Paviour Obsessed with Quality	**PAVIOUR PHARMACEUTICALS PVT. LTD.** **PHARMACOVIGILANCE DEPARTMENT**

ADVERSE EVENT (AE) REPORT FORM

Report Type: ❒ Initial ❒ Follow-up Follow-up No:

Date of AE Report:

Please fill and return this form to Paviour Pharmaceuticals Pvt. Ltd. 311-312, Suneja Tower-1, District Centre, Janak Puri, New Delhi - 110058 within 24 hours of knowledge of adverse event
E-mail ID: drugsafety@paviour.org

1. Patient Information

Initials/identifier:	**Date of Birth** (e.g. 01 Jan 1940) _____	**Ethnic Origin:** ❒ White ❒ Asian ❒ Black/African American ❒ Other, Please Specify___
Sex: ❒ Male ❒ Female	**Height (cm):**	**Weight (kg):**
Pregnant: [ ] Yes [ ] No	**Country of occurrence:**	**Tel. No:**

2. Adverse Event Information

AE term(s):

Course of event:

❒ Onset of AE or date and time when AE occurred:	**Date:**	**Time:**
❒ Onset of AE or date and time when event became serious, if applicable:	**Date:**	**Time:**

Present Status:
❒ Ongoing → AE currently treated ☐ Yes ☐ No
❒ Resolved Please Specify **Date:**_____**Time:** _____

Case description: Detailed description of the event (Include related signs/symptoms, course, outcome)

Reason for seriousness:

❒ resulted in death ❒ life-threatening ❒ required inpatient hospitalization or prolongation of existing hospitalization ❒ resulted in persistent or significant disability/ incapability (as per reporter's opinion)/ congenital anomaly/ birth defect ❒ other medically important event (reporter's discretion)

Intensity: ❒ Mild ❒ Moderate ❒ Severe

Reporter's Causality: [ ] certainly [ ] probably [ ] possibly [ ] unlikely [ ] conditional [ ] unassessable [ ] not related

Outcome of AE:
❒ Completely recovered/resolved ❒ Ongoing ❒ Fatal ❒ Lost to follow-up
❒ Unknown ❒ Recovered with sequelae → specify:_____

If outcome is fatal:
Cause of death:_____Date:_____Time:_____
Report of Autopsy available? □ No □ Yes (Please attach copy to this report)
Further information:_____
_____

Lab test Details (with dates, results and normal range):

3. Drug Details

Name of the drug:_____ **Batch no**. _____

Strength:_____ **Indication:**_____

Route of Admin:_____ **Dosage form:**_____ **Dose:**_____
_____

Frequency:_____ **Expiry date:** _____

Start date: _____ **Stop date:** _____ **Ongoing:**

Action taken with suspect drug:
❒ None
❒ Dosage changed temporarily: Date:_____○ Dosage reduced ○Dosage increased
❒ Drug stop temporarily: Date:_____
○ Drug restarted: Date:_____
❒ Drug withdrawn permanently ❒ Dosage not changed ❒ Unknown ❒ Not applicable

Additional suspect drug (if any) details as above:

Event abated after drug stopped or dose reduced:	**Event reappeared after reintroduction of suspect drug:**	**If yes, did reaction recur?**
❒ Yes ❒ No ❒ Not applicable	❒ Yes ❒ No ❒ Not applicable	❒ Yes ❒ No ❒ Not applicable

4. Patient's Relevant Medical History (Supplement attached Yes/No)

(E.g. concomitant diseases, previous history of present condition, allergy, drug or alcohol abuse)
_____
_____
_____

5. Concomitant Drugs							
Drug Name (generic)	**Dose / Unit**	**Route**	**Frequency**	**Start date**	**Stop date**	**Ongoing**	**Causal relationship to event**
						❒	❒ None ❒ Possible
	Indication:						
						❒	❒ None ❒ Possible
	Indication:						
						❒	❒ None ❒ Possible

6. Reporter Details	
Name: **Address:** **Country:** **Tel. No:** **Email:**	**Occupation:** [ ] Physician [ ] Pharmacist [ ] Nurse [ ] Consumer [ ] Other, specify: ..... **Also reported to:** [ ] Regulatory Authority [ ] Distributor [ ] None **Date :** , **Signature:**
7. Send this report to:	**8. To be filled by Manufacturer:**
Paviour Pharmaceuticals Pvt. Ltd. **311-312, Suneja Tower-1, District Centre, Janak Puri, New Delhi – 110058** **Tel No. +91-11-46539679** **E-mail: drugsafety@paviour.org**	**Date received by receiver:** **Name and sign of receiver:** **Safety Report ID:**