SAFFRON PHARMACEUTICALS (PVT.) LTD.

For Office Use Only	Form ID: _____ Patient registration No. _____ Date : _____	ADR Reporting ☐ Drug Evaluation ☐

Patient information

Patient Name : _____ Age : ☐ Weight : ☐
Gender : Male ☐ Female ☐
Pregnancy status : No ☐ Yes ☐
Lactation Status : No ☐ Yes ☐
Any allergy : No ☐ Yes ☐
Specify _____ ☐
Liver dysfunction : No ☐ Yes ☐
Kidney dysfunction:No ☐ Yes ☐ If yes then,
Creatinine(mg/dl) ☐
Any allergy : No ☐ Yes ☐ Specify: _____
Previous Medical History :

Medicine advised by

Physician ☐
Name of physician_____
Physician location or adddress:
_____
_____

Is Adverse Reaction due to

a) Product quality defect
Color change ☐
Odor change ☐
Defective packing ☐
Contaminants ☐
Separation of components ☐

b) Therapeutic Failure
Improper storage ☐ Inappropriate route of administration ☐
Under dosing ☐ Expired ☐
Over dosing ☐ Antimicrobial resistance ☐
Drug interaction ☐

Details about reaction/event observed including related laboratory results

Suspect Drugs Information or Evaluation Drug

Name Of Drug	Strength And Dose	Used for Indication	Route Of Administration	Expiry Date	Batch No.	Start date	End date	Frequency	Manufacturer Name

Adverse Drug Event Information

Drug Start date	Date of event/onset	De-challenge	Re-challenge	Therapy duration	Still Continued?

Details of patient condition/Indication for which drug is being used.

List below all other drugs taken at same time. If none, check box ☐

Concomitant Drugs (If any)

Name of drug	Strength	Dosage form	Daily dose	Indication	Medicine Still Continued?

Do you consider reaction to be serious? If yes indicate why?
1. Involved or prolonged in-patient hospitalization
2. Life threatening
3. Involved persistent or significant disability
4. Congenital anomaly in the newborn
5. Patient died due to reaction

Severity	Side Effects				
	Stomach upset	Nausea and vomitting	Headache	Tiredness	Blurred vision
Mild					
Moderate					
Severe					

Management of Event

Action taken : None ☐ Yes ☐
Specify : _____
Corrective Treatment : No ☐ Yes ☐
Specify : _____
_____
_____

Outcomes :
Fatal ☐ **Recovering** ☐ **Recovered** ☐ **Not Recovered** ☐ **Unknown** ☐

Can this be due to Medication Error? **Yes** ☐ **No** ☐ **, If yes**
Prescribing ☐ **Administration** ☐
Dispensing ☐

Reporter information

Name _____ **Email Address** _____ **Telephone no.** _____ **Signature** _____

Doctor ☐
Pharmacist ☐
Nurse ☐
Consumer ☐
Company representative ☐

Contact Us
Email: Pharmacovigilance@saffronpharma.com
Fax :041-2423919
Telephone No. 041-2423914-17

Saffron Pharmaceuticals (Pvt.) Ltd.