



STANDARD OPERATING PROCEDURE		Page No.	1 of 3
		SOP No.	IPC/PvPI/QA/006
Section	All Sections	Revision No.	00
Effective Date	01/09/2016	Review Date	31/08/2019
Title: SOP for Corrective and Preventive Action			

1.0 OBJECTIVE

- 1.1 To lay down the procedure for Corrective and Preventive Action (CAPA) in case of observation of any non-conforming work, unforeseen incidences / incidents occurred.

2.0 SCOPE

- 2.1 This procedure 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 CAPA related activities.
3.3 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 In case of any observed unforeseen incidence like Computer system /Software failures, errors observed in the approved / master documents, the concerned individual shall report the incidence immediately to the QA section.
5.2 Concern personnel shall raise the requisition for CAPA report to document the incidence observed in as per **Annexure I (Format No. IPC/PvPI/QA/006-F01)**.

	Name	Designation	Signature	Date
Prepared by	Saurabh K. Jain	PV Associate		16/08/2016
Reviewed by	Dr. Pawan K. Saini	Scientific officer		17/08/2016
Approved by	Dr. V. Kalaiselvan	Principal Scientist		18/08/16



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- 5.3 CAPA report shall be documented as per the **Annexure II (Format No. IPC/PvPI/QA/006-F02)**.
- 5.4 A register of CAPA shall be maintained in QA section as per the **Annexure III (Format No. IPC/PvPI/QA/006-F03)**.
- 5.5 QA section shall ensure that immediate corrective action is taken and shall initiate the root cause analysis in coordination with the concern section.
- 5.6 Impact assessment on quality / safety shall be done by quality assurance in coordination with concern section.
- 5.7 Based on the evaluation of the impact assessment, further preventive action shall be planned and approved by Quality Manager.
- 5.8 Concern section in-charge and Quality Manager shall ensure compliance.
- 5.9 After satisfactory compliance, the CAPA report shall be closed.
- 5.10 General procedure for handling such incidences are given as below. These are examples and shall not restrict the scope of the procedure.
- 5.10.1 Computer system /Software failures during the ICSRs processing.
- 5.10.1.1 Appropriate corrective action shall be initiated for repair of the computer system.
- 5.10.2 Document Error:
- 5.10.2.1 Any error observed in document, shall be informed to QA section.
- 5.10.2.2 Root cause analysis of the error shall be jointly undertaken by a team of persons from QA section and other sections as applicable.
- 5.10.2.3 Impact assessment of the error on the quality of the ICSRs processing shall be critically done.
- 5.10.2.4 After approval from Quality Manager required corrective action shall be taken.
- 5.10.2.5 Other master, controlled documents shall be corrected and the correction in the document shall be approved by Quality Manager. Subsequently, the document shall be amended through change control procedure defined in SOP No. IPC/PvPI/QA/003.

	Name	Designation	Signature	Date
Prepared by	Sausabh kv Jain	PV Associate	Sausabh	16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	P.K.S.	17/08/2016
Approved by	Dr. V. Kalaiselvaraj	Principal Director	V.K.	18/08/16.



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5.11 Appropriate training to the concerned personnel shall be given based on the findings of the root cause analysis and CAPA.

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 to outside the organization.

7.0 REFERENCES : In-house

8.0 ABBREVIATIONS

- SOP : Standard Operating Procedure
- IPC : Indian Pharmacopoeia Commission
- PvPI : Pharmacovigilance Programme of India
- NCC : National Coordination Centre
- QA : Quality Assurance
- CAPA : Corrective and Preventive Action

9.0 ANNEXURE

- Annexure-I Request form – CAPA report
- Annexure II CAPA Report
- Annexure-III Format CAPA Register

	Name	Designation	Signature	Date
Prepared by	Saurabh Kr Jain	PV Associate	<i>[Signature]</i>	16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	17/08/2016
Approved by	Dr. V. F. A. Laise Van	Principal Scientist	<i>[Signature]</i>	18/8/2016

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 भारत गणराज्य 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India
	Annexure I REQUEST FORM – CAPA REPORT

Format No. IPC/PvPI/QA/006-F01

Section	
Incidence Observed	

Requested By	Name / Sign and Date
Reviewed By Section In-charge	Remarks : Name / Sign and Date
Reviewed By QA Representative	Comments : Name / Sign and Date

CAPA No. : CAPA/XX/YYY

XX- stands for current year last two digits
YYY – stands for three digits serial number

Issued By (QA)	Received By
Sign and Date	Sign and Date

	Name	Designation	Signature	Date
Prepared by	Saurabh K. Jain	Pv Associate	Saurabh	16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	PWS	17/08/2016
Approved by	Dr. V. Kalaiselvan	Principal su officer	VK	18/08/2016

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Annexure II
CAPA REPORT

Format No. IPC/PvPI/QA/006-F02

CAPA No. :	
Section	

Document / Title	
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Incidence Observed	
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Corrective Action Taken	
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Root Cause Analysis	
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Impact Assessment	
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Preventive Action Taken	
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Training Given	Yes / No
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Closure of CAPA Report (Remarks):	
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Quality Manager (Sign/Date)

Officer Incharge (Sign/Date)

(If require additional sheet attach)

	Name	Designation	Signature	Date
Prepared by	Saurabh K. Jha	PR Associate	<i>[Signature]</i>	16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	17/08/2016
Approved by	Dr. V. Kalaiselvan	PSO	<i>[Signature]</i>	18/08/2016

