Annexure - II(b)
Details of clinical trial Permissions (Form CT-06)
Year 2024

S.No.	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date of Issue	Summary
1	BIO/CT/23/000127	M/s Biological E - Shameerpet, Plot No 1, Phase II, Kolthur Village Shameerpet, Medchal-Malkajgiri District, Telangana-500078, India	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Inactivated Poliomyelitis and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed)	Phase II	"A prospective randomised active controlled Phase-II safety and immunogenicity study with 3-doses of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old infants" [Protocol no. BECT084/LHV-P-II/CTP-01, Version no. 1.0 dated 15.09.2023]	CT- 01/2024	16-02-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 14.12.2023 CT permission was granted.
2	BIO/CT/23/000027	M/s Cadila Pharmaceuticals Limited, 1389, Trasad Road, Dholka, Ahmedabad, Gujarat (India) - 382225	Varicella Zoster Virus (VZV) Vaccine	Phase I	A randomized, open label clinical trial to evaluate the safety and immunogenicity of varicella-zoster virus (VZV) vaccine in healthy subjects [Protocol No.: CRSC23001, Version no.: 02 dated 16.06.2023].	CT- 02/2024	21-02-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 14.09.23 CT permission was granted.
3	BIO/CT/21/000117	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"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]	CT- 03/2024	28-02-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 24.01.2023 CT permission was granted.
4	BIO/CT/23/000112	M/s Bharat Biotech International Ltd., Sy. No. 230,231 & 235, Genome Valley, Turkapally, Shameerpet Mandal, Medchal - Malkagiri District, Telangana (India) - 500078	Typhoid Vi Conjugate Vaccine (Typhoid (Vi Capsular Polysaccharide) - Tetanus Toxoid Conjugate Vaccine)	Phase III	"A Phase III Open-label Study to Evaluate the Immunogenicity and Safety of Typhoid Tetanus Toxoid Conjugate Vaccine; Typbar TCV® in Adults (>65Years)" [Protocol no. BBIL/TCV-III/2023, Version no. 02 dated 03.11.2023.	CT- 04/2024	19-03-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.10.2023 CT permission was granted.
5	BIO/CT/24/000042	M/s Bharat Biotech International Ltd., Sy. No. 230,231 & 235, Genome Valley, Turkapally, Shameerpet Mandal, Medchal - Malkagiri District, Telangana (India) - 500078	Mycobacterium Tuberculosis (Live, Attenuated) Vaccine	Phase II	A Phase II Randomized, Double-blind Trial to Access the Safety and Immunogenicity of MTBVAC (BBV169), with BCG vaccine as a comparator in Healthy adolescent and adult populations [Protocol no. BBIL/MTBVAC-II/2024, Version no. 2.0 dated 30.04.2024].	CT- 05/2024	25-06-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 30.04.2024 CT permission was granted.
6	BIO/CT/24/000027	M/s Biological E - Shameerpet, Plot No 1, Phase II, Kolthur Village Shameerpet, Medchal-Malkajgiri District, Telangana-500078, India	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)	Phase IV	A Phase-IV multicentre follow-up study to assess the continued safety of Biologica E's 14-valent pneumococcal polysaccharide conjugate vaccine in subjects, who received 3-dose (3+0) primary PCV vaccination as part of BECT051 and BECT061 studies " [Protocol no. BECT087/PCV-Phase-IV_SF/CTP-01, Version no. 1.0 dated 16.01.2024].	CT - 06/2024	23-07-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 30.04.2024 CT permission was granted.

7	BIO/CT/24/000013	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village: Changodar, Tal.: Sanand, Dist.: Ahmedabad – 382213, State: Gujarat, (India)	Bivalent Typhoid and Paratyphoid A Conjugate Vaccine	Phase I	An open-label, single-treatment, single-period, single dose, clinical phase 1 study to assess the safety and tolerability of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine (BTPT) of M/s Zydus Lifesciences Ltd., India in healthy, adult human subjects" vide [Protocol No.: BTPT 1001 Version No. 02 Dated 16th May 2024]	CT- 07/2024	31-07-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 27.03.2024 CT permission was granted.
8	BIO/CT/23/000155	M/s GSK Pharma India Private Limited, 01, Battery House Bhulabhai Desai Road Mumbai (India) - 400026	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	Phase III	A Phase 3, randomized, placebo-controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocol no.: 221265 protocol amendment 01 Dated 19-Apr-2024	CT- 08/2024	19-08-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.05.2024 CT permission was granted.