



STANDARD OPERATING PROCEDURE

Page No.	1 of 3
SOP No.	IPC/PvPI/QA/017
Revision No.	01
Review Date	31/08/2019

Section	All Section
Effective Date	01/09/2016

Title: SOP for ensuring the functioning of AMCs.

1.0 OBJECTIVE

To lay down the procedure to ensure the functioning of Adverse Drug Reaction Monitoring Centres.

2.0 SCOPE

2.1 This SOP shall be applicable to AMCs under PvPI.

3.0 RESPONSIBILITY

3.1 The Pharmacovigilance Associates working at AMCs and Coordinators/Deputy Coordinators of respective AMCs shall be responsible for adhering to this SOP.

3.2 The Coordinators/Deputy Coordinators of respective AMCs shall ensure that this SOP has been reflected in the Pharmacovigilance division of AMC.

3.3 Quality-Manager/Technical-Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

4.1 Officer Incharge - Pharmacovigilance Programme of India.

5.0 PROCEDURE

5.1 The AMCs Coordinator/deputy coordinator and the pharmacovigilance associate shall be responsible for the effective functioning of the AMCs. The NCC-PvPI shall ensure the smooth functioning of the AMCs.

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Ranank. Saini	Scientific Officer	[Signature]	25/08/2016
Approved by	Dr. Kalalsharan	PSO	[Signature]	26/08/2016

 गत्यमेव जयते 	INDIAN PHARMACOPEL COMMISSION National Coordination Centre-Pharmacovigilance Programme of India			Sign. <i>[Signature]</i> Dt. 26/08/2016
	STANDARD OPERATING PROCEDURE		Page No.	2 of 3
			SOP No.	IPC/PvPI/QA/017
	Section	All Section	Revision No.	01
Effective Date	01/09/2016	Review Date	31/08/2019	
Title: SOP for ensuring the functioning of AMCs.				

- 5.2 The personnel authorized/assigned by NCC-PvPI shall visit the respective AMCs to monitor the functioning of AMCs. The auditor(s) shall contact the AMCs Coordinator/deputy coordinator and Pharmacovigilance Associate prior to visit of AMCs. PvPI also permits for surprise visit to AMCs.
- 5.3 The Coordinator/deputy coordinator and Pharmacovigilance associate of the AMCs shall cooperate with the auditor(s) during the audit. The auditor(s) shall inspect all the records/documents according to the parameters/indicators mentioned in the Checklist for Pharmacovigilance Monitoring (Annexure I).
- 5.4 The auditor(s) shall submit the audit report of AMCs in the space provided. The additional sheet shall be used by the auditor(s) (if required) to give their audit comments/report. The auditor shall submit the audit report to NCC through mail or by hand/post.
- 5.5 The AMCs audit preferably shall be done at least once in a year or as per the instructions of NCC-PvPI as or when necessary.

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.
- 6.4 Smooth functioning of college/hospital shall not be affected by this procedure.

6.5 REFERENCES : In-house

8.0 ABBREVIATIONS

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PvA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	25/08/2016
Approved by	Dr. Kalaiselvan	PSO	<i>[Signature]</i>	26/08/2016

MASTER COPY
26/08/2016CONTROLLED COPY
26/08/2016

 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India		
	STANDARD OPERATING PROCEDURE		Page No. 3 of 3
			SOP No. IPC/PvPI/QA/017
	Section All Section	Revision No. 01	
Effective Date 01/09/2016		Review Date 31/08/2019	
Title: SOP for ensuring the functioning of AMCs.			

SOP	:	Standard Operating Procedure
IPC	:	Indian Pharmacopoeia Commission
PvPI	:	Pharmacovigilance Programme of India
AMCs	:	Adverse Drug Reaction Monitoring Centres
NCC	:	National Coordination Centre
ICSRs	:	Individual Case Safety Reports
ADR	:	Adverse Drug Reaction
QA	:	Quality Assurance

9.0 ANNEXURE(s):

Annexure I : Checklist for Pharmacovigilance Monitoring
(Format No. IPC/PvPI/QA/017-F01-00)

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Bawan K. Saini	S.O.		25/08/2016
Approved by	Dr. Kalisekhar	PSO		26/08/2016



Annexure-I

CHECKLIST FOR PHARMACOVIGILANCE MONITORING

Format No. IPC/PvPI/QA/017-F01-00

Coordinator contact(s) for AMC

Name of Coordinator	
Contact number and e-mail address of Coordinator	
Date of Visit	

AMC where pharmacovigilance activities are performed

AMC name	
AMC Address	
Telephone number(s)	

Qualified Person(s) for Pharmacovigilance (QPPV)

	Name	Designation	Signature	Date	Page
Prepared by	Pranay Kumar	PvA	Pranay Kumar	24/08/2016	1 of 7
Reviewed by	Dr. Raman K. Saini	S.O.	[Signature]	25/08/2016	
Approved by	Dr. Kalaiselvan	PS-8	[Signature]	26/8/2016	



Sig of India Dt. 26/08/2016

Annexure-I

CHECKLIST FOR PHARMACOVIGILANCE MONITORING

Format No. IPC/PvPI/QA/017-F01-00

Name of Pharmacovigilance Associate (QPPV)	
Contact number and e-mail address of Pharmacovigilance Associate	

Check list of Pharmacovigilance monitoring for AMCs

S.No	Parameter	Status		Remarks
		Yes	No	
Personnel's details				
1	Personnel education and prior GVP experience.			
2	Whether GVP training provided by the Zonal centre/NCC?			
3	Do personnel know the job descriptions/responsibilities?			
Administrative Responsibility				
4	Whether infrastructure is sufficient for PvPI?			

	Name	Designation	Signature	Date	Page
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016	2 of 7
Reviewed by	Dr Pawan K. Sahni	S.O.	[Signature]	25/08/2016	
Approved by	Dr. Kalaiselvan	PSO	[Signature]	26/08/2016	



Annexure-I

CHECKLIST FOR PHARMACOVIGILANCE MONITORING

Format No. IPC/PvPI/QA/017-F01-00

5	Whether sufficient working place for PvPI activities?			
6	Whether logistic support provided by NCC such as Computer system, internet connection are working properly?			
7	Storage of hard copies as well as soft copies of documents.			
8	Whether co-operation by other dept. to PvPI?			
Documents Review to ensure the Authenticity of data				
9	Mechanism of identifying the patient from the registration number of the case report – random check should be done by the inspecting team.			
10	Verify version number and effective date of SOPs provided by NCC with AMC's SOPs.			
11	Verify Training Records / Certificates.			
S. No.	Parameter	Status		Remarks
		Yes	No	
12	Randomly verify the data of source documents which entered			

	Name	Designation	Signature	Date	Page
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016	3 of 7
Reviewed by	Dr. Bawan K. Saini	S.O.	[Signature]	25/08/2016	
Approved by	Dr. Kalaiselvan	PJO	[Signature]	26/08/2016	



Annexure-I

CHECKLIST FOR PHARMACOVIGILANCE MONITORING

Format No. IPC/PvPI/QA/017-F01-00

	in software.			
Quality Assurance				
13	Does the source document mentions Essential Required Item (ERI) such as patient information/ division/ reaction with date/ suspected drug with date/ outcome and sender information?			
14	Determine whether data entry by Pharmacovigilance Associate in software is same with source documents.			
15	Whether all ADRs were reported in Suspected ADR Reporting Form?			
16	Verify the timeline for reporting the SAE to NCC/CDSCO.			
Data collection and its security				
17	Use of electronic data capture or data transcription from Suspected ADR Reporting into an electronic record (Software).			
18	Record retention.			
19	Data security in case of disasters, e.g., power failure.			
20	Contingency plans and backup files.			
21	Determine whether personnel has			

	Name	Designation	Signature	Date	Page
Prepared by	Pranay Kumar	PvA	Pranay Kumar	24/08/2016	4 of 7
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	25/08/2016	
Approved by	Dr. Kaluichan	PRO	[Signature]	26/08/2016	



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme Of India

Sign: *[Signature]* Dt: 26/08/2016

Annexure-I

CHECKLIST FOR PHARMACOVIGILANCE MONITORING

Format No. IPC/PvPI/QA/017-F01-00

	Access methods e.g., User ID/password for the security of electronic data?			
Competence of Pharmacovigilance Associate				
22	He/She is conversant with the drug for which he/she is sending the report?			
S. No	Parameter	Status		Remarks
		Yes	No	
23	Is he/she conversant with the rechallenge and dechallenge process?			
24	Is this a side effect or ADR?			
25	How many times PvA visits various wards?			
26	How quickly he/she sends the report to NCC.			
27	Is he/she taking interest in reporting drugs of current interest i.e. from CVS, Psychiatry, Oncology and Diabetes?			
Core Structural Indicators				
28	Does the AMC have standard accommodation?			
29	Whether NCC has given acceptance letter?			

	Name	Designation	Signature	Date	Page
Prepared by	Pranay Kumar	PvA	<i>[Signature]</i>	24/08/2016	5 of 7
Reviewed by	Dr. Rawan K. Saini	S.O.	<i>[Signature]</i>	25/08/2016	
Approved by	Dr. Kalishwar	PSO	<i>[Signature]</i>	26/08/2016	



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme Of India

Sign _____ Dt. 26/08/16

Annexure-I

CHECKLIST FOR PHARMACOVIGILANCE MONITORING

Format No. IPC/PvPI/QA/017-F01-00

30	A regular financial provision for the AMC?			
31	Human resources to carry out its functions properly?			
32	A standard ADR reporting form?			
33	A process in place for collection, recording and entering of ADRs in software?			
34	Newsletters/NFI/Information bulletin/website for Pharmacovigilance information dissemination?			
35	A Pharmacovigilance advisory committee or expert committee in the setting?			

S. No.	Core Process Indicators	Remarks
36	Total number of ADR reports reported to NCC last calendar year.	
37	Percentage of total annual reports acknowledged by NCC.	
38	Percentage of reports subjected to causality assessment in the year.	
39	Percentage of reports on therapeutic ineffectiveness.	
40	Percentage of reports on medication error.	

	Name	Designation	Signature	Date	Page
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016	6 of 7
Reviewed by	Dr. Ramesh K. Saini	S.O.	[Signature]	25/08/2016	
Approved by	Dr. Lalit Selwan	PSO	[Signature]	26/08/2016	



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme Of India

Annexure-I

CHECKLIST FOR PHARMACOVIGILANCE MONITORING

Format No. IPC/PvPI/QA/017-F01-00

41	Number of active surveillance activities initiated, ongoing or completed, the last 5 years.	
Comments of Auditor/Inspector:		

Name of Auditor/Inspector:

Date of Audit:

Stamp/Seal:

Auditor/Inspector

	Name	Designation	Signature	Date	Page
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016	7 of 7
Reviewed by	Dr. Pawan K. Saini	S.O.		28/08/2016	
Approved by	Dr. Kalise Wang	K.S.O.		26/9/2016	