

LOGO CENTRE NAME CENTRE ADDRESS	Adverse Drug Reaction Event	Date of Issue : 01/06/2021 Issue No. : JSL/I//01 Date of Revision: 31/05/2022 Revision No. : 00
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SERVICE NAME :	ADVERSE DRUG REACTION EVENT
DATE CREATED :	01/06/2021
APPROVED BY :	DOCTOR NAME
REVIEWED BY :	DOCTOR NAME

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AMENDMENT SHEET

LOGO CENTRE NAME CENTRE ADDRESS		
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A. Purpose:

To provide guideline instruction for monitoring adverse drug reaction event and ensure its proper reporting.

A. **Scope:** Hospital wide

B. Protocol:

In case of any drug reaction / adverse reaction actions taken are as follows:

1. The person noticing the reaction i.e. Doctor / Patient immediately informs the concerned doctor and clinical management is initiated then & there.
2. The Doctor informs in charge pharmacy & Main Medicine store.
3. The ADR [Adverse drug reaction] form is filled up by the concerned doctor
4. Drug responsible for adverse reaction is identified.
5. Batch of the drug identified.
6. All Patient rooms & areas where the drug has been issued are advised NOT to use the drug of that particular batch.
7. Information regarding any such similar reactions anywhere in the hospital is gathered and documented and forwarded to the Medical Superintendent.
8. All such events are monitored and evaluated and appropriate action taken depending on the nature of the adverse reaction
9. Such action may take the form of observation or in extreme cases withdrawal of the drug throughout the hospital.
10. Drug causing adverse reaction is closely monitored and analyzed by drug and therapeutic committee

1. Drug Recall Procedure

1. Once the drug causing adverse reaction is identified, particular batch of the drug is immediately withdrawn by pharmacy, wherever issued within the hospital.
2. Company & distributor are immediately informed regarding the adverse reaction and called to find out the reasons & actions to be taken.
3. Total medicine of that particular batch is returned to supplier.
4. Report is presented before Quality management committee and further action is taken.

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SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

A. Patient information <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">1. Patient identifier initials</td> <td style="width: 50%;">2. Age at time of event: or Date of Birth:</td> <td style="width: 50%;">3. Sex <input type="checkbox"/> M <input type="checkbox"/> F</td> </tr> <tr> <td colspan="3" style="text-align: center;">In confidence</td> </tr> <tr> <td colspan="3" style="text-align: center;">4. Weight _____ Kgs</td> </tr> </table>		1. Patient identifier initials	2. Age at time of event: or Date of Birth:	3. Sex <input type="checkbox"/> M <input type="checkbox"/> F	In confidence			4. Weight _____ Kgs			<p style="text-align: center;">For VOLUNTARY reporting of Adverse Drug Reactions by health care professionals</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> Report # <div style="border: 1px solid black; padding: 2px; height: 40px; margin-top: 10px;"></div> </td> <td style="width: 50%; vertical-align: top; text-align: center;">To be filled in by Pharmacovigilance centres receiving the form.</td> </tr> </table>	Report # <div style="border: 1px solid black; padding: 2px; height: 40px; margin-top: 10px;"></div>	To be filled in by Pharmacovigilance centres receiving the form.																																																																																																																
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