2025/H/4/1/DP/BiologicalELtd.

GOVERNMENT OF INDIA/भारत सरकार

MINISTRY OF RAILWAYS/रेल मंत्रालय

(RAILWAY BOARD/रेलवे बोर्ड)

No.2025/H/4/1/DP/BiologicalELtd

New Delhi dated:03.06.2025.

Principal Chief Medical Director South Central Railway Secunderabad.

Sub:- Renewal of registration of drug supply firm M/s Biological E Ltd.- reg.

Ref:- EComp. No.3494675 & File No.:SCRHQ-MED0STOR(FIRM)/3/2025-O/o ACMD/HNFW/PCMD/SCR.

Kind attention is invited to Zonal Railways' file cited under reference on the subject cited above. As recommended by PCMD, registration of **M/s Biological E Ltd.** is renewed with validity upto **01/06/2028.** The product list of the firm has been uploaded on Health Directorate, Railway Board website for supply of drugs/pharmaceuticals products over Indian Railways.

Digitally signed by NITI KUMARI Date: 03-06-2025 (Dr. Niti Kumari/डा. नीती कुमारी) Joint Director/IH (संयुक्त निदेशक/औद्योगिक स्वास्थ्य) Railway Board/रेलवे बोर्ड Ministry of Railways (रेल मंत्रालय)

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

BIOLOGICAL E LIMITED, HYDERABAD PRODUCTS LIST

S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc.	Name of the manufacturer and full address of manufacturing units along with phone nos. and e mail address	Name of the marketing firms/companies with full address along with phone nos. and e-mail address.	Inspected / Not Inspected	Remarks
1	Each dose of 0.5 mL contains: Tetanus Toxoid ≥ 5 Lf to ≤ 25 Lf Adsorbed on Aluminium Phosphate (AIPO ₄): ≥ 1.5 mg Preservative: Thiomersal IP-0.01% w/v	BETT INJ 0.5ML	0.5ml amp	M/s. BIOLOGICAL E. LIMITED 18/1&3, Azamabad, Hyderabad, Telangana – 500 020	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	Nil
2	Snake Antivenin (Polyvalent) IP - 10 mL Vial (Enzyme Refined Equine Globulins) Each 1 mL Neutralizes: NLT 0.60 mg of Cobra Venom (Naja naja) NLT 0.45 mg of Common Krait Venom (Bungarus caeruleus) NLT 0.60 mg of RUSSELLS VIPER VENOM (VIPERA RUSSELLI) NLT 0.45 mg of SAW SCALED VIPER VENOM (ECHIS CARINATUS) Preservative: Phenol IP - ≤ 0.25 % w/v	BENOM (Liquid)	10ml Vial	M/s. BIOLOGICAL E. LIMITED 18/1&3, Azamabad, Hyderabad, Telangana – 500 020	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	Nil
3	Snake Antivenin IP (Lyophilized Polyvalent, Enzyme refined, Equine F(ab)2 immunoglobulin) Upon reconstitution with 10 mL Sterile Water for Injectin Each mL of Antiserum neutralizes: Cobra Venom (Naja naja) ≥ 0.60 mg Common krait Venom (Bangarus caeruleus)≥0.45 mg Russell's Viper Venom (Vipera russelli) ≥ 0.60 mg Saw Scaled Viper Venom (echis carinatus) ≥ 0.45 mg Preservative: Phenol IP ≤ 0.25%	BENOM (Lyo)	Combepack	M/s. BIOLOGICAL E. LIMITED 18/1&3, Azamabad, Hyderabad, Telangana – 500 020	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New

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DR. H. K.

Digitally signed by DR. H. K. CHALAGERI

Date: 2025.04.16
15:42:38 +05'30'

S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc.	Name of the manufacturer and full address of manufacturing units along with phone nos. and e mail address	Name of the marketing firms/companies with full address along with phone nos. and e-mail address.	Inspected / Not Inspected	Remarks
4	Each mL Contains: Diptheria Antitoxin ≥ 1000 IU Preservative Cresol ≤ 0.25% v/v	Diptheria Antitoxin IP 1000IU/mL	10 mL	M/s. BIOLOGICAL E. LIMITED 18/1&3, Azamabad, Hyderabad, Telangana – 500 020	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
5	Each dose of 0.5 ml contains: Diphtheria Toxoid ≥ 2 IU Tetanus Toxoid ≥ 5 Lf to ≤ 25 Lf or ≥20 IU Adsorbed on Aluminium Phosphate (AIPO₄) ≥1.5 mg Preservative: Thiomersal I.P. 0.01% w/v	BE Td 0.5 ML	0.5 mL Amp.	M/s. BIOLOGICAL E. LIMITED 18/1&3, Azamabad, Hyderabad, Telangana – 500 020	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
6	Tetanus Antitoxin I.P 1500 IU 1 mL Ampoule For Prophylactic use Each Ampoule contains Tetanus Antitoxin I.P ≥ 1500 IU Preservative: cresol ≤ 0.25 % w/v	Tetanus Antitoxin I.P 1500 IU/mL	1 mL Amp.	M/s. BIOLOGICAL E. LIMITED 18/1&3, Azamabad, Hyderabad, Telangana – 500 020	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
7	Tetanus Antitoxin I.P 1500 IU/mL 1 mL Ampoule For Prophylactic use Each Ampoule contains Tetanus Antitoxin I.P 1500 IU Preservative: Thiomersal I.P 0.01 % w/v	Tetanus Antitoxin I.P 1500 IU/mL	1 mL Amp.	M/s. BIOLOGICAL E. LIMITED 18/1&3, Azamabad, Hyderabad, Telangana – 500 020	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
8	Hepatitis B Vaccine (rDNA) I.P. (For Paediatric use) 0.5 ml Vial Each 0.5 ml contains: Purified HBsAg ≥10ug Aluminium Hydroxide gel equivalent to Al+++ - 0.25mg Preservative: Thiomersal I.P: 0.025 mg	BEVAC 0.5 ML	0.5ml Vial	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New

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DR. H. K.

CHALAGERI
Date: 2025.04.16
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CHIEF HEALTH DIRECTOR

SOUTH CENTRAL RAILWAY

S. MAHIPAL REDDY COMPANY SECRETARY

S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc.	Name of the manufacturer and full address of manufacturing units along with phone nos. and e mail address	Name of the marketing firms/companies with full address along with phone nos. and e-mail address.	Inspected / Not Inspected	Remarks
9	Hepatitis B Vaccine (rDNA) I.P. (For Adult use) 1 ml Vial Each dose of 1 mL contains: Purified HBsAg ≥20ug, Aluminium Hydroxide gel equivalent to Al+++ - 0.5mg Preservative: Thiomersal I.P: 0.05 mg	BEVAC 1 ML	1ml Vial	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
10	Hepatitis B Vaccine (rDNA) I.P. (For Adult use) 10 ml Vial Each dose of 1 mL contains: Purified HBsAg ≥20ug, Aluminium Hydroxide gel equivalent to Al+++ - 0.5mg Preservative: Thiomersal I.P: 0.05 mg	BEVAC 10 ML	10ml Vial	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
11	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents IP 5 ml Vial Each dose of 0.5 ml contains: Diphtheria Toxoid ≥ 2 IU Tetanus Toxoid ≥ 5 Lf to ≤ 25 Lf or ≥20 IU Adsorbed on Aluminium Phosphate (as AIPO4) ≥1.5 mg Thiomersal I.P. 0.01% w/v	BE Td 5 ML	5 ml Vial.	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New

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S. MAHIPAL REDDY

COMPANY SECRETARY

DR. H. K. Digitally signed by DR. H. K. CHALAGERI Date: 2025.04.16 15:44:02 +05'30'

S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc.	Name of the manufacturer and full address of manufacturing units along with phone nos. and e mail address	Name of the marketing firms/companies with full address along with phone nos. and e-mail address.	Inspected / Not Inspected	Remarks
12	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophllus Influenzae Type b conjugate vaccine (Adsorbed) I.P Single Dose Vial 0.5 ml Each dose of 0.5 ml Diphtheria Toxoid ≥ 30 IU (≥ 20 Lf to ≥ 30 Lf) Tetanus Toxoid ≥ 60 IU (≥ 5 Lf to ≤ 25 Lf Bordetella Pertussis (Whole Cell, Killed) ≥ 4 IU r-HBbsAg 12.5 ug (Recombinant HBs Antigen produced in Pichia pastoris) Purified capsular Polysaccharide of Hib (PRP) covalently linked to 20 to 36.7 mg of Tetanus Toxoid: 11 ug Al+++ (as AIPO4) ≤ 1.25 mg Preservative: Thiomersal I.P: 0.01% w/v	ComBE Five 0.5 ML	0.5 ml Vial	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
13	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophllus Influenzae Type b Conjugate Vaccine (Adsorbed) I.P Single Dose Pre-filled Syringe 0.5 ml Each Pre-filled Syringe (0.5 mL) contains: Diphtheria Toxoid ≥ 30 IU (≥ 20 Lf to ≥ 30 Lf) Tetanus Toxoid ≥ 60 IU (≥ 5 Lf to ≤ 25 Lf Bordetella Pertussis (Whole Cell, Killed) ≥ 4 IU r-HBbsAg 12.5 ug (Recombinant HBs Antigen produced in Pichia pastoris) Purified capsular Polysaccharide of Hib (PRP) covalently linked to 20 to 36.7 mg of Tetanus Toxoid: 11 ug Al+++ (as AIPO4) ≤ 1.25 mg Preservative: Thiomersal I.P: 0.01% w/v	ComBE Five 0.5 ML	0.5 ml PFS	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New

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DR. H. K. CHALAGI Digitally signed by DR. H. K.

CHALAGERI

CHALAGERI Date: 2025.04.16

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CHIEF HEALTH DIRECTOR SOUTH CENTRAL RAILWAY

S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc.	Name of the manufacturer and full address of manufacturing units along with phone nos. and e mail address	Name of the marketing firms/companies with full address along with phone nos. and e-mail address.	Inspected / Not Inspected	Remarks
14	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P, Single Pediatric dose Vial 0.5 ml Each dose of 0.5 ml contains: Purified inactivated Japanese Encephalitis Virus Vaccine Strain (SA14-14-2) - 3 µg Aluminium as Aluminium Hydroxide - 0.1% W/V Phosphate Buffer Saline: q.s.	JEEV 3mcg, 0.5 ML	0.5ml Vial	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
15	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P, 0.5 ml Single dose Pre-filled Syringe Each dose of 0.5 ml contains: Purified inactivated Japanese Encephalitis Virus Vaccine Strain (SA14-14-2) - 3 µg Aluminium as Aluminium Hydroxide - 0.1% W/V Phosphate Buffer Saline: q.s.	JEEV 3mcg, 0.5 ML	0.5ml PFS	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
16	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P, 0.5 ml in 3ml Vial Each dose of 0.5 ml contains: Purified inactivated Japanese Encephalitis Virus Vaccine Strain (SA14-14-2) - 6 µg Aluminium as Aluminium Hydroxide - 0.1% w/v Phosphate Buffer Saline: q.s.	JEEV 6mcg, 0.5 ML	0.5ml Vial	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
17	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P, 0.5 ml Single Dose Pre-filled Syringe Each dose of 0.5 ml contains: Purified inactivated Japanese Encephalitis Virus Vaccine Strain (SA14-14-2) - 6 µg Aluminium as Aluminium Hydroxide - 0.1% W/V Phosphate Buffer Saline: q.s.	JEEV 6mcg, 0.5 ML	0.5 ml PFS	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New

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COMPANY SECRETARY

DR. H. K. CHALAGERI Date: 2025.04.16

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S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc.	Name of the manufacturer and full address of manufacturing units along with phone nos. and e mail address	Name of the marketing firms/companies with full address along with phone nos. and e-mail address.	Inspected / Not Inspected	Remarks
18	Typhoid Vi Conjugate Vaccine I.P Single dose Vial of 0.5 mL supplied along with 2 mL syringe and two 25 G needles Each dose of 0.5 mL contains: Typhoid Vi Polysaccharide ¹ conjugated to 16.7µg to 100 µg of CRM ₁₉₇ 25 µg Sodium Chloride and Phosphate Buffer q.s 2-Phenoxyethanol (as Preservative) 5 mg Produced from C. freundii sensu lato 3056	Typhibev 0.5 ML	0.5ml Vial	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
19	Typhoid Vi Conjugate Vaccine I.P 0.5 mL Single Dose Pre-filled Syringe Each Pre-filled Syringe (0.5 mL) contains: Typhoid Vi Polysaccharide ¹ 25 µgconjugated to 16.7µg to 100 µg of CRM ₁₉₇ Phosphate Buffer with Sodium Chloride and Polysorbate 80 q.s Produced from C. freundii sensu lato 3056	Typhibev 0.5 ML	0.5ml PFS	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
20	Inactivated Hepatitis A Vaccine (Adsorbed) I.P. 0.5 ml Single Dose Pre-filled Syringe Each Pre-filled Syringe (0.5 mL) Contains: Inactivated HAV Antigen (TZ84 strain) 250 u Aluminium (as Aluminium hydroxide) 0.175- 0.31 mg Disodium Hydrogen Phosphate q.s Sodium Chloride 4.5 mg Sodium Dihydrogen Phosphate q.s Water for Injection q.s to 0.5 mL	HAPIBEV , 0.5 ML	0.5 mL PFS	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New

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DR. H. K. CHALAGERI Date: 2025.04.16 15:47:10 +05'30'

Digitally signed by DR. H. K. CHALAGERI

CHIEF HEALTH DIRECTOR SOUTH CENTRAL RAILWAY

S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc.	Name of the manufacturer and full address of manufacturing units along with phone nos. and e mail address	Name of the marketing firms/companies with full address along with phone nos. and e-mail address.	Inspected / Not Inspected	Remarks
21	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. (14 Valent) 0.5 ml Single Dose Vial Each dose of 0.5 mL contains: Pneumococcal polysaccharide serotype 1 3.0 µg Pneumococcal polysaccharide serotypes 3, 4, 5, 7F, 9V, 14, 18C, 19A,19F, 22F, 23F and 33F 2.2 µg Pneumococcal polysaccharide serotype 6B 4.4 µg Adsorbed onto Aluminium +++ Phosphate, as Al ≤ 0.75 mg Polysaccharides conjugated to 20-50 µg of CRM197	PNEUBEVAX 14 0.5 ml Vial	0.5 ml Vial	M/s.BIOLOGICAL E LTD, PLOT NO.1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE-500 078, SHAMEERPET MANDAL, MEDCHAL MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	New
22	Each MI Contains: Heparine Sodium IP - 1000 IU (Derived from Porcine Mucosa) Preservative: Benzyl Alcohol IP-0. 95% W/V Water for Injections IP q.s	Beparine 5000IU INJ	5 mL Vial.	M/s.BIOLOGICAL E LTD C/o AKUMS Drugs & Pharmaceuticals Limited, Plot No 2- 5, Sector 6B, IIE, SIDCUL, Ranipur, Haridwar - 249403 DEHRADUN	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	Nil
23	Each MI Contains: Heparine Sodium IP - 5000IU (Derived from Porcine Mucosa) Preservative: Benzyl Alcohol IP- 0.95% W/V Water for Injections IP q.s	Beparine 25000IU INJ	5 mL Vial.	M/s.BIOLOGICAL E LTD C/o AKUMS Drugs & Pharmaceuticals Limited, Plot No 2- 5, Sector 6B, IIE, SIDCUL, Ranipur, Haridwar - 249403 DEHRADUN	M/s Biological E Limited, 18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana, Email: Institution.Sales@biologicale.com	Inspected	Nil



DR. H. K. Digitally signed by DR. H. K. CHALAG CHALAGERI **ERI**

Date: 2025.04.16 15:47:37 +05'30'