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INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre-Pharmacovigilance Programme of India



STANDARD OPERATING PROCEDURE

Page No.	1 of 4
SOP No.	IPC/PvPI/QA/004
Revision No.	00
Review Date	30/06/2019

Section	All sections
Effective Date	01/07/2016

Title: SOP for Handling of Deviation

**1.0 OBJECTIVE**

1.1 To lay down the procedure for investigation and control of deviations that occur during ICSRs processing and documented procedures wherever applicable.

**2.0 SCOPE**

2.1 This SOP shall be applicable to all related user section at NCC-PvPI.

**3.0 RESPONSIBILITY**

3.1 It is the responsibility of the person whoever identifies a deviation, to record the event and to forward it to their respective section Incharge.

**3.2 Responsible Person**

3.2.1 Initiator (Person who identifies the deviation)

3.2.2 Section Incharge

3.2.3 QA Manager

**4.0 ACCOUNTABILITY**

4.1 Officer Incharge –Pharmacovigilance Programme of India

**5.0 PROCEDURE**

5.1 The user section shall ensure that are no deviations to the approved established procedure under normal condition.

	Name	Designation	Signature	Date
Prepared by	Saurabh Kr. Jain	PR Associate	<i>Saurabh</i>	21/06/2016
Reviewed by	Dr. Pawan K. Saini	Scientific officer	<i>PWS</i>	22/06/2016
Approved by	Dr. Kalw Selvan	Principal Sci officer	<i>KS</i>	23/06/2016

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5.2 Deviations are classified as:

5.2.1 **Planned Deviation:** Any deviation from documented procedure opted deliberately for temporary period to manage unavoidable situation without affecting the quality system and Patient safety shall be termed as planned deviation.

5.2.2 **Unplanned Deviation:** Any deviation occurred in unplanned manner due to system failure or software breakdown or Utility service failure or manual error shall be termed as unplanned deviation.

5.3 No process deviation shall be permitted under normal operating conditions however in case the deviation is unavoidable; the same should be immediately brought to the notice of QA manager.

5.4 No deviation shall be permitted for Regulatory requirement.

5.5 Before initiating the deviation form evaluation shall be done to assess whether the deviation has any quality impact or quality non-impact.

5.5.1 **Quality Impacts** are occurrences during execution of an activity which shall affect the quality of ICSRs and Patient Safety.

5.5.2 **Quality Non-impacts** are occurrences during execution of an activity which shall have no impact on the quality of ICSRs and Patient Safety.

	Name	Designation	Signature	Date
Prepared by	Saurabh Kr Jain	PV Associate	Saurabh	21/06/2016
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Approved by	Dr. V. Kalaiselvan	Principal QA Officer	[Signature]	23/06/2016

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## 5.6 Procedure to handle deviations:

- 5.6.1 In case of planned deviation- the initiator shall raise the Deviation Control Report Form in advance and in case of unplanned deviation- the initiator shall raise the Deviation Control Report Form as per the **Annexure No. I (Format no. IPC/PvPI/QA/004-F01)** with deviation details, reason for deviation, immediate action taken, with present status details and forward to QA section.
- 5.6.2 QA shall enter the details of deviation in "Deviation Control Log" as per the **Annexure No. II (Format no. IPC/PvPI/QA/004-F02)**.
- 5.6.3 QA shall review the reason for deviation whether it has any impact on quality and safety. Based on remarks by QA section, the finding shall be communicated to concern section for corrective and preventive action as per SOP No. IPC/PvPI/QA/006.
- 5.6.4 Finally the deviation shall be approved by the Quality Manager and Officer Incharge PvPI.
- 5.6.5 QA shall assign Deviation control numbering system as given below:  
PvPI/D/YY/ZZ  
D - stand for Deviation  
YY- Current year last two digits  
ZZ- Serial number in three digits  
Example: PvPI/D/15/001
- 5.6.6 Deviation log shall be reviewed on monthly basis to review adequacy of corrective action.
- 5.6.7 There shall be more than three planned deviation for incorporation as documentation change through appropriate change control procedure as per (SOP No. IPC/PvPI/QA/003).

	Name	Designation	Signature	Date
Prepared by	Sausabh Kr. Jain	PV Associate	Sausabh	21/06/2016
Reviewed by	Dr. Pawan K. Sahni	S.O.	[Signature]	22/06/2016
Approved by	Dr. V. Karaiselvan	Principal Sci officer	[Signature]	23/06/2016

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## 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

QA	:	Quality Assurance
NCC	:	National Coordination Centre
PvPI	:	Pharmacovigilance Programme of India
SOP	:	Standard operating procedure

## 9.0 ANNEXURE(s)

Annexure-I-Deviation Control Report Form (Format No. IPC/PvPI/QA/004-F01)

Annexure-II- Deviation Control Log (Format No. IPC/PvPI/QA/004-F02)

	Name	Designation	Signature	Date
Prepared by	Saurabh Kr Jain	PR Associate	Saurabh	21/06/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	22/06/2016
Approved by	Dr. Kabir Selwan V	Principal Sci. Officer	<i>[Signature]</i>	23/06/2016

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<b>Annexure-I</b>	
<b>DEVIATION CONTROL REPORT FORM</b>	

**Format No. IPC/PvPI/QA/004-F01-00**

<b>Deviation Control No.</b>		<b>Date:</b>	
<b>Type of deviation</b>	<b>Planned</b>	<b>Unplanned</b>	
<b>Deviation Details :</b>			
<b>Initiated by (Sign &amp; Date)</b>			
<b>Reason for Deviation:</b>			
<b>Verified by Section Incharge ( Sign &amp; Date)</b>			
<b>Justification/Review comments for deviation (other related Section –as applicable )</b>			
<b>Section Incharge or Designee (Sign &amp; date)</b>			

	Name	Designation	Signature	Date	Page 1 of 2
<b>Prepared by</b>	<i>Sanskrit K. Jain</i>	<i>PV Associate</i>	<i>[Signature]</i>	<i>21/06/2016</i>	
<b>Reviewed by</b>	<i>Dr. Pawan K. Saini</i>	<i>S.O.</i>	<i>[Signature]</i>	<i>22/06/2016</i>	
<b>Approved by</b>	<i>Dr. V. Kalachandran</i>	<i>Principal Sr. Officer</i>	<i>[Signature]</i>	<i>23/06/2016</i>	

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	<b>Annexure-I</b>
	<b>DEVIATION CONTROL REPORT FORM</b>

Format No. IPC/PvPI/QA/004-F01-00

<b>QA Evaluation :</b>	<b>Quality Impact</b>	<b>Quality Non-impact</b>	<b>Others</b>
<b>Comments by Quality Manager/ Designated Representative</b>			
<b>Deviation Approved by Quality Manager ( Sign &amp; Date)</b>			
<b>Comments by / Officer-Incharge, PvPI</b>			
<b>Deviation Approved by Officer-Incharge, PvPI ( Sign &amp; Date)</b>			
<b>Corrective action taken and Implementation:</b>			
<b>Done by Initiator section</b>		<b>Verified by QA</b>	
<b>(Sign/Date)</b>		<b>(Sign/Date)</b>	

	Name	Designation	Signature	Date	Page 2 of 2
Prepared by	Sandeep K. Jain	PR Associate	<i>Sandeep</i>	21/06/2016	
Reviewed by	Dr Pawan K. Saini	S.O.	<i>PWS</i>	22/06/2016	
Approved by	Dr. Kalaiselvan	Principal Scientist	<i>KS</i>	23/06/2016	

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Annexure-II

**DEVIATION CONTROL LOG**

Format No. IPC/PvPI/QA/004-F02-00

No.	Date	Source of Complaint	Deviation Control No.	Type of Deviation	Quality Control/Manufacturing Section	Remarks

	Name	Designation	Signature	Date
Prepared by	Sausobh K. Jaisin	PV AS Associate	Sausobh	21/06/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	P.K.S.	22/06/2016
Approved by	Dr. V. Kalaitelvan	PJO	V.K.	23/06/2016