Form No.: QAD/F/127/R0 SOP No.: QAD/SOP/042/R0

# ADVERSE DRUG REACTION REPORTING FORM

## SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

| | |
|---|---|
| Regulatory Department:<br>Megasys Biotek Private Limited<br>Kinfra Small Industries Park, Kinfra Park,<br>Koratty, Thrissur, Kerala-680309, India<br>Email: info@megasysbiotek.com<br>Contact: 0480 2735991/2733158<br>(Monday to Saturday between 9.00 am to 5.30 pm, except on public holidays) | **FOR MEGASYS USE ONLY**<br>Report No.:<br>Report Type: ☐ Initial ☐ Follow up<br>12. Relevant test/laboratory data with dates |

### A. PATIENT INFORMATION

| | | | | |
|---|---|---|---|---|
| 1.Patient Initials- | 2.Age at time of Event or Date of Birth- | 3.<br>☐ M<br>☐ F<br>☐ Others | 4. Weight_____Kgs<br>4. a)Height_____Cm | 13.Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic or renal dysfunction, past surgery etc)- |

### B. SUSPECTED ADVERSE REACTION

| | | |
|---|---|---|
| 5. Event/Reaction start date (dd/mm/yyyy)- | 14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone) | |
| 6. Event/Reaction stop date (dd/mm/yyyy)- | ☐ Death (dd/mm/yyyy) | ☐ Congenital anomaly |
| 6 (A). Onset Lag Time- | ☐ Life threatening | ☐ Disability |
| 7. Describe Event/Reaction with treatment details, if any- | ☐ Hospitalization/Prolonged | ☐ Other Medically important |
| | 15.Outcomes | |
| | ☐ Recovered | ☐ Fatal |
| | ☐ Recovering | ☐ Recovered with sequelae |
| | ☐ Not recovered | ☐ Unknown |

### C. SUSPECTED MEDICATION(S)

| S.No. | 8. Name (Brand/Generic) | Manufacturer (if known) | Batch No./Lot No. | Exp. Date (if known) | Dose used | Route used | Frequency (OB, BD etc.) | Therapy | | Indication | Casuality Assessment |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Date Started | Date Stopped | | |
| i | | | | | | | | | | | |

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| ii | | | | | | | | | | | |
| iii | | | | | | | | | | | |
| iv* | | | | | | | | | | | |

| S. No as per C | 9.Action Taken (please tick) | | | | | 10.Reaction reappeared after reintroduction (please tick) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Drug withdrawn | Dose increased | Dose reduced | Dose not changed | Not applicable | Unknown | Yes | No | Effect Unknown | Dose (if reintroduced) |

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

| S.No. | Name (Brand/Generic) | Dose used | Route used | Frequency (OD,BD,etc) | Therapy dates Indication | | Indications |
|---|---|---|---|---|---|---|---|
| | | | | | Date Started | Date Stopped | |
| i | | | | | | | |
| ii | | | | | | | |
| iii * | | | | | | | |

Additional Information:

## D. REPORTER DETAILS

16.Name and Professional Address:_____

Pin: _____ E-mail:

Tel. No. (with STD code)

Occupation:_____ Signature:

_____ _____

17.Date of the report (dd/mm/yyyy):

Sign and Name of Receiver-

Confidentiality: The patients identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submssion of an ADR report does not have any legal implication on the reporter.

*use separate page for more information