

File No: BIO/CT/25/000063
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., B-1 Extn. -/A-27, Mohan Co-Op, Industrial Estate, Mathura Road, Delhi (India) – 110044, Telephone No: 911141678000, FAX: 911141679063, E-mail: kumargaurav@panaceabiotec.com to conduct clinical trial of the new drug or investigational new drug as per Protocol number: PBL/24/07/MyFive, Version Number: 01 Dated: 14-04-2025 in the below mentioned clinical trial sites.

CT No.: CT- 23/2025

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:

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

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Date: 2025.11.12 10:57:58 +05'30'

Annexure: Details of new drug or investigational new drug:

Name of the new drug or investigational new drug:	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and <i>Haemophilus influenzae</i> type b conjugate vaccine (Adsorbed) I.P.	
Therapeutic class:	Vaccine	
Dosage form:	Liquid vaccines in multi dose (10 dose) vials (5.0 mL) for Intramuscular injection.	
Composition:	Each single human dose of 0.5 mL contains:	
	Active Ingredients	Quantity per dose of 0.5 ml
	Diphtheria Toxoid	≥ 30 IU
	Tetanus Toxoid	≥ 60 IU
	Inactivated Whole cell pertussis	≥ 4 IU
	r Hepatitis B surface antigen	≥ 10 µg
	<i>Haemophilus influenzae</i> type b conjugate (PRP-TT) conjugated to carrier protein Tetanus Toxoid (18-33 µg)	10 µg
	Inactive Ingredients	
	Aluminium content (Al ³⁺) (as Aluminium phosphate gel)	NMT 1.25 mg
2-phenoxyethanol	2.5 mg	
Physiological saline	q.s. to 0.5 ml	
Indication(s):	Immunization against Diphtheria, Pertussis, Tetanus, Hepatitis B and <i>Haemophilus influenzae</i> type b pathogens.	

Details of clinical trial sites:

S. No.	Name and address of clinical trial sites	Ethics committee details	Name of principal investigators
1.	Guru Teg Bahadur Hospital and UCMS, Dilshad Garden, Delhi-110095, India.	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden, Delhi-110095, India. [ECR/510/Inst/DL/2014/RR-25]	Dr. Manish Narang M.B.B.S, MD (Pediatrics)

2.	All India Institute of Medical Sciences, Patna -Aurangabad Road, Phulwari Sharif, Patna Bihar -801507, India.	Institutional Ethics Committee All India Institute of Medical Sciences, Patna, Phulwari Sharif, Patna, Bihar - 801507, India. [ECR/1387/Inst/BR/2020/RR-25]	Dr. Chandra Mohan Kumar M.B.B.S, MD (Pediatrics)
3	King George Hospital, Department of Paediatrics, 1 st floor, Collectorate Junction, Maharanipeta, Visakhapatnam 530002, Andhra Pradesh, India.	Institutional Ethics Committee M/s King George Hospital, Maharanipeta, Near Collectorate office junction Visakhapatnam – 530002, Andhra Pradesh, India. [ECR/197/Inst/KGH/2013/RR-20]	Dr. B. S. Chakravarthy M.B.B.S, MD (Pediatrics)

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

- I. The Phase I clinical trial should be conducted as per title “An open label, non-comparative, Phase I study to evaluate the safety, tolerability and preliminary immunogenicity of a fully liquid pentavalent DTwp-HepB-Hib Vaccine (MyFive™, Panacea Biotec Ltd.) in healthy subjects 15-18 months of age” (Protocol number: PBL/24/07/MyFive, Version Number: 01 Dated: 14-04-2025).
- II. The formulation intended to be used in the clinical trial shall be manufactured under GMP Conditions.
- III. Only CDL, Kasauli certified batches shall be used in Phase-I clinical trial.
- IV. To submit Ethics Committee approval for Phase I clinical trial.
- V. To submit CRO registration details once obtained from the CDSCO.

Place: New Delhi

Date:

RAJEEV SINGH Digitally signed by RAJEEV SINGH RAGHUVANSHI
RAGHUVANSHI Date: 2025.11.12 10:58:16
 (Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

File No: BIO/CT/25/000063
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

From:

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

To

M/s Panacea Biotec Ltd.,
B-1 Extn. -/A-27, Mohan Co-Op,
Industrial Estate, Mathura Road,
Delhi (India) – 110044

Subject: Permission for conducting a clinical trial titled “An open label, non-comparative, Phase I study to evaluate the safety, tolerability and preliminary immunogenicity of a fully liquid pentavalent DTwp-HepB-Hib Vaccine (MyFive™, Panacea Biotec Ltd.) in healthy subjects 15-18 months of age” [Protocol number: PBL/24/07/MyFive, Version Number: 01 Dated: 14-04-2025]- regarding.

Reference: Your Application No. BIO/CT04/FF/2025/49086 dated 25-Apr-2025 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2025/49086 dated 25-Apr-2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of “Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and *Haemophilus influenzae* type b conjugate vaccine (Adsorbed) I.P.” 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 Digitally signed by RAJEEV
SINGH RAGHUVANSHI
RAGHUVANSHI Date: 2025.11.12 10:57:18
+05'30'
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority