Suyaash PHARMACEUTICALS
॥ नेत्र दीप्ती देह कांती ॥

## Pharmacovigilance Department

# ADVERSE EVENT REPORTING FORM

**Type of Report:** ☐ Initial case ☐ Follow up

**(A) Patient Details***

| | | | |
|---|---|---|---|
| Patient Initials | _____[ex. Vishal Kumar Sharma VKS] | Country | |
| Age/ Date of Birth | | Weight | |
| Gender | ☐ Male ☐ Female ☐ Other | Pregnant | ☐ Yes ☐ No ☐ Unknown |

**(B) Suspected Medication(s) ***

| S. No. | Product Name | | Manufacturer name | Marketer Name | Batch number/ Expiry Date | Dose, Route & Frequency (OD/BD etc.) | Therapy Start date DD/MM/YYYY | Therapy Stop date DD/MM/YYYY | Indication | # Action Taken |
|---|---|---|---|---|---|---|---|---|---|---|
| | Brand Name | Generic Name with strength/ formulation | | | | | | | | |
| 1. | | | | | | | | | | |
| 2. | | | | | | | | | | |
| 3. | | | | | | | | | | |

# Select appropriate action taken:
Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable

| Did event abated after drug withdrawn/ dose reduced? | Did event reappeared after reintroduction? |
|---|---|
| ☐ Yes / ☐ No / ☐ Unknown / ☐ Not applicable | ☐ Yes / ☐ No / ☐ Unknown / ☐ Not applicable |

Concomitant medications (Any other medications consumed along with our company drugs):

| Drug Name | Dose & Frequency | Route | Therapy dates | | Reason for use |
|---|---|---|---|---|---|
| | | | From | To | |
| | | | | | |
| | | | | | |
| | | | | | |

**(C) Adverse Event Details ***

| Adverse event | Date of event Onset | Date of event stopped | ##Outcome |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

## Select outcome of the event: *Recovering; Recovered; Not Recovered; Recovered with sequelae; Unknown; Fatal*

Is the adverse event serious? ☐ Yes / ☐ No

If yes, please indicate why it is serious? (Check all that apply)

☐ Death ☐ Life threatening ☐ Hospitalization-Initial /Prolonged

☐ Congenital anomaly/birth defect ☐ Disability ☐ Other important medical event

## Pharmacovigilance Department

# ADVERSE EVENT REPORTING FORM

| If hospitalized provide:<br>Date of admission _____<br>Date of discharge _____<br>Attach the copy of discharge summary with this form. | If Death provide:<br>Date of death DD/MM/YYYY _____<br>Cause of death _____<br>Autopsy: ☐ Yes ☐ No ☐ Unknown<br>Autopsy result (If yes): _____ |
|---|---|
| Description of adverse events: (including sign and symptoms with specific diagnosis, treatment): | |
| Relevant Lab test Details (with dates, results and normal range) : | |
| Other relevant history including pre-existing medical conditions: (e.g. allergies, smoking, alcohol use, liver/kidney problems etc.) | |

| **(D) Reporter details*** | |
|---|---|
| Name: | Occupation: |
| Email: | Phone No. |
| Address: | Date of this report: |
| Consent to contact Healthcare Professional (HCP) / Prescribing Physician: ☐ Yes ☐ No | |
| If yes, provide contact Healthcare Professional (HCP) / Prescribing Physician details | |
| Name: | Qualification: |
| Address: | |
| Email: | Phone No. |

* *Mandatory Fields for Adverse Event Reporting Form.*

**Please send the complete form to:**

*Registered office:* **Suyaash Pharmaceuticals**, 216/5-6, Village Khundh, Near A.B. High School, Vansda Road, Tal. Chikhli, Dist. Navsari (Guj.), India.

Email the completed form to: pharmacovigilancesuyaash@gmail.com

If any additional data are available, please attach them with this form.

| **This section is for Suyaash Pharmaceuticals use only:** | |
|---|---|
| Report ID: _____ | Receipt Date: _____ |
| *Name and signature of receiving Pharmacovigilance personnel:* | |