled Syringe .
83	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: 0.5 ml in 1ml Pre-Filled Syringe .
84	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)
85	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 this pack . To be packed as combi pack with 0.5 ml of Sterilised water for injections B.P. .
86	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 pack . To be packed as combi pack with 0.5 ml of sterile water for injection BP .
87	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 BP . For Subcutaneous use only .
88	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)

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

Date:04 Jul 2022



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**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
89	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 mg 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 .
90	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 .
91	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 pack . To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P. .
92	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 pack . To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P. .
93	FORMONE 150 [Urofollitropin for Injection B.P.] [FSH] Freeze Dried	Each Vial contains: Urofollitropin equivalent to activity of Follicle Stimulating hormone BP 150 IU Reconstitute with 1ml of Sodium Chloride Injection B.P. provided with this pack .
94	FORMONE 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 .
95	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 pack . To be packed as combi pack with 1 ml of Sodium Chloride Injection B.P. .
96	FUNGIPLUS 50 mg (Amphotericin B for Injection U.S.P.) (Lyophilized)	Each Vial contains: Amphotericin B USP 50 mg Sodium Deoxycholate . qs

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Name of the Authorised person : D. R. GAHANE

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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
97	GAMMA IV – 0.5 [Normal Immunoglobulin for Intravenous use B.P.]	Each ml contains: Immunoglobulin G 0.05 gm Excipients & Stabilizer : Maltose . Pack Size: 10 ml .
98	GAMMA IV – 5 [Normal Immunoglobulin for Intravenous use B.P.] (Dosage form: Injectable Solution)	Each ml contains: Immunoglobulin G 0.05 gm Excipients & Stabilizer : Maltose . Pack Size : 100 ml .
99	GAMMA IV Normal immunoglobulin for intravenous use BP 0.05 g/ml	Each ml contains: Immunoglobulin G 0.05 gm Stabilizer : Maltose 100 mg/ml [Pack Size: 10 ml (Protein: 0.5 g)], [Pack Size: 50 ml (Protein: 2.5 g)] [Pack Size: 100 ml (Protein: 5.0 g)] .
100	Ganimet Antithymocyte Globulin - Equine	Each 5 ml vial contains: Antithymocyte Globulin (Equine) 250 mg Water for Injection USP . qs Excipients and stabilizers: Glycine BP , Sodium Chloride BP . For Intravenous use only .
101	GOSELIN 3.6 Goserelin Implant BP 3.6 mg (1 Month Depot Injection)	Each Implant contains: Goserelin BP (as acetate) 3.6 mg Lactide / Glycolide Copolymer IH . For Subcutaneous Injection .
102	HCG-COX 5000 I.U. (Chorionic Gonadotrophin Injection B.P.) (Highly Purified) (Freeze Dried)	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. .
103	HCG-R.B.A. – 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. .
104	HISTOGLOB	Each ml 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 .

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/39826

Name of the Authorised person : D. R. GAHANE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority  
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Date:04 Jul 2022



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**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, KDS In Form 28E

Sr.No.	Name of the Product	Composition
105	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 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. .
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
109	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
110	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
111	HuCoG – 2000 HP (Highly Purified Chorionic Gonadotropin Injection 2000 I.U.)	Each ml contains: Chorionic Gonadotropin highly purified IH 2000 IU Water for Injection USP . qs
112	HuCoG – 2000 I.U. Chorionic Gonadotropin Injection 2000 I.U.	Each ml contains: Chorionic Gonadotropin highly purified IH 2000 IU Water for Injection USP . qs

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NEW-WHO-GMP/CERT/KD/107921/2022/11  
/39826

Name of the Authorised person : **D. R. GAHANE**

Signature :

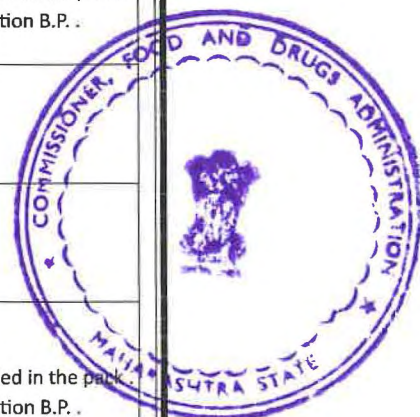
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**  
**Food & Drug Administration, M.S.**  
**Bandra (E), Mumbai.**  
**Maharashtra State, India**  
Date:04 Jul 2022



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

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**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 B.P.) (Freeze Dried) (FOR MALAYSIA ONLY)	Each vial contains: Chorionic Gonadotrophin BP 5000 IU Reconstitute with 1 ml of Sodium Chloride Injection B.P. provided in the pack. For Subcutaneous & Intramuscular use . .
114	HuCoG – 5000 HP (Chorionic Gonadotrophin Injection B.P.- Freeze Dried) (Highly Purified)	Each vial contains: Chorionic Gonadotrophin BP 5000 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. .
115	HuCoG – 5000 HP Highly Purified Chorionic Gonadotrophin Injection 5000 I.U.	Each ml contains: Chorionic Gonadotrophin highly purified IH 5000 IU Water for Injection USP . qs
116	HuCoG – 5000 I.U. Chorionic Gonadotrophin Injection 5000 I.U.	Each ml contains: Chorionic Gonadotrophin highly purified IH 5000 IU Water for Injection USP . qs
117	HUCOG 5000 IU (Chorionic Gonadotrophin Injection B.P. (Highly Purified) (Freeze Dried)]	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. .
118	HuMoG – 150 I.U. (Menotrophin for injection B.P.) (Freeze Dried) (FOR MALAYSIA ONLY)	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. .
119	HuMoG – 75 I.U. (Menotrophin for injection B.P.) (Freeze Dried) (FOR MALAYSIA ONLY)	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. .
120	HUMOG 150 Menotrophin for Injection BP (Freeze Dried)(Highly Purified) (For Export only in Philippines)	Each vial contains Menotrophin BP 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 .



... [11](#) [12](#) [13](#) [14](#) [15](#) [16](#) [17](#) [18](#) [19](#) [20](#) ...

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Name of the Authorised person : **D. R. GAHANE**

Signature :

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**Food & Drug Administration, M.S.**  
**Bandra (E), Mumbai.**  
**Maharashtra State, India**  
 Date:04 Jul 2022

**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

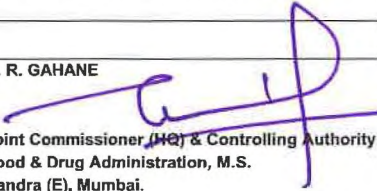
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**Drug License No** : KD360 In Form 28, KD4 In Form 28D, KDS In Form 28E

Sr.No.	Name of the Product	Composition
121	HUMOG 150 IU [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 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 .
122	HUMOG 150 IU Menotrophin for injection B.P. - Freeze Dried (For Russia Export Only)	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. .
123	HUMOG 75 Menotrophin for Injection BP (Freeze Dried) (Highly Purified) (For Export only in Philippines)	Each vial contains Menotrophin BP 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 .
124	HuMoG -75 HP (Menotrophin for Injection B.P. (Highly Purified) -Freeze Dried	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 B.P. .
125	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 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 Menotrophin for injection B.P. - Freeze Dried (For Russia Export Only)	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. .
127	HUMOG BSV 150 HP Menotrophin for Injection BP (Freeze Dried) (Highly Purified)	Each vial contains Menotrophin BP 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 .
128	HUMOG BSV 75 HP Menotrophin for Injection BP (Freeze Dried) (Highly Purified)	Each vial contains Menotrophin BP 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 .

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

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**Drug License No** : KD360 In Form 28, KD4 In Form 28D, KDS 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 IU

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**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. .
143	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. .
144	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. .

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Address of certifying authority :  
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Bandra-kurla Complex,  
Bandra (E), Mumbai - 400 051.  
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**  
**Date:04 Jul 2022**



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**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, KDS In Form 28E

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

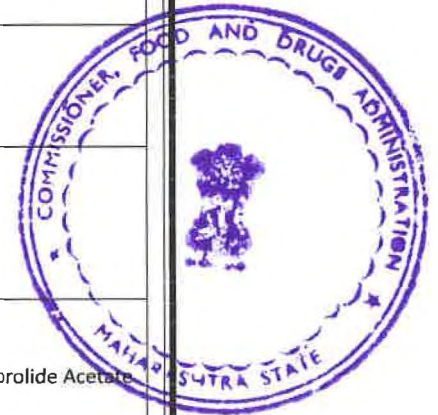
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Name of the Authorised person : **D. R. GAHANE**

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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
153	MENACT 75 Menotrophin for Injection BP - Freeze Dried (Highly Purified) (Powder for Injection)	Each vial contains: Menotrophin B.P. equivalent to activity of . Follicle stimulating Hormone 75 IU 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 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 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 INTRAVENOUS USE B.P.	Each ml contains: Immunoglobulin G 0.05 gm Pack Size: 50 ml .
156	NORMAL IMMUNOGLOBULIN FOR INTRAVENOUS USE B.P.	Each ml contains: Immunoglobulin G 0.05 gm Pack Size: 100 ml .
157	ORMOLON FSH 150 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 0.5ml 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 B.P. .
158	ORMOLON FSH 75 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 0.5ml 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 .
159	ORMOLON HCG 5000 IU Chorionic Gonadotrophin Injection B.P. 5000 IU - 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. .
160	ORMOLON HMG 150 IU Menotrophin for injection B.P. 150 IU - 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. .

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Date:04 Jul 2022



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

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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
161	ORMOLON HMG 75 IU Menotrophin for injection B.P. 75 IU - 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. .
162	Ovifol – R 150 I.U. (Recombinant - Human Follicle Stimulating Hormone for Injection) - Freeze Dried	Each vial contains: Recombinant - Human Follicle Stimulating Hormone 150 IU For Subcutaneous use only . 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 I.U. (Recombinant - Human Follicle Stimulating Hormone for Injection) - Freeze Dried	Each vial contains: Recombinant - Human Follicle Stimulating Hormone 75 IU For Subcutaneous use only . 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 Polymyxin B for Injection U.S.P. - Lyophilized	Each vial contains 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. .
166	POLYMxB 25 mg Polymyxin B for Injection USP 25 mg (Lyophilized)	Each Vial Contains: Polymyxin B Sulphate USP equivalent to sum of Polymyxin B1, B2, B3, B1-I 25 mg For Intrathecal / I.M / I.V. Infusion .
167	POLYMxB 50 mg Polymyxin B for Injection USP 50 mg (Lyophilized)	Each Vial Contains: Polymyxin B Sulphate USP equivalent to sum of Polymyxin B1, B2, B3, B1-I 50 mg For Intrathecal / I.M / I.V. Infusion .
168	POLYMX-E 1 Colistimethate Sodium for Injection BP 1 MIU (Lyophilized)	Each vial contains Colistimethate Sodium BP 1000000 IU To be reconstituted using Sodium Chloride Injection BP or Water for Injection BP . For I.V. use only . Single dose vial .

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Name of the Authorised person : D. R. GAHANE

Signature :

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

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**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 Colistimethate Sodium for Injection BP 2 MIU (Lyophilized)	Each vial contains Colistimethate Sodium BP 2000000 IU 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. [Recombinant - Human Follicle Stimulating Hormone for Injection] -Freeze Dried	Each vial contains: Recombinant - Human Follicle Stimulating Hormone 75 IU 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. Recombinant-Human Follicle Stimulating Hormone for Injection- Freeze Dried	Each vial contains: Recombinant-Human Follicle Stimulating Hormone IHS 150 IU Reconstitute with 0.5 ml of Sterilised 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 [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 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. [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. . qs
176	r-FSH-COX 75 I.U. Recombinant - Human Follicle Stimulating Hormone for Injection -Freeze Dried	Each Vial Contains Follitropin Concentrated Solution (Recombinant) Ph.Eur 75 IU For Subcutaneous and Intramuscular use only . 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. .

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

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**Drug License No** : KD360 In Form 28, KD4 In Form 28D, KD5 In Form 28E

Sr.No.	Name of the Product	Composition
177	RHOCLONE 150 mcg (Anti Rho-D Immunoglobulin Injection) (Monoclonal) (Freeze Dried)	Each vial contains: Monoclonal Anti Rho-D Immunoglobulin 150 mcg To be reconstituted with 1 ml of sterile water for Injection U.S.P. provided with this pack .
178	RHOCLONE 150 mcg [Anti - D (Rho) Immunoglobulin] (Monoclonal) (Liquid Injection)	Each ml contains: Anti Rho - D Immunoglobulin 150 mcg Water for Injection USP . qs
179	RHOCLONE 300mcg (Anti Rho-D Immunoglobulin Injection) (Monoclonal) (Freeze Dried)	Each vial contains: Monoclonal Anti Rho-D Immunoglobulin 300 mcg To be reconstituted with 2ml of sterile water for Injection U.S.P. provided with this pack .
180	RHOCLONE 300mcg (Anti Rho-D Immunoglobulin Injection) (Monoclonal) (Liquid Injection)	Each ml contains: Anti Rho-D Immunoglobulin 300 mcg Water for Injection USP . qs
181	r-HUCOG RECOMBINANT HUMAN CHORIONIC GONADOTROPIN FOR INJECTION (r-HCG) 6500 IU	Each Pre-filled Syringe contain Recombinant Human Chorionic Gonadotropin 1H 6500 IU Water for Injection BP . qs
182	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 Stabilizer: Glycine B.P Excipient: Mannitol B.P. & Sodium chloride B.P. . Pack size: 10ml, 20ml, 50ml .
183	SNAKE VENOM ANTISERUM (Lyophilized)	After reconstitution 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 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

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**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. (Small Volume parenterals)	Each pack contains: 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 .
187	STERILISED WATER FOR INJECTIONS B.P. (Small Volume parenterals)	Pack Size: 1.0 ml .
188	STREPTOKINASE FOR INJECTION B.P. (Lyophilized)	Each Vial contains: Streptokinase BP 7,50,000 IU Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
189	STREPTOKINASE FOR INJECTION B.P. [Lyophilized]	Each Vial contains: Streptokinase BP 15,00,000 IU Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
190	STREPTOLASE 15,00,000 I.U. [Streptokinase for Injection B.P.] - Lyophilized	Each Vial contains: Streptokinase BP 1500000 IU Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin . For I.V. Use .
191	STROKINASE Streptokinase for Injection B.P. (Lyophilized)	Each Vial contains: Streptokinase BP 15,00,000 IU Excipients and stabilizers: Human Albumin B.P, Polygeline / Gelofusin .
192	Tetanus Immunoglobulin B.P 1000 I.U. (Human)	Each vial contains: Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 1000 IU

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**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 I.U. (Human)	Each vial contains: Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 250 IU
194	Tetanus Immunoglobulin B.P 500 I.U. (Human)	Each vial contains: Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 500 IU
195	TETGLOB 250 I.U. [Tetanus Immunoglobulin B.P.] (Human)	Each vial contains: Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 250 IU
196	TETGLOB 500 I.U. [Tetanus Immunoglobulin B.P.] (Human)	Each vial contains: Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 500 IU
197	TETGLOB 1000 I.U. Tetanus Immunoglobulin B.P (Human)	Each vial contains: Human Tetanus Immunoglobulin equivalent to tetanus antitoxin 1000 IU
198	THROMBOFLUX (Streptokinase for Injection B.P.) Lyophilized	Each vial contains: Streptokinase BP 750000 IU 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 [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. .
200	THROMBOFLUX 7,50,000 IU [Streptokinase for Injection BP 7,50,000 IU - Lyophilized]	Each Vial Contains: Streptokinase BP 7,50,000 IU Excipients and Stabilizers : Human Albumin BP... 0.17 mg/1 lac IU, Gelofusin ... 2.67 mg/1 lac IU . For I.V. Use .
... 18 19 20 21 22 23 24 25 26 27		

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





**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**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
201	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 .
202	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 .
203	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 .
204	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. , Disodium hydrogen phosphate Dihydrate B.P., Sodium dihydrogen phosphate Dihydrate B.P. . For I.V. use. .
205	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. .
206	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 .
207	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 .
208	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 .

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

Address of certifying authority :  
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Bandra-kurla Complex,  
Bandra (E), Mumbai – 400 051.  
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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 :

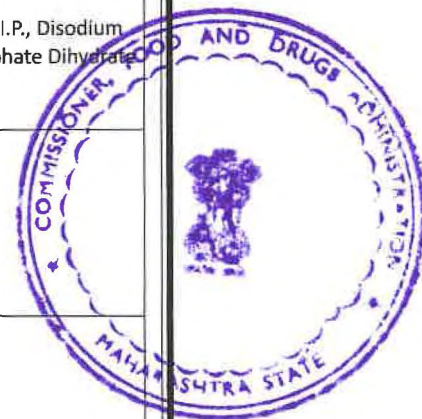
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India

Date:04 Jul 2022



**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**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
209	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 .
210	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. .
... <a href="#">18</a> <a href="#">19</a> <a href="#">20</a> <a href="#">21</a> <a href="#">22</a> <a href="#">23</a> <a href="#">24</a> <a href="#">25</a> <a href="#">26</a> <a href="#">27</a>		

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/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**

