Annexure 1
AX 01/SOP 11-B/V6.1
Table 5 THIRD SCHEDULE

Data Elements for Reporting Serious Adverse Events occurring in a clinical trial or bioavailability or bioequivalence study of Initial Report/Follow up report

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No. .....

Sr.No.	Details		
1.	**Country (Name of the country should be specified)**	**INDIA**	
2.	**SAE report of death or other than death, Please tick (✓)**	**Death** □	**Other than Death** □
		Page No.	**Yes/No**
3.	Patient Details:		
	Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc)*		
	Gender		
	Age or date of birth		
	Weight		
	Height		
4.	Suspected Drug(s) :		
	Generic name of the drug*		
	Indication(s) for which suspect drug was prescribed or tested.		
	Dosage form and strength.		
	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).		
	Route of administration.		
	Starting date and time of day.		
	Stopping date and time, or duration of treatment		
5.	Other Treatment(s):		
	Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).		
6.	Details of Serious Adverse Event :		
	Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*		
	Start date (and time) of onset of event.		
	Stop date (and time) or duration of event.		
	Dechallenge and rechallenge information.		
	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
7.	Outcome:		
	Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted.		
	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings.		
	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		

8.	Details about the Investigator*		
	Name and Address		
	Telephone number		
	Profession (specialty)		
	Date of reporting the event to Central Licencing Authority:		
	Date of reporting the event to ethics committee overseeing the site:		
	Signature of the Investigator or Sponsor		
	Note: Information marked * must be provided.		