

File No: BIO/CT/24/000158
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

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. Biological E. Limited, Plot No. 1, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India -500 078 to conduct clinical trial of the new drug or investigational new drug as per protocol number: BECT089/IPV-Phase-III/CTP-01, Version no:1.0 dated 02.12.2024 in the below mentioned clinical trial sites.

CT No.: CT- 03/2025

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.

Place: New Delhi
Date:

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Inactivated Poliomyelitis Vaccine (Adsorbed).
Therapeutic class:	Vaccine (Viral vaccine)
Dosage form:	Solution for Intramuscular Injection
Composition:	<p>Composition:</p> <p>Each dose of 0.5 mL contains:</p> <p>Inactivated monovalent Poliomyelitis : 20 D-antigen unit Virus Type 1 (S19/MahP1/N18S)#</p> <p>Inactivated monovalent Poliomyelitis : 4 D-antigen unit Virus Type 2 (S19/MEF2P1/N18S)#</p> <p>Inactivated monovalent Poliomyelitis : 16 D-antigen unit Virus Type 3 (S19/SktP1/N18S)#</p> <p>Aluminium Hydroxide gel (equivalent to Al⁺⁺⁺) : ≤ 1.25 mg</p> <p>2-Phenoxyethanol (Preservative) : 4 mg</p> <p>#Produced in Vero cells</p> <p>Poliomyelitis vaccine bulks (Types 1, 2 and 3) were inactivated using formaldehyde.</p>
Presentation:	2.5mL (5 dose) vial
Indication(s):	Inactivated Poliomyelitis Vaccine (Adsorbed) is indicated for active immunization against Poliomyelitis Types 1, 2 and 3.

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Adichunchanagiri Hospital, Department of General Medicine, Ground floor, B G Nagara, Nagamangala Taluk, Mandya District- 571448. Karnataka, India.	EC Name: Institutional Ethics Committee of AH and RC EC Address: Adichunchanagiri Hospital & Research Center, Balagangadharanathanagara, Bellur Hobli, Nagamangala taluk, Mandya, Bengaluru, Urban Karnataka- 571 448, India. ECR/1456/Inst/KA/2020	Dr. Ravi B. Nagarajaiah M.B.B.S, MD & DNB (General Physician)
2	Aditya Multispecialty Hospital, 13-3- 52, 3rd Line, Gunturuvuri Thota, Kothapet, Beside Peoples Trauma, Guntur-522001, Andhra Pradesh, India.	EC Name: I E C ADITYA MULTISPECIALITY HOSPITAL EC Address: Aditya Multispeciality Hospital, 13-3-52, 3rd Line, Gunturivuri Thota, Kothapet Beside Peoples Trauma, Guntur, Andhra Pradesh - 522001 India. ECR/1347/Inst/AP/2020	Dr. Nagarjuna Chadalavada M.B.B.S & MD (Paediatrics)
3	All India Institute of Medical Sciences (AIIMS), Department of Pharmacology & Therapeutics	EC Name: Institutional Human Ethics Committee AIIMS Gorakhpur	Dr. Hira Lal Bhalla M.B.B.S & MD (Pharmacology)

	Gorakhpur, Uttar Pradesh-273008, India.	EC address: Academic Block, Opp Army Public School, All India Institute of Medical Sciences, Gorakhpur, Kunraghat, Gorakhpur, Uttar Pradesh-273008. ECR/1476/Inst/UP/2020	
4	All India Institute of Medical Sciences (AIIMS), Gate No, 1, Great Eastern Rd, opposite Gurudwara, AIIMS Campus, Tatibandh, Raipur-492099, Chhattisgarh, India.	EC Name: Institute Ethics Committee AIIMS Raipur, EC Address: Room No. 2103, 2nd Floor, South Wing, Medical College Complex, Gate No.5, All India Institute of Medical Sciences, G.E Road, Tatibandh, Raipur, Pin-492099, Chhattisgarh, India. ECR/714/Inst/CT/2015/RR-21	Dr. Atul Jindal M.B.B.S, DCH & MD (Paediatrics)
5	All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar-751019, Odisha, India.	EC Name: Institutional Ethics Committee, AIIMS, Bhubaneswar EC Address: All India Institute of Medical Sciences, BBSR, AIIMS Bhubaneswar Sijua P/O Patrapada, Bhubaneswar, Khordha Orissa - 751019, India ECR/534/Inst/OD/2014/RR-20	Dr. Bhagirathi Dwibedi M.B.B.S & MD (Paediatrics)
6	Belagavi Institute of Medical Sciences, Dr. B. R. Ambedkar Road, Sadashiv Nagar, Belgaum-590001, Karnataka, India.	EC Name: Institutional Ethics Committee BIMS. EC Address: Belagavi Institute of Medical Sciences, Belagavi, 3rd Floor, BIMS Building, Dr BR Ambedkar road, Belagavi-590001 Karnataka, India ECR/801/Inst/KA/2016/RR-20	Dr. Shailesh Patil M.B.B.S, MD (Paediatrics)
7	BGS Global Institute of Medical Sciences, Department of Paediatrics, No. 67, BGS Health and Education city Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka, India.	EC Name: Institutional Ethics Committee EC Address: Department of Community Medicine, Room No.01, Second Floor, College Building, BGS Global Institute of Medical Sciences, No. 67, BGS Health and Education City, Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka, India ECR/1307/Inst/KA/2019	Dr. Ramesh.M M.B.B.S, DCH & MD (Paediatrics)
8	Bharati Vidyapeeth (Deemed to be University) Medical College Hospital and Research Centre, Department of Paediatrics,	EC Name: Institutional Ethics Committee Bharati Vidyapeeth Deemed University EC Address: Institutional Ethics Committee Office 4th floor,	Dr. Sonali Hemant Palkar MBBS, DCH & MD (Community Medicine)

	Ground floor, Pune-Satara Road, Dhankawadi, Pune-411043, Maharashtra, India.	Bharati Hospital & Research Centre Pune - Satara Road, Dhankawadi Pune - 41 1043, Maharashtra, India. ECR/313/Inst/MH/2013/RR-24	Fellowship in Paediatrics infectious diseases.
9	Cheluvamba Hospital, Mysore Medical College & Research Institute, Irwin Rd, Mysore-570001, Karnataka, India	EC Name: IEC-MMC and RI and Associated Hospital EC Address: Mysore Medical College and Research Institute Irwin Road Mysuru, Karnataka - 570001 India ECR/134/Inst/KA/2013/RR-19	Dr. Pradeep.N M.B.B.S, MD (Paediatrics)
10	Chettinad Hospital & Research Institute, Chettinad Academy of Research and Education, Chettinad Health City, SH 49A, Kelambakkam Dist., Chennai-603103, Tamil Nadu, India.	EC Name: CARE-IHEC for Faculty Research EC Address: Chettinad Academy of Research and Education, Rajiv Gandhi Salai (OMR) Kelambakkam, Kanchipuram Tamil Nadu - 603103, India. ECR/1589/Inst/TN/2021	Dr. Jaishree Vasudevan M.B.B.S, MD (Paediatrics)
11	Chirayu Hospital, Kalwar Rd, Hathoj, Jaipur-302012, Rajasthan, India.	EC Name: IEC Chirayu Hospital (A Unit of KSCH Pvt. Ltd) EC Address: Chirayu Hospital (A Unit of KSCH Pvt. Ltd), Kalwar Road, Hathoj, Jaipur 302012 ECR/1582/Inst/RJ/2021	Dr. Kishori Sharan Agarwal M.B.B.S & DNB (Paediatrics)
12	Christian Medical College & Hospital, Brown Road, CMC Campus, Ludhiana-141008, Punjab, India.	EC Name: Institutional Ethics Committee EC Address: 2nd Floor Nr. Ward No.15, Room No. 3201, Christian Medical College & Hospital, Brown Road Ludhiana, Punjab-141008 ECR/120/Inst/PB/2013/RR-24	Dr. Deepshikha Kamra MBBS, MD (Community Medicine)
13	ESIC Medical College & Hospital, Clinical Trial Unit (MRU) Multidisciplinary Research Unit, Basement, NH-3, NIT, Faridabad-121001, Haryana, India.	EC Name: Institutional Ethics Committee for ESIC Faridabad. EC Address: ESIC Medical College and Hospital, NH-3, NIT, Behind BK Hospital, Faridabad, Haryana, India-121001. ECR/1539/Inst/HR/2021	Dr. Pankaj Kumar Gupta M.B.B.S & MD (Paediatrics)
14	Gandhi Hospital, Department of Paediatrics, 1st Floor, Musheerabad, Secunderabad, Telangana-500003, India	EC Name: Institutional Ethics Committee EC Address: 3rd Floor, Gandhi Medical College, Musheerabad, Secunderabad, Telangana, India. 500003 ECR/180/Inst/AP/2013/RR-24	Dr. Kompally Vasudev MBBS, MD (Paediatrics)

15	GMERS Medical College and Civil Hospital, Department of Paediatrics, Near Gujarat High Court, S.G. Highway, Sola, Ahmadabad-380061, Gujarat, India.	EC Name: Institutional Ethics Committee GMERS Medical College & Civil Hospital Sola EC Address: Department of Pharmacology, 4th Floor College Building, Nr. Gujarat, High Court, S.G, Highway Sola, Ahmedabad- 380061, Gujarat, India. ECR/404/Inst/GJ/2013/RR-20	Dr. Nehal Suryakant Patel M.B.B.S & MD (Paediatrics)
16	Government General Hospital, Budhawara Peta, Alluri Sitarama Raju Nagar, Kurnool-518002, Andhra Pradesh, India.	EC Name: Institutional Ethics Committee Kurnool Medical College. EC Address: Institutional Ethics Committee, Room No:07, Kurnool Medical College/Government, General Hospital, Budhawarpeta, Kurnool, Andhra Pradesh - 518002, India. ECR/1397/INST/AP/2020.	Dr. B. Vijai Anand Babu M.B.B.S, MD (Paediatrics)
17	Govt. Medical College & SSG General Hospital, Department of Paediatrics Jail Road, Indira Avenue, Vadodara-390001, Gujarat, India.	EC Name: Institutional Ethics Committee for Human Research. (IECHR) Medical College Baroda. EC Address: 1st Floor, New Library Building, Govt. Medical College, Baroda & SSG.Hospital, Vadodara-390001, Gujarat, India. ECR/85/Inst/GJI2013/RR-24	Dr. Pareshkumar.A.Thakkar M.B.B.S, MD & DNB (Paediatrics)
18	Institute of Child Health (ICH)11, Dr. Biresh Guha Street, Kolkata, West Bengal-700017, India.	EC Name: Institutional Ethics Committee, Institute of Child Health EC Address: 11, Dr. Biresh Guba Street, Kolkata- 700017. ECR/359/Inst/WB/2013/RR-24	Dr. Monjori Mitra M.B.B.S, DCH & DNB (Paediatrics)
19	Institute of Medical Science & SUM Hospital, K-8, Kalinga Nagar, Ghatikia, Bhubaneswar-751003, Odisha, India.	EC Name: Institutional Ethics Committee, Institute of Medical Science and SUM Hospital EC Address: Institute of Medical Science and SUM Hospital K-8, Kalinganagar, Shampur, Bhubaneswar, Khordha Odisha - 751003, India. ECR/627/Inst/OR/2014/RR-20	Dr. Mruthunjay Dash M.B.B.S, MD (Paediatrics) & APGPN

20	JLN Medical College, Kala Bagh, Ajmer 305001, Rajasthan, India.	EC Name: Institutional Ethies Committee, Jawahar Lal Nehru Medical College, EC Address: Kala Bagh, Ajmer-305001, Rajasthan, India ECR/1156/Inst/RJ/2018/RR-22	Dr. Jai Prakash Narayan M.B.B.S & M.D (Paediatrics)
21	JSS Hospital, Mahatma Gandhi Road, Mysuru-570004, Karnataka, India.	EC Name: Institutional Ethics Committee JSS Medical College EC Address: JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar Mysore, Karnataka - 570015 India ECR/387/Inst/KAJ2013/RR-22	Dr. M.D.Ravi M.B.B.S, DCH & M.D (Paediatrics)
22	Kanchi Kamakoti Childs Trust Hospital, 12-A Nageswara Road, Nungambakkam, Chennai-600034, India.	EC Name: Ethics committee of KKCTH and CTMRF EC Address: Kanchi Karnakoti Childs Trust Hospital, 12-A Nageswara Road, Nungambakkam, Chennai-600034, India ECR/676/Inst/TN/2014/RR-20	Dr. Janani Sankar MBBS & DNB (Paediatrics) & Ph.d.
23	KEM Hospital Research Centre, Vadu Rural Health Program at Post Vadu (Budruk), Taluka Shirur District Pune-412216, Maharashtra, India.	EC Name: KEM Hospital Research Centre Ethics Committee EC Address: KEM Hospital Research Centre, TDH building, Sardar Moodliar Road, Rasta Peth, Pune 411011, Maharashtra, India. ECR/272/Inst/MH/2013/RR-22	Dr. Anand Shantaram Kawade M.B.B.S, MD (Paediatrics) & DCH
24	King George Hospital, Collectorate Junction, Maharani-peta, Visakhapatnam-530002, Andhra Pradesh, India.	EC Name: Institutional Ethics Committee EC Address: King George Hospital, Department of Paediatrics, Collectorate junction, Maharani-peta, Visakhapatnam-530002, Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR-20	Dr. B. S. Chakravarthy M.B.B.S, M.D (Paediatrics)
25	KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India.	EC Name: Institutional Ethics Committee EC Address: KAHER (Formerly Known as KLEs University) Nehru Nagar, Belagavi-590010 ECR/211/Inst/KA/2013/RR-24	Dr. N. S. Mahantshetti M.B.B.S & M.D (Paediatrics)
26	Latha Mangeshkar Hospital, 5YMCA Complex Maharajbagh Road, Sitabuldi, Nagpur-440012,	EC Name: Institutional Ethics Committee EC Address: NKP Salve Institute of Medical Sciences	Dr. Anju J.K Mehrotra M.B.B.S & DCH (Paediatrics)

	Maharashtra, India.	Digdoh Hills, Hingna Road, Nagpur 440019 Maharashtra, India. ECR/88/Inst/MH/2013/RR-24	
27	Maharaja Agrasen Superspeciality Hospital Sec 7, Central Spin, Vidyadhar Nagar, Jaipur- 302039, Rajasthan, India.	EC Name: IEC Maharaja Agrasen Hospital EC Address: Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur- 302039, Rajasthan ECR/1222/Inst/RJ/2019/RR-22	Dr. Mohit Poddar M.B.B.S MD (Paediatrics)
28	Medipoint Hospitals Pvt. Ltd. 241/1 New D.P. Road, Aundh, Pune- 411007, Maharashtra, India.	EC Name: Penta-Med Ethics Committee EC Address: Medipoint Hospitals Pvt. Ltd. 241/1 New D.P. Road, Near Sai Heritage, Aundh, Pune 411007, Maharashtra, India. ECR/357/Inst/MH/2013/RR-20	Dr. Jog Pramod Prabhakar M.B.B.S, M.D. & DNB, FIAP (Paediatrics)
29	Niloufer Hospital for Women and Children Redhills, Lakdikapool, Hyderabad-500004, Telangana, India.	EC Name: Institutional Ethics Committee, Osmania Medical College. EC Address: Koti, Hyderabad - 500095, Telangana ECR/300/Inst/AP/2013/RR-24	Dr. N. Ravi Kumar M.B.B.S & MD (Paediatrics)
30	NKP Salve Institute of Medical sciences & Research Centre & Lata Mangeshkar Hospital, Digdoh Hills, Hingna Road Nagpur-440019, Maharashtra, India.	EC Name: Institutional Ethics Committee EC Address: NKP Salve Institute of Medical Sciences, Digdoh Hills Hingna road Nagpur Nagpur Maharashtra - 440019 India ECR/88/Inst/MH/2013/RR-24.	Dr. Girish Nanoti M.B.B.S, M.D & DCH (Paediatrics)
31	Old Government General Hospital (Associated By Govt. Siddhartha Medical College), Two Town, Hanumanpet, Vijayawada- 520002, Andhra Pradesh, India.	EC Name: Institutional Ethics Committee Siddhartha Medical College & Govt. General Hospital EC Address: 1st Floor, Central Diagnostic Block, Govt. Siddhartha Medical College, Campus, Ring Road, Gunadala, Vijayawada - 520008, Andhra Pradesh, India. ECR/633/INST/AP/2014/RR-19	Dr. Paruchuri Anil Kumar M.B.B.S, DCH & DNB (Paediatrics)
32	Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Poonamallee, Chennai-600123 Tamil Nadu, India	EC Name: PMCHRI - IHEC EC Address: Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Poonamallee, Chennai-600123 ECR/1399/Inst/TN/2020	Dr. Ramanath Andy Karayalar M.B.B.S, DCH, MD (Paediatrics)

33	PT. B D Sharma Post Graduate Institute of Medical Sciences, University of Health Sciences, Room No:428 Rohtak-124001, Haryana, India	EC Name: Institutional Ethics Committee Clinical Trial EC Address: PGIDS, Pt. B.D. Shanna University of Health Sciences, Rohtak-124001 ECR/495/Inst/HR/2013/RR-20	Dr. Savita Verma M.B.B.S & M.D (Pharmacology)
34	Sant Dnyaneshwar Medical Education & Research Centre, 695-A, Sadashiv Peth, Opp. Vijay Talkies, Laxmi Road, Pune-411030, Maharashtra, India.	EC Name: Sant Dnyaneshwar Medical Education Research Centre Institutional Ethics Committee EC Address: 695-A, Sadashiv Peth, Laxmi Road, Opp. Vijay Talkies, Pune: 411030 ECR/127/Inst/MH/2013/RR-19	Dr. Dhongade Ramchandra Keshav M.B.B.S, MD (Paediatrics)
35	Sardar Vallabhbhai Patel Post Graduate Institute of Paediatrics and SCB Medical College and Hospital, Oriya Bazar, Cuttack, Odisha-753002, India.	EC Name: Institutional Ethics Committee EC Address: SCB Medical College & Hospital. Cuttack-753007, Odisha, India ECR/84/Inst/OR/2013/RR-20	Dr. Pravakar Mishra MBBS, MD (Paediatrics)
36	Sarajini Naidu Medical College & Hospital, Moti Katra, Mantola, Agra, Uttar Pradesh-282003, India.	EC Name: Institutional Ethics Committee S.N Medical, S N Medical College, EC Address: Raja Mandi Near Agra College Agra Central Library, Moti Katra Mantola Agra, Uttar Pradesh 282003, India ECR/1409/Inst/UP/2020	Dr. Neeraj Kumar M.B.B.S & MD (Paediatrics)
37	Shubham Sudbhawana Superspeciality Hospital, B31/80-23B, Bhogabeer, Lanka Varanasi-221005, Uttar Pradesh, India.	EC Name: Shubham Sudbhawana Super. Hosp. Ethics Committee EC Address: B 31/80, 23B - Bhogabeer, Lanka, Varanasi, 221005, U.P. Varanasi, Uttar Pradesh - 221005, India ECR/667/Inst/UP/2014/RR-20.	Dr. Madhukar Pandey M.B.B.S, MD (Paediatrics)
38	Signus Hospital, 5th Floor, Atlanta Shoppers, Pathardi Phata, Pathardi Road, Nashik-422010, Maharashtra, India	EC Name: Signus Hospital Ethics Committee EC Address: Signus Hospital Ethics Committee, 5th Floor, Atlanta Shoppers, Pathardi Road, Pathardi Phata, Nashik- 422010, Maharashtra, India. ECR/1733/Inst/MH/2022	Dr. Patil Shyamkant Suresh MBBS, DCH

39	Smt. B. K. Shah Medical Institute & Research Centre, Sumandeep Vidhyapeeth At & Po Piparia, Ta. Waghodia, Vadodara-391760, Gujarat, India.	EC Name: Institutional Ethics Committee, SV EC Address: Sumandeep Vidhyapeeth, At and Post Pipariya, Vadodara, Gujarat, 391 760 India ECR/152/Inst/GJ/2013/RR-24	Dr. Javadekar Bakul Balchandra M.B.B.S, MD (Paediatrics)
40	Sri Ramachandra Hospital, Clinical Research Division, Dental College Basement, No. 1 Ramachandra Nagar, Porur, Chennai-600116, Tamil Nadu, India.	EC Name: Institutional Ethics Committee SRIHER EC Address: SRIHER, No.1 Ramachandra Nagar, Porur, Chennai, Tamil Nadu - 600116, India ECR/203/Inst/TN/2013/RR-24	Dr. Sarala Premkumar M.B.B.S, M.D (Paediatrics)
41	St. Theresa's Hospital (STH), 1 st Floor, Room No. 05, Erragadda Main Road, Czech Colony Sanath Nagar, Hyderabad-500018, Telangana, India	EC Name: Ethics committee St Theresas Hospital. EC Address: Sanathna gar, Opp Erragadda Raitu Bazar, Hyderabad, Telangana 500018, India ECR/230/Inst/AP/2013/RR-22	Dr. G. Balakishor M.B.B.S DCH & DNB (Paediatrics)
42	UCMS & GTB Hospital, Dilshad Garden, Delhi-110095, India.	EC Name: Guru Teg Bahadur Hospital Ethics Committee EC Address: Guru Teg Bahadur Hospital, Dilshad Garden, Delhi East, Delhi 110095, India ECR/510/Inst/DL/2014/RR-20	Dr. Manish Narang M.B.B.S & MD (Paediatrics)

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

1. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
2. The firm shall use CDL, Kasauli certified validated batches in the Phase III clinical trial.
3. Firm shall submit Ethics Committee approval for proposed Phase-III Clinical trial.
4. Variation of rat potency test results should be evaluated further in subsequent lots.
5. Firm needs to submit New Generation Sequence (NGS) testing procedure/ method development & validation report for Genome sequencing to consensus sequence matching with S19/MahP1/N18S and other strain.

Place: New Delhi

Date:

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

File No: BIO/CT/24/000158
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

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

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

To

M/s Biological E. Limited, Plot no.1,
Biotech Park, Phase II, Kolthur Village,
Shameerpet, Medchal-Malkajgiri District,
Telangana, India – 500078.

Subject: Permission for conducting a clinical trial titled “A single blind, randomized, active-controlled, phase-III study to evaluate immunogenicity and safety of Biological E’s inactivated poliomyelitis vaccine, administered to 6-8 weeks old healthy infants in 6-10-14 weeks dosing schedule”. [Protocol No. BECT089/IPV-Phase-III/CTP-01 Version No.1.0 Dated 02.12.2024]”-regarding.

Reference: Your Application No. BIO/CT04/FF/2024/46784 dated 11-DEC-2024 on the subject mentioned above.

Sir,

Please refer to your application no. No. BIO/CT04/FF/2024/46784 dated 11-DEC-2024, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase III Clinical Trial of “Inactivated Poliomyelitis Vaccine (Adsorbed)” 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,

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