File No: BIO/CT/21/000156

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 Licensing Authority hereby permits Ms. Palivela Madhavi of M/s Dr Reddy's Laboratories Limited, IPDO, Survey no 54, Bachupally Vilage Qutubullapur Mandal (India)-500090, Telephone No.: null, FAX:null, E-Mail: MADHAVIK@DRREDDYS.COM to conduct clinical trial of the new drug or investigational new drug as per Protocol no.: DRL-SLB-007 in the below mentioned clinical trial sites.

CT No.: CT- 04/2022

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.

VENUGOPAL G SOMANI

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(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority

Date: 22-Mar-2022
Place: New Delhi

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	A vector vaccine for the prevention of the coronavirus infection induced by the SARSCoV-2 virus - (Sputnik Light)	
Therapeutic class:	Vaccine	
Dosage form:	Solution (Frozen) for Intramuscular route of administration. To be given in single dose (0.5 ml)	
Composition: Component I	Each dose of 0.5 ml contains:	
	Active ingredient	**Quantity**
	Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene	$1.0\pm0.5 \times 10^{11}$ particles
	Inactive ingredients	
	Tris (Hydroxymethyl) amino methane	1.21 mg
	Sodium Chloride	2.19 mg
	Sucrose	25.00 mg
	Magnesium Chloride Hexahydrate	102.00 µg
	EDTA disodium salt dehydrate	19.00 µg
	Polysorbate 80	250.00 µg
	Ethanol 95%	2.50 µg
	Water for injection	Q.s to 0.5 ml
Indication:	For the prevention of the COVID-19 in adults aged over 18 years.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Indraprastha Apollo Hospitals, Sarita Vihar, Mathura Road New Delhi-110076, India.	Institutional Ethics Committee- Clinical Studies Indraprastha Apollo Hospitals, New Delhi. [ECR/5/inst/DL/2013/RR-19]	Dr Viny Kantroo
2	Maharaja Agrasen Superspecialty Hospital Central Spine, Agrasen Aspatal Marg, Sec 7 Vidyadhar Nagar,Jaipur -302039, India	Institute of Ethics committee, Maharaja Agrasen Hospital, Central Spine, Agrasen Aspatal Marg Sector 7,Vidhyadhar Nagar, Jaipur Rajasthan – 302039 [ECR/1222/Inst/RJ/2019]	Dr. Manish Kumar Jain
3	JSS Hospital, Mahathma Gandhi Road, Ramachandra Agrahara, Mysuru	Institutional Ethics Committee, JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar Mysore Mysore,Mysuru (Mysore) Karnataka - 570015 India [ECR/387/Inst/KA/2013/RR-19]	Dr Tejeswini CJ

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 Phase III, Randomized, Open Label, Multicentre Clinical Study in Parallel Assignment to Evaluate Immunogenicity and

Safety of a Booster Dose of Sputnik Light Vector Vaccine against COVID-19 in Adult Indian Subjects" [Protocol No: DRL-SLB-007].

2. DSMB is required to be constituted to review the safety data of phase III clinical trial.
3. Firm shall use the Sputnik Light vaccine holding permission to import /manufacture issued by CDSCO as an investigational product for the proposed phase III clinical trial.
4. The firm is required to submit the following information/documents:
   a) Revised clinical trial protocol to include the objective of at least 2 fold rise in the neutralizing antibody titres in the investigational arm comparing with approved homologous booster vaccine in line with recommendations of SEC (Covid) dated 04/03/2022 in addition to the existing objectives along with Informed Consent Form (ICF) or Patient Information Sheet (PIS) and CRF.
   b) Copy of the Insurance Certificate.
5. 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.
6. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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