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 सत्यमेव जयते 	<b>INDIAN PHARMACOPOEIA COMMISSION</b>			
	<b>National Coordination Centre-Pharmacovigilance Programme of India</b>			
	<b>STANDARD OPERATING PROCEDURE</b>		<b>Page No.</b>	<b>1 of 4</b>
			<b>SOP No.</b>	<b>IPC/PvPI/QA/005</b>
	<b>Section</b>	All Sections	<b>Revision No.</b>	<b>00</b>
<b>Effective Date</b>	01/09/2016	<b>Review Date</b>	31/08/2019	
<b>Title: SOP for Handling of Non-Conforming work</b>				

## 1.0 OBJECTIVE

1.1 To lay down the procedure for Handling of Non-Conforming work.

## 2.0 SCOPE

2.1 This SOP shall be applicable to all the 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 section shall be responsible for monitoring the Non-Conforming activities.

3.2 Quality Manager /Technical Manager shall be ensuring overall implementation of this SOP.

## 4.0 ACCOUNTABILITY

4.1 Officer Incharge- Pharmacovigilance Programme of India

## 5.0 PROCEDURE

5.1. Non-Conforming work shall be observed by Quality Assurance personnel and recorded as per Annexure-I (Format No. IPC/PvPI/QA/005-F01).

	Name	Designation	Signature	Date
Prepared by	Sansabh Kr. Jain	Pr Associate	Jansabh	16/08/2016
Reviewed by	Dr. Pawan K. Saini	Scientific officer	PWS	17/08/2016
Approved by	Dr. V. Kalaiselvan	Principal Sci officer	VK	18/08/2016

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5.2. QA section shall be classify the type of non- conforming work, as per given below:

5.2.1 In case directly impact of Quality/Safety – Critical

5.2.2 In case indirectly impact of Quality/Safety – Major

5.2.3 In case no impact of Quality/Safety –Minor

5.3. The non-conformance report shall be handed over to concerned section in charge or Designee.

5.4. After receiving of the NCR the concern section shall write the reason of non-conforming work and immediately rectify the non-conformance by the investigation of the root cause analysis.

5.4 After root cause analysis of the non- conforming work the concern section shall propose corrective and preventive action as per SOP No. IPC/PvPI/QA/003 and NCC-PvPI to prevent the recurrence of the non- conforming work in future.

5.5 The final review shall be done by Quality Manager and Officer Incharge -PvPI for the corrective and preventive action mentioned and closes the non-conformance report after completion of the actions planned.

5.6 Quality Assurance section shall maintain all copies of the closed non-conformance reports.

	Name	Designation	Signature	Date
<b>Prepared by</b>	Saurabh K. Jain	PV Associate	<i>[Signature]</i>	16/08/2016
<b>Reviewed by</b>	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	17/08/2016
<b>Approved by</b>	Dr. V. Kalaiselvan	Principal sci. officer	<i>[Signature]</i>	18/08/2016

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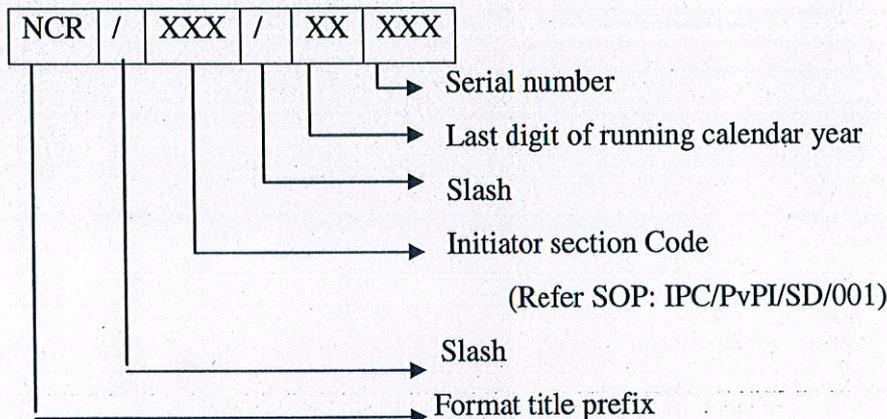
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5.7 Quality Assurance section shall maintain the non-conformance log as per Annexure – II (Format No. IPC/PvPI/QA/005-F02).

5.8 All the concerned personnel involved in the non-conforming work shall be given necessary training, if required.

**5.9 Numbering System for NCR**

Numbering system is given below:



Example: NC found in Signal detection section: NCR/SD/16/001

**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.

	Name	Designation	Signature	Date
<b>Prepared by</b>	Saurabh Kr. Jain	Rv Associate	<i>[Signature]</i>	16/08/2016
<b>Reviewed by</b>	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	17/08/2016
<b>Approved by</b>	Dr. V. Kalaiselvan	Principal S.O. Officer	<i>[Signature]</i>	18/08/2016

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7.0 REFERENCES: In House

8.0 ABBREVIATIONS

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

9.0 ANNEXURES:

Annexure I : Non-Conformance Report (Format No. IPC/PvPI/QA/005-F01)

Annexure II: Non-Conformance Log (Format No. IPC/PvPI/QA/005-F02)

	Name	Designation	Signature	Date
Prepared by	<i>Sausabh Kr Jain</i>	<i>Pv Associate</i>	<i>Sausabh</i>	<i>16/08/2016</i>
Reviewed by	<i>Dr. Pawan K. Saini</i>	<i>S.O.</i>	<i>[Signature]</i>	<i>17/08/2016</i>
Approved by	<i>Dr. V. Kalaiselvan</i>	<i>Principal Scientist</i>	<i>[Signature]</i>	<i>18/08/2016</i>

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Annexure-I  
 NON-CONFORMANCE REPORT

Format No. IPC/PvPI/QA/005-F01-00

NCR No.		Date of Initiation	
Type of Non-conformance work	Critical	Major	Minor
Non-Conformance Details :			
Observed by/on		Received by/on	
Reason for Non-Conformance:			
CAPA taken and Implementation:			
Done by Section (Sign/Date)		Verified by	
QA(Sign/Date)			
Closure of Non-Conformance Report (Remarks):			
Quality Manager (Sign/Date)		Officer Incharge (Sign/Date)	

	Name	Designation	Signature	Date	Page
Prepared by	Saurabh Kr Jain	PV Associate	Saurabh	16/08/2016	1 of 1
Reviewed by	Dr Pawan K. Saini	S.O.	[Signature]	17/08/2016	
Approved by	Dr. Kalaiselvan	Principal ses officer	[Signature]	18/08/2016	

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Annexure-II  
NON-CONFORMANCE LOG

Format No. IPC/PvPI/QA/005-F02-00

S. No	NCR No.	Initiation Date	Type of Non-conforming work	Observed By (Sign/Date)	Received By (Sign/Date)	CAPA Completed on	Closed By (Quality Manager)

	Name	Designation	Signature	Date	Page
Prepared by	Saurabh Kr Joshi	PV ASSOCIATE	Saurabh	16/08/2016	1 of 1
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	17/08/2016	
Approved by	Dr. V. Kalaiselvan	Principal Scientist	[Signature]	18/08/2016	