

File No: BIO/CT/21/000102
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 M/s Dr Reddy's Laboratories Limited, IPDO, Survey no 54 Bachupally Vilage Qutubullapur Mandal (India) - 500090 Telephone No.: nil FAX: nill E-Mail : MADHAVIK@DRREDDYS.COM to conduct clinical trial of the new drug or investigational new drug as per Protocol no.: DRL-SPL-005 Version No. 2.0 dated 09-AUG-2021 in the below mentioned clinical trial sites.

CT No.: CT- 27/2021

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.

Date: 16-Aug-2021
Place: New Delhi

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

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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±0.5 x 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.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Noble Hospital Pvt Ltd, 153, Magarpatta City Road, Hadapsar, Pune - 411013 Maharashtra India 020-43285	Noble Hospital Institutional Ethics Committee ECR/259/Inst/MH/2013/RR-19	Dr. S. K. Raut
2	Yashwantrao Chavan Memorial Hospital, Pimpri, Pune, Maharashtra	Institutional Ethics Committee PCMC'S PGI Yashwantrao Chavan Memorial Hospital ECR/1236/Inst/MH/2019	Dr. Pravin Soni
3	Dhadiwal Hospital & Research Centre, Nashik, Maharashtra	Shree Institutional Ethics Committee. ECR/1149/Inst/MH/2018	Dr. Krishna Giri
4	Ashirwad Hospital And Research Centre, Ulhasnagar, Maharashtra, India	Ashirwad Ethics committee, Ulhasnagar, Maharashtra, India ECR/247/Inst/MH/2013-RR19	Dr. Shrikant Vishnu Deshpande
5	Batra Hospital and Medical Research Centre, 1, Tughlakabad Institutional Area, Mehrauli Badarpur Road, New Delhi-11006	Scientific Research and Ethical Review Committee ECR/295/Inst/DL/2013/-RR19	Dr. Suninder Singh Arora
6	Shlok Hospital, Khed Shivapur, Pune, Maharashtra	AMAI Trust Ace Hospital IEC, Ace Hospital and Research Center, 32/2 A , Erandwane, Gulwani Mhj Rd; Pune, Maharashtra - 411004 India ECR/474/INST/MH/2013/RR-19	Dr. Koustubh Khare

7	Ace Hospital and research centre, Pune, Maharashtra	AMAI Trust Ace Hospital IEC, Ace Hospital and Research Center, 32/2 A , Erandwane, Gulwani Mhj Rd; Pune, Maharashtra - 411004 India ECR/474/INST/MH/2013/RR-19	Dr. Himanshu Pophale
8	BAJRR Hospital And Research Centre, P-14, MIDC, Phase-1, Milap Nagar, Dombivali (E) Maharashtra-421203, Indi	Altezza Institutional Ethics Committee, Shree Ashirwad Hospital ECR/1457/Inst/MH/2020	Dr. Deepak Bhanudas Varade
9	Indraprastha Apollo Hospitals Sarita Vihar, Mathura Road, New Delhi-110	Institutional Ethics Committee for Clinical Studies of Indraprastha Apollo Hospital Sarita Vihar, Mathura Road , New Delhi-11076 ECR/5/Inst/DL/2013/RR-16	Dr. Viny Kantro

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

- I. The Phase III clinical trial should be conducted as per title "Phase III, open label, un-controlled, multicentre, bridging study to evaluate immunogenicity and safety of single dose of Sputnik Light in Indian adults and elderly for prevention of SARS-CoV-2 Infection" Protocol No: DRL-SPL-005 Date of Protocol Version 2.0 dated 09 Aug 2021.
- II. The specification of the IMP i.e. Sputnik Light vaccine shall be same as approved Gam-COVID-Vac combined vector vaccine (Sputnik V) Component I.
- III. The clinical trial shall be conducted in the geographically distributed clinical trial sites.
- IV. DSMB is required to be constituted to review the safety data of phase III clinical trial.
- V. The firm is required to submit the following information/documents:
 - a) Validation of analytical procedures.
 - b) Stability data (real time & accelerated) of Sputnik Light vaccine.
 - c) Analytical certificates of Sputnik Light
 - d) Details (Presentation, mfg. site) of batches of Sputnik Light proposed to be used in proposed Phase III trial
 - e) Stability data of Sputnik Light Batches manufactured at all manufacturing sites.
 - f) Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator
 - g) IMP Label as per requirements of rule 66 of ND&CT Rules 2019.
 - h) Copy of the Insurance Certificate
 - i) Medical Registration Certificates & CV of all PI's & PI undertaking, MRC & CV for PI Dr. Viny Kantro & Dr. Suninder Singh Arora along with EC details.
- VI. 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.
- VII. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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