

File No: BIO/CT/22/000015

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 permits M/s Gennova Biopharmaceuticals Limited, T-184 Emcure House, Bhosari, M.I.D.C, Pune Maharashtra (India) - 411026 Telephone No.: 020-39821300 FAX: 020-39821300 E-Mail : rajeshkumar.singh@gennova.co.in to conduct clinical trial of the new drug or investigational new drug as per protocol no. GBL/GEMCOVAC-OM/2022/02 in the below mentioned clinical trial sites.

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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 trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

Place: New Delhi
Date: 03.10.2022

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Lyophilized mRNA Vaccine for Injection(COVID-19) [Omicron variant - sublineage BA.1]	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized powder for Injection for Intradermal route of administration.	
Composition:	Each dose (0.1 mL) Contains:	
	Ingredients	Quantity
	m-RNA(Omicron variant- sublineage BA.1)	10 µg
	DOTAP	0.3 mg
	Squalene	0.38 mg
	Sorbitan Monostearate	0.37 mg
	Polysorbate 80	0.37 mg
	Sucrose IP	10.0 mg
	Citric acid monohydrate	1.05 mg
Indications:	Sterile Water for Injection (For reconstitution)	
	For active immunization against COVID-19 caused by SARS-CoV-2 Omicron variant.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	All India Institute of Medical Sciences (AIIMS), Basni Phase II, Jodhpur, Rajasthan, 342005.	Institutional Human Ethics Committee, AIIMS Jodhpur, Basni Phase II, Jodhpur, Rajasthan, 342005. ECR/866/Inst/RJ/2016/RR-19	Dr. Pankaj Bhardwaj
2	St. Theresa's hospital, Sanathnagar, opposite Erragadda Raitu bazar, Hyderabad - 500018, Telangana, India	Ethics committee, St. Theresa's hospital Sanathnagar, opposite Erragadda Raitu bazar, Hyderabad - 500018, Telangana, India ECR/230/Inst/AP/2013/RR-19	Dr. A. Venkateshwar Rao
3	Pad. Dr. D. Y. Patil Hospital, Pimpri, Pune, Maharashtra	Ethics Committee, Dr D Y Patil Hospital, Pimpri, Pune, Maharashtra ECR/361/Inst/MH/2013/RR-19	Dr. Vikram Vikhe
4	Induss Hospital, 13-23-93/1, Krishnaveninagar, Gaddiannaram Near Muncipal Office, Saroornagar Hyderabad Ranga, Reddy Telangana - 500035	Institutional Ethics Committee, Induss Hospital, 13-23-93/1, Krishnaveninagar, Near Muncipal Office, Saroornagar Hyderabad Ranga, Reddy Telangana -500035 ECR/1606/Inst/TG/2021	Dr. V. Reddy Tummuru
5	CIMETs Inamdar Mutispeciality Hospital, Hospital Building S. No.15, Fatima Nagar, Wanawadi. Pune Maharashtra -411040 India	Ethics Committee Inamdar Multispeciality Hospital, CIMETs Inamdar Mutispeciality Hospital, Hospital Building S.No .15, Fatima Nagar, Wanawadi. Pune Maharashtra -411040 India ECR/354/Inst/MH/2013/RR-20	Dr. RavindraShinde
6	V.S Hospital, Ahmedabad Riddhi Medical Nursing Home	IEC Riddhi Medical Nursing Home, A/101 Jalaram Plaza Jawahar Chowk Maninagar, Ahmedabad, Gujrat. ECR/886/Inst/GJ/Inst/2016/RR-19	Dr. Dhaiwat Shukla

7	Downtown hospital ltd, G S Road Dispur Guwahati Kamrup Metropolitan, Assam -781006	Ethics Committee Down Town Hospital, Downtown hospital ltd, G S Road Dispur Guwahati Kamrup Metropolitan, Assam - 781006 ECR/549/Inst/AS/2014/RR-20	Dr. SwapnavBorthakur
8	JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar, Mysuru (Mysore) Karnataka	Institutional Ethics Committee JSS Medical College, JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar Mysore Mysore Mysuru (Mysore) Karnataka -570015 ECR/387Inst/KA/2013/RR-19	Dr. Tejeswini.C.J
9	Lokmanya Hospital, 314/B Telco Road, Chinchwad Pune Maharashtra -411033	Lokmanya Medical Research Centre, Lokmanya Hospital, 314/B Telco Road, Chinchwad Pune Maharashtra - 411033 ECR/175/Inst/MH/2013/RR-19	Dr. Prakash Sadashi vShinde
10	All India Institute of Medical Sciences (AIIMS), Tatibandh, GE Road, Raipur, 492099, Chhattisgarh	Institute Ethics Committee, Room no. 2103, 2 nd Floor South Wing Medical College Complex, Gate No. 5, AIIMS, Tatibandh, GE Road, Raipur, 492099, Chhattisgarh	Dr. Sabab Siddique

In addition to point 4, the permission is subject to following condition(s):

- I. The proposed clinical trial should be conducted as per protocol titled "A Prospective, Multi-centre, Open-labelled, Randomized, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability and Immunogenicity of GEMCOVAC-OM as a booster in Subjects 18 years of age and older" vide protocol no. GBL/GEMCOVAC-OM/2022/02.
- II. The firm is required to include in protocol the comparison of neutralizing antibody (Nab) seroconversion rate between GEMCOVAC-OM and COVISHIELD along with test for non-inferiority for Nab GMT ratio in primary endpoint of Phase III part and submit the same.
- III. Firm is required to take DSMB recommendations of Phase II part to this office, for proceeding to Phase III part of trial and submit the same to this office.
- IV. Firm is required to submit permission in Form CT-14 for packaging & labeling activity at M/s Seveillar Clinical Supplies Services Pvt Ltd.
- V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
- VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
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