

File No: BIO/CT/20/000159

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)

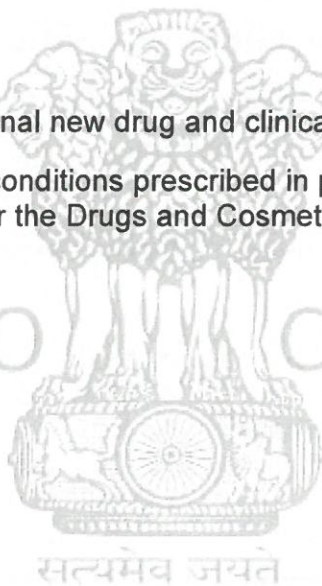
**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG**

The Central Licencing Authority hereby permits M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: BBIL/BBV152-C/2020 Version No: 3.0 Date: 20-10-2020** in the below mentioned clinical trial sites.

**CT No.: CT- 23/2020**

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: 23/10/2020



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SOMANI

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(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

CT No.: CT- 23/2020

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**Annexure:****Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Whole Virion Inactivated Corona Virus Vaccine, [BBV152B]	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for intramuscular injection	
Composition:	Each dose of 0.5 ml contains	
	<b>Active ingredient</b>	<b>Quantity</b>
	Whole Virion, Inactivated Corona Virus antigen Strain: NIV-2020-770	6 mcg
	<b>Inactive ingredients</b>	
	Aluminium Hydroxide gel equivalent to Al+++	250 mcg
	TLR 7/8 Agonist	15 mcg
	2-Phenoxyethanol (2PE) I.P.	2.5 mg
	Phosphate Buffered Saline	Qs to 0.5 ml
Indications:	For active immunization against Corona Virus Disease(SARS-COV-2) COVID-19	

**Details of clinical trial sites-**

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Institute of Medical Sciences (IMS) & SUM Hospital, K 8, Kalinga Nagar, Ghatikia, Bhubaneswar -751003, Odisha	Institutional Ethics Committee, IMS & SUM Hospital, K 8, Kalinga Nagar, Ghatikia, Bhubaneswar 751003, Odisha ECR/627/Inst/OR/2014/RR-20	Dr. E. Venkata Rao
2	Guwahati institute of medical sciences Bhangagarh, Kamrup, Assam - 781032	State Cancer Institute Ethics Committee Bhangagarh, Guwahati-781032 ECR/1289/Inst/AS/2019	Dr. Anjan Jyoti Talukdar
3	Lokmanya Tilak Municipal Medical College & General Hospital, Dr. Ambedkar Road, Sion, Mumbai 400022	Institutional Ethics Committee Lokmanya Tilak Municipal Medical College & General Hospital, Dr. Ambedkar Road, Sion, Mumbai 400022 ECR/266/Lokamanya/Inst/MH2013/RR-19	Dr. N.T. Awad
4	Nizam's institute of Medical Sciences, Punjagutta, Hyderabad, Telangana, 500082	NIMS Institutional Ethics Committee, Nizam's institute of Medical Sciences, Punjagutta, Hyderabad, Telangana, 500082	Dr Prabhakar Reddy
5	Vagus Super Specialty Hospital, #18th Cross, Margosa Road, Malleshwaram, Bangalore - 560003	Vagus Institutional Ethics Committee, 1 8 <sup>th</sup> Cross Rd, Margosa Road, Malleshwaram West, Bengaluru, Karnataka 560003	Dr. Meghana Murthy

6	UCMS & GTB Hospital, Dilshad Garden Delhi 110095	Institutional Ethics Committee, UCMS & GTB Hospital, Dilshad Garden Delhi 110095 ECR/510/Inst/DL/2014/RR-20	Dr. Shiva Narang
7	Rahate Surgical Hospital & ICU, near telephone exchange square, 517, Juni Mangalwari, Central Avenue, Nagpur 440008	Ethics Committee Rahate Surgical Hospital & ICU, near telephone exchange square, 517, Juni Mangalwari, Central Avenue, Nagpur 440008	Dr Manish Kishore Multani
8	ESIC Medical College and Hospital NH-3, behind BK Hospital, New Industrial Town, Faridabad, Haryana 121012	Ethics Committee ESIC Medical College and Hospital NH-3, behind BK Hospital, New Industrial Town, Faridabad, Haryana 121012	Dr Anil Kumar Pandey
9	All India Institute of Medical Sciences, Ansari Nagar New Delhi India 110029	Ethics Committee All India Institute of Medical Sciences, Ansari Nagar New Delhi India 110029	Dr Sanjay Kumar Rai
10	Grant Government Medical College and Sir J.J. Group of Hospitals. J J Marg, Nagpada, Mumbai Central, Mumbai, Maharashtra 400008	Grant Government Medical College and Sir J.J. Group of Hospitals. J J Marg, Nagpada, Mumbai Central, Mumbai, Maharashtra 400008	Dr Priti Meshram
11	Prince Aly Khan Hospital, Jamatkhana uilding, Nesbit Rd, Tara Bagh, Mazagon, Mumbai, Maharashtra 400010	Ethics Committee Prince Aly Khan Hospital, Jamatkhana Building, Nesbit Rd, Tara Bagh, Mazagon, Mumbai, Maharashtra 400010	Dr. Tapan Kumar Saikia
12	All India Institute of Medical Sciences, Aurangabad Road Phulwari Sharif Patna Bihar-801507	Ethics Committee All India Institute of Medical Sciences, Aurangabad Road Phulwari Sharif Patna Bihar-801507	Dr Chadramani Singh
13	Baba Raghav Das Medical College, Gorakhpur, Uttar Pradesh 273013	Ethics Committee Baba Raghav Das Medical College, Gorakhpur, Uttar Pradesh 273013	Dr Azhar Ali Khan
14	Mahatma Gandhi Medical College & Research Institute, Pondicherry- Cuddalore, ECR Main Road, Pillayarkuppam 607-402, Pondicherry, India	Ethics Committee Mahatma Gandhi Medical College & Research Institute, Pondicherry- Cuddalore, ECR Main Road, Pillayarkuppam 607-402, Pondicherry, India	Dr. Pajanivel Ranganadin
15	Vydehi Institute of Medical Sciences and Research Centre 82, near BMTC 18 <sup>th</sup> Depot, Vijayanagar, Nallurhalli, Whitefield, Bengaluru, Karnataka 560066	Ethics Committee Vydehi Institute of Medical Sciences and Research Centre 82, near BMTC 18 <sup>th</sup> Depot, Vijayanagar, Nallurhalli, Whitefield, Bengaluru, Karnataka 560066	Dr Akshata
16	King George Hospital, KGH Down Rd, Opp KGH OP Gate, Maharani Peta, Visakhapatnam, Andhra Pradesh 531011	Ethics Committee King George Hospital, Opp KGH OP Gate, Maharani Peta, Visakhapatnam, Andhra Pradesh 531011	Dr R Vasudev
17	People's university Ayodhya Bypass Rd, Peoples Campus, Bhanpur, Bhopal, Madhya Pradesh 462037	Ethics Committee People's university Ayodhya Bypass Rd, Peoples Campus, Bhanpur, Bhopal, Madhya Pradesh 462037	Dr Raghavendra Gumashta

18	Gandhi Medical College Sultania Rd, near Hamidia Hospital, Royal Market, Medical College Campus, Kohefiza, Bhopal, Madhya Pradesh 462001	Ethics Committee Gandhi Medical College Sultania Rd, near Hamidia Hospital, Royal Market, Medical College Campus, Kohefiza, Bhopal, Madhya Pradesh 462001	Dr Simmi Dube
19	Pt BD Sharma,PGIMS/UHS. Rohtak, Haryana	Ethics Committee Pt BD Sharma,PGIMS/UHS.Rohtak, Haryana	Dr Savita Verma
20	Redkar Hospital and Research Centre Oshalbag Village Dhargal, Tal- Pernem. Goa- 403513, India	Ethics Committee Redkar Hospital and Research Centre Oshalbag Village Dhargal, Tal- Pernem. Goa- 403513, India	Dr. Sagar Vivek Redkar
21	Guntur Medical College, Government Fever Hospital, Government General Hospital, Gorantla, Guntur - 5220020	Ethics Committee, Guntur Medical College, Government Fever Hospital, Government General Hospital, Gorantla, Guntur - 5220020	Dr Laxmi S Kumari

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

- I. The Phase III clinical trial should be conducted as per protocol titled "An Event-Driven, Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity, and Lot-to-Lot consistency of BBV152, a Whole-virion Inactivated SARS-CoV-2 Vaccine in Adults  $\geq 18$  Years of Age" vide Protocol No: BBIL/BBV152-C/2020 Version No: 3.0 Date: 20-10-2020.
- 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.

Place: New Delhi  
Date: 23/10/2020

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(Dr. V. G. Somani)

Drugs Controller General (India)  
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