

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)

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Grade 5 (Death)

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

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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: