File No. EC/20/000192



Government of India Directorate General of Health Services Central Drugs Standard Control Organization (Ethics Committee Registration Division)

FDA Bhawan, Kotla Road, New Delhi - 110002, India Dated: 19-Jun-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Com
1	Dr. Anita Ajit Saibannvar	MBBS (MD - Pulmonary Medicine)	Clinician
2	Ms. Shivani Jadhav	B. COM (Not Applicable)	Member
3	Ms. Suvarna Shivaji Sawant	MA (Not Applicable)	Lay Person
4	Dr. Dhananjay Hari Lad	BAMS, PGDCR (Not	Chair Person
5	Dr. Sunita Jayprakash Ramananad	Applicable) MBBS (MD, Pharmacology)	Member Secretary
6	Dr. Vijay Narayan Kulkarni	MBBS (MD, Microbiology)	Basic Medical Scientist
7	Dr. Vijaykumar Bhagwan Barge	MBBS (MD, General	Clinician
8	Dr. Namita Mahesh Prabhu	Medicine) MBBS (MS Surgery)	
9	Mr. Kishore Shamrao Patil		Clinician
0	Mr. Nitin Patil	LLB (NA)	Legal Expert
_	,	B. COM (Journalism)	Social Scientist

VENUGOPAL GROMANIAL SOMAN

(Dr. V.G. Some Drugs Controller General (Central Licensing Author

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Government of India Directorate General of Health Services Central Drugs Standard Control Organization (Ethics Committee Registration Division)

FDA Bhawan, Kotla Road, New Delhi - 110002, India Dated: 19-Jun-2020

To

The Chairman RCSMGMCIEC2 RCSMGMC and CPR Hospital, Kolhapur Building No. 2, Qurter No 3, Room No. 7 Dassara Chowk Kolhapur Kolhapur Maharashtra - 416007 India

Subject: Ethics Committee Re-Registration No. ECR/703/Inst/MH/2015/RR-20 issued under New Drugs and CHONTO CONTA Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2020/8614 dated 16-Jun-2020 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/703/Inst/MH/2015/RR-20. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

VENUGOPAL GIRDHARILA E L SOMANI =

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

Conditions of Registration

- 1. The registration is valid from 19-Jun-2020 to 18-Jun-2025, unless suspended or cancelled by the Centi Licencing Authority.
- 2. This certificate is issued to you on the basis of declaration/submission made by you.
- Composition of the said Ethics Committee is as per the Annexure.
- 4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by Ethics Committee in meeting unless at least five of its members as detailed below are present in the meet namely:-
 - (i) medical scientist (preferably a pharmacologist);
 - (ii) clinician;
 - (iii) legal expert;
- (iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicis theologian or a similar person;
 - (v) lay person.