

File No: BIO/CT/21/000055
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:27-April-2021

To

M/s Hetero Biopharma Limited,
H.No. 8-3-166/1 & 2, 105 to 108, 1st Floor, G Block, East
Wing, Challa Estates, Erragadda, Hyderabad, , Telangana
(India) – 500018

Subject: Permission for conducting a clinical trial titled “A Prospective, Randomized, Interventional, Parallel, Multi-Center, Comparative Clinical Trial to Evaluate the Safety and Immunogenicity of COVID-Vac Combined Vector Vaccine (Manufactured by Hetero) in Healthy Adult Human Subjects” [Protocol Number: HCR/III/SARSCOV2VAC/04/2021, Version:2.0, dated 24.04.2021- regarding.

Reference: Your Application No. BIO/CT04/FF/2021/25247 dated 25-April-2021 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2021/25247 dated 25-April-2020 received by this office on the above subject. In this regard, please find enclosed herewith permission to conduct a Phase III clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

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

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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. Hetero Limited, H. No. 8-3-166/1 & 2, 105 To 108, 1st Floor, G Block, East Wing, Challa Estates, Erragadda, Hyderabad (India) - 500018 Telephone No.: 40-23810110 FAX: 40-23810110 E-Mail :VIJAYNAG.T@HETERODRUGS.COM conduct clinical trial of the new drug or investigational new drug as per Protocol no.: HCR/III/SARSCOV2VAC/04/2021, Version:2.0, dated 24.04.2021 in the below mentioned clinical trial sites.

CT No.: CT- 09/2021

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:27-April-2021
Place: New Delhi

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Gam-COVID-Vac combined vector vaccine (Component I & Component II)	
Therapeutic class:	Vaccine	
Dosage form:	Solution (Frozen) for Intramuscular route of administration. when given in two separate doses three weeks apart. Day 0: Component I (0.5 ml) & Day 21: Component II (0.5ml)	
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
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	25.00 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	KLE'S Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum 590010, Karnataka.	Institutional Ethics Committee, KLE University, Belgaum Karnataka - 590010 [ECR/211/Inst/KA/2013/RR-19]	Dr. Jayaprakash Appajigol
2	Peerless Hospitex Hospital and Research Center Limited, 360, Panchasayar, Kolkata - 700094	Institutional Ethics Committee, Peerless Hospitex Hospital and Research Center Limited, 360, Panchasayar, Kolkata – 700094	Dr. Subhrojyoti Bhowmick

		[ECR/232/Inst/WB/2013/RR-19]	
3	St. George Hospital, Grant Government Medical College and Sir J J Group of Hospitals PD Mello Road, CST, Mumbai 400001	Institutional Ethics Committee, Department of Pharmacology, Grant, Government Medical College & Sir J.J group of Hospitals, Byculla, Mumbai 400008, Maharashtra, [ECR/382/Inst/MH/2013/RR-19]	Dr. Akash Ashok kumar Khobragade
4	St, Theresa's Hospital, Sanath Nagar, Hyderabad-500018	Institutional Ethics Committee, St, Theresa's Hospital, Sanath Nagar, Hyderabad-500018 [ECR/230/Inst/AP/2013/RR-19]	Dr. A. Venkateshwar Rao
5	Nizam Institute of Medical Sciences, Punjagutta, Hyderabad -500088	Institutional Ethics Committee, Nizam Institute of Medical Sciences, Punja gutta, Hyderabad-500088. [ECR/303/Inst/AP/2013/RR-19]	Dr. Prabhakar Reddy
6	SSG Hospital , Medical College Baroda, Vadodara-390001	Institutional Ethics Committee of Human Research Sir Sayajirao General Hospital (SSG Hospital), Medical College Baroda, Maharaja Sayajirao. University of Baroda, Jail Road (Indira Avenue), Anandpura, Vadodara, Gujarat- 390001 [ECR/85/Inst/GJ/2013/RR-19]	Dr. Keyur Madan Brahme
7	AIG Hospitals, 136, Plot no- 2/3/4/5, Survey-1, Mind space Road, Gachibowli, Hyderabad -500032	Institutional Ethics Committee, AIG(IEC-AIG), 6-3-661, Somajiguda, Hyderabad -500082 [ECR/346/Inst/AP/2013/RR-19]	Dr. Naveen Chander Reddy

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 "A Prospective, Randomized, Interventional, Parallel, Multi-Center, Comparative Clinical Trial to Evaluate the Safety and Immunogenicity of COVID-Vac Combined Vector Vaccine (Manufactured by Hetero) in Healthy Adult Human Subjects" & Protocol Number– HCR/III/SARSCOV2VAC/04/2021, Version:2.0, dated 24.04.2021.
- II. The firm is required to comply and submit the following information/documents:
 - a. The updated stability data for component-I & Component-II.
 - b. The complete validation report for three consecutive batches of Component-II part and Media fill report.
 - c. The COAs of the three batches of COVID-Vac Combined Vector Vaccine sent to CDL, Kasauli.
 - d. The determinations and characterization of impurities.
 - e. Duly signed declaration regarding financial status of the applicant vis-à-vis medical management and compensation to be paid to the trial participants.
 - f. The legal affidavit declaring that the information about the study drug as mentioned in Investigator Brochure is correct and based on the available facts.
 - g. Copy of Insurance certificate before the initiation of proposed phase III clinical trial.

- h. Assessment of risk vs benefit to the patients.
 - i. Contract with the investigator/institutions with regard to financial support, amount of fees, honorarium and payments in kind etc. to be paid to the investigator before initiation of clinical trial.
- III. The firm is required to constitute a DSMB to review the safety data.
- IV. Specification of the Drugs substance and drug product shall be same as that of imported vaccine
- V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures.
- VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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