

File No: BIO/CT/21/000117
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 Panacea Biotech Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044 Telephone No.: null FAX: null E-Mail: shafiqurrahman@panaceabiotec.com to conduct clinical trial of the new drug or investigational new drug as per [Protocol no. PAN-ICMR-DengiAll-001, Version no. 4.0 dated 24 Nov 2022] in the below mentioned clinical trial sites.

CT No.: CT- 03/2024

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:	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized vaccine supplied with sterile water for Injection as a diluent (Single Dose presentation in vial) for Subcutaneous use.	
Composition:	Each dose (0.5 ml) of reconstituted vaccine contains	
	Active ingredient	Quantity
	Serotype 1 (rDEN-1Δ30)	Not less than 3.0 log ₁₀ PFU
	Serotype 2 (rDEN-2/4Δ30)	Not less than 3.0 log ₁₀ PFU
	Serotype 3 (rDEN-3/30 Δ31)	Not less than 3.0 log ₁₀ PFU
	Serotype 4 (rDEN-4Δ30)	Not less than 3.0 log ₁₀ PFU
	Inactive ingredient	Quantity
	Gelita Vaccipro (Collagen Hydrolysate)	22.00 mg
	Mannitol	15.00 mg
	Trehalose	8.00 mg
	Sucrose	37.31 mg
	Potassium Phosphate, Monobasic (KH ₂ PO ₄)	258.50 µg
	Potassium Phosphate, Dibasic (K ₂ HPO ₄)	627.00 µg
	Monosodium glutamate	456.65 µg
	Dulbecco's Modified Eagle's Medium, High glucose	500.00 µg
	Sterile Water for Injection	q.s
Indication(s):	Prevention of Dengue fever	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	JSS Medical College and Hospital JSS AHER Shivarathreeshwara Nagara, Bannimantap, Mysuru 570015	Institutional Ethics Committee, JSS Medical College, JSS Hospital, Mysore, JSS Medical College, Sri Shivarathreeshwara Nagara, Mysuru Mysore Mysuru (Mysore) Karnataka -570015 [ECR/387/Inst/KA/2013/RR-22]	Dr. Anil Bilimale
2	All India Institute of Medical Sciences, Bibinagar, Hyderabad	AIIMS BBN- institutional Ethics Committee All India Institute of Medical Sciences Bibinagar Bibinagar Hyderabad Metropolitan Region Hyderabad, Yadadri, Telangana - 508126 India [ECR/1596/Inst/TG/2021]	Dr. Rashmi Kundapur,

3	Pondicherry Institute of Medical Sciences (A unit of the Madras Medical Mission), Ganapathichettikulam, Kalapet, Puducherry – 605014	Institute Ethics Committee Pondicherry Institute of Medical Sciences, No.20, Ganapathichettikulam Kalapet Puducherry (India) -605014 India [ECR/400/Inst/PY/2013/RR-20]	Dr. Anil Jacob Purty
4	Amrita Institute of Medical Sciences, Kochi, Ponekkara, P.O. – 682041 Kerala	Institutional Ethics Committee Amrita Institute of Medical Sciences AIMS-Ponekkara Kochi Edappally Ernakulam Kerala -682041 India [ECR/129/Inst/KL/2013/RR-19]	Dr. Teena Mary Joy
5	All India Institute Of Medical Sciences, Jodhpur – 342005 (Rajasthan)	INSTITUTIONAL HUMAN ETHICS COMMITTEE All India Institute of Medical Sciences Basni Jodhpur Jodhpur Rajasthan -342005 India [ECR/866/Inst/RJ/2016/RR-19]	Dr. Pankaj Bhardwaj
6	Rajendra Institute Of Medical Sciences, Ranchi – 834009, Jharkhand	Institutional Ethics Committee, RIMS, Ranchi Rajendra Institute of Medical Sciences 4th Floor, Administrative Building Bariatu, Ranchi Jharkhand -834009 [ECR/769/Inst/JH/2015/RR-21]	Dr. Mithilesh Kumar
7	ICMR-National Institute Of Cholera and Enteric Diseases(ICMR-NICED) P-33, C.I. T, Road, Scheme - XM, Beliaghata, Kolkata – 700010 West Bengal	IEC, ICMR-NICEDICMR-NICEDP-33 CIT Road Scheme XM Beliaghata Kolkata West Bengal - 700010 India [ECR/416/Inst/WB/2013/RR-20]	Dr. Suman Kanungo
8	ICMR-Rajendra Memorial Research Institute of Medical Sciences, Agamkuan, Patna 800007, Bihar, India	Ethics Committee ICMR, RMRIMS ICMR, Rajendra Memorial Research Institute of Medical Sciences, (RRIMS), Agamkuan, Patna, Bihar-800007 [ECR/480/Inst/BR/2014/RR-19]	Dr. Krishna Pandey
9	Pt. B.D. Sharma, Postgraduate Institute of Medical Sciences, University of Health Sciences, Rohtak Haryana, 124001	Institutional Ethics Committee, PGIMS UHS Rohtak PGIMS UHS Rohtak Pt. BD Sharma, Post Graduate Institute Of Sciences PGIMS UHS Rohtak-124001 Rohtak Rohtak Haryana -124001 India [ECR/293/Inst/HR/2013/RR-19]	Dr. Savita Verma
10	Christian Medical College & Hospital Brown Road, Ludhiana 141008 Punjab, India	Institutional Ethics Committee, Christian Medical College & Hospital Brown Road Ludhiana, Punjab - 141008 India [ECR/120/Inst/PB/2013/RR-19]	Dr. Clarence J. Samuel
11	Kalinga Institute of Medical Sciences (KIMS), Campus 5, KIIT University, Patia, Bhubaneswar, Odisha – 751024	Institutional Ethics Committee-KIMS Kalinga Institute of Medical Sciences Kushabhadra campus (Campus 5) KIIT University,	Dr. Sonali Kar

		Patia Bhubaneswar Khordha Orissa - 751024 India [ECR/321/Inst/OR/2013/RR-20]	
12	All India Institute of Medical Sciences Rishikesh, Virbhadr Road, Shivaji Nagar, Near Barrage, Sturida Colony, Rishikesh	Ethics Committee relating to Clinical Trial All India Institute of Medical Sciences Rishikesh Virbhadr Marg Pashulok Rishikesh Dehradun Uttarakhand -249203 India [ECR/736/Inst/UK/2015/RR-21]	Dr. Yogesh Bahurupi
13	JN Institute of Medical Sciences, Porompat, Imphal	Institutional Ethics Committee, JNIMS Jawaharlal Nehru Institute of Medical Sciences Porompat Imphal East Imphal Imphal East Manipur - 795005 India [ECR/1333/Inst/MN/2020]	Dr. Haobijam Narendra kumar Singh
14	Seth G.S. Medical College & KEM Hospital, Parel Mumbai 400012	Institutional Ethics Committee-I, Seth GS Medical College and KEM Hospital, Mumbai. Acharya Donde Marg, Parel, Mumbai 400 012. India Mumbai, Maharashtra - 400012 India [ECR/229/Inst/MH/2013/RR-19]	Dr. Ravindra S. Kembhavi
15	Atal Bihari Bajpayee Institute of Medical Science & Dr Ram Manohar Lohia Hospital, New Delhi-110001	Ethics Committee, Atal Bihari Vajpayee Institute of Medical Sciences (ABVIMS) & Dr. RML Hospital, Baba Kharakh Singh Marg, Central Delhi, Delhi – 110001 [ECR/78/Inst/DL/2013/RR-19]	Dr. Neelam Roy
16	Jawaharlal Nehru Medical College, Aligarh Muslim University Aligarh UP 202002	Institutional Ethics Committee, Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Civil Line, Koil, Aligarh Uttar Pradesh – 202002 [ECR/1418/Inst/UP/2020]	Dr. Mohammad Shameem
17	Dr. D.Y. Patil Medical College, Hospital and Research Centre, Pimpri Pune	Ethics Committee, Dr. D.Y. Patil Vidyapeeth, Pimpri, Pune, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra – 411018 [ECR/361/Inst/MH/2013/RR-19]	Dr. Shubhangi Kanitkar
18	SRM Medical College Hospital & Research Centre Kattankulathur, Chengalpatt 603203	Ethics Committee, SRM Medical College Hospital and Research Centre, SRM Nagar, Potheri, Kattankulathur, Chennai, Kanchipuram, Tamil Nadu – 603203 [ECR/431/Inst/TN/2013/RR-19]	Dr. Melvin George
19	Gauhati Medical College and Hospital Bhangagarhm Guwahati, Kamrup Metro, Assam Pin-781032	Institutional Ethics Committee, GMCH, Gauhati Medical College and Hospital, Guwahati, 2nd Floor, Gauhati Medical College Main Building, Narakasur Hill Top,	Dr. Jutika Ojah

		Guwahati, Kamrup Metropolitan, Assam – 781032 [ECR/1470/Inst/AS/2020]	
20	Bangalore Medical College & Research Institute, KR. Road, Fort, Bengaluru - 560002.	Ethics Committee of BMCRI, Bangalore Medical College & Research Institute, Fort KR. Road, Bengaluru, Urban, Karnataka - 560002. [ECR/302/Inst/KA/2013/RR-20]	Dr. Shantala G.B

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

- I. The clinical trial should be conducted as per approved protocol titled “A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – “DengiAll” of Panacea Biotec Limited in Healthy Indian Adults.” [Protocol no. PAN-ICMR-DengiAll-001, Version no. 4.0 dated 24 Nov. 2022]
- II. The firm is required to constitute a DSMB to review the safety data.
- III. Firm is required to submit Ethics Committee approval for Phase-III clinical trial.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures and shall have ongoing stability program.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.
- VI. Firm is required to submit revised principal investigator undertaking as per approved protocol.
- VII. Firm is required to submit draft label as per proposed composition.

Place: New Delhi

Date:

(Dr. Rajeev Singh Raghuvanshi)
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Central Licencing Authority