

File No: BIO/CT/20/000162
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 Dr Reddys Laboratories Limited, 8-2-337, Road No. 3 Banjara Hills Hyderabad (India) - 500034 Telephone No.: 04044346200, 04044346572 FAX: 04044346285 E-Mail : madhavik@drreddys.com, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: Protocol number: RDI-GCV-001 Version No: 3.0 Date: 19-10-2020** in the below mentioned clinical trial sites.

CT No.: CT- 22/2020

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.

Place: New Delhi
Date: 22 OCT 2020

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

Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Gam-COVID-Vac combined vector vaccine for SARS-CoV-2 infection (Component I & Component II)	
Therapeutic class:	Vaccine	
Dosage form:	Frozen Solution for Intramuscular route of administration	
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) aminomethane	1.21 mg
	Sodium Chloride	2.19 mg
	Sucrose	25.0mg
	Magnesium Chloride Hexahydrate	102.0µg
	EDTA disodium salt dehydrate	19.0 µg
	Polysorbate 80	250.0 µg
	Ethanol 95%	2.50 µg
	Water for injection	Q.s to 0.5 ml
Composition: Component II	Each dose of 0.5 ml contains	
	Active ingredient	Quantity
	Recombinant adenovirus serotype 5 particles containing the SARS-CoV-2 protein S gene	1.0±0.5 x 10 ¹¹ Particles
	Inactive ingredients	
	Tris (hydroxymethyl) aminomethane	1.21 mg
	Sodium Chloride	2.19 mg
	Sucrose	25.0mg
	Magnesium Chloride Hexahydrate	102.0µg
	EDTA disodium salt dehydrate	19.0 µg
	Polysorbate 80	250.0 µg
	Ethanol 95%	2.50 µg
	Water for injection	Q.s to 0.5 ml
Indications:	To help prevent the novel corona virus COVID-19	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	KEM Hospital Research centre, Vadu Rural Health Program, P. O. Vadu (Budruk), Taluka Shirur, Dist Pune - 41221	KEM Hospital Research Centre Ethics Committee 3 rd Floor, TDH Building, 489, Rasta Peth, Sardar Moodliar road, Pune - 411043 ECR/272/Inst/MH/2013/RR-19	Dr. Anand Kawade
2	JSS Hospital, Mahatma Gandhi Road, Mysore-570004, Karnataka, India	Institutional Ethics Committee. JSS Medical College & Hospital, 3 rd floor, JSS Medical College, Mysore -570015,	Dr. Shilpa Avarebeel

		Karnataka ECR/387/Inst/KA/2013/R-19	
3	KLE's DrPrabhakar Kore Hospital & MRC, Nehru Nagar, Belgavi-590010, Karnataka, India	Institutional ethics committee. JNMC Campus, Nehru nagar, Belagavi, Karnataka-590010, India ECR/211/Inst/KA/2013/RR-2019	Dr Jayaprakash Appaji gol
4	Christian Medical College Vellore Association 9/1, Natter Krishnamachari street, Krishna Nagar, Vellore, Tamil Nadu 632001	Institutional Review Board, Christian Medical College, 9/1, Natter Krishnamachari street, Krishna Nagar, Vellore, Tamil Nadu 632001 ECR/326/Inst/TN/2013/RR-19	Dr Winsley Rose
5	Pondicherry Institute of Medical Sciences Village no. 20, Ganapathychettikulam, Kalapet, Puducherry - 605014	PIMS Institute Ethics Committee, Pondicherry Institute of Medical Sciences Village no. 20, Ganapathychettikulam, Kalapet, Puducherry - 605014	Dr Anil Purty
6	GSVM Medical College, Swaroop Nagar, Kanpur Uttar Pradesh - 208002	Ethics Committee GSVM Medical College, Room No. 125, 1 st Floor, GSVM Medical College, Swaroop Nagar Kanpur-208002. ECR/680/Inst/UP/2014/RR-17	Dr Saurabh Agarwal

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

- I. The Phase II/III clinical trial should be conducted as per protocol titled "Randomized, double-blind, placebo-controlled, parallel-group, multi-centre phase II/III adaptive clinical trial to assess the safety and immunogenicity of Gam-COVID-Vac combined vector vaccine for SARS-CoV-2 infection in Indian Healthy Subjects" vide Protocol No: Protocol No.: Protocol number: RDI-GCV-001 Version No: 3.0 Date: 19-10-2020.
- II. 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.
- III. Only CDL, Kasauli certified batches shall be used in the clinical trial.
- IV. The firm should obtain approval from the Central Licencing Authority before proceeding to Phase-III clinical trial.

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GIRDHARILAL SOMANI
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Place: New Delhi
Date: 22 OCT 2020

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

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

(See rules 68, 69, 70, 71 and 72)

**LICENCE TO IMPORT NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR THE
PURPOSE OF CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY
OR FOR EXAMINATION, TEST AND ANALYSIS**

Licence Number: **TL/BIO/20/000053**

The Central Licencing Authority hereby grants licence to **M/s Dr Reddys Laboratories Limited 8-2-337, Road No. 3 Banjara Hills Hyderabad - 500034 Telangana** to import new drug or investigational new drug for conduct of clinical trial ~~or bioavailability or bioequivalence study as per~~ protocol number **Protocol number: RDI-GCV-001 Version No: 3.0 Date: 19-10-2020** in the below mentioned clinical trial sites or bioavailability or bioequivalence study centre.

S.No.	Name of Drugs and Brand Name	Class of Drug	Strength	Quantities which may be imported
1	Gam-COVID-Vac Combined vector vaccine (Investigational Study Product - Component I	Vaccine	0.5 ml/dose	1700 vials (single)
2	Gam-COVID-Vac Combined vector vaccine (Investigational Study Product - Component II	Vaccine	0.5 ml/dose	1700 vials (single)
3	Gam-COVID-Vac Combined vector vaccine (Comparator /Placebo - Component II	Vaccine	0.5 ml/dose	525 vials (single)
4	Gam-COVID-Vac Combined vector vaccine (Comparator /Placebo - Component I	Vaccine	0.5 ml/dose	525 vials (single)

2. This licence is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.

3. This licence shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.

4. Details of overseas manufacturer and manufacturing site under this licence.

Name and address of manufacturer :

M/s National Research Center for Epidemiology and Microbiology named after Honorary Academician N.F. , Gamaleya of the Ministry of Health of the Russian Federation, 18 Gamalei Street, Moscow (Russia) – 123008 Telephone No.: 4991933050 FAX: 4991906671

Name and address of manufacturing site :

M/s National Research Center for Epidemiology and Microbiology named after Honorary Academician N.F. , Gamaleya of the Ministry of Health of the Russian Federation, 18 Gamalei Street, Moscow (Russia) – 123008 Telephone No.: 4991933050 FAX: 4991906671

5. The licensee shall maintain the record of imported new drug or investigational new drugs

Place : New Delhi
Date : 22-OCT-2020

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GIRDHARILAL
SOMANI

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Central Licencing Authority
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