ADVERSE EVENT REPORTING FORM

RPG LIFE SCIENCES LIMITED

Send this report to:

Medical Affairs Department
RPG Life Sciences Ltd.
463, 4th Floor, RPG HOUSE, Dr. Annie Besant Road, Worli, Mumbai – 400 030

Date of this Report

_____/_____/_____

A. Patient Information

1. Patient identifier initials

(First) (Last)

_____ _____

2. Age at time of Event:_____

or _____
Date of Birth

3. Sex: ☐ F ☐ M

4. Weight_____kgs

B. Suspected Adverse Event

5. Outcomes attributed to adverse event (check all that apply)

☐ death_____ (dd/mm/yy)

☐ life-threatening

☐ hospitalization-initial or prolonged

☐ disability

☐ congenital anomaly

☐ required intervention to impairment/damage

☐ other:_____

6. Dates of event starting (dd/mm/yy)

7. Dates of event stopping (dd/mm/yy)

8. Describe event or problem

9. Relevant tests/laboratory data, including dates

10. Other Relevant History, Including Pre-existing Medical Conditions (e.g.allergies race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

11. Severity: Mild ☐ Moderate ☐ Severe ☐

12. Causality: Drug ☐ Concomitant medication ☐

Co-existing disease ☐ Other(Specify):_____

C: Suspect medication(s)

13. Name (Brand and / or generic name)		(Labeled Strength)	(Manufacturer)
#1			
#2			

14. Dose	Frequency	Route used	15. Therapy dates (if unknown, give duration)
#1			#1
#2			#2

16. Diagnosis for use (separate indications with commas)

#1 _____

#2 _____

17. Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☐ not applicable

#2 ☐ yes ☐ no ☐ not applicable

18. Lot #(if known) Exp date (if known)

#1 _____ #1 _____

#2 _____ #2 _____

19. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☐ not applicable

#2 ☐ yes ☐ no ☐ not applicable

20. Concomitant medical products and therapy dates including self medication & herbal remedies (exclude those used to treat event):

D. Clinician

21. Name and Professional Address:_____

_____

_____ Pin Code:_____

Tel No:_____ Specialty:_____
with STD code

Dr's Signature with seal:

_____

E. Medical Representative Details (To be filled by MR/Field Staff)

Name : _____

Headquarter: _____

Sign : _____

Date _____