Adverse Event (AE) Report Form

RADIANT PHARMACEUTICALS

Attachment of the SOP No.: PV-004.04	SOP version: 04	SOP issue date: 18 October, 2018	Doc. No.: PV/AEF/001	Page 1 of 2

To be filled by Pharmacovigilance Dept. of Radiant

Date of receipt of AE report/ Info:	Processed by:	Checked by:	Case ID:
Day Zero:	Type of Report: ☐ Initial ☐ Follow-up ☐ Final ☐ Initial & Final		
Source: ☐ Spontaneous ☐ Patient survey ☐ Study report ☐ Literature ☐ Other:			

REGION: **TERRITORY/COUNTRY:**

REPORTER DETAILS	PATIENT DETAILS
Reporter Name:	Initials/Name/ID:
Designation/Title	Name of health facility (If applicable):
Address:	Patient Address:
E-mail address:	Contact Number:
Contact number:	Age_____ (yr) Weight_____ kg Height_____ (cm/ft)
Date of submission:	Gender ☐ Male ☐ Female
Occupation ☐ Physician (Specialty)_____ ☐ Pharmacist ☐ Nurse ☐ Consumer ☐ Company Rep.	Pregnant ☐ Yes ☐ No ☐ Unknown ☐ Not Applicable Breastfeeding ☐ Yes ☐ No ☐ Unknown ☐ Not Applicable

ADVERSE EVENTS (Please continue in additional information section or use duplicate form if needed)

Symptoms	Date of Onset/Start (Day/Month/Year)	Was any diagnosis done for AE? (Yes/No, if yes, specify)	Was AE/symptom treated? (Yes/No, if yes, specify)	Date of Resolve/Stop (Day/Month/Year)

Nature of Event (Tick where applicable)
☐ Adverse Drug Reaction ☐ Overdose ☐ Off label use ☐ Abuse ☐ Misuse ☐ Occcupational Exposure
☐ Medication errors ☐ Lack of efficacy ☐ Product quality problem ☐ Other_____

Action taken after the adverse reaction
☐ Dose stopped
☐ Dose reduced
☐ No action taken/dose continued

Did adverse reaction diminish after stopping/ reducing dose of product?
☐ Yes ☐ Unknown
☐ No ☐ Not Applicable

Was product restarted after adverse reaction diminished?
☐ Yes ☐ No ☐ Unknown ☐ Not Applicable

If yes, did adverse reaction reappear?
☐ Yes ☐ No ☐ Unknown ☐ Not Applicable

Seriousness of the adverse event (Tick where applicable)
☐ Death ☐ Required/prolongation of hospitalization ☐ Congenital anomaly/birth defect ☐ Persistent/significant disability
☐ Life threatening ☐ Other medical significant event (specify):_____ ☐ Non-serious

Outcome of the adverse event (at the time of this report) ☐ Complete Recovery ☐ Recovering ☐ Not recovered/On-going
☐ Unknown ☐ Fatal_____ ☐ Recovered with sequelae, specify sequelae_____

SUSPECT DRUG DETAILS (If more than 3, please list in additional information section or use duplicate form if needed)

Particulars	Suspect drug product 1	Suspect drug product 2	Suspect drug product 3
Brand name, strength & dosage form			
Generic Name			
Dose(unit) & Frequency			
Indication			
Batch Number			
Route			
Manufacturer			
Medication start date (Day/Mon/Yr)			
Medication stop date (Day/Mon/Yr)			

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CONCOMITANT MEDICATION

Particulars	Product 1	Product 2	Product 3
Brand name, strength & dosage form			
Generic Name			
Dose(Unit) & Frequency			
Indication			
Route			
Medication start date (Day/Mon/Yr)			
Medication stop date (Day/Mon/Yr)			

Other Relevant medical history [Provide any other information that can help in the evaluation of the reported adverse event such as relevant medical history (diabetes, hypertension, liver/kidney problems, etc.), race, allergies, smoking and alcohol use, etc]

Causality relationship with Drug Reaction: ☐ Certain ☐ Probable ☐ Doubtful ☐ Unassessable ☐ Not assessed

Has the regulatory authority been notified of this report? ☐ Yes ☐ No ☐ Not applicable

Has the patient discussed the event with health care professional? ☐ Yes ☐ No ☐ unknown

If yes, name of health care professional_____ Contact :_____

Case narratives including relevant tests & laboratory results (Attachment if any)

(Detail description, investigation of ADR, Product quality problem associated adverse event, medication error)

Additional information section (List of attachment if any)

Remarks (of Pharmacovigilance Dept. of Radiant)

_____

Signature & date

_____

Reporter's Signature

Date:_____/_____/_____ (Day/month/Year)