Surge Laboratories Pvt. Ltd.	*Pharmacovigilance Department*
Title:- Adverse Event Data Collection Form	**PVD-QSF-004**
	SOP Ref # PVD-SOP-001
	Page 1 of 1

FOR OFFICE USE ONLY
Company Recipient Name: _____
PV Recipient Name: _____
Date Received: _____
PV Reference No: _____

SUSPECTED ADVERSE DRUG EVENT REPORTING FORM

This form is for voluntary/ spontaneous reporting of adverse drug reactions of products marketed by Nabiqasim Group of Companies

A. PATIENT INFORMATION

1. Patient Name*: _____ **2. Patient identification Number** (If any): _____
3. Sex: Male/ Female **4. If female, Pregnant:** Yes / No (Trimester ☐) **5. Age (years):** _____ **6. Weight (kgs):** _____
7. Allergies (if any): _____ **8. Liver/Kidney Dysfunction** (If yes, extent): _____

B. PRODUCT INFORMATION

Name of the product and strength*	Route	Therapy Dates (from/to)	Dose	Indication	Batch No

1. Did reaction stopped after stopping/ changing the dose: Yes/ No (If dose changed, please specify dose: _____)
2. Did the reaction reappear after drug was reintroduced: Yes/ No **3. Product available for evaluation*:** Yes/ No

C. EVENT INFORMATION

1. Date of Onset: _____

2. Describe the event with relevant lab tests or any data known*+

3. You consider the problem related to which of the following:
☐ *Adverse Event/Reaction*
☐ *Quality Problem*
☐ *Medication Error*
Others (please specify) _____

4. Outcome:
☐ *Fatal* ☐ *Unknown*
☐ *Recovered* *Other:* _____
☐ *Recovering* _____

5. Do you consider this event serious: *Yes / No*
If yes please indicate why? ☐ *Patient died due to reaction* ☐ *Life threatening*
☐ *Caused disability/incapacity* ☐ *Involved / prolonged inpatient hospitalization*

D. OTHER DRUG(s)/ ALTERNATIVE MEDICINE (s) AND HISTORY

1. Concomitant Drugs used (if any) *(exclude those used to treat reaction)*+

2. Other Relevant History *(diagnostics, lab tests, etc, etc)*+

E. REPORTER INFORMATION*

1. Reporter's Name: _____ **2. Affiliation:** _____
3. Contact Details: _____ **4. Mailing address:** _____
4. Profession: ☐ *Physician* ☐ *Pharmacist* ☐ *Nurse* ☐ *Patient* ☐ *Other*
5. Date Reported: _____ **6. Signature:** _____

"Send signed filled form Virtually at medsafety@nabiqasim.com/medsafety@surgelaboratories.com/medsafety@etdc.com.pk or Physically at Pharmacovigilance Department, 5th Floor,Commerce Centre, Hasrat Mohani Road, Karachi- Pakistan."

**Compulsary Information*

+Additional pages can be used if required

"This form neither has legal value nor can it be presented before any court"