Suspected Adverse Event Report Form (Human)

☑ *I consent to Piramal's use of this data to respond to my complaint. Any and all information collected will be kept secure and will not be sold, rented, loaned, or otherwise disclosed to anyone except to the drug regulatory agency to comply with regulatory obligations for monitoring of drug safety profile throughout life cycle of medicinal product. For more details regarding privacy policy, refer http://www.piramalcriticalcare.com/privacy-policy/ or write to us at dpo.criticalcare@piramal.com.*

1.	**Patient Data:**					
Initials	**Date of Birth/ Age**	**Gender:**		**Height**	**Weight**	**Ethnicity**
S	22 **yrs /** 11 **Mnts/** 20 **dys**	**Male** ☑	**Female** ☐ **Pregnant Yes** ☐ **No** ☐	175 **(cm/in)**	75 **(kg/lb)**	H

2.	**Report:** Select date	
Initial ☑	**Follow-up** ☐ ___	**Final** ☐

3.	**Patient's Relevant Medical/ Surgical/ Drug/ Family history** (use a separate page, if needed)**:**			
Sr. No.	***Condition/ Procedure/ Drug***	***Start date***	***Stop date***	***Comments, if any***
1.	Drug 231	Select date	Select date	None
2.	Drug 619	Select date	Select date	None
3.	Drug 718	Select date	Select date	None
4.	Paracetomol	Select date	Select date	None
5.	Cipla	Select date	Select date	None
6.	Dolo 650	Select date	Select date	None

4.	**Suspected Pharmaceutical Products** (use a separate page, if needed)**:**						
Brand Name (Generic Name)	***Manufacturer***	***Indication***	***Batch Number & Expiry Date***	***Route of Administration***	***Dose & Frequency***	***Start Date/ Time***	***Stop Date/ Time***
Dolo 650	Jay Industries	No	32 & 22/12/19	Yes	Daily	Select date &	Select date &

						time	time
						Select date & time	Select date & time
						Select date & time	Select date & time
						Select date & time	Select date & time
Use according to label		Unknown ☐	Yes ☐	No ☐	Explain		
Previous Exposure and Reaction(s) to Primary suspect product: ☐ Yes ☐ No							
If yes, describe with AE, if any:							

5.	**Concomitant Medication Details** (Give the list of the other medicinal products used concurrently, use separate page if needed)**:**					
Brand Name	**Indication**	**Batch Number & Expiry Date**	**Route of Administration**	**Dose & Frequency**	**Start Date**	**Stop Date**
					Select date	Select date
					Select date	Select date
					Select date	Select date
					Select date	Select date
					Select date	Select date
					Select date	Select date

6.	**Adverse Event (AE) Data** (For all adverse event(s) reported following administration of suspect product)**:**						
Adverse Event	**Serious** (For Yes, choose the criteria)	**Start Date/ Time**	**Ongoing**	**Stop Date/ Time**	**Outcome**	**Suspect drug/s**	**Comments:** (write reason with contributory factors)
	Choose an item.	Select date & time	☐	Select date & time	Choose an item.		
	Choose an item.	Select date & time	☐	Select date & time	Choose an item.		
	Choose an	Select date & time	☐	Select date & time	Choose an		

	item.				item.		
	Choose an item.	Select date & time	☐	Select date & time	Choose an item.		
	Choose an item.	Select date & time	☐	Select date & time	Choose an item.		

If multiple suspect drug then write the drug name with causality in comments section

Action taken with Suspect product after adverse event		Did event abate after stopping drug?/ De-challenge	Did event reappear after reintroduction?/ Re-challenge
☐ Temporarily held	☐ Withdrawn/ Permanently stopped	☐ Yes	☐ Yes
☐ No change	☐ Dose reduced	☐ No	☐ No
☐ Dose reduced	☐ Not Applicable/Unknown	☐ Not Applicable	☐ Not Applicable

For fatal outcome, was a Post-Mortem/Autopsy performed?	NA ☐	No ☐	Yes ☐	
			Autopsy report/death certificate available	
			No ☐	Yes ☐ (Please Attach)

How was the adverse event treated?	No treatment ☐	Prescription drug ☐, Please give details
	Other ☐	

If the patient was enrolled in any clinical study, specify	Protocol No.:	
	Patient no.:	

Has this case been reported to Regulatory Authority?	No ☐	
	Yes ☐	Reference Number:

10.	**Reporter's details**	**Patient's treating Physician details (if reporter is not the physician)**

Name:		
Occupation		
Address:		
Tel. No:		
Email:		
Signature:		

***Note**: Template can be edited as per requirements.