"For Office Use Only"

Date:
Report #:
PV-ICR #:

SHAIGAN PHARMACEUTICALS (PVT) LTD.

Doc:	**4/RA-PhV-01**
Rev:	**02**
Rev Date:	**22-01-2028**

SUSPECTED ADVERSE EVENT REPORTING FORM

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***All fields marked with an '*' are mandatory.**

***Patient Name/contact details & Reporter Name with Contact details are mandatory.**

A: Patient Details and History *

Patient Name: _____ **ID/ Hospital Ref :** _____

Contact: _____ **Wt** (kg) & **Height** (cm) _____:_____

Age(At the time of reaction): _____ (DD/MM/YY)

Pregnancy Status (if female):_____ **Period:** Trimester **1st** ☐ **2nd** ☐ **3rd** ☐ **Lactation:** _____

Allergies (if any): _____

Pre-Existing Medical Problems (if any) : _____

Alcohol Use : Yes ☐ No ☐

Liver Dysfunction : Yes ☐ No ☐

Smoking : Yes ☐ No ☐

Renal Dysfunction : Yes ☐ No ☐

Creatinine : _____(mg/dl)

B: Suspected Drug(s) *

		Brand and Generic name	Batch No.	Expiry date.	Route of Adm.	Daily dose (Freq.)	Dosage & Strength	Start date	Stop Date	Indication/ Disease
Suspected	1									
	2									
Concomitant	1									
	2									
	3									

C: Details of the Event:

Reaction Onset Date & Time: _____(DD/M/YY):____:____Am/Pm **Recovery start Date & Time:** _____(DD/M/YY) ____:____Am/Pm

Describe the reaction (s) : *

Relevant laboratory data (if available)**:**

Is the Drug (s) a new Medicine? Yes ☐ No ☐

Severity of the reaction (CTCAE criteria) :

Mild ☐ Moderate ☐ Severe ☐ Life Threatening ☐ Fatal ☐

Medication Prescribed or advised by:

Doctor ☐ Pharmacist ☐ Nurse ☐ Self-medication ☐

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Do you consider the reaction(s) to be serious? Yes ☐ No ☐

If yes, please tick all that apply of the following :

- ☐ **Patient died due to reaction**
- ☐ **Involved or prolonged inpatient hospitalization**
- ☐ **Life Threatening**
- ☐ **Involved persistent or significant disability or incapacity**
- ☐ **Congenital anomaly/Birth Defects**

Other Serious (Medically Important Condition): _____

please give details: _____.

D: Management and Outcome :

Action taken:-

Drug Withheld Yes ☐ No ☐

Drug Discontinued Yes ☐ No ☐

Dose changed: Yes ☐ No ☐ if yes, specify: _____

Frequency Changed: Yes ☐ No ☐ if yes, specify: _____

Treatment Given? Yes ☐ No ☐ if yes, then specify: _____

Did Reaction subside after stopping drug/changing dose? Yes ☐ No ☐

Did reaction re-occur when the drug was re-started? Yes ☐ No ☐

Outcome:

☐ Recovered (Date of Recovery) : _____ Unknown ☐

☐ Fatal (Date of Death): _____ Continuing ☐

E. Cause of Adverse Event :

Was the reaction linked to "Therapeutic failure" : No ☐ Yes ☐ if yes then tick the reason :

Poor Quality ☐ Improper administration of drug ☐ Drug interaction ☐ Counterfeit ☐

Expired ☐ Improper storage ☐ Over-dosing ☐ Under dosing ☐

Was the reaction due to Medication Errors? ☐ Yes ☐ No

Dispensing Error ☐

Administrative Error ☐ Prescribing Error ☐

F. Reporter details : *

Reporter Name*: _____ **Address:** _____

Affiliation: _____ **Profession:** _____

Contact No*: _____ **Reporter's signature:** _____

E-mail: _____ **Reporting Date*:** ____/ ____ / _____.