File No: BIO/CT/24/000069
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division-Vaccine)

FDA Bhawan Kotla Road,
New Delhi-110002

From

The Drugs Controller General, India
Directorate General of Health Services,

To

M/s Bharat Serums and Vaccines Limited,
3rd Floor, Liberty Towers, Plot No. K-10 Behind Reliable Plaza,
Kalwa Industrial Estate, Airoli,
Navi Mumbai (India) – 400708,

Subject: Permission for conducting a clinical trial titled "An open label, Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of different strengths of Equine Klebsiella Immunoglobulin Injection in adult healthy volunteers" vide protocol no. BSV_KLEBSIELLA_EQ-AB_24_03, Version 3.0 dated 11.08.2025.

Reference: Your Application No. BIO/CT04/FF/2024/43840 dated 24.06.2024 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2024/43840 dated 24.06.2024, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of "Equine Klebsiella Immunoglobulin Injection 500 mg/5ml (100mg/ml)" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.02.17 05:19:54 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

File No: BIO/CT/24/000069
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division-Vaccine)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits M/s Bharat Serums and Vaccines Limited, 3rd Floor, Liberty Towers, Plot No. K-10, Behind Reliable Plaza, Kalwa Industrial Estate, Airoli, Navi Mumbai (India) – 400708, Telephone No.: 02245043456, FAX: 022 45043200 E-Mail: regaffairsbsv@bsvgroup.com to conduct clinical trial of the new drug or investigational new drug as per protocol no. BSV_KLEBSIELLA_EQ-AB_24_03, Version 3.0, dated 11.08.2025 in the below mentioned clinical trial sites.

CT No.: CT- 01/2026

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

RAJEEV SINGH RAGHUVANSHI

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Date: 2026.02.17 05:20:05 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Equine Klebsiella Immunoglobulin Injection 500 mg/5ml (100mg/ml)
Therapeutic class:	Immunoglobulin
Dosage form:	Solution for Infusion
Composition:	Composition: Each vial contains: **Active ingredient** — **Quantity** Equine Klebsiella Immunoglobulin IH — 500 mg/5ml (100 mg/ml) **Inactive ingredients** — **Quantity** Sodium Chloride IP/BP/USP — 155 mg Glycine IP/BP — 50 mg Water for injection IP — q.s.
Presentation:	100 mg/ml in 5ml vial
Indication(s):	To be administered as a treatment regimen along with the indicated antibiotics: Blood stream infections (eg: Septicaemia) Hospital acquired pneumonia (HAP) / Ventilator acquired pneumonia (VAP)

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Jahangir Clinical Development Centre Pvt. Ltd., Jahangir Hospital premises, 32 Sassoon Road, Pune Maharashtra - 411001	Ethics Committee of Jehangir Clinical Development Center Pvt. Ltd., Jehangir hospital premises, 32 Sasoon Road, Pune Maharashtra – 411001, India [ECR/352/Inst/MH/2013/RR-24]	Dr. Piyush Chaudhari

In addition to point 3, the permission is subject to following conditions:

1. The clinical trial should be conducted as per approved protocol titled, “An open label, Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of different strengths of Equine Klebsiella Immunoglobulin Injection in adult healthy volunteers” vide Protocol No. BSV_KLEBSIELLA_EQ-AB_24_03, Version 3.0 dated 11.08.2025.
2. The firm shall constitute a DSMB to review the safety data.
3. The formulation intended to be used in Phase I clinical trial shall be manufactured under GMP conditions and shall have ongoing stability program to ascertain that available long term stability data cover the entire duration of clinical trial.
4. Only CDL, Kasauli certified batches shall be used in the clinical trial.
5. Firm shall submit copy of COA of MSL & WSL and SOP for it’s maintenance.
6. The firm shall submit Ethics Committee approval for Phase I clinical trial.
7. The firm shall submit Insurance Policy for Phase I clinical trial.

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: