File No: BIO/CT/21/000108

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 Licencing Authority hereby grant permission to M/s Reliance Life Sciences, Center, R-282, TTC Area of MIDC, Thane -Belapur Road, Rabale, Navi Mumbai (India) – 400 701 Telephone No.: 022-40678770 FAX: 022-40678099, E-Mail: bobby.george@relbio.com to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

CT No.: CT- 31/2021

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.
4. It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country with automatically be granted to you.

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2021.09.03 17:48:53 +05'30'

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

Date:03-Sept-2021
Place: New Delhi

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Protein subunit vaccine against SARS-CoV-2 Virus	
Therapeutic class:	Vaccine	
Dosage form:	Liquid (Solution for injection) [1µg RBD+ 1µg Nucleocapsid protein], [5µg RBD+ 5µg Nucleocapsid protein] and [10µg RBD+ 10µg Nucleocapsid protein] Presentations: • 5R type I glass vial with a fill volume of 5.0 mL • 2R type I glass vial with a fill volume of 2.0 mL	
Composition:	Each dose of 0.5 ml contains:	
	Active ingredient	Quantity
	Receptor Binding Domain (RBD) of SARS cov 2	1mcg/5mcg/10mcg
	Nucleocapsid protein of SARS Cov2 Virus	1mcg/5mcg/10mcg
	2-Phenoxy ethanol	1%
Indication:	For vaccination against SARS Corona virus 2 infection.	

Details of clinical trial sites-

S. No.	**Name and Address of Clinical Trial Site**	**Ethics Committee details**	**Name of Principal Investigator**
1	D Y Patil University School of Medicine and Hospital Plot NO. 2, Sector-5, Nerul, Navi Mumbai,Thane, Maharashtra-400706, India	Institutional Ethics Committee, D Y Patil Medical College and Research Centre [ECR/195/Inst/MH/2013/RR-19]	Dr. Deepak kumar Langade
2	Grant Government Medical College & Sir J.J. Group of Hospitals, Byculla, Mumbai-400008.Maharashtra,India	Institutional Ethics Committee , GGMC, Mumbai [ECR/382/Inst/MH/2013/RR-19]	Dr. Akash Khobragade
3	Lifepoint Hospital, 145/1, Mumbai –Bangalore Highway, Near Hotel Sayaji, Bhumkar Chowk, Wakad,Pune-411057	Institutional Ethics Committee, Lifepoint Research-Ethics Committee, Lifepoint Multispecialty Hospital [ECR/751/INST/MH/2015/RR-21]	Dr. Sonali Nirhali
4	Medipoint Hospitals Pvt. Ltd, 241/1, New D. P. Road, Aundh, Pune-411007, Maharashtra, India	Institutional Ethics Committee, Penta-Med Ethics Committee, Medipoint Hospitals Pvt. Ltd. [ECR/357/Inst/MH/2013/RR-20]	Dr. Girish Gokuldas Bhatia
5	PCMC S PGI Yahwantrao Chavan Memorial Hospital ,Sant Tukaram Nagar, Near D Y Patil Medical College , Vallabhnagar, Pimpri, Pune -411018,	Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital [ECR/1236/Inst/MH/2019]	Dr. Pravin Nagulal Soni

	Mahrashtra, India		
6	Bhrati Vidyapeeth (Deemed to be University) Medical College and Hospital, Pune	Institutional Ethics Committee, Bhrati Vidyapeeth Medical College and Hospital, Pune [ECR/313/Inst/MH/2013/RR-19]	Dr. Prachee Makashir
7	Orchid Speciality Hospital, L-Square, Porwal Road, Sr.No-282-3/3, Off,Dhanori JakatNaka, Lohgaon, Pune-411047, Maharashtra,India	Institutional Ethics Committee, Orchid Speciality Hospital, L-Square, Porwal Road. [ECR/1089/Inst/MH/2018/RR-21]	Dr. Ashish Goyal
8	Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai - 400022, Maharashtra, India	Institutional Ethics Committee, Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai [ECR/266/Lokmanya/Inst/MH/2013/RR-19]	Dr. Sudhir Pawar

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

I. The Phase I clinical trial should be conducted as per title “A prospective, open label, dose escalation phase I clinical study to evaluate the safety, tolerability and immunogenicity of Reliance Life Sciences SARS-CoV-2 Recombinant protein subunit vaccine in healthy volunteers” as per protocol no. RLS/VAC/2021/07.
II. Firm is required to submit the revised clinical trial protocol for the immunogenicity to be assessed at day 42 instead of day 14 as per the SEC (COVID) recommendations dated 26-August-2021.
III. DSMB is required to be constituted to review the safety data of phase I clinical trial.
IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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

Date: 03-Sept-2021
Place: New Delhi