

Annexure XIII  
**INSTITUTIONAL ETHICS COMMITTEE**  
**HM PATEL CENTRE FOR MEDICAL CARE AND EDUCATION,**  
**KARAMSAD**

**APPENDIX XI [Schedule Y]**

Initial Report Final Report

**Reference:**

Ref: Protocol no:

**1. Patient Details:**

Subject initials and subject Id:

Initials & other relevant identifier (hospital/OPD record number etc.)\*Hospital No:

Gender:

Age and/or date of birth:

Weight:

Height:

**2. Suspected Drug(s)**

Generic name of the drug\*:

Indication(s) for which suspect drug was prescribed or tested:

Dosage form and strength

Route of administration:

Starting date and time of day:

date and time: Stopping date and time, or duration of treatment (last dose taken):

Comments (if there were any dose interruption in between please provide details):

**3. Other Treatment(s)**

**Provide the same information for concomitant drugs (including non prescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).**

**4. Details of Suspected Adverse Drug Reaction(s)**

• **Event term:**

• **Grade:**

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Life threatening)

Grade 5 (Death)

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• **Criteria for qualification of SAE:**

- Death
- Life threatening
- Requires or prolongs hospitalization
- Results in persistent or significant disability or incapacity,
- Congenital anomaly or birth defect
- Significant medical event
- Disease Progression

• **Causality**

- to study drug
- to concomitant medication
- to coexisting medical condition

Comments (Clarify the causality):

- **Full description of reaction(s) including body site and severity and the reported signs and symptoms (whenever possible, describe a specific diagnosis for the reaction):**

**5. Outcome**

- Resolved/ended (Date: \_\_/ \_\_/ \_\_)
- Ongoing
- Stabilized (Date: \_\_/ \_\_/ \_\_)
- Resolved without Sequelae
- Resolved with Sequelae: Record Sequelae: \_\_\_\_\_
  
- Death (please attach copy of death certificate)
- Unknown

**6. Laboratory results (list the results of any lab test done during the time of SAE):**

**7. Other information:**

- medical history:

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- history of any allergy
- history of addiction to drug or alcohol:
- any significant family history:

**8. Details about the Investigator\*:**

Name of Investigator:

Institution Address:

Telephone number:

Profession (specialty):

Date of reporting the event to Ethics Committee overseeing the site

Form Completed By:

Signature of the Investigator:

Date: