Adverse Event (AE) Report Form

RADIANT PHARMACEUTICALS

Originated by: Adittya Arefin	Attachment of the SOP No: PV-004.02	Creation date: March, 2017	Doc. No.: PV/AEF/001.04	Page 1 of 2	Approved by: Mohammad Moinul Hakim

REGION: **TERRITORY:** **DATE RECEIVED:** **CASE ID:**

REPORTER DETAILS ◆

Reporter Name:

Designation/Title:

Address:

E-mail Address:

Date of Submission:

Contact number:

Occupation: ☐ Physician (Speciality)______ ☐ Nurses

☐ Pharmacist ☐ Consumer ☐ Company Rep ☐ Others________

Has the regulatory authority been notified of this report?

☐ Yes ☐ No ☐ Unknown

PATIENT DETAILS ◆

ID/Name:				
Name of Health Facility:				
Gender:	☐ Male ☐ Female			
Age:	Weight:		Height:	
Patient Address:				
Contact number:				
Pregnant:	☐ Yes ☐ No ☐ N/A			

Report type: ☐ Initial ☐ Follow-up

Nature of event: (check all that apply) ☐ Adverse Drug Reaction ☐ Pregnancy/lactation ☐ Abuse ☐ Overdose ☐ Lack of efficacy ☐ Misuse

ADVERSE EVENTS ◆ (please continue in Additional Relevant Information section or on Supplementary Form if needed)

Symptoms	Date of onset	Diagnosis	Treatment of AE	Date of Resolve

Outcome: (at the time of this report) ☐ Complete recovery ☐ Recovered with sequelae (specify sequelae):___________

☐ Recovering ☐ Not recovered/ongoing ☐ Fatal (date of death): ☐ Unknown

Seriousness: ☐ Death ☐ Required/prolonged hospitalization ☐ Life threatening

(check any that apply): ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly ☐ Not Serious

☐ Any other Medically Significant event (specify) ____

SUSPECT DRUG DETAILS ◆ (if more than 3 please list in Additional Relevant Information section or on Supplementary Form)

Brand Name	Generic Name	Indication	Batch Number	Dose	Route	Frequency	Manufacturer	Start Date DD-MM-YYYY	Stop Date DD-MM-YYYY

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Did reaction abate after stopping drug?	Was drug restarted after reaction abated?	If yes, did reaction recur?
☐ Yes ☐ Unknown ☐ No ☐ Not applicable	☐ Yes ☐ Unknown ☐ No ☐ Not applicable	☐ Yes ☐ Unknown ☐ No ☐ Not applicable
Causal relationship to ADR:	☐ Yes ☐ No	☐ Not assessable/Can't Say

CONCOMITANT MEDICATIONS

Brand Name	Generic Name	Indication	Dosage Form	Route	Dose	Frequency	Start Date DD-MM-YYYY	Stop Date DD-MM-YYYY

Case Narratives including relevant tests and laboratory results:

Other relevant Medical History:

Reporter Signature:

Date: DD/MM/YYYY

Send all completed forms to:
Radiant Pharmaceuticals Limited
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