

Annexure - II(b)
Details of clinical trial Permissions (Form CT-06)
Year 2025

S.No.	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date Issued	Summary
1	BIO/CT/24/000037	M/s Dr Reddys Laboratories Limited, 8-2-337, Road No. 3 Banjara Hills Hyderabad (India) - 500034	Live Attenuated Varicella Vaccine	Phase III	A Phase III, Multicentre, Randomized, Observer-blind, Active-controlled, Parallel group, Non-inferiority Study to Evaluate Immunogenicity and Safety of Varicella vaccine (Barycela-) in Healthy Pediatric Population 12 months to 12 years of age" vide protocol number DRL-VAR-008 Version 3.0 dated 04 Sep 2024.	CT- 01/2025	17-01-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 22.08.2024 CT permission was granted.
2	BIO/CT/24/000082	M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India –500078	Pneumococcal polysaccharide conjugate vaccine (Adsorbed) (14 Valent)	phase-IV	"A single blind, randomized, active-controlled, phase-IV study to evaluate immunogenicity and safety of Biological E's 14-valent pneumococcal polysaccharide conjugate vaccine (PNEUBEVAX-14), administered to healthy children aged 5 years to <18years and healthy adults aged 18 years and above" [Protocol no. BECT090/PCV14-Phase IV/CTP-01 Version No.: 1.0 dated 17.06.24]	CT-02/2025	20-03-2025	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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