SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

CDSCO

Central Drugs Standard Control Organization

Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India
FDA Bhavan, ITO, Kotla Road, New Delhi
www.cdsco.nic.in

(AMC/NCC Use only)	
AMC Report No.	**Worldwide Unique no.**

A. Patient Information

1. Patient Initials	2. Age at time of Event or date of birth	3. Sex ☐M ☐F 4. Weight _____ kg.
_____		

12. Relevant tests/laboratory data with dates

B. Suspected Adverse Reaction

5. Date reaction stated (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunciton etc.)

14. Seriousness of the reaction

- ☐ Death (dd/mm/yyyy)_____
- ☐ Life threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability
- ☐ Not applicable
- ☐ Congenitial anomaly
- ☐ Required intervention to prevent permanent impairment/damage
- ☐ Other (Specify)_____

15. Outcomes

☐ Fatal ☐ Recovering ☐ Unknown
☐ Continuing ☐ Recovered ☐ Other (Specify)_____

C. Suspected medication (s)

Sl.No.	8. Name (brand and / or generic name)	Manufacturer (if known)	Batch No./Lot No. (if known)	Exp. Date if known	Dose used	Route used	Frequency	Therapy dates (if unknown give duration)		Reason for use or prescribed for
								Date started	Date stopped	
I.										
II.										
III.										
IV.										

Sl. No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced, dose
I.										
II.										
III.										
IV.										

11. Concomitant medical products including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

D. Reporter

16. Name and Professional Address : _____

_____

Pin Code _____ E-mail _____

Tel. No. (with STD code) : _____

Occupation _____ Signature _____

17. Causality assessment	18. Date of this report (dd/mm/yyyy)