File No: BIO/CT/22/000154

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 TechInvention Lifecare Pvt. Ltd., # 1004, The Summit Business Bay, Off. WEH Metro Station, Andheri Kurla Road, Andheri E, Mumbai – 400093 E-mail: syed@techinvention.biztoconduct clinical trial of the new drug or investigational new drug as per Protocol No. CRNI/CTP/009, Version 1.0, dated 17-11-2022 in the below mentioned clinical trial sites.

CT No.: CT-11/2023

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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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority
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Place: New Delhi
Date:

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Combined tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine. (Tdapgen)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for Injection.	
Composition:	Each single dose 0.5 ml contains	
	Ingredients	**Quantity**
	Diphtheria Toxoid	2.0 Lf
	Tetanus Toxoid	7.5 Lf
	Bordetella pertussis antigen	
	Recombinant Pertussis Toxin (rPT)*	2 µg
	Filamentous Hemagglutinin (FHA)	5 µg
	*(rPT) is genetically –detoxified PT (PTgen) obtained by recombinant DNA technology Adsorbed on aluminium hydroxide.	
Indications:	For active booster immunization against tetanus, diphtheria and pertussis.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Dept. of Community Medicine, All India Institute of Medical Sciences, Patna Bihar-801507.	Institute Ethics Committee All India Institute of Medical Sciences, Phulwarisharif Patna Bihar-801507,India [ECR/1387/Inst/BR/2020]	Dr. Chandramani Singh
2	Jeevan Rekha Hospital, Dr. B R Ambedkar Road, Belagavi, Karnataka-590010	Institutional Ethics Committee, Dr. B.R. Ambedkar Road Opp Civil Hospital, Belagavi(Belgaum) Karnataka-590002 India [ECR/1242/Inst/KA/2019]	Dr. Amit S Bhate
3	Department of Pediatrics, Niloufer Hospital, Red Hills, Lakdikapool,Hyderabad -500004	Institutional Ethics Committee Osmania Medical College, Koti, Telangana-500095 India. [ECR/300/Inst/AP/2013/RR-19]	Dr. N Ravi Kumar
4	Department of Pediatrics, S. N. Medical college, Agra, Moti Katra, Mantola, Agra, UP-282003	Institutional Ethics Committee, S. N. Medical college, Agra, UP-282003 [ECR/1409/Inst/UP/2020]	Dr. Ram Kshitij Sharma
5	Aatman Hospital, 5, Anveshan Row House, Opposite umiya mata mandir, Bopal Ghuma main road,	Institutional Ethics Committee Aatman Hospital 5, Anveshan Row House, Opposite umiya mata mandir, Bopal Ghuma	Dr. Shreyans Shah

	Ahmedabad-380058	main road, Ahmedabad-380058. [ECR/1565/Inst/GJ/2021]	
6	New Leelamani hospital 14 /116,c-1 parade Chauraha Civil lines Kanpur, UP-208001.	Institutional Ethics Committee New Leelamani hospital 14 /116, c-1 parade chauraha civil lines Kanpur, UP 208001. [ECR/1696/Inst/UP/2022]	Dr. Vinod Kumar Kapoor
7.	Rana Hospital Pvt Ltd, Rail Vihar Medical College Road, Chargawa Gorakhpur-273001.	Institutional Ethics Committee , Rana Hospital Pvt. Ltd, Rail Vihar Medical College Road Chargawan Gorakhpur Uttar Pradesh - 273001 India. [ECR/1332/Inst/UP/2020]	Dr. Ajeet Pratap Singh

In addition to point 3, the permission is subject to following condition(s):

1. The Phase III clinical trial should be conducted as per title “a Multicentre, Randomized, Observer-blind, Non-inferiority, Phase III Study to Evaluate the Immunogenicity and Safety of BoostagenRED (combined tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine) by BioNet-Asia compared to ADACEL vaccine by Sanofi Pasteur Limited in Healthy Subjects Aged 4-65 years Protocol Number: CRNI/CTP/009 Version Number: 1.0 dated 17-11-2022.
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 and using validated procedures and shall have ongoing stability program.
4. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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Date: 2023.11.03 10:05:52 +05'30'

Place: New Delhi
Date:

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