GOVERNMENT OF INDIA/भारत सरकार

MINISTRY OF RAILWAYS/रेल मंत्रालय

(RAILWAY BOARD/रेलवे बोर्ड)

No. 2025/H/4/1/DP/BharatBiotech New Delhi dated: 16.10.2025.

Principal Chief Medical Director
South Central Railway
Secunderabad.

Sub:-Renewal of registration of drug/pharmaceutical products supply firm M/s. Bharat Biotech International Limited-reg.

Ref:- E-3510604 & File No. SCRHQ-MED0STOR(REGN)/6/2025-O/o ACMD /HNFW/PCMD/SCR.

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Kind attention is invited to Zone's file cited under reference on the subject cited above. As approved by the competent authority, the firm **M/s. Bharat Biotech International Limited** is renewed with the validity upto **15/10/2028.**

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NITI KUMARI
Date: 16-10-2025
16:38:13

Dr. Niti Kumari/(डॉ. नीती कुमारी)
Joint Director/IH (संयुक्त निदेशक/औद्योगिक स्वास्थ्य)
Railway Board/ रेलवे बोर्ड
Tele No. 011-47843133
4th Floor, Room No. 404.
E-mail:- jdihealth@rb.railnet.gov.in

Copy to:- PCMD(s)/PCMO(s), all Indian Railways including PUs & RDSO.

COFMOW Railway Offices Complex, Tilak Bridge, New Delhi-110002.

BHARAT BIOTECH INTERNATIONAL LIMITED

Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078, India.

PRODUCT LIST

Sl. No	Name of the Product (Brand Name)	Pharmaceutical Content	Ingredients/ Packing/ Other	Manufacturing Address	Mfg Unit Inspected or Not	Remarks
1	REVAC-B^{+}	**Recombinant Hepatitis-B Vaccine** Each dose of 0.5mL contains (paediatric dose): Hepatitis B surface Antigen.....≥ 10µg Aluminium Hydroxide Gel as Al+++)..... 0.25mg Thiomersal (as preservative)..... 0.025mg Phosphate buffer saline q.s. to 0.5 mL	0.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
2	REVAC-B^{+}	**Recombinant Hepatitis-B Vaccine** Each 1.0mL dose contains (Adult dose): Hepatitis B surface Antigen.....≥20µg Aluminium Hydroxide Gel as Al+++.... 0.5mg Thiomersal I.P. …..... 0.05mg Phosphate buffer saline q.s. To 1.0 mL	1 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
3	REVAC-B^{+}	**Recombinant Hepatitis-B Vaccine** Each 1.0mL dose contains (Adult dose): Hepatitis B surface Antigen.....≥20µg Aluminium Hydroxide Gel as Al+++.... 0.5mg Thiomersal I.P. …..... 0.05mg Phosphate buffer saline q.s. To 1.0 mL	10 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
4	REVAC- B mcf	**Recombinant Hepatitis-B Vaccine (Thiomerosal Free)** Each dose of 0.5mL contains (paediatric dose): Hepatitis B surface Antigen.....≥ 10µg Aluminium Hydroxide Gel as Al+++..... 0.25mg Phosphate buffer saline q.s. to 0.5 mL	0.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	

MIHIR NIRANJAN CHHAYA

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Date: 2025.09.13 15:32:57 +05'30'

DR. H. K. CHALAGERI

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Date: 2025.09.18 16:07:46 +05'30'

Dr. H. K. CHALAGERI
CHD/SCR

Sl. No	Name of the Product (Brand Name)	Pharmaceutical Content	Ingredients/ Packing/ Other	Manufacturing Address	Mfg Unit Inspected or Not	Remarks
5	TYPBAR	**Vi Capsular Polysaccharide Typhoid Vaccine** Each dose of 0.5mL contains: Purified Vi Capsular Polysaccharide of Salmonella typhi Ty2 ..... 25 µg Phenol ..... 0.25% w/v Isotonic buffer solution ..... q.s. to 0.5 mL	0.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
6	TYPBAR	**Vi Capsular Polysaccharide Typhoid Vaccine** Each dose of 0.5mL contains: Purified Vi Capsular Polysaccharide of Salmonella typhi Ty2 ..... 25 µg Phenol ..... 0.25% w/v Isotonic buffer solution ..... q.s. to 0.5 mL	2.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
7	TYPBAR	**Vi Capsular Polysaccharide Typhoid Vaccine** Each dose of 0.5mL contains: Purified Vi Capsular Polysaccharide of Salmonella typhi Ty2 ..... 25 µg Phenol ..... 0.25% w/v Isotonic buffer solution ..... q.s. to 0.5 mL	0.5 ml PFS	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
8	Typbar TCV	**Vi Capsular Polysaccharide Typhoid- Tetanus Toxoid Conjugate Vaccine** Dose of 0.5mL contains Purified Vi Capsular Polysaccharide of S. typhi Ty2 conjugated to Tetanus Toxoid.....25 µg Sodium Chloride ….....4.5 mg WFI ..... q.s to 0.5mL	0.5 ml PFS	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	

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DR. H. K. CHALAGERI

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Date: 2025.09.18 16:08:28 +05'30'

Dr. H. K. CHALAGERI
CHD/SCR

Sl. No	Name of the Product (Brand Name)	Pharmaceutical Content	Ingredients/ Packing/ Other	Manufacturing Address	Mfg Unit Inspected or Not	Remarks
9	INDIRAB	**Purified, Inactivated, Lyophilized Rabies Vaccine, Prepared on Vero Cells, IM/ID** Prepared on Vero Cells, IM/ID On reconstitution each vial (0.5mL) of Lyophilized vaccine contains: Purified BPL Inactivated Rabies virus (Prepared on Vero cells, Pitman Moore strain of Rabies virus)..... ≥ 2.5 I.U. Thiomersal (as preservative) I.P. …..... 0.01% Maltose: up to 1 immunizing dose (5%) Human Albumin I.P. : up to 1 immunizing dose (1%)	0.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
10	INDIRAB	**Purified, Inactivated, Lyophilized Rabies Vaccine, Prepared on Vero Cells, IM/ID** Prepared on Vero Cells, IM/ID On reconstitution each vial (1.0mL) of Lyophilized vaccine contains: Purified BPL Inactivated Rabies virus (Prepared on Vero cells, Pitman Moore strain of Rabies virus)..... ≥ 2.5 I.U. Thiomersal (as preservative) I.P. …..... 0.01% Maltose: up to 1 immunizing dose (5%) Human Albumin I.P. : up to 1 immunizing dose (1%)	1 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
11	JENVAC	**Purified, Inactivated Japanese Encephalitis Vaccine** for Intramuscular use Each dose of 0.5mL contains: Purified, Inactivated Japanese Encephalitis Virus Protein NLT 5µg Aluminium Hydroxide gel as Al+++ I.P. 0.25mg Thiomersal (Preservative) I.P. 0.025mg Phosphate Buffered Saline q.s. to 0.5mL	0.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	

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DR. H. K. CHALAGERI
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Dr. H. K. CHALAGERI
CHD/SCR

Sl. No	Name of the Product (Brand Name)	Pharmaceutical Content	Ingredients/ Packing/ Other	Manufacturing Address	Mfg Unit Inspected or Not	Remarks
12	BioHiB	**Haemophilus Influenzae type b-conjugate Vaccine** Each reconstituted dose of 0.5mL contains: Purified Capsular polysaccharide of Hib 10 µg.[Covalently bound to 20-40 µg Tetanus Toxoid (PRP-TT)] Sucrose I.P. 21.40mg. Sodium Chloride I.P. 4.50mg. Sterile Water for Injection I.P. q.s. to 0.5mL	0.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
13	ComVac 5	**Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (Absorbed)** Each dose of 0.5mL contains: Diphtheria Toxoid ≥20Lf to ≤30 Lf (≥30 IU) Tetanus Toxoid ≥5Lf to ≤25 Lf (≥60 IU) B.pertussis (Whole Cell inactivated) ≥4 IU HBsAg (rDNA) 10 µg Hib PRP-TT Conjugate 10 µg Aluminium Phosphate Gel As Aluminium (Al+++) 0.3mg Thiomersal I.P 0.021 mg to 0.029 mg	0.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
14	ComVac 5-PFS	**Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (Absorbed)** Each dose of 0.5mL contains: Diphtheria Toxoid ≥20Lf to ≤30 Lf (≥30 IU) Tetanus Toxoid ≥5Lf to ≤25 Lf (≥60 IU) B.pertussis (Whole Cell inactivated) ≥4 IU HBsAg (rDNA) 10 µg Hib PRP-TT Conjugate 10 µg Aluminium Phosphate Gel As Aluminium (Al+++) 0.3mg Thiomersal I.P 0.021 mg to 0.029 mg	0.5 ml PFS	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	

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DR. H. K. CHALAGERI
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Date: 2025.09.18 16:09:17 +05'30'

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Sl. No	Name of the Product (Brand Name)	Pharmaceutical Content	Ingredients/ Packing/ Other	Manufacturing Address	Mfg Unit Inspected or Not	Remarks
15	ComVac3+ BioHib	**DTP+Hib (Combopack)** **(DTP - Liquid suspension Hib – Lyophilized Powder Reconstitute Hib component with DTP Vaccine 0.5ml)** Each reconstituted dose of 0.5mL contains: a) Diphtheria Toxoid ≥20Lf to ≤30 Lf (≥30 IU) Tetanus Toxoid ≥5Lf to ≤25 Lf (≥60 IU) Inactivated B.pertussis (W) ≥4 IU Aluminium Phosphate Gel As Aluminium (Al+++) 0.3mg Thiomersal (Preservative) I.P 0.021 mg to 0.029 mg	0.5 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
16	BIOPOLIO	**Poliomyelitis Vaccine Typbe 1 & 3 Live (Oral)** 1 Dose = 0.1 ml (2 drops) contains: Polio virus Type 1 (Sabin Strain) - NLT 106.0 CCID50 Polio virus Type 3 (Sabin Strain) - NLT 105.8 CCID50 MgCl26H2O I.P. - 20.33 mg Poly Sorbate 80 I.P. - 10 mcg Neomycin Sulphate I.P. - 15 mcg Kanamycin Sulphate I.P.- 15 mcg Water for Injection I.P. - q.s. to 0.1ml	2 ml vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
17	ROTAVAC	**Oral Rotavirus Vaccine 116E Live Attenuated** Each dose of 0.5ml contains: Rotavirus 116E Bulk, Live Attenuated NLT 105.0 FFU/0.5ml Potassium Phosphate monobasic 0.258mg Potassium phosphate dibasic 0.625mg Sucrose 37.31mg Potassium L-glutamate, monohydrate 1.0mg Neomycin sulphate 15mcg Kanamycin sulphate 15mcg Dulbecco's Modified Eagle's Medium (DMEM) 4.4mg Water for Injection q.s	0.5ml Vial	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	

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Dr. H. K. CHALAGERI
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Sl. No	Name of the Product (Brand Name)	Pharmaceutical Content	Ingredients/ Packing/ Other	Manufacturing Address	Mfg Unit Inspected or Not	Remarks
18	REGEN-D™ 60	**Recombinant Human Epidermal Growth Factor Gel** Each gram contains: Purified bulk of rh-Epidermal Growth Factor : 60µg Methyl Paraben (Sod. Salt) 1.8mg (0.18% w/w) Propyl Paraben (Sod. Salt) 0.2mg (0.02% w/w) Carbopol Ultrez 14mg Mannitol 50mg Glycerol 0.025mL L-Lysine Hydrochloride 2.52 mg Triethanolamine 0.016mL	7.5 gms Tube	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
19	REGEN-D™ 60	**Recombinant Human Epidermal Growth Factor Gel** Each gram contains: Purified bulk of rh-Epidermal Growth Factor : 60µg Methyl Paraben (Sod. Salt) 1.8mg (0.18% w/w) Propyl Paraben (Sod. Salt) 0.2mg (0.02% w/w) Carbopol Ultrez 14mg Mannitol 50mg Glycerol 0.025mL L-Lysine Hydrochloride 2.52 mg Triethanolamine 0.016mL	15 gms Tube	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
20	REGEN-D™ 150	**Recombinant Human Epidermal Growth Factor Gel** Each gram contains: Purified bulk of rh-Epidermal Growth Factor : 150µg Methyl Paraben (Sod. Salt) 1.8mg (0.18% w/w) Propyl Paraben (Sod. Salt) 0.2mg (0.02% w/w) Carbopol Ultrez 14mg Mannitol 50mg Glycerol 0.025mL L-Lysine Hydrochloride 2.52 mg Triethanolamine 0.016mL	7.5 gms Tube	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	

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DR. H. K. CHALAGERI
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Dr. H. K. CHALAGERI
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Sl. No	Name of the Product (Brand Name)	Pharmaceutical Content	Ingredients/ Packing/ Other	Manufacturing Address	Mfg Unit Inspected or Not	Remarks
21	REGEN-D™ 150	**Recombinant Human Epidermal Growth Factor Gel** Each gram contains: Purified bulk of rh-Epidermal Growth Factor : 150µg Methyl Paraben (Sod. Salt) 1.8mg (0.18% w/w) Propyl Paraben (Sod. Salt) 0.2mg (0.02% w/w) Carbopol Ultrez 14mg Mannitol 50mg Glycerol 0.025mL L-Lysine Hydrochloride 2.52 mg Triethanolamine 0.016mL	15 gms Tube	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	
22	SLVRGEN	**Recombinant Human Epidermal Growth Factor, Silver Sulfadiazine & Chlorhexidine Gluconate Cream** Each gram contains Recombinant EGF - 10µg Silver Sulfadiazine - 1% Chlorhexidine Gluconate – 0.2% Light liquid paraffin - 10.0% Pemulen TR-1 - 0.5% Carbopol ultrez - 1.3% Sodium Methyl paraben – 0.18% Sodium Propyl paraben - 0.02% Mannitol - 5% 20% Triethanolamine - q.s to adjust the pH to 6.2 - 6.3 Purified water - 78%	15 gms Tube	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	

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CHD/SCR

Sl. No	Name of the Product (Brand Name)	Pharmaceutical Content	Ingredients/ Packing/ Other	Manufacturing Address	Mfg Unit Inspected or Not	Remarks
23	SLVRGEN	**Recombinant Human Epidermal Growth Factor, Silver Sulfadiazine & Chlorhexidine Gluconate Cream** Each gram contains Recombinant EGF - 10µg Silver Sulfadiazine - 1% Chlorhexidine Gluconate – 0.2% Light liquid paraffin - 10.0% Pemulen TR-1 - 0.5% Carbopol ultrez - 1.3% Sodium Methyl paraben – 0.18% Sodium Propyl paraben - 0.02% Mannitol - 5% 20% Triethanolamine - q.s to adjust the pH to 6.2 - 6.3 Purified water - 78%	30 gms Tube	Bharat Biotech International Limited Sy. No. 230, 231 & 235, Genome Valley, Turkapally (V), Shamirpet (M), Medchal - Malkajgiri (D), Telangana - 500078	Inspected	

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Dr. H. K. CHALAGERI
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