Annexure 13

# Format of IEC Report to CDSCO in case of SAE

# INSTITUTIONAL ETHICS COMMITTEE-CHARUSAT

To,

Assistant Drug Controller [I]

Central Drugs Standard Control Organization [CDSCO] Office of Drug Controller General (India)

FDA Bhawan, Kotla Road, New Delhi - 110002

Date:

***Reference:*** ProtocolNumber:

Centre Number:

***Subject:*** Opinion on Serious Adverse event (SAE) Death/ Injury other than Death

PatientID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dear Sir/ Madam,

## Details of Examination of the said SAE Death/ Injury other than Death [including Key events]

**Minutes of the Meeting conductedby the Institutional Ethics Committee-CHARUSAT**

**Analysisof the Key events**

**Causality assessment and justification**

* WHO Causality Categories/ Naranjo Toolcriteria
* Criteria under Rule 122DAB and Appendix XII of Schedule Y of Drugs and Cosmetics Rules’ [criteria from ‘a’ to ‘g’ under the saidrules]

## Opinion [Report]

Date:

Place:

Member Secretary

Institutional Ethics Committee - CHARUSAT