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.
9	BIO/CT/23/000101	M/s Novo Medi Sciences Private Limited, Ground Floor & 1st Floor Plot No. 133 to 154, Jawahar CO-OP Industrial Estate Ltd. Kamothe, Raigad, Panvel, Maharashtra- 410209,	13-valent Pneumococcal Polysaccharide Conjugate Vaccine (TT/DT)	Phase III	A prospective, randomized, double-blind, multi-center, phase III study to assess and compare the immunogenicity and safety of the 13-valent Pneumococcal Polysaccharide Conjugate Vaccine in healthy Indian subjects." [Protocol no. CRNI/CTP/018, Version no. 2.0 dated 04.11.2023]	CT- 09/2024	24-09-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 14.12.2023 CT permission was granted.

10	BIO/CT/24/000048	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, Taluka: Sanand, Dist.: Ahmedabad, Gujarat (India) - 382213	Measles and Rubella Vaccine (Live) LP. (Freeze Dried) in Multidose vial (2.5 ml — 5 dose)	Phase IV	A prospective, randomized, parallel, single-blind, four-arm, active-controlled, multicentre, phase IV clinical trial to evaluate the immunogenicity and safety of Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. compared to Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Serum Institute of India Pvt. Ltd. and to evaluate lot-to-lot consistency of Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. in healthy infants aged 9-12 months [Protocol No.: 24-02, Version no.00 dated 09/03/2024]	CT- 10/2024	21-10-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.07.2024 CT permission was granted.
11	BIO/CT/24/000001	M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana–500078, India;	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24 Valent	Phase II	An open label randomised Phase-II study to evaluate safety, reactogenicity and immunogenicity of Biological E's 24-valent pneumococcal polysaccharide conjugate vaccine when administered to 6-8 weeks old healthy Indian infants in 6-10-14 weeks dosing schedule" [Protocol no. BECT085/PCV-Phase-II/CTP-02, Version No.: 2.0 dated 02.04.24, Amendment No.: 1.0 dated 02.04.24]	CT-11/202	30-10-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 27.03.2024 CT permission was granted.

12	BIO/CT/24/000070	M/s Serum Institute of India Pvt. Ltd., 212/2 Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India) – 411028	Meningococcal(A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)	Phase III	A Phase 3, Randomized, Double-blind, Controlled, Multi-Center Study to Compare Immunogenicity and Safety of SIIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) with that of Licensed Meningococcal ACWY Vaccine Menactra® in Healthy Indian Children of 9 months to 17 Years of Age" vide Protocol no. ACYWX-05, Version No. 1.0 Dated 16-MAY-2024	CT- 12/2024	05.11.2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.07.2024 CT permission was granted.
13	BIO/CT/24/000018	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road Hadapsar Pune (India)	Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze-Dried)	Phase IV	phase IV, double blind, randomized, active control clinical study comparing safety and immunogenicity of SIIMeasles-Mumps-Rubella vaccine with PRIORIX (GSK) in healthy infants in India" as per Protocol No: MMR-01/23 Version 02 dated 17 Apr 2024	CT- 13/2024	11-11-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 03.10.2024 CT permission was granted.
14	BIO/CT/24/000041	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Survey No. 281-284 & 321, Biotech Park Phase-III, Karkapatla Village, Markook Mandal, Siddipet District – 5002281, Telangana, India	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P.	Phase I	An open label single centric Phase I clinical trial to evaluate the safety and immunogenicity of Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P. of HBI when administered in two groups of healthy male subjects" [Protocol Number: HBI/JE1/24/02.1.1, Version: 01; Amendment: 01, Dated: 08 July 2024	CT- 14/2024	07-11-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.05.2024 CT permission was granted.
15	BIO/CT/24/000101	M/s Urihk Pharmaceutical Private Limited, 602-603, Sai Samarth Business Park, Near Wasan Motors, Deonar Village Road, Deonar, Govandi (East) Mumbai (India) - 400088	Recombinant Hepatitis E Vaccine (E. Coli)	Phase-IV	A Prospective, Multicentre, Single Arm, Phase-IV Study to evaluate the Safety and Immunogenicity of Recombinant Hepatitis E Vaccine (E. Coli) in Healthy Adults. [Protocol Number: CRNI/CTP/24/07, Version Number: 02; dated 15/Oct/2024]	CT- 15/2024	30.12.2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 03.10.2024 CT permission was granted.
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