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INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme of India

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STANDARD OPERATING PROCEDURE

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SOP No.

IPC/PvPI/QA/003

Section

All section

Revision No.

00

Effective Date

08/03/2016

Review Date

07/03/2019

Title: Change Control Procedure

1.0 OBJECTIVE

1.1 To lay down a procedure for Change Control System.

2.0 SCOPE

2.1 This Standard Operating Procedure shall be applicable to all section of NCC-PvPI.

3.0 RESPONSIBILITY

3.1 All sections are responsible for initiation of change control whenever change is required.

3.2 QA section will be responsible for monitoring, assessment & approval of the change.

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

4.0 ACCOUNTABILITY

4.1 Officer Incharge - Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 Change Control System gives the procedure for the following:-

5.1.1 Initiation of Change Control.

5.1.2 Review, change and assessment by QA.

5.1.3 Final approval of change from QA.

5.1.4 Monitoring and closing of Change Control.

	Name	Designation	Signature	Date
Prepared by	Sanskrit K. Jain	Tech. Associate	Sanskrit	07/03/2016
Reviewed by	Dr. Kawan K. Saini	Scientific Officer	MW	07/03/2016
Approved by	Dr. Kolai Selvan	PSO	KS	07/3/2016

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5.2 Part-I Initiation of Change Control:

- 5.2.1 The ownership of the change is with the head of the originating section who is responsible for initiating the change.
- 5.2.2 Respective section shall make request to “Change Control Request” to QA as per Format No. **IPC/PvPI/QA/001-F04**.
- 5.2.3 QA will issue Change Control Request as per Format No. **IPC/PvPI/QA/003-F01**.
- 5.2.4 The initiating section shall be indicating the change request under section 2.0 of Change Control Request.
- 5.2.5 QA shall allot the Change Control Request number (CCR No.) against the Change Control Log which is maintained year-wise in QA as per Format No. **IPC/PvPI/QA/003-F02**.
- 5.2.6 Initiating section shall furnish the details of proposed change(s) as per section 3.0 of Part-I under “Change Control Request”.
- 5.2.7 Reason for change (s) shall be indicated as under section 4.0 of “Change Control Request” Attach supporting documents as applicable based on which change is proposed.
- 5.2.8 Document affected by the change shall be indicated as under section 5.0 of “Change Control Request.”
- 5.2.9 The tentative date of implementation shall be indicated under section 6.0 and filled accordingly.
- 5.2.10 Request for the document nature under section 7.0.
- 5.2.11 All changes proposed shall be authorized by respective initiating section Head / authorized person.
- 5.2.12 The representative /responsible person of the initiating section shall sign in the change initiated by under section 7.0 of Part-I in “Change Control Request”.
- 5.2.13 Head of the initiating section / Authorised person shall approve the proposed change and shall sign as authorized under section 7.0 of “Change Control Request”.

	Name	Designation	Signature	Date
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Reviewed by	Dr. Kawan K. Saini	S.O.	[Signature]	07/03/2016
Approved by	Dr. Kalai Selvan	PSO	[Signature]	07/3/2016

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5.3 Part-II A: Change Control Consent and Review:

- 5.3.1 User section /initiating section to submit the "Change Control Request" to QA.
- 5.3.2 QA section will circulate the change control request to all concerned sections and obtain their review comments.
- 5.3.3 Responsible person of the section shall review the proposed change and record the review comments under section 8.0 of "Change Control Request".
- 5.3.4 The section head / Authorised person shall finally indicate the change acceptance and shall sign and date under section 8.0 of "Change Control Request".

5.4 Part-II B: Change Control Assessment By QA:

- 5.4.1 On receipt of change control request along with review comments of all other concerned sections, the QA representative shall assess the type of change level under the section 9.0.
- 5.4.2 QA shall assign the Change Control Request Number as given below:

PvPI/CCR/YY/ZZ

CCR - Change control request

YY- Current year last two digits

ZZ- Serial number in three digits

Example: PvPI/CCR/15/001

- 5.4.3 Record the Change Control Request Number (CCR No.) in the Change Control Log as per Format No. **IPC/PvPI/QA/003-F02**.
- 5.4.4 QA shall assess the level of change as under:
 - 5.4.4.1 **Type -A:** Minor changes who do not have any detectable impact on the quality attributes of the reports and having no regulatory impact.
 - 5.4.4.2 **Type -B:** Changes that are likely or may have minor impact on the quality attributes of the reports.

	Name	Designation	Signature	Date
Prepared by	Saurabh K. Jain	Tech. Associate	<i>[Signature]</i>	07/03/2016
Reviewed by	Dr. Ruman K. Saini	SO	<i>[Signature]</i>	07/03/2016
Approved by	Dr. Kalaiselvan	PSO	<i>[Signature]</i>	07/03/2016

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07/03/2019

Title: Change Control Procedure

5.4.4.3 **Type -C:** Changes that are having significant impact on the quality attributes of the reports.

5.4.5 QA shall also assess and review the impact of change on related documents under section no 10.0, Part-II of "Change Control Request".

5.4.6 QA shall evaluate the impact of the proposed change and shall sign as change evaluated by in the "Change Control Request".

5.5 Part-III : Final Approval of Change Control By QA:

5.5.1 QA shall evaluate the proposed change as per the checklist mentioned in section no 11.0, Part-III of "Change Control Request as per Format no. **IPC/PvPI/QA/003-F01**.

5.5.2 QA shall evaluate the action points mentioned under section 11.0 of "Change Control Request" as per Format no. **IPC/PvPI/QA/003-F01**.

5.5.3 Finally Officer Incharge PvPI & Head-QA shall approve the proposed change and shall sign with date under section no 12.0 of "Change Control Request" as per Format no. **IPC/PvPI/QA/003-F01**.

5.6 Part-IV: Monitoring & Closing of Change Control:

5.6.1 If the change proposed is approved by Head-QA, QA shall indicate and inform the initiating section for executing the proposed change.

5.6.2 Intimation shall be given if required, by calling for a meeting with the initiating section head and concerned section heads as applicable.

5.6.3 The approved "Change Control Request" shall be sent to the initiating section for executing the proposed change.

5.6.4 After the execution of the proposed change the completed "Change Control Request" shall be returned to QA for archival.

5.6.5 QA section shall monitor and ensure the completion of change and record under section no 13.0 of "Change Control Request".

5.6.6 Closing of Change Control

	Name	Designation	Signature	Date
Prepared by	Saurabh K. Jain	Tech. Associate	Saurabh	07/03/2016
Reviewed by	Dr. Pawan K. Saini	SO	[Signature]	07/03/2016
Approved by	Dr. Kalai Selvan	PSO	[Signature]	07/3/2016

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5.6.6.1 On approval of change control, it is the responsibility of QA to verify that whether the change is implemented as per the proposal and verification shall be documented in section no 13.0 of the "Change control request" as per Format No. **IPC/PvPI/QA/003-F01.**

5.6.6.2 Head-QA shall approve the closing of change control after ensuring the completion of change along with the other related requirement implementation as described under section 13.0 of Change Control Request.

5.6.7 QA shall complete the "Change Control Log" as per Format No. **IPC/PvPI/QA/003-F02.**

5.7 QA shall compile and archive all executed forms of Change Control along with all supporting documents.

6.0 SAFETY AND PRECAUTIONS :

6.1 Do not use any SOP if it is not signed and issued by QA Personnel's or the authorized signatories.

6.2 Do not use adhesive tape or whitener on SOP.

6.3 Do not share the SOP information out side the organization.

7.0 **REFERENCES:** In house

8.0 ABBREVIATIONS:

CCR No. : Change Control Request number

QA : Quality Assurance

NCC : National Coordination Centre

PvPI : Pharmacovigilance Programme of India

9.0 ANNEXURE(s):

9.1 **Annexure I** Change Control Request Form **Format No.** IPC/PvPI/QA/003-F01

9.2 **Annexure II** Change Control Log **Format No.** IPC/PvPI/QA/003-F02

	Name	Designation	Signature	Date
Prepared by	<i>Saurabh K. Jain</i>	<i>Tech. Associate</i>	<i>Saurabh</i>	07/03/2016
Reviewed by	<i>Dr. Pawan K. Saini</i>	<i>SO</i>	<i>[Signature]</i>	07/03/2016
Approved by	<i>Dr. Kalaisekhar</i>	<i>PSO</i>	<i>[Signature]</i>	07/03/2016

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Dt. 8/3/16

**Annexure-I
CHANGE CONTROL REQUEST FORM**

Format No. IPC/PvPI/QA/003-F01-00

PART-I : INITIATION OF CHANGE CONTROL

(Section 1.0) Initiator Department Name/code		Date of Initiation	
		Change control request no. (CCR NO.)	

(Section 2.0) Change Requested for	<input type="checkbox"/> Documented procedure <input type="checkbox"/> Facility <input type="checkbox"/> Process <input type="checkbox"/> Software <input type="checkbox"/> Others Specify _____
--	--

(Section 3.0) Details of Change(s) (Proposed)	
--	--

Attach supporting document as applicable based on the change proposed

(Section 4.0) Reason for change (s)	
---	--

(Section 5.0) Documents Affected by the Change

S.No.	Document No.	Document Title	Effective Date
1			
2			
3			

(Section 6.0) Tentative date of Implementation	
---	--

(Section 7.0) Request for the document nature	<input type="checkbox"/> To be Amended <input type="checkbox"/> To be Cancelled								
	<table border="1"> <tr> <th>CHANGE INITIATED BY (Section Representative)</th> <th>AUTHORIZED BY (Head/ Authorized person)</th> </tr> <tr> <td>NAME</td> <td></td> </tr> <tr> <td>SIGN</td> <td></td> </tr> <tr> <td>DATE</td> <td></td> </tr> </table>	CHANGE INITIATED BY (Section Representative)	AUTHORIZED BY (Head/ Authorized person)	NAME		SIGN		DATE	
CHANGE INITIATED BY (Section Representative)	AUTHORIZED BY (Head/ Authorized person)								
NAME									
SIGN									
DATE									

	Name	Designation	Signature	Date	Page no
Prepared by	Saurabh K. Jain	Tech. Associate	Saurabh	07/03/2016	Page 1 of 4
Reviewed by	Dr. Pawan K. Saini	Se	[Signature]	07/03/2016	
Approved by	Dr. Kalaiselvan	PSO	[Signature]	7/3/16	

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**Annexure-I
CHANGE CONTROL REQUEST FORM**

Format No. IPC/PvPI/QA/003-F01-00

PART-II (A) CHANGE CONTROL CONSENT & REVIEW

(Section 8.0) Consent of other sections (write NA if not applicable)

Section Name/Code	Review Comments (Attach additional sheet for more details if required)	Change Accepted/ Not accepted	Reviewed by (Section Head/Deputy)

PART-II (B) CHANGE CONTROL ASSESSMENT BY QA

(Section 9.0) Level of change (Tick whichever is applicable)	Type-A: Minor changes who do not have any detectable impact on the quality attributes of the reports and having no regulatory impact.	<input type="checkbox"/>
	Type-B: Changes that are likely or may have minor impact on the quality attributes of the reports.	<input type="checkbox"/>
	Type -C: Changes that are having significant impact on the quality attributes of the reports.	<input type="checkbox"/>

(Section 10.0) QA Assessment /Comments:

	CHANGE EVALUATED BY (Representative of QA section)	CHANGE EVALUATED BY (Head of QA section)
NAME		
SIGN		
DATE		

	Name	Designation	Signature	Date	Page no
Prepared by	Sansrathi Jain	Tech. Associate	Sansrathi	07/03/2016	Page 2 of 4
Reviewed by	Dr Pawan K. Saini	SO	[Signature]	07/03/2016	
Approved by	Dr. Kalai Selvan	PSO	[Signature]	7/3/16	

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Annexure-I
CHANGE CONTROL REQUEST FORM

Format No. IPC/PvPI/QA/003-F01-00

PART-IV : MONITORING & CLOSING OF CHANGE CONTROL

(Section 13.0) Approval checklist

S.No.	Action	Check point		
1	Whether all applicable documents are revised, distributed and implemented.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
2	All the superceded documents are retrieved, made obsolete and destroyed.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
3	The change is implemented as proposed.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
5.	Training is completed and evaluated to all concerned.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
6.	Others , Specify _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA

	CHANGE MONITORED BY (Representative of QA Section)	CHANGE CLOSED BY (Head-Quality Assurance)
NAME		
SIGN		
DATE		

	Name	Designation	Signature	Date	Page no
Prepared by	Saurabh K. Jain	Tech Associate	Saurabh	07/03/2016	Page 4 of 4
Reviewed by	Dr. Parwan K. Saini	SO	[Signature]	07/03/2016	
Approved by	Dr. Kalaiselvan	PSO	[Signature]	7/3/16	

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Annexure-II
CHANGE CONTROL LOG

Format No. IPC/PvPI/QA/003-F02-00

S. No	Date	Issued by QA (Sign/date)	Issued to (Sign/date)	CCR No.	Status	Date of closing	Remarks

Prepared by	Name	Designation	Signature	Date
Prepared by	Susobh K. Jais	Tech. Associate	<i>[Signature]</i>	07/03/2016
Reviewed by	Dr. Pawan K. Saini	So	<i>[Signature]</i>	07/03/2016
Approved by	Dr. Kalaisevaran.v	PSO	<i>[Signature]</i>	7/3/16