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INDIAN PHARMACOPOEIA COMMISSION  
National Coordination Centre-Pharmacovigilance Programme of India

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26/08/2016



STANDARD OPERATING PROCEDURE		Page No.	1 of 3
		SOP No.	IPC/PvPI/QA/009
Section	All section	Revision No.	01
Effective Date	01/09/2016	Review Date	31/08/2019

Title: SOP for Collection of ADR/AE Reports at AMC.

### 1.0 OBJECTIVE

1.1 To lay down a procedure for collection of ADR/AE reports at Adverse Drug Reaction Monitoring Centres.

### 2.0 SCOPE

2.1 This SOP shall be applicable to Pharmacovigilance Associates working at AMCs.

### 3.0 RESPONSIBILITY

3.1 The personnel engaged in the PvPI activities at AMCs shall be responsible for adhering to this SOP.

3.2 All AMC's Coordinators shall be responsible for adhering to this SOP.

3.3 Quality Manager, Technical Manager, Section In-charge & AMC Coordinator shall ensure overall implementation of this SOP.

### 4.0 ACCOUNTABILITY

4.1 Officer In-charge - Pharmacovigilance Programme of India

### 5.0 PROCEDURE

5.1 PvA shall report to AMCs coordinator on each working day.

5.2 PvA shall visit each ward and OPD of the AMC for collection of AE Reports.

5.3 During collection of AE, PvA must ask for additional information related to AE from the doctor or Patient.

	Name	Designation	Signature	Date
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Reviewed by	Dr. Pawan K. Saini	Scientific Officer		17/08/2016
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STANDARD OPERATING PROCEDURE		Page No.	2 of 3
		SOP No.	IPC/PvPI/QA/009
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- 5.4 PvA shall ensure the signature of concern AE reporter on the suspected ADR reporting form.
- 5.5 The causality assessment of the AE report can be done by the primary reporter and further it shall be vetted by Causality Assessment Committee of AMC.
- 5.6 The ADR report by the coordinator shall be entered in VigiFlow.
- 5.6 The PvA shall be responsible to maintain the e-ICSRs at the AMC.
- 5.7 All ADR reporting form shall be considered as source document, and to be stored at AMCs minimum for the period of ten years. These documents shall be shared with NCC on request.

6.0 SAFETY AND PRECAUTIONS

- 6.1 Do not use any SOP if it is not signed and issued by QA Personnel or the authorized signatories.
- 6.2 Do not use adhesive tape or whitener on SOP.
- 6.3 Do not share the SOP information outside the organization.

7.0 REFERENCES : In-House

8.0 ABBREVIATIONS

- SOP : Standard Operating Procedure
- AMC : Adverse Drug Reaction Monitoring Centre
- PvPI : Pharmacovigilance Programme of India
- NCC : National Coordination Centre
- QA : Quality Assurance

	Name	Designation	Signature	Date
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Sign. [Signature] Dt. 28/08/2016

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## STANDARD OPERATING PROCEDURE

Page No.

3 of 3

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Section

All section

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Title: SOP for Collection of ADR/AE Reports at AMC.

ADR	:	Adverse Drug Reaction
ICSRs	:	Individual Case Safety Reports
PvA	:	Pharmacovigilance Associate
AE	:	Adverse Event
OPD	:	Out Patient Department

9.0 ANNEXURE(s): Not Applicable

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