



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: 20-Jul-2021

To

The Chairman
Institutional Ethics Committee
Sri Sairam Ayurveda Medical College ResearchCentre
Saileo Nagar Poonthandalam SRIPERUMPUDUR
Kanchipuram Tamil Nadu - 600044 India

Subject: Ethics Committee Registration No. ECR/1577/Inst/TN/2021 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2021/9022 dated 24-Jun-2021 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/1577/Inst/TN/2021. The said registration is subject to the conditions as mentioned below:

Yours faithfully

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

Conditions of Registration

- 1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.
- 2. This certificate is issued to you on the basis of declaration/submission made by you.
- 3. 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 an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, 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 ethicist or

FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. ECR/1577/Inst/TN/2021

20172

The Central Licencing Authority hereby registers and permits Institutional Ethics Committee , Sri Sairam Ayurveda Medical College ResearchCentre Saileo Nagar Poonthandalam SRIPERUMPUDUR Kanchipuram Tamil Nadu - 600044 Contact No.: 09444960308 Fax No.: 914422512121 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place : New Delhi

Date: 20-JUL-2021

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Central Licencing Authority Stamp

File No. EC/21/000197



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Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Mr. UMAPATHY KANNAPPAN	BA-Sociology (MA - Sociology)	Social Scientist
2	Dr. KALA P	MBBS (MD-Pharmacology)	Medical Scientist
3	Dr. ASHOK KUMAR R	M.S-SHALYA AYURVEDA (Not Applicable)	Member
4	Dr. Kothainayagi B	M.D AYURVEDA SAMHITHA (Not Applicable)	Member Secretary
5	Ms. SUVEDHA S	B. COM (Not Applicable)	Lay Person
6	Mr. SRIDHARAN R	BL (BACHELOR IN LAW)	Legal Expert
7	Dr. SETHUKRISHNA E	M.S SHALYA (AYURVEDA)	Chair Person
8	Mr. KIRAN B	MSc. Medical Pharmacology	Member
9	Dr. J. Selvakumar	MBBS (F.Diab, DFID)	Clinician

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