



**INDIAN PHARMACOPOEIA COMMISSION**  
**National Coordination Centre-Pharmacovigilance Programme of India**

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**STANDARD OPERATING PROCEDURE**

Page No.

1 of 4

SOP No.

IPC/PvPI/QA/007

Section

All Sections

Revision No.

00

Effective Date

1/09/2016

Review Date

31/08/2019

**Title: SOP for Internal audit**

**1.0 OBJECTIVE**

1.1 To lay down the procedure for planning and conducting of an internal audit to evaluate the effectiveness of NCC-PvPI quality management system and to verify the compliance of technical activities to the standard requirements.

**2.0 SCOPE**

2.1 This SOP shall be applicable to all sections of NCC-PvPI.

**3.0 RESPONSIBILITY**

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

3.2 QA representative shall be responsible to organize & conduct internal audit at NCC-PvPI.

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 Internal audit shall be conducted as per audit program that comprises of audit plan, schedule and scope as per Annexure No. I (Format No. IPC/PvPI/QA/007-F01).

5.2 The quality manager shall be responsible to prepare audit program & notification as per Annexure No. II (Format No. IPC/PvPI/QA/007-F02).

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pr. Associate		16/08/2016
Reviewed by	Dr. Pawan K. Saini	Scientific officer		17/08/2016
Approved by	Dr. Kalai Selvan	PSO		18/8/2016

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STANDARD OPERATING PROCEDURE		Page No.	2 of 4
		SOP No.	IPC/PvPI/QA/007
Section	All Sections	Revision No.	00
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Title: SOP for Internal audit

- 5.3 The audit shall be conducted at least once in a year or whenever required, in such a manner that all activities are covered to meet the regulatory requirement.
- 5.4 Officer In-charge PvPI shall nominate auditors with suitable qualification and technical experience and shall be approved by the Secretary-cum-Scientific Director for auditing, not directly connected with the activities meant for auditing.
- 5.5 Quality Manager shall issue an audit notification at least three days prior to the audit date.
- 5.6 All sections of NCC-PvPI shall schedule, to evaluate itself before audit to ensure that comply with the standards and requirement as per procedure.
- 5.7 Section Incharge shall be responsible to hand over all audit related documents and information to the auditor when required.
- 5.8 Audit shall be carried out as per the audit schedule prepared by the Quality Manager.
- 5.9 Audit check list shall be issued by QA and used by the auditors as per **Annexure No-III (Format No. IPC/PvPI/QA/007-F03)**.
- 5.10 Audit shall be conducted within the estimated duration in terms of number of days and as per the audit program and notification schedule.
- 5.11 Evidences shall be collected through examination of documents and records, related to report observations.
- 5.12 The report of audit shall be submitted in the audit observation report format as per **Annexure No. III (Format No. IPC/PvPI/QA/007-F03)**. If requires more information additional sheet shall be enclosed.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pv. Associate		16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		17/08/2016
Approved by	Dr. Kalousekaran	H/ISO		18/08/2016

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IPC

## STANDARD OPERATING PROCEDURE

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SOP No.

IPC/PvPI/QA/007

Section

All Sections

Revision No.

00

Effective Date

01/09/2016

Review Date

31/08/2019

Title: SOP for Internal audit

- 5.13 Necessary corrective action shall be taken based on the audit report/ a non-compliance report shall be address within the time bound manner.
- 5.14 Quality Manager shall be responsible for monitor the corrective actions proposed as per audit report.
- 5.15 Corrective action reports shall be taken after the root cause analysis by going through the evaluation of all the potential causes of the problem as per **Annexure No. IV (Format No. IPC/PvPI/QA/007-F04)**.
- 5.16 Responsibility in terms of time required for completion of corrective action, shall be fixed at the time of recording the non compliances of the concerned section of NCC-PvPI.
- 5.17 The Quality Manager shall be responsible to verify the effective implementation of corrective actions.
- 5.18 The final audit report completed in all aspects shall be submitted to Quality Manager. The report shall be signed by all the auditors who are involved in the internal audit and by the auditee. Audit reports shall be circulated to all concern sections.
- 5.19 Final outcome of the audit shall be discussed in management review meeting.
- 5.20 If any additional audit is required and same shall be communicate to concern sections.

## 6.0 SAFETY AND PRECAUTIONS

- 6.1 Do not use 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.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pr. Associate		16/08/2016
Reviewed by	Dr. Pawan K. Saini	SO		17/08/2016
Approved by	Dr. Kalai Selvan	PSO		18/08/16

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STANDARD OPERATING PROCEDURE		Page No.	4 of 4
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Title: SOP for Internal audit

6.3 Do not share the SOP information outside the organization.

7.0 REFERENCES - In House

8.0 ABBREVIATIONS

- QA : Quality Assurance
- SOP : Standard Operating Procedure
- PvPI : Pharmacovigilance Programme of India
- NCC : National Coordination Centre

9.0 ANNEXURES:

Annexure-I Audit Plan and Schedule :( Format No.IPC/PvPI/QA/007-F01)

Annexure-II Audit Program and Notification :( Format No.IPC/PvPI/QA/007-F02)

Annexure-III Audit Check lists :( FormatNo.IPC/PvPI/QA/007-F03)

Annexure-IV Audit Observation report: (Format No. IPC/PvPI/QA/007-F04)

Annexure-V Corrective and Preventive Action Report:  
(FormatNo.IPC/PvPI/QA/007-F05)

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pc. Associate		16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		17/08/2016
Approved by	Dr. Karan Lehra	PSO		18/8/2016

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	<b>Annexure-I</b> <b>AUDIT PLAN AND SCHEDULE</b>

Format No. IPC/PvPI/QA/007-F01-00

YEAR: .....

S. No.	SCOPE OF ACTIVITY	PERIOD

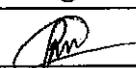
Prepared By  
(Name/Sign/Date)

Approved By  
(Name/Sign/Date)

Quality Manager

Officer Incharge-PvPI

copy to:

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pv. Associate		16/08/2016
Reviewed by	Dr. Pawan K. Saini	SO.		17/08/2016
Approved by	Dr. Kalai Selvan	P.S.O.		18/08/2016

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**INDIAN PHARMACOPOEIA COMMISSION**  
**National Coordination Centre-Pharmacovigilance Programme of India**  
**Annexure-II**  
**AUDIT PROGRAMME AND NOTIFICATION**

Format No. IPC/PvPI/QA/007-F02-00

Ref.No.

Audit Program for Year:

Date of Audit:

Audit frequency:

Duration:

Activities / Elements to be covered:

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.....  
.....  
.....

Responsibility for conducting the audit: .....

Type of audit: .....

Auditors profile:

.....

Name:

.....

.....

	Name	Designation	Signature	Date	Page
Prepared by	<i>Rishi Kumar</i>	<i>Pr. Associate</i>	<i>[Signature]</i>	<i>16/08/2016</i>	1 of 2
Reviewed by	<i>Dr. Pawan K. Saini</i>	<i>S.O.</i>	<i>[Signature]</i>	<i>17/08/2016</i>	
Approved by	<i>Dr. Kalan Selvan</i>	<i>P.S.O.</i>	<i>[Signature]</i>	<i>18/08/2016</i>	

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	<b>Annexure-II</b>

**AUDIT PROGRAMME AND NOTIFICATION**

Format No. IPC/PvPI/QA/007-F02-00

**Audit requirements:**

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**Referral Documents:**

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**Sections covered:**

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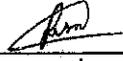
**Prepared By**  
(Name/Sign/Date)

**Approved By**  
(Name/Sign/Date)

**Quality Manager**

**Officer Incharge-PvPI**

**Copy to:**

	Name	Designation	Signature	Date	Page
Prepared by	Rishi Kumar	Pv. Associate		16/08/2016	2 of 2
Reviewed by	Dr. Rawan K. Saini	S.O.		17/08/2016	
Approved by	Dr. Kalan Selvan	P.S.O.		18/8/2016	



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National Co-ordinating Centre for Pharmacovigilance Programme of India

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Annexure-III  
Audit Checklist

Format No. IPC/PvPI/QA/007-F03-00

Date	From	dd/mm/yyyy	To	dd/mm/yyyy
------	------	------------	----	------------

Audit Team	Name	Designation	Signature	Date

Coordinating Personnel at NCC-PvPI for audit	Name	Designation	Signature	Date

Prepared by	Name	Designation	Signature	Date	
					Page 1 of 13
	Rishi Kumar	Pr. Associate	<i>[Signature]</i>	16/08/2016	
Reviewed by	Dr. Rawan K. Saini	S.O.	<i>[Signature]</i>	17/08/2016	
Approved by	Dr. Kalaiarasan	P.S.O.	<i>[Signature]</i>	28/8/16	



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**Annexure-III**  
**Audit Checklist**

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Format No. IPC/PI/QA/007-F03-00

S. No.	Measurable Indicators	Document Verification	Grading Level*	Remarks
		Yes/No/Not Applicable		

The following items should be reviewed as part of the Pharmacovigilance inspection:-

Technical Secretariat  
 Standard-TS

TS 1.0	Legal and administrative aspects			
TS 1.0.1	Legal Identity / Status/documentation of Pharmacovigilance Programme of India			
TS 1.0.2	Legal Identity / Status/ documentation of the all AMCs under Pharmacovigilance Programme of India			
TS 1.0.3	Legal Identity / Status / documentation of the all RNTCP, ART and Active Surveillance centers under Pharmacovigilance Programme of India			
TS 1.0.4	Legal Identity / Status/ documentation of the all Regional Training Centre under Pharmacovigilance			

Prepared by	Name	Designation	Signature	Date
	Rishi Kumar	Pr. Associate	<i>Rishi</i>	16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>PWS</i>	17/08/2016
Approved by	Dr. Kalai veeran	PSO	<i>Dr</i>	18/8/2016



**INDIAN PHARMACOPOEIA COMMISSION**  
National Coordinating Centre for Drug Regulatory Programme of India

**Annexure-III**  
**Audit Checklist**

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**Format No. IPC/PvPI/QA/007-F03-00**

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No/Not Applicable			
<b>Programme of India</b>					
<b>Quality Assurance/Quality Control Standard: QA</b>					
QA 1.0	Organisational charts of PvPI				
QA 1.1	Personnel with responsibility, authority and resource				
QA 1.2	Ensure the documents are designed, prepared, reviewed and approved with signature and dated by appropriate and authorized person				
QA 1.3	Ensure the documents specify title, objective and scope				
QA 1.4	Ensure the documents are regularly reviewed and kept up to date. If yes. Please specify review period.				
QA 1.6	Ensure the Functioning of Quality Review Panel and Documentation				

Prepared by	Name	Designation	Signature	Date	Page 3 of 13
Reviewed by	Dr. Rishi Kumar	Asst. Associate	<i>[Signature]</i>	16/08/2016	
Approved by	Dr. Gansan R. Saini	S.O.	<i>[Signature]</i>	17/08/2016	
	Dr. Kailash Chandra	P.S.O.	<i>[Signature]</i>	18/8/2016	



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**Annexure-III**  
**Audit Checklist**

Format No. IPC/PvPI/QA/007-F03-00

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No/Not Applicable			
QA 17	Ensure the availability of Quality Manual				
QA 18	Are there documented statements for Quality Policy & Objectives and Core Principle				
QA 19	Documentation of SOPs and instructions to cover all aspects of Pharmacovigilance/drug Safety				
QA 110	Control of SOPs and other procedural documentation, including writing, review, approval, updating, distribution and implementation				
QA 111	Quality system and Standard Operating Procedures for Pharmacovigilance activities				
QA 112	Records maintained to provide evidence of conformity. Records are legible, identifiable and retrievable. Records are controlled for identification, storage, protection, retrieval, retention, and disposal				
QA 113	Auditing of a Pharmacovigilance system				

Prepared by	Name	Designation	Signature	Date	Page 4 of 13
Approved by	<i>[Signature]</i>	17/08/2016			
		18/08/2016			



**Annexure-III**  
**Audit Checklist**

**Format No. IPC/PvPI/QA/007-F03-00**

S. No.	Measurable Indicators	Document Verification	Grading Level*	Remarks
		Yes/No/Not Applicable		
QA 1.13.1	The processes for communicating and addressing audit findings			
QA 1.13.2	Review of corrective and preventive action processes and documentation			
QA 1.14	Specify the comprehensive quality management system maintained by the PvPI Inter-alia to cover change control, deviation, non-conformance			
QA 1.15	Collection/Processing/Analysis of Pharmacovigilance data like ICSRs (from AMCs, RNTCP, ART, Active surveillance Centres, consumers, healthcare professionals, medical information departments)			
QA 1.16	Causality assessment procedure & implementation			
QA 1.17	Determination of seriousness and listedness/expectedness of ADRs			

Prepared by	Name	Designation	Signature	Date	Page
	Rishi Kumar	Asst. Associate	<i>Rishi</i>	16/08/2016	5 of 13
Reviewed by	Dr. Sanjay K. Saini	S.O.	<i>Sanjay</i>	17/08/2016	
Approved by	Dr. Kalisekhar	P.I.O.	<i>Kalisekhar</i>	18/08/2016	



**INDIAN PHARMACEUTICALS COMMISSION**  
National Co-ordinating Centre for Drug Regulatory Programme of India

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Annexure-III  
Audit Checklist

Format No. IPC/PvPI/QA/007-F03-00

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No/Not Applicable			
QA 1.18	Ensuring reporting compliance as per SOP				
QA 1.19	Ensuring an adequate and complete follow-up ICSRs				
QA 1.20	Review, validation and follow-up of suspected ADRs				
QA 1.21	Ensure the quality review of ICSRs as per SOP				
QA 1.22	Ensure the status of ICSRs under the central Assessment				
QA 1.23	Ensure proper documentation of ICSRs including maintaining a record of Completeness Score Sheet and PDF version (centre wise) of ICSRs as per SOP				
QA 1.24	Ensure proper communication between NCC & AMCs personnel as per requirement				

Signal Detection

Name	Designation	Signature	Date	Page
Prepared by <i>Rishi Kumar</i>	<i>Pr. Associate</i>	<i>RK</i>	<i>16/08/2016</i>	6 of 13
Reviewed by <i>Dr. Sawan K. Saini</i>	<i>S.O.</i>	<i>SK</i>	<i>17/08/2016</i>	
Approved by <i>Dr. Kalaitelwan</i>	<i>P.S.O.</i>	<i>KL</i>	<i>18/8/2016</i>	



**INDIAN PHARMACEUTICALS AND DRUGS CONTROL COMMISSION**  
**National Coordination Centre for Pharmacovigilance Programme of India**

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**Annexure-III**  
**Audit Checklist**

Format No. IPC/PvPI/QA/007-F03-00

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No/Not Applicable			

**Standard -SD**

SD 1.0	Identification of the responsible staff related to the signal detection (qualifications and training)				
SD 1.1	Ensure the functioning of signal review panel and Documentation				
SD 1.2	Ensure documents and signal detection procedure				
SD 1.3	Ensure Signal assessment and Documentation				
SD 1.4	Ensure the Communication between NCC-PvPI and CDSCO				
SD 1.5	Ensure Recommendation to CDSCO for drug alert, Change in package inserts etc.				
SD 1.6	Serious Adverse Event Notification				

**Training and Education**

Prepared by	Name	Designation	Signature	Date
	Rishi Kumar	P. Associate	<i>[Signature]</i>	16/08/2016
Reviewed by	Dr. Rawson K. Saini	S.O.	<i>[Signature]</i>	17/08/2016
Approved by	Dr. Rajeshwar	P.S.O.	<i>[Signature]</i>	18/8/2016



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National Coordination Centre, Pharmacovigilance Programme of India

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**Annexure-III**  
**Audit Checklist**

Format No. IPC/PvPI/QA/067-F03-00

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No/Not Applicable			

**Standard - IIE**

TE 1.0	Ensure the Functioning of Core Training Panel and Documentation				
TE 1.2	Training records of all personnel involve in Pharmacovigilance Programme of India				
TE 1.3	Documentation on policies and procedures for training of personnel and implementation				
TE 1.4	Allocation of duties to key personnel for training				

**Standard - MvPI**

MvPI 1.0	Ensure the communication between NCC-PvPI, SCTIMST and NHSRC related to the MvPI activities and its documentation				
----------	---	--	--	--	--

**Standard - NHP**

National Health Programme (NHP)			Date		Page	
Name	Designation	Signature			8 of 13	
Prepared by	<i>Rishi Kumar</i>	<i>RK</i>	16/08/2016			
Reviewed by	<i>Dr. Ranjan K. Saini</i>	<i>RKS</i>	17/08/2016			
Approved by	<i>Dr. K. Jayasekaran</i>	<i>KJ</i>	18/08/2016			



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**Annexure-III**  
**Audit Checklist**

**Format No. IPC/PvPI/QA/007-F03-00**

**Measurable Indicators**

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No	Not Applicable		

**Standard - NHP**

NHP 1.0	Ensure the Coordination between PvPI and National AIDS Control Programme (NACP) and documentation				
NHP 1.1	Ensure the Coordination between PvPI and Revised National TB Control Programme (RNTCP) and documentation				
NHP 1.2	Ensure the Coordination between PvPI and Active surveillance centres and documentation				
NHP 1.3	Ensure the Coordination between PvPI and AEFI and documentation				
NHP 1.4	Ensure the proper documentation of Serious/Non Serious Vaccine ICSRs as per SOP				

**Promotional & Technology Development Cell (PTD)**

Prepared by	Name	Designation	Signature	Date	Page
	Rishi Kumar	P. Associate	<i>[Signature]</i>	16/08/2016	
Reviewed by	Dr. Lawrence K. Saini	S.O.	<i>[Signature]</i>	17/08/2016	
Approved by	Dr. Kabir Chavan	P.S.O.	<i>[Signature]</i>	18/08/2016	



**INDIAN PHARMACEUTICALS AND DRUGS CONTROL**  
**COMMISSION**  
 National Coordination Centre, Pharmacovigilance Programme of India  
 Sign: M. D. ... Date: 16/08/2016

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**Annexure-III**  
**Audit Checklist**

Format No. IPC/PvPI/QA/007-F03-00

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No/Not Applicable			
<b>Standard-PTD</b>					
PTD 1.0	Ensure the promotional & technology related activities and documentation				
<b>International Cell</b>					
<b>Standard-IC</b>					
IC 1.0	Ensure the International collaboration related activities and documentation				
<b>Human Resource (HR)</b>					
<b>Standard-HR</b>					
HR 1.0	Ensure the Recruitment & Selection of New Employees as per organization recruitment rules and regulation				
HR 1.1	Ensure job descriptions for each position within the organization				

Prepared by	Name	Designation	Signature	Date	Page
	Rishi Kumar	As. Associate	<i>[Signature]</i>	16/08/2016	
	Dr. Rawan K. Saini	S.O.	<i>[Signature]</i>	17/08/2016	
	Dr. K. Rajeshwar	P.S.O.	<i>[Signature]</i>	18/08/2016	



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National Coordination Centre, Pharmacovigilance Programme of India

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Annexure-III  
Audit Checklist

Format No. IPC/PvPI/QA/007-F03-00

S. No. Measurable Indicators

Document Verification

Yes/No/Not Applicable

Grading Level\*

Remarks

HR 1.2 Ensure employees provided training for new processes and procedures required to complete their job duties

HR 1.3 Ensure the Specimen signature as per the SOP and documentation

HR 1.4 Documentation of attendance record of each employee

HR 1.5 Ensure employee files up to date

HR 1.6 Ensure confidentiality of employees information

Communication and Publication (CP)

Standard-CP

CP 1.0 Ensure the availability and distribution record of resource materials like News Letter/Pamphlet/Leaflet/PvPI posters etc.

CP 1.1 SOP for Communication between NCC-PvPI and stakeholders

Prepared by	Name	Designation	Signature	Date	Page 11 of 13
Reviewed by	Dr. Rajesh Kumar	Pr. Associate	<i>[Signature]</i>	16/08/2016	
Approved by	Dr. Rajesh K. Saini	S.O.	<i>[Signature]</i>	17/08/2016	
	Dr. Kalai Selvan	ISO	<i>[Signature]</i>	18/08/2016	



**INDIAN PHARMACEUTICALS COMMISSION**  
**National Coordination Centre-Pharmaceuticals**  
**Pharmacovigilance Programme of India**

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**Annexure-III**  
**Audit Checklist**

Format No. IPC/PvPI/QA/007-F03-00

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No/Not Applicable			

CP 1.2	Availability of records of research publications under PvPI				
Miscellaneous					
Standard- MIS					
MIS 1.0	Ensure the ADR received through PvPI helpline (Toll Free) as per SOP and Documentation				
MIS 1.2	Efficient functioning and maintenance of desktop used in PvPI activities				
MIS 1.3	Migration and legacy system of relevant data				
MIS 1.4	System for the archiving and retrieval of documents				
MIS 1.5	Controlled access to the archives				
Industries ICSRs Processing and PSURs					
Standard-IP					
IP 1.0	Processing of ICSRs received from MAHs and Documentation				

If required separate sheet may be used for observations

Name	Designation	Signature	Date	Page
Prepared by	Rishi Kumar	<i>[Signature]</i>	16/08/2016	12 of 13
Reviewed by	Dr. Ranveer Saini	<i>[Signature]</i>	17/08/2016	
Approved by	Dr. Kalpalalva	<i>[Signature]</i>	18/8/2016	



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National Coordination Centre-Pharmaceuticals Covigilance Programme of India

Sign. M. D. S. ...

Annexure-III  
Audit Checklist

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Sign. M. D. S. ...

Format No. IPC/PvPI/QA/007-F03-00

S. No.	Measurable Indicators	Document Verification		Grading Level*	Remarks
		Yes/No	Not Applicable		

**GRADING LEVEL\***

**Grade A**

**Well controlled**

Controls evaluated are adequate, appropriate, and effective to provide reasonable assurance that system is being managed and objectives should be met.

**Grade B**

**Satisfactory-High**

A few specific control weaknesses were noted; generally however, controls evaluated are adequate, appropriate, and effective to provide reasonable assurance that system is being managed and objectives should be met.

**Grade C**

**Satisfactory-Low**

Numerous specific control weaknesses were noted. Controls evaluated are unlikely to provide reasonable assurance that system is being managed and objectives should be met.

**Grade D**

**Material Opportunities for improvement**

Controls evaluated are not adequate, appropriate, or effective to provide reasonable assurance that system is being managed and objectives should be met.

Prepared by	Name	Designation	Signature	Date	Page
	Rishi Kumar	As. Associate	<i>[Signature]</i>	16/08/2016	13 of 13
Reviewed by	Dr. Ramesh K. Saini	S.O.	<i>[Signature]</i>	17/08/2016	
Approved by	D. K. Kalishwar	PSO	<i>[Signature]</i>	18/8/2016	

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Annexure-IV

AUDIT OBSERVATIONS REPORT

Format No. IPC/PvPI/QA/007-F04-00

Ref.: Audit notification No.....

Date: .....

Reference Document: .....

Audited activity: .....

Summary of findings /Observation details:

-----  
-----  
-----  
-----

Number of non conformity raised :

a) Major .....

Ref.-Audit check list Observation S. No. : .....

b) Minor.....

Ref.-Audit check list Observation S. No. : .....

Description of non conformity: -----

-----  
-----  
-----

	Name	Designation	Signature	Date	Page no.
Prepared by	Rishi Kumar	Pr. Associate		16/08/2016	1 of 2
Reviewed by	Dr. Pawan K. Saini	S.O.		17/08/2016	
Approved by	Dr. Kalish Kumar	P.S.O.		18/8/2016	

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Sign... Dt.../.../16

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 सत्यमेव जयते 	<b>INDIAN PHARMACOPOEIA COMMISSION</b> <b>National Coordination Centre-Pharmacovigilance Programme of India</b>
	<b>Annexure-IV</b> <b>AUDIT OBSERVATIONS REPORT</b>

Format No. IPC/PvPI/QA/007-F04-00

**ROOT CAUSE ANALYSIS**

The possible causes of the non- conformity are listed below:

1. -----
2. -----
3. -----
4. -----
5. -----

**Observation Review and Remarks:**

-----  
-----  
-----  
-----

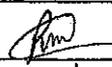
Any requirement for an additional or unplanned audit: Yes / No

Auditor Name:

Auditee Name:

Signature:

Date :

	Name	Designation	Signature	Date	Page no.
Prepared by	Rishi Kumar	Pr. Associate		16/08/2016	2 of 2
Reviewed by	Dr. Parveen K. Saini	S.O.		17/08/2016	
Approved by	Dr. Kalei Selam	PSO		18/8/2016	

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INDIAN PHARMACOPOEIA COMMISSION  
National Coordination Centre-Pharmacovigilance Programme Of India

Annexure-V

CORRECTIVE AND PREVENTIVE ACTION REPORT

Format No. IPC/PvPI/QA/007-F05-00

Audit outcome

Need for corrective action to be taken: Yes / No

Corrective and Preventive action proposed: -----  
-----  
-----

Signature of Auditee: \_\_\_\_\_ Date: \_\_\_\_\_

Person responsible for taking corrective action:

Required time frame: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Corrective and Preventive action taken: -----  
-----  
-----

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Corrective action verification:

Corrective action completed on: -----

Corrective action verified on: -----

Corrective action implementation: Effective / Not effective

Comments, if any: -----  
-----  
-----

Verified by QA: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

	Name	Designation	Signature	Date	Page
Prepared by	Rishi Kumar	Pr. Associate	<i>RK</i>	16/08/2016	1 of 1
Reviewed by	Dr Pawan K. Saini	S.O.	<i>PKS</i>	16/08/2016	
Approved by	Dr. Kalai B.	PJO	<i>KB</i>	16/08/2016	