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)

- **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:

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: