N.K.P. Salve Institute of Medical Sciences & Research Centre and
Lata Mangeshkar Hospital
Digdoh Hills, Hingna Road, Nagpur - 440019
Phone (07104) 665000, 244291, Fax : (07104) 306111 mail : nkpsims1@rediffmail.com / website : www.nkpsims.in

ANNEXURE-IX-B

Details of Institutional Ethical Committee

A) Details of Institutional Ethical Committee

Sr. No.	Name of Ethical Committee Member	Designation
1	Dr. Ajeet Saoji	Clinician
2	Dr. Shadma H. Quazi	Medical Scientist
3	Mrs. Shalini B. Thakre	Lay Person
4	Dr. Shriram C. Karandikar	Chair Person
5	Dr. Sushil Yashwant Pande	Clinician
6	Mr. Rajesh S. Nagpure	Legal Expert
7	Ms. Ashwini N Girish	Social Scientist
8	Dr. Riyaz A. Siddiqui	Member Secretary

Date:

Date Verified by the Committee members:

Dr. Ajeet Saoji
Member

Dr. Madhur Gupta
Member

Dr. Rhutuja Deo
Member

Dr. Sajal Mitra
Chairman

DEAN
N.K.P. Salve Institute
Of Med. Sciences & RC
and LMH, NAGPUR

File No. EC/24/000128

सत्यमेव जयते

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: 25-Jul-2024

To

The Chairman
Institutional Ethics Committee
NKP Salve Institute of Medical Sciences
Digdoh Hills Hingna road Nagpur Nagpur
Maharashtra - 440019 India

Subject: Ethics Committee Re-Registration No. **ECR/88/Inst/MH/2013/RR-24** issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2024/16775 dated 28-Mar-2024 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/88/Inst/MH/2013/RR-24**. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, 2.5.4.20=42d7189b1c0981bb5a263a4a73d025ff4b11b680a91f0877348040 0a43ee361b, postalCode=110002, st=Delhi, serialNumber=657f5e47d940985d8f03bdc902d0e1fe73cfa12a1a126ea94fa5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2024.07.26 14:15:29 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 21-Apr-2024 to 20-Apr-2029, unless suspended or cancelled by the Central Licencing Authority.

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 theologian or a similar person;
   (v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,
   (i) one lay person;
   (ii) one woman member;
   (iii) one legal expert;

required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

सत्यमेव जयते

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: 25-Jul-2024

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Ajeet Saoji	MBBS (MD - Community Medicine)	Clinician
2	Dr. Shadma H Quazi	MBBS (MD-Pharmacology)	Medical Scientist
3	Ms. Shalini B Thakre	BA (Not Applicable)	Lay Person
4	Dr. Shriram C Karandikar	MBBS (MS-Ophthalmology)	Chair Person
5	Dr. Sushil Yashwant Pande	MBBS (MD-Dermatology)	Clinician
6	Mr. Rajesh S Nagpure	B.Com (LLB)	Legal Expert
7	Ms. Ashwini N Girhe	BA (MSW)	Social Scientist
8	Dr. Riyaz A Siddiqui	MBBS (MD Pharmacology)	Member Secretary

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Date: 2024.07.26 14:15:44 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I) &
Central Licensing Authority