SUSPECT ADVERSE DRUG REACTION REPORTING FORM

(For **VOLUNTARY** reporting of Adverse Drug Reaction by Healthcare Professionals& Consumers)

A. PATIENT INFORMATION *		**Report Type : Initial □ Follow up □**
1. Patient Name	**2. Age or Date of Birth**	**12. Relevant investigations with date:**
3. Gender **M □ F □ Other □**	**4. Weight: _____** **Height: _____**	
B. SUSPECTED ADVERSE REACTION *		**13. Relevant medical/medication history**
5. Side Effect/Reaction start date :		
6. Side Effect /Reaction stop date:		
7. Describe Side Effect /Reaction with treatment details, if any		**14. Serious Yes □ - (if yes, please tick anyone)** **☐ Death (dd/mm/yyyy)** **☐ Life threatening** **☐ Hospitalization (Initial/Prolonged)** **☐ Congenital-anomaly** **☐ Disability** **☐ Surgical implantation** **Non Serious □**
		12. Outcome of Side effect **□ Recovered □ Recovering** **□ Not recovered □ Fatal □ Unknown**

C. Suspected Medication *

S. No	Product Name	Manufacturer	Batch/Lot No	Expiry Date	Dose	Route	Frequency	Therapy dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i											
ii											
iii											
iv											

9. Action taken after reaction (please tick) □							10. Reaction reappeared after reintroduction of suspected medication (please tick) □			
S.No as per C	**Drug withdrawn**	**Dose increased**	**Dose reduced**	**Dose not changed**	**Not applicable**	**Unknown**	**Yes**	**No**	**Effect unknown**	**Dose(if re-introduced)**
i										
ii										
iii										
iv										

*Mandatory fields for suspect ADR reporting form

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11. Concomitant medical product including self-medication and herbal remedies with therapy date

S.no	Name	Dose	Route	Frequency (OD, BD,etc.)	Therapy dates		Indication
					Date Started	Date Stopped	
i							
ii							
iii							

Additional information :

D. Reporter details *

Name & address: _____

_____

Pin :_____ **Email:** _____

Contact No: _____

Occupation : _____ **Signature:** _____

Date of this report:

Signature and name of receiving person

For office use only

ADR Report No :

For ADRs Reporting to Hetero	
Hetero Labs Limited, 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018. Telangana,INDIA Tel.: +91 40 23704923/24/25 Fax: +91-40 23813359 **Email: ae.pvg@hetero.com (for global cases)** **drugsafetyindia@hetero.com (for India)**	 **Call us on Helpline/ 1800-120-8689 (Toll Free) (9:00 AM to 6:00 PM Monday-Friday/ All Working days).**

*Mandatory fields for suspect ADR reporting form