File No. ECR/455/South/Indt/GJ/2013

From:

O/o The Drugs Controller General (India)
Directorate General of Health Services

FDA Bhawan, Kotla Road,
New Delhi – 110 002
Dated: 25/06/2013

To

The Chairman
Ethics Committee
South Gujarat Independent Ethics Committee,
101, Divya Darshan Apartment, Ghod Dod Road, Surat-395007
Gujarat, India.

SUB: - Ethics Committee Registration No. **ECR/ 71 /Indt/GJ/2013** issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Dear Sir,

Please refer to your application no. nil, dated 03.06.2013, Diary No. 26911 dated 06.06.2013, FTS no. 37457 dated 07.06.2013 submitted to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby Registers the **South Gujarat Independent Ethics Committee** situated at **101, Divya Darshan Apartment, Ghod Dod Road, Surat-395007 Gujarat, India** with Registration number **ECR/ 71 /Indt/GJ/2013** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to 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.