Annex-I

Adverse Event (AE) Report Form

RADIANT PHARMACEUTICALS

Attachment of the SOP No.: PV-004.05	SOP version: 05	SOP issue date: 20 January, 2022	Doc. No.: PV/AEF/001	Page of

To be filled by Pharmacovigilance Dept. of Radiant

Date of receipt of AE by PV Dept:	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:	**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 ☐ Unknown
Occupation ☐ Physician (Specialty)_____ ☐ Pharmacist ☐ Nurse ☐ Consumer ☐ Company rep.	Pregnant ☐ Yes ☐ No ☐ Unknown ☐ Not applicable Breastfeeding ☐ Yes ☐ No ☐ Unknown ☐ Not applicable

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

Particulars	Suspected drug product 1	Suspected drug product 2	Suspected drug product 3
Brand name			
Generic name			
Strength			
Dosage form			
Dose(unit)			
Frequency			
Indication			
Batch number			
Route			
Manufacturer			
Medication start date (Day/Mon/Yr)			
Medication stop date (Day/Mon/Yr)			

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)
☐ Suspected ADR ☐ Overdose ☐ Off label use ☐ Abuse ☐ Misuse ☐ Occupational exposure
☐ Medication errors ☐ Lack of efficacy ☐ Product quality problem ☐ Other_____

Action taken after the adverse reaction
☐ Dose stopped ☐ Unknown
☐ 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 ☐ Non-serious
☐ Other serious (specify):_____ ☐ Other medically significant event (specify):_____

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_____

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CONCOMITANT MEDICATION (If more than 3, please list in additional information section or use duplicate form if needed)

Particulars	Product 1	Product 2	Product 3
Brand name			
Generic name			
Strength			
Dosage form			
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/initial of health care professional_____ Contact :_____

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

(Detail description, investigation of ADR, PQC/MIQ associated with adverse event, medication error etc)

Additional information section (List of attachment if any)

Consent taken for follow-up ☐ Yes ☐ No ☐ Not given

Remarks (of Pharmacovigilance Dept. of Radiant)

_____

Signature & date

_____

Reporter's signature

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