

File No: BIO/CT/25/000002  
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 grant permission to M/s Biological E. Limited, Sy. No: 549,550,552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana -500078, India. Telephone No.: 91-40-67588301, FAX: 91-40-30128159, E-mail: [info@biologicale.com](mailto:info@biologicale.com) to conduct clinical trial of the new drug or investigational new drug as per Protocol No: BECT094/LHV-Phase-III/CTP-01, Version No.: 1.0 dated 16.12.24 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

**CT No.: CT- 04 /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:**

<b>Name of the new drug or investigational new drug:</b>	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), inactivated Poliomyelitis and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) (Liquid Hexavalent Vaccine)	
<b>Therapeutic class:</b>	Vaccine	
<b>Dosage form:</b>	Suspension for Intramuscular Injection	
<b>Composition:</b>	<b>Each dose of 0.5 mL Vaccine contains:</b>	
	<b>Composition</b>	<b>Quantity</b>
	<b>Active Ingredients</b>	
	Diphtheria Toxoid	≥ 30 IU (≥20Lf to ≤ 30Lf)
	Tetanus Toxoid	≥ 60 IU (≥5Lf to ≤ 25 Lf)
	B.Pertussis (Whole cell, Killed)	≥ 4 IU
	r-HBsAg (Recombinant HBs Antigen produced in <i>Pichia pastoris</i> )	12.5 µg
	Inactivated poliomyelitis virus Type -1(S19/MahP1/N18S)# Type-2(S19/MEF2P1/N18S)# Type -3(S19/SktP1/N18S)#	40 D-Antigen Units 8 D-Antigen Units 32 D-Antigen Units
	Purified Capsular Polysaccharide of Hib (PRP) covalently linked to 20 to 36.7ug of Tetanus Toxoid	11 µg
	<b>Inactive ingredients</b>	
	Al <sup>+++</sup> (As AIPO <sub>4</sub> )	≤ 1.25 mg
2-Phenoxyethanol	4.0 mg	
# Produced in Vero cells. Poliomyelitis vaccine bulks (Types 1,2 and 3) were inactivated using formaldehyde		
<b>Presentation</b>	2.5 mL (5 dose)	
<b>Indication</b>	For active immunization to prevent Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis type 1, 2, and 3 and <i>Haemophilus influenzae</i> type b.	

**Details of clinical trial sites-**

S.No.	Names and Address of Clinical Trial Site	Ethics Committee Details	Name of Investigator(s) & Designation
1.	Adichunchanagiri Hospital, Department of General Medicine, Ground floor, B G Nagara, Nagamangala Taluk, Mandya District-571448. Karnataka, India.	Institutional Ethics Committee of AH and RC, Adichunchanagiri Hospital & Research Center, Balagangadharanathanagara, Bellur Hoblli, Nagamangala Taluk, Mandya, Bengaluru, Urban Karnataka- 571 448, India.	Dr. Ravi B. Nagarajaiah M.B.B.S, MD & DNB (General Physician)

		[ECR/1456/Inst/KA/2020]	
2.	Aditya Multispecialty Hospital, 13-3-52, 3rd Line, Gunturivari Thota, Kothapet, Beside Peoples Trauma, Guntur-522001, Andhra Pradesh, India.	I E C ADITYA MULTISPECIALITY HOSPITAL, Aditya Multispeciality Hospital, 13-3-52, 3 <sup>rd</sup> Line, Gunturivari 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, Gorakhpur, Uttar Pradesh-273008, India.	Institutional Human Ethics Committee AIIMS Gorakhpur, Academic Block, Opp Army Public School, All India Institute of Medical Sciences, Gorakhpur, Kunraghat, Gorakhpur; Uttar Pradesh-273008. [ECR/1476/Inst/UP/2020]	Dr. Hira Lal Bhalla M.B.B.S & MD (Pharmacology)
4.	All India Institute of Medical Sciences (AIIMS), Gate No 1, Great Eastern Rd, opposite Gurudwara, AIIMS Campus, Tatibandh, Raipur-492099, Chhattisgarh, India.	Institute Ethics Committee AIIMS Raipur, 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.	Institutional Ethics Committee, AIIMS, Bhubaneswar, 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.	Institutional Ethics Committee BIMS, 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.	Institutional Ethics Committee 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-5 60060, 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, Ground floor, Pune-Satara Road, Dhankawadi-411043, Pune, Maharashtra, India.	Institutional Ethics Committee Bharati Vidyapeeth Deemed University, Institutional Ethics Committee, Bharati Hospital & Research Centre Pune - Satara Road, Dhankawadi Pune - 411043, Maharashtra, India. [ECR/313/Inst/MH/2013/RR-24]	Dr. Ramdas Manikrao Dahiphale MBBS, (Paediatrics)
9.	Cheluvamba Hospital, Mysore Medical College & Research Institute, Irwin Rd, Mysore-570001, Karnataka, India.	IEC-MMC and RI and Associated Hospital Mysore Medical College and Research Institute Irwin Road Mysuru, Karnataka- 570001, India [ECR/134/Inst/KA/2013/RR-19]	Dr. Prashanth S 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.	CARE—IHEC for Faculty Research, 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.	IEC Chirayu Hospital (A Unit of KSCH Pvt. Ltd) 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, Broom Road, CMC Campus, Ludhiana- 141008, Punjab, India.	Institutional Ethics Committee, 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.	Datta Meghe Medical College and Shalinitai Meghe Hospital and Research Centre, Hingna Road, Wanadongari, Nagpur-441110, Maharashtra, India.	Ethics Committee, SMHRC Ethics Committee Shalinitai Meghe Hospital and Research Center Opp.big Bazar, Panchashil Square, Dhantoli Nagpur Maharashtra - 441110 India. [ECR/1603/Inst/MH/2021]	Dr. Kush Damodar Jhunhunwala M.B.B.S, M.D (Paediatrics), DNB
14.	Dhiraj Hospital and S. B. K. Shah Medical Institute & Research Centre, Sumandeep Vidhyapeeth Deemed to be University At & Po Piparia, Ta. Waghodia, Vadodara- 391760, Gujarat, India.	Institutional Ethics Committee, Institutional Ethics Committee, SV, Sumandeep Vidyapeeth Sumandeep Vidyapeeth At and Post Pipariya Pipariya Vadodara Gujarat- 391760 [ECR/152/Inst/GJ/2013/RR-24]	Dr.Javadekar Bakul Balchandra M.B.B.S, MD (Paediatrics)

15.	Elite Mission Hospital, P.B No. 1414, Koorkenchery, Thrissur- 680007, Kerala, India.	Institutional Ethics Committee Institutional Ethics Committee, Elite Mission Hospital, Koorkenchery, Thrissur, Kerala - 680007, India [ECR/243/Inst/Ker/2013/RR-19]	Dr. Satish Chandran Vazhappilly Ramachandran M.B.B.S, MD (Paediatrics)
16.	ESIC Medical College & Hospital, Clinical Trial Unit (MRU) Multidisciplinary Research Unit, Basement, NH-3, NIT, Faridabad- 121001, Haryana, India.	Institutional Ethics Committee for ESIC Faridabad, ESIC Medical College and Hospital, NH-3, NIT, Behind BK Hospital, Faridabad, Haryana, India- 121001. [ECR/1539/Inst/HR/2021]	Dr. Onkar Singh Bhinder M.B.B.S, MD(Paediatrics)
17.	Galaxy Superspeciality Hospital and Research Institute, Agnihotra Chowk Opposite to Punjab National bank Ulkanagari, Aurangabad-431001, Maharashtra, India.	Ethics Committee of Ishwar Institute of Health Care, Ishwar Institute of health care 3rd Floor, Ishwar heights, Plot no-7, Gut no.6 /1, Beside Punjabi Bhawan, Padegaon, Jaisinghpura, Aurangabad-431002, Maharashtra, India. [ECR/988/Inst/MH/2017/RR-20]	Dr. Mohd Haseeb Nazeeb Mohd M.B.B.S, MD(Paediatrics)
18.	GMERS Medical College and Civil Hospital, Department of Paediatrics, Near Gujarat High Court, S.G. Highway, Sofa, Ahmadabad-380061, Gujarat, India.	Institutional Ethics Committee GMERS Medical College & Civil Hospital Sola ,Department of Pharmacology, 4th Floor College Building, Nr. Gujarat, High Court, S.G, Highway Sola, Ahmedabad-380061, Gujarat, India. [ECR/404/Inst/GJ/2023/RR-20]	Dr. Nehal Suryakant Patel M.B.B.S & MD (Paediatrics)
19.	Govt. Medical College Baroda & SSG General Hospital, Department of Paediatrics, Jail Road, Indira Avenue, Vadodara- 390001, Gujarat, India.	Institutional Ethics Committee for Human Research. (IECHR) Medical College Baroda, Department of Pediatics, Ward 17, First Floor, Medical College & SSG Hospital, Vadodara India 390001, Gujarat, Vadodara Gujarat - 390001 India [ECR/85/Inst/GJ/2013/RR-24]	Dr. Pareshkumar. A. Thakkar M.B.B.S, DCH, MD, DNB (Paediatrics)
20.	Indira Gandhi Institute of Child Health, South Hospital Complex, Dharmaram College Post- 560029, Bangalore, Karnataka, India.	Institutional Ethics Committee Indira Gandhi Institute of Child Health, Indira Gandhi Institute of Child Health, South Hospital Complex, Dharmaram College Post, Bangalore-560029, Karnataka, India. [ECR/441/Inst/KA/2013/RR-19]	Dr. Sanjeeva G.N M.B.B.S, DCH, DNB

21.	Institute of Child Health (ICH), Dr. Biresh Guha Street, Kolkata, West Bengal-700017, India.	Institutional Ethics Committee, Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata-700017. [ECR/359/Inst/WB/2013/RR-24]	Dr. Monjori Mitra M.B.B.S, DCH & DNB (Paediatrics)
22.	Institute of Medical Science & SUM Hospital, K-8, Kalinga Nagar, Ghatikia, Bhubaneswar-751003, Odisha, India.	Institutional Ethics Committee IES, IMS & SUM Hospital, K-8, Kalinga Nagar, Ghatikia, Bhubaneswar- 751003, Odisha, India [ECR/627/Inst/OR/2014/RR-20]	Dr. Mrutunjay Dash M.B.B.S, MD (Paediatrics)
23.	JLN Medical College, Kala Bagh, Ajmer 305001, Rajasthan, India.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India. [ECR/1156/Inst/RJ/2018/RR-22]	Dr. Jai Prakash Narayan M.B.B.S & M.D (Paediatrics)
24.	JSS Hospital, Mahatma Gandhi Road, Mysuru-570004, Karnataka, India.	Institutional Ethics Committee JSS Medical College, JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar Mysore, Karnataka - 570015 India. [ECR/387/Inst/KA/2013/RR-22]	Dr. M.D. Ravi M.B.B.S, DCH & M.D (Paediatrics)
25.	Kanchi Kamakoti Childs Trust Hospital, 12-A Nageswara Road, Nungambakkam, Chennai-600034, India.	Ethics committee of KKCTH and CTMRF, Kanchi Kamakoti Childs Trust Hospital, 12-A Nageswara Road, Nungambakkam, Chennai- 600034, India. [ECR/676/Inst/TN/2014/RR-20]	Dr. Vasanthi Thiruvengadam M.B.B.S, DNB, MNAMS, Ph.d.
26.	King George Hospital, Collectorate Junction, Maharani-peta, Visakhapatnam-530002, Andhra Pradesh, India.	Institutional Ethics Committee, 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)
27.	KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India.	Institutional Ethics Committee KAHAR (Formerly Known as KLEs University) Nehru Nagar, Belagavi-590010. [ECR/211/Inst/KA/2013/RR-24]	Dr. Niranjana. S. Mahantshetti M.B.B.S, M.D (Paediatrics)
28.	Kurnool Medical College/Government General Hospital, Budhawara Peta, Kurnool-518002, Andhra Pradesh, India.	Institutional Ethics Committee, Institutional Ethics Committee, 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)

29.	Latha Mangeshkar Hospital, 5YMCA Complex Maharajbagh Road, Sitabuldi, Nagpur-440012, Maharashtra, India.	Institutional Ethics Committee NKP Salve Institute of Medical Sciences Digdoh Hills, Hingna Road, Nagpur 440019 Maharashtra, India. [ECR/88/Inst/MH/2013/RR-24]	Dr. Anju J.K Mehrotra M.B.B.S & DCH (Paediatrics)
30.	Maharaja Agrasen Superspeciality Hospital Sec 7, Central Spin, Vidyadhar Nagar, Jaipur-302039, Rajasthan, India.	IEC Maharaja Agrasen Hospital 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)
31.	Mandya Institute of Medical Science, MC Road, Nehru Nagar, Mandya 571401, Karnataka, India.	Institution Ethics Committee, MIMS Mandya, Mandya Institute of Medical Science, MC Road, Nehru Nagar, Mandya Karnataka-571401, India. [ECR/405/Inst/KA/2013/RR-21]	Dr. Sridhar P.V. M.B.B.S, MD (Paediatrics)
32.	Medipoint Hospitals Pvt. Ltd. 241/1 New D.P.Road, Aundh, Pune-411007, Maharashtra, India.	Penta-Med Ethics Committee 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)
33.	Medstar Speciality Hospital, #641 /17/1/3, Kodigehalli Main Road, Sahakar Nagar-560092, Bangalore, Karnataka, India.	Medstar Speciality Hospital Ethics Committee, Medstar Speciality Hospital, #641/17 /1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore-560092, Karnataka, India. [ECR/1324/Inst/KA/2019/RR-24]	Dr. Prashanth M. V M.B.B.S, MD (Paediatrics), FIPM (Neonatology)
34.	Niloufer Hospital for Women and Children, Redhills, Lakdikapool, Hyderabad-500004, Telangana, India.	Institutional Ethics Committee, Osmania Medical College Koti, Hyderabad- 500095, Telangana, India. [ECR/300/Inst/AP/2013/RR-24]	Dr. N. Ravi Kumar M.B.B.S, MD (Paediatrics)
35.	NKP Salve Institute of Medical Sciences & Research Centre & Lata Mangeshkar Hospital, Digdoh Hills, Hingna Road, Nagpur-440019, Maharashtra, India.	Institutional Ethics Committee, NKP Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital, Digdoh Hills, Hingana Road, Nagpur- 440019. [ECR/88/Inst/MH/2013/RR-24]	Dr. Girish Nanoti M.B.B.S, DCH, M.D (Paediatrics)
36.	Old Government General Hospital (Associated By Govt. Siddhartha Medical College), Two Town, Hanumanpet, Vijayawada-520002, Andhra Pradesh, India.	Institutional Ethics Committee SMC & GGH, Siddhartha Medical College and Govt. General Hospital Ring Road Gunadala Vijayawada Krishna Andhra Pradesh - 520008 India. [ECR/633/Inst/AP/2014/RR-19]	Dr. Paruchuri Anil Kumar M.B.B.S, DCH, DNB (Paediatrics)

37.	Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Poonamallee, Chennai-600123, Tamil Nadu, India.	PMCHRI – IHEC, 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)
38.	Priya Children Hospital, D.No. 57, 12-3, Panta Kaluva Rd, Maruti Colony, New P & T Colony, Patamata, Vijayawada-520010, Andhra Pradesh, India.	Independent Ethics Committee-Fusion Clinical Research, Flat No GF2 TV Sharma Residency SER centre Prasadampadu Krishna Andhra Pradesh- 521108, India. [ECR/375/Indt/AP/2023]	Dr. B. Sudhakar M.B.B.S & DCH
39.	PT. B D Sharma Post Graduate Institute of Medical Sciences, University of Health Sciences, Room No:428 Rohtak-124001, Haryana, India.	Institutional Ethics Committee Clinical Trial, 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)
40.	Sant Dnyaneshwar Medical Education & Research Centre, 695-A, Sadashiv Peth, Opp. Vijay Talkies, Laxmi Road, Pune-411030, Maharashtra, India.	Sant Dnyaneshwar Medical Education Research Centre Institutional Ethics Committee, 695-A, Sadashiv Peth, Laxmi Road, Opp. Vijay Tallies, Pune: 411030. [ECR/127/Inst/MH/2013/RR-19]	Dr. Dhongade Ramchandra Keshav M.B.B.S, MD (Paediatrics)
41.	Sardar Vallabhbhai Patel Post Graduate Institute of Paediatrics and SCB Medical College and Hospital, Cuttack, Odisha-753002, India.	Institutional Ethics Committee, SCB Medical College and Hospital, Cuttack- 753007, Odisha, India. [ECR/84/Inst/OR/2013/RR-20]	Dr. Pravakar Mishra MBBS, M.D (Paediatrics)
42.	Sarojini Naidu Medical College & Hospital, Moti Katra, Mantola, Agra, Uttar Pradesh-282003, India.	Institutional Ethics Committee, S.N. Medical College Raja Mandi near Agra College, Central Library, Moti Katra Mantola, Agra, Uttar Pradesh 282003 India. [ECR/1409/Inst/UP/2020]	Dr. Neeraj Kumar M.B.B.S, M.D (Paediatrics)
43.	Shardaben Chimanlal Lalbhai Municipal General Hospital, Bhagwati Nagar, Saraspur, Ahmedabad-380018, Gujarat, India.	Institutional Ethics Committee, NHLIEC, Smt. NHL Municipal Medical College, V S Hospital Campus, Ellisbridge, Ahmedabad, 380006. [ECR/245/Inst/GJ/2013/RR-24]	Dr. Hetal Vora M.B.B.S, M.D (Paediatrics)
44.	Shubham Sudbhawana Superspeciality Hospital, B31 /80-23B, Bhogabeer, Lanka Varanasi-221005, Uttar Pradesh, India.	Institutional Ethics Committee, Shubham Sudbhawana Super Speciality Hospital, B31 /80-23B, Bhogabeer Lanka Varanasi- 221005 Uttar Pradesh, India. [ECR/667/Inst/UP/2014/RR-20]	Dr. Madhukar Pandey M.B.B.S, M.D (Paediatrics)

45.	Sri Ramachandra Hospital, Clinical Research Division, Dental College Basement, No. 1 Ramachandra Nagar, Porur, Chennai-600116, Tamil Nadu, India.	Institutional Ethics Committee SRIHER, Sri Ramachandra No: 1, Ramachandra Nagar, Porur, Chennai, Tiruvallur, Tamil Nadu - 600116, India. [ECR/203/Inst/TN/2013/RR-24]	Dr. Elayaraja Sivaprakasam M.B.B.S, DCH, DNB (Paediatrics)
46.	St. Theresa's Hospital (STH), 1st Floor, Erragadda Main Road, Sanath Nagar, Hyderabad- 500018, Telangana, India	Ethics Committee, St. Theresa's Hospital, 1st Floor, EC office, PRD block, Sanathnagar, 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)
47.	Suyog Hospital, 2nd Floor, B-wing, Krushi Utapanna Bazar Samiti, Sankul, Dindori Road, Panchavati, Nashik-422003, Maharashtra, India.	Signus Hospital Ethics Committee, Signus Hospital, 01, Sai Darshan Bunglow, Prashant Nagar, Pathardi, Phata, Nashik Nashik Maharashtra- 422010, India. [ECR/1733/Inst/MH/2022]	Dr. Kalantri Reena Gopaldas MBBS, DCH, PGDAP
48.	UCMS & GTB Hospital, Dilshad Garden, Delhi- 110095, India.	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur Hospital Ethics Committee Dilshad Garden, Delhi - 110095, India. [ECR/510/Inst/DL/2014/RR-20]	Dr. Manish Narang M.B.B.S, MD(Paediatric )

सत्यमेव जयते

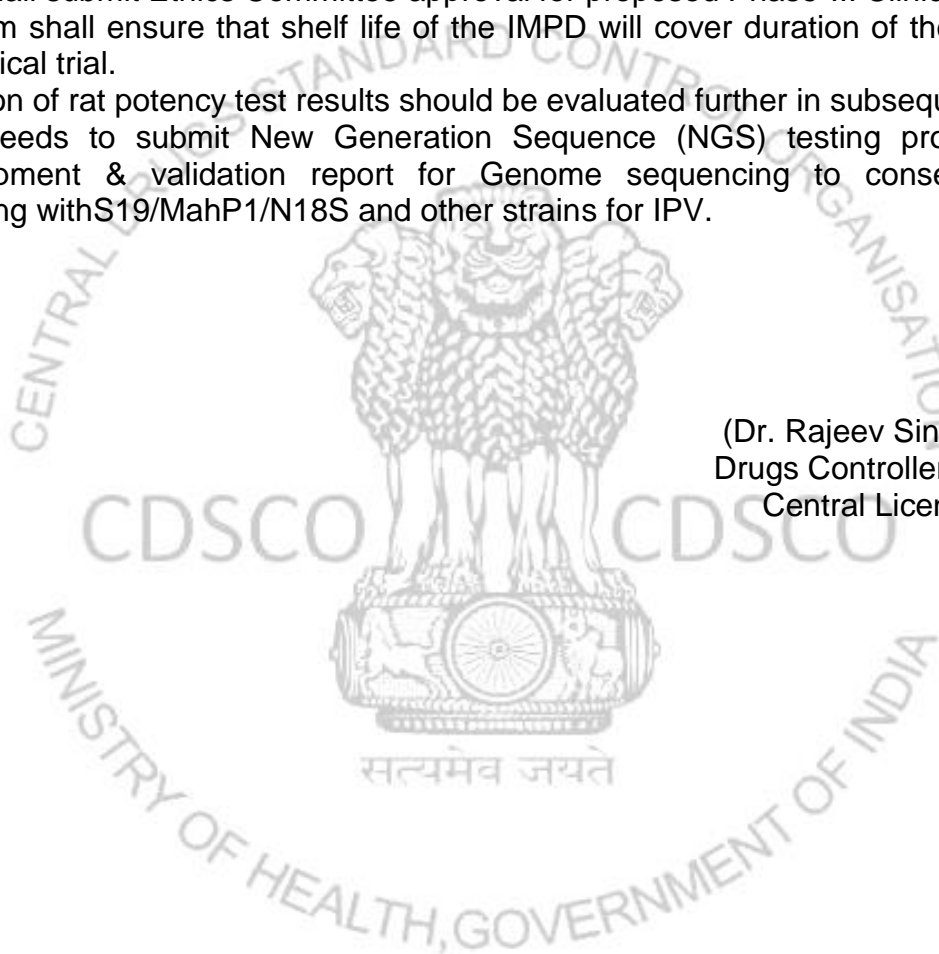
## File No: BIO/CT04/FF/2025/47160

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

1. The clinical trial should be conducted as per approved protocol titled "A prospective, single blind, randomised, active controlled Phase-III study to assess the immunogenicity and safety of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old healthy infants in a 6-10-14 weeks dosing schedule with Protocol No: BECT094/LHV-Phase-III/CTP-01, 1.0 Final dated 16.12.24.
2. The firm is required to constitute a DSMB to review the safety data.
3. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
4. Firm is required to submit copy of Insurance Certificate of subject trial.
5. The firm shall use CDL, Kasauli certified validated batches in the Phase III clinical trial.
6. Firm shall submit Ethics Committee approval for proposed Phase-III Clinical trial.
7. The firm shall ensure that shelf life of the IMPD will cover duration of the study period of the clinical trial.
8. Variation of rat potency test results should be evaluated further in subsequent lots for IPV.
9. 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 strains for IPV.

Place: New Delhi  
Date :

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



File No: BIO/CT/25/000002  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

FDA Bhawan Kotla Road,  
New Delhi-110002

**From:**

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

**To,**

M/s Biological E Limited, Plot No I,  
Biotech Park Phase II, Kolthur Village,  
Shameerpet, Medchal-Malkajgiri District,  
Telangana, India -500 078.

**Subject:** Permission for conducting a clinical trial titled "A prospective, single blind, randomised, active controlled Phase-III study to assess the immunogenicity and safety of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old healthy infants in a 6-10-14 weeks dosing schedule. (ProtocolNo:BECT094/LHV-Phase-III/CTP-01)Version no. 1.0 dated16.12.2024-Biological E. Limited

**Reference:** Your Application No. BIO/CT04/FF/2025/47160 dated 11-Jan-2025 on the subject mentioned above.

**Sir,**

Please refer to your application no. BIO/CT04/FF/2025/47160 received by this office on the above subject. In this regard, please find enclosed herewith permission to conduct a Phase III clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

You are required to comply with the requirements of Drugs and Cosmetics Rules, 1945 and communication of Central Licencing Authority.

Please acknowledge receipt of the same.

**Yours faithfully,**

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