

File No: BIO/CT/19/000079
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)

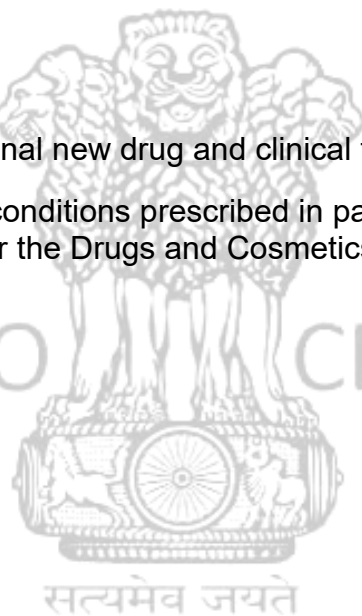
PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits Dr. VK Srinivas of 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/ZIKV/IIa/2019, Version No. V 1.0 dated 13 Aug 2019** in the below mentioned clinical trial sites.

CT No.: CT- 05/2020

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



VENUGOPAL
L
GIRDHARIL
AL SOMANI
(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Digitally signed by VENUGOPAL
GIRDHARIL SOMANI
DN: cn=IN, o=MINISTRY OF HOME
AFFAIRS, ou=CDSCO DIGS,
postalCode=4311401,
st=Maharashtra,
2.5.4.20=17360334580348963237
ba147118d4e9b0b2b0e56c83b0ba2
154c399b1af7, cn=VENUGOPAL
GIRDHARIL SOMANI
Date: 2020.03.16 16:44:44 +05'30'

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

Name of the new drug or investigational new drug:	Zika Virus Vaccine (Adsorbed)		
Therapeutic class:	Vaccine		
Dosage form:	Liquid		
Composition:	Each dose of 0.5 ml contains		
	Name of Active ingredient	Quantity	Quantity
	Purified Inactivate Zika Virus	5 µg	10 µg
	Name of Inactive ingredients	Quantity	Quantity
	Aluminium Hydroxide gel equivalent to Al+++	0.25 mg	0.25 mg
	2-Phenoxyethanol (2PE) I.P.	2.5 mg	2.5 mg
	Phosphate Buffered Saline	0.5 mL	0.5 mL
Indications:	For active immunization against Zika Virus infection		

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	SMS Medical College, JLN Marg, Jaipur, Rajasthan 302004	Ethics committee, SMS Medical College & attached Hospitals, JLN Marg, Jaipur, Rajasthan 302004	Dr. Raman Sharma
2	King George Hospital Maharanipeta, Visakhapatnam- 530002, Andhra Pradesh, India.	Institutional Ethics Committee, King George Hospital, Maharanipeta, Visakhapatnam -530002, Andhra Pradesh, India. ECR/197/Inst/KGH/2013/RR-2016	Dr. R. Vasudev
3	KLE's Dr Prabhakar Kore Hospital & MRC, Nehru Nagar Belgaum, 590010	Institutional Ethics Committee, KLE's Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgaum ECR/211/Inst/KA/2013/RR-16	Dr. Madhav Balakrishna Prabhu

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

- The clinical trial should be conducted as per approved protocol titled "A Phase 2a Double-Blind, Placebo-Controlled Randomized Clinical trial to Evaluate Immunogenicity and Safety of A Zika Virus Vaccine (BBV121) in Dengue Sero-Negative and Dengue Sero-Positive Healthy Adults" vide Protocol Number: BBIL/ZIKV/IIa/2019 Version and date: 1.0 dated 13 August 2019.
- As per recommendations of IND committee "Tubectomised women of child bearing age should be included in the study and analysis in respect of pregnancy reported and analysis in respect of pregnancy reported, if any, should be carried out."

VENUGOPAL
GIRDHARILA
L SOMANI

(Dr. V. G. Somani)

Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi