APPENDIX XI [Schedule Y]

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: