Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 12/05/2015

To,

The Chairman,
Institutional Ethics Committee,
AMC Dental College & Hospital,
Bhalakia Mill Compound, Khokhra,
Ahmedabad, Gujarat-380008, India.

SUB: – Ethics Committee Registration no. ECR/236 /Indt/GJ/2015 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945

Sir/ Madam,

Please refer to your application no. Nil dated Nil submitted and your response dated 05.03.2015 to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the **INSTITUTIONAL ETHICS COMMITTEE, AMC DENTAL COLLEGE & HOSPITAL** situated at **BHALAKIA MILL COMPOUND, KHOKHRA, AHMEDABAD, GUJARAT-380008, INDIA** with Registration number **ECR/236 /Indt/GJ/2015** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 on the following conditions:

1. **The Ethics Committee shall review and approve only the study protocols and related documents of Bioavailability/Bioequivalence studies of the approved drug molecules and also carry ongoing review of such studies.**
2. The Ethics Committee shall review and accord its approval to Bioavailability/Bioequivalence studies and also carry ongoing review of such studies at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well being of the trial subjects.
3. In the case of any serious adverse event occurring during Bioavailability/Bioequivalence studies, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to Bioavailability Bioequivalence studies and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of Bioavailability Bioequivalence studies.

19/5/15

17. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

18. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

19. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

20. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.

21. This certificate is issued to you on the basis of declaration/ submission by you and that re-inspection is sought for Independent Ethics Committee.

22. Ethics committee should review such number of protocols of Bioavailability/Bioequivalence studies of approved drug molecules which should be commensurate to the infrastructure and facilities available with them.

23. Status report of the functioning of the Ethics Committee should be submitted to the CDSCO headquarters and concerned zonal office on quarterly basis.

24. The details of funding support and amount of honorarium, if any, payable to the ethics committee members should be defined in the Standard Operating Procedure (SOP) of the committee and records to this extent shall be maintained.

25. Ethics committee should have dedicated office with required infrastructure and supporting staff.

However, it is informed that this Ethics Committee can carry out periodic review of ongoing clinical trials already approved by them prior to 30.01.2013.

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

File No. ECR/1242/AMC Dental Indt/GJ/2014

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FDA Bhawan, Kotla Road,
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Dated: 12/05/2015

To,

The Chairman,
Institutional Ethics Committee,
AMC Dental College & Hospital,
Bhailakia Mill Compound, Khokhra,
Ahmedabad, Gujarat-380008,
India.

Subject: Ethics Committee Registration No. **ECR/236 /Indt/GJ/2015** issued under Rule 122DD of the Drugs & Cosmetics Rules1945

Sir/Madam,

Please refer to your application no. Nil dated 22.03.2014 submitted your response dated 05.03.2015 to this office for the registration of Ethics Committee.

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No. **ECR/236 /Indt/GJ/2015** with the following composition and all the condition mentioned under the Registration certificate issued to you.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1	Dr. A N Shah	MBBS, MD (General Medicine)	Chairman
2	Dr. Ramita Sonsa	B.D.S, M.D.S (Oral & Maxillofacial Surgery)	Member Secretary
3	Dr. Dolix Pankaj Patel	BDS, M.D.S (Orthodontics)	Clinician
4	Dr. Bela Dave	B.D.S, M.D.S (Periodontia)	Clinician
5	Dr. Darshna Shah	B.D.S, M.D.S (Prosthodontia)	Clinician
6	Dr. Supriya Malhotra	MBBS, MD (Pharmacology)	Basic Medical Scientist
7	Mr. Satyam Desai	B.Com, LL.B.	Legal Expert
8	Mrs. Krishna Shah	Numerologist	Lay Person
9	Dr. Priti G. Adani	B.D.S	Social Scientist
10	Dr. Kinnari Rajpura	B.D.S, M.D.S (Oral Pathology)	Scientific Member
11	Dr. R G Agnihotri	B.D.S, M.Sc (Anatomy)	Scientific Member

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