| | | | |
|---|---|---|---|
| | **INDIAN PHARMACOPOEIA COMMISSION**<br>**National Coordination Centre-Pharmacovigilance Programme of India** | | |
| | **STANDARD OPERATING PROCEDURE** | **Page No.** | **1 of 10** |
| | | **SOP No.** | **IPC/PvPI/QA/001** |
| | **Division** All division | **Revision No.** | **01** |
| | **Effective Date** 01/11/2016 | **Review Date** | 31/10/2019 |
| **Title:** SOP for making SOP | | | |

## 1.0 OBJECTIVE

1.0 To lay down the procedure for the preparation of SOP, Format, Numbering, Initiation, Review, Approval, Implementation, Distribution, Retrieval and Control of Standard Operating Procedures.

1.1 This SOP describes how to prepare detailed written instructions for the function of PvPI related activities.

## 2.0 SCOPE

This SOP shall be applicable to all SOPs of Pharmacovigilance Programme of India.

## 3.0 RESPONSIBILITY

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

3.2 All the Officers and Division-Incharge shall ensure that this parent SOP has been reflected in the division.

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

## 4.0 ACCOUNTABILITY

Officer-in-charge - Pharmacovigilance Programme of India

## 5.0 PROCEDURE

5.1 The person who performs / supervises the activities in consultation with the division Incharge or after a group discussion on the matter shall prepare the SOP.

5.2 All the SOPs shall be generated by computer on the format known as **"Standard Operating Procedure" (Ref. Format No.IPC/PvPI/QA/001-F01).** SOP is

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saurabh Kr Jain | PV Associate | Saurabh | 19/10/2016 |
| **Reviewed by** | Dr. Pawan K. Saini | Scientific officer | | 25/10/2016 |
| **Approved by** | Dr. Kalaiselvan | PSO | | 26/10/2016 |

mainly in three parts, viz header, footer, front page/ body. The contents of each part of SOP shall be as follows:

5.2.1 **Header:** The header shall provide the following details as against the alphabet show in (Format No.IPC/PvPI/QA001-F01).

**a) Organization logo** -The logo of the institute shall be placed.

**b) Name of the Organization**

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre-Pharmacovigilance Programme of India

**c) Name of the document**

Standard operating procedure shall be written in this cell.

**d) Page no.**

Page no. indicates serial no. of pages in "X of Y" pattern.

**e) SOP No.**

SOP no. shall be alphanumeric unique number.

**f) Division**

Specify particular division of the PvPI (if any) where the SOP shall be applicable. If any specific division does not exist then word "All division" shall be written under this column.

**g) Version no. or Revision no.**

Version no/Revision no shall be numeric, consisting of maximum two digits.

**h) Effective Date:** DD/MM/YYYY

The effective date is the date when the contents of the SOP become operative, after training of the concerned personnel on the SOP.

**i) Review Date:** DD/MM/YYYY

SOP shall be reviewed every three years. If there is no change, then the same SOP shall be implemented for next three years.

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| Prepared by | Saurabh Kr Jain | PV Associate | Saurabh | 19/10/2016 |
| Reviewed by | Dr. Pawan K. Saini | S.O. | | 25/10/2016 |
| Approved by | Dr. Kalaiselvan | PSO | | 26/10/2016 |

If any major change impact on quality, SOP shall be reviewed before three years as per change control procedure (SOP No. IPC/PvPI/QA/003)

**j) Title:** Indicate heading of the SOP.

**Note:** In case of SOP annexure/ format, header shall contain organization logo, name of the organization, title, format no. & Page no. (If required)

5.2.2 **Footer:** The following information shall be appearing in the "Footer" of SOP format:

5.2.2.1 **Name:** all pages

5.2.2.2 **Designation:** all pages

5.2.2.3 **Signature:** all pages

5.2.2.4 **Date:** DD/MM/YYYY all pages

5.2.2.5 **Prepared by:** all pages

The personnel supervising the particular activity/operation, or who is directly involved in the activity of their concerned division shall sign below the column marked as "**Prepared by**".

5.2.2.6 **Reviewed by:** all pages

The Quality Manager/Technical Manager & Division Incharge of the user division shall review the adequacy of the procedure and shall sign below in the column marked as "**Reviewed by**".

5.2.2.7 **Approved by:** all pages

All the SOPs of the Organization shall be approved by Director/Head/ Incharge PvPI and shall sign as "**Approved by**".

5.2.3 **Body:** The SOP shall be prepared in the sequence as follows:

5.2.3.1 **Objective:** An overview of the intent of the SOP shall be briefly mentioned here.

5.2.3.2 **Scope:** Shall specify the boundary limits for the application of the SOP.

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| Prepared by | Saurabh Kr. Jain | PV Associate | Saurabh | 19/10/2016 |
| Reviewed by | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| Approved by | Dr. Kalaiselvan | PSO | | 26/10/2016 |

5.2.3.3 **Responsibility:** Shall specify the personnel responsible to prepare the SOP and ensure the implementation & compliance. (viz., who performs the procedure, and who ensures that it is performed correctly.)

5.2.3.4 **Accountability:** Shall specify the personnel overall responsibilities for implementation of the SOP & accountability of work.

5.2.3.5 **Procedure:** Procedure shall provide the step wise actions to be taken for implementation of the SOP.

5.2.3.6 **Safety & Precautions:** Shall be mentioning the salient features of operation, behaviour precaution and safety measures. (If require)

5.2.3.7 **References:** List out the references (if any) used during the preparation of SOP else mention In-house, wherever applicable.

5.2.3.8 **Abbreviation:** List out all the abbreviations used in the SOP and their elaboration.

5.2.3.9 **Annexure:** In all SOPs, wherever applicable, the format shall be attached as Annexure.

5.3 **Formatting of the SOP:**

5.3.1 The title and text shall be clearly understood and written in clear and simple English so that everyone who carries out a particular activity/operation/function able to performs/ in the clear way.

5.3.2 The language used shall be in directive form that gives step-wise instruction, the words like "shall", "must" are to be used rather than "should" , "may" or "might' to the possible extent.

5.3.3 It is recommended (but not limited to) that all the characters of SOP text matter shall be in "Times New Roman" and with font size '12'. All the characters in SOP header and footer shall be in "Times New Roman". Format numbering shall be taken in Font '12'& bold. The line spacing shall be 1.5.

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| Prepared by | Sawash Kv. Jain | Pv Associate | Sawash | 19/10/2016 |
| Reviewed by | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| Approved by | Dr. Kalaiselvan | PSO | | 26/10/2016 |

5.3.4 The page setting and text shall conform to the following specification:

| S.No | Contents | Specification |
|---|---|---|
| 1 | Paper size | A4 Size |
| 2 | Language | English |
| 3 | Font Type | Times New Roman |
| 4 | Font Size | 12 point |
| 5 | Line Spacing | 1.5 |
| 6 | Printing | One Side |

5.3.5 Text shall be divided into logical divisions numbered 1.0, 2.0, 3.0 etc. whereas 1.0 relates to Objective, 2.0 Scope etc. Type the division in Uppercase (Capital) letters & bold.

5.3.6 These division shall be sub-divided in to logical division 1.1, 1.2 etc. where required, these sub-divisions may further be sub divided as 1.1.1, 2.1.1 etc. Bullets can be used instead of use of numeric system.

5.3.7 The Name, Designation, Signature and Date shall be entered in blue ink pen only. Effective date and Review date shall be handwritten.

5.4 In case of a new SOP, follow the procedure for reviewer comment, as below:

5.4.1 The SOP draft copy duly stamped as **"DRAFT COPY"** (in Red `ink, on top right hand corner, first page only) along with signature/date and shall be circulated to all the related operational groups to ascertain the operational suitability of the SOP and a time frame of two week shall be given for the feedback.

5.4.2 Circulate the draft copy of SOP along with **"Document Review Comment Format" (Ref: Format no. IPC/PvPI/QA/001-F02)** to all concern staff members for review.

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saulabh Kr. Jain | Pr Associate | Saulabh | 19/10/2016 |
| **Reviewed by** | Dr. Pawan K. Saini | S.O. | | 25/10/2016 |
| **Approved by** | Dr. Kalaiselvan | PSO | | 26/10/2016 |

5.4.3 QA shall incorporate all the necessary changes suggested as per review comments in the SOP and file the SOP review comment and Draft copy.

5.4.4 QA shall take out the final draft of the SOP and send it to Officer Incharge for final review along with **"Document Review Comment Format".**

5.4.5 Officer In charge shall ensure the regulatory compliance of the procedure and approve the **"Document Review Comment Format".**

5.4.6 Take out the final print of SOP in standard A4 size paper in a prescribed format i.e. **(Ref: Format No. IPC /PvPI/QA/001-F01).**

5.5 **Document Identification/ Indexing system:**

5.5.1 **Level - 1** Document i.e. Quality Manual shall be indexed Numeric-alphabetically.

**IPC/PvPI/QM** Where,

IPC- Indian Pharmacopoeia Commission

PvPI- Pharmacovigilance Programme of India

QM- Quality Manual

XX- Version no. or Revision no.

e.g. In case new quality manual express as **IPC/PvPI/QM & Version : 00**

5.5.2 **Level – 2** Documents i.e. Standard Operating Procedure shall be indexed as follows:

**IPC/PvPI/XX/YYY** Where,

IPC- Indian Pharmacopoeia Commission

PvPI- Pharmacovigilance Programme of India

XX- Stand for specific Division /Field code as under:

- MvPI- stands for Materiovigilance programme of India
- NHPs – stands for National Health Programmes
- MAHs- stands for Marketing Authorization Holders
- IC- stands for International Cooperation

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| Prepared by | Santosh Kv. Jain | PV Associate | Santosh | 19/10/2016 |
| Reviewed by | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| Approved by | Dr. Kalaiselvan | PSO | | 26/10/2016 |

- IT- stands Information Technology
- SD- stands for Signal Detection
- BR- stands for Benefit- Risk Assessment
- QA-stands for Quality Assurance
- QC-stands for Quality Control
- PCP- stands for Promotion, Communication & Publication
- TE- stands for Training and Education
- HR- stands for Human Resource
- MISC- stands for Miscellaneous

YYY- stands for three Digit Serial Number

For example: IPC/PvPI/QA/001

5.5.3 **Level – 3** Documents i.e. Formats or Annexure shall be indexed as follows:

**XW- FXX-XY**

Where, XW- stands for SOP No.

XX- stands for Two Digit Serial Number

XY- stands for Two Digit revision Number

For example: IPC/PvPI/QA/001-F01-00

5.5.4 **Level – 4** Documents i.e. Record Files, Record Registers, Logbooks, Worksheet, Charts, Drawings, Plans, Check list etc. shall be indexed as per their usage.

**XW/ XX/ XY/XZ**

Where, XW is stands for:

- RF- stands for Record File
- RG -stands for Register
- LOG- stand for Logbook

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| Prepared by | Saurabh Kr Jain | PV Associate | Saurabh | 19/10/2016 |
| Reviewed by | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| Approved by | Dr. Kalai Selvan | PSO | | 26/10/2016 |

- WS- stands for Work sheet
- CT- stands for Charts
- DW- stands for Drawing
- CL- stands for Check List
- XX- stands for Division code/ specific Field
- XY- stands for specific Sub division/Subject of file/Code etc.(Free text)
- XZ- stands for three digit serial number

For example: RF/QA/SOP/001

5.5.5 **Master list of record file:** All division shall prepare the list of record file as per Format No.IPC /PvPI/QA/001-F08.

Document numbering system:

**MLD/ XX/ RF/YYY**

**XX-** stands for code

For example MLD/HR/RF/001

5.6 **Document Distribution and Issue control:**

5.6.1 All original signed copies of SOPs in standard A4 size should be stamped as **"MASTER COPY"** in Green ink along with sign/date at top middle centre of all the pages of the SOP and shall be archived in the Quality Assurance Division.

5.6.2 Further photocopy of **"MASTER COPY"** shall be taken in plain A4 size paper and stamped as **"CONTROLLED COPY"** in blue ink along with signature/date at right top corner of all the pages of SOP and distribute to the division by using **"ISSUED COPY No...."** in blue ink at bottom centre of front page only (If Require).

5.6.3 Division Incharge shall have to indent the number of copies required for the division reference, user point display, other file copy, as applicable in the prescribed format as per **"Document Requisition Form" (Ref: Format No. IPC/PvPI/QA/001-F04)**.

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saulash Kr. Jain | PV Associate | Saulash | 19/10/2016 |
| **Reviewed by** | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| **Approved by** | Dr. Kalaiselvan | PSO | | 26/10/2016 |

5.6.4 Document like SOP the Controlled copy issued as per **"Document Distribution, Retrieval and Destruction Record" (Ref: Format No.IPC/PvPI/QA/001-F03).**

5.6.5 Photocopying of any SOP shall be prohibited, unless written permission is obtained from the Officer Incharge / Quality Manager & Technical Manager. If need arises for an additional copy of SOP, the concerned Division Incharge shall make request to the Officer Incharge, Quality Manager & Technical Manager.

5.6.6 Any SOP issued for non-operational or outside the organizational use shall be photocopy of **"MASTER COPY"** and stamped as **"UNCONTROLLED COPY"** in blue ink at right top corner along with signature/date at every page.

5.6.7 Any SOP issued for display purpose only shall be stamped as **"DISPLAY COPY"** in blue ink at right bottom corner along with signature/date at front page only.

5.6.8 In case any SOP shall be revised, that time old SOP shall be stamped as **"OBSOLETE COPY"** in red ink at impress the cross stamp on middle of the all page along with signature/date at every page.

5.6.9 QA (IPC-NCC-PvPI) stamp in green colour shall be used as per the requirement.

5.6.10 In case of any Cancellation of SOP shall be stamped as **"CANCELLED COPY"** in red ink at impress the cross stamp on middle of the all page.

5.7 **Revision history detail:** Any changes in the SOP shall be recorded in the revision history annexure **(Ref: Format No.IPC/PvPI/QA/001-F06).**

5.8 **Log Book Issue Format:** All log books shall be issued to the concern division as per Format No.IPC/PvPI/QA/001-F01-09.

## 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.

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| Prepared by | Saurabh Kr Jain | PV Associate | Saurabh | 15/10/2016 |
| Reviewed by | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| Approved by | Dr. Kaliselvan | PSO | | 26/10/2016 |

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**

| | | |
|---|---|---|
| SOP | : | Standard Operating Procedure |
| IPC | : | Indian Pharmacopoeia Commission |
| PvPI | : | Pharmacovigilance Programme of India |
| NCC | : | National Coordination Centre |
| QA | : | Quality Assurance |
| ICSRs | : | Individual Case Safety Report |

**9.0 ANNEXURE(s):**

Annexure I : Standard operating procedure Format No. IPC/PvPI/QA/001-F01

Annexure II : Document review comment Format No. IPC/PvPI/QA/001-F02

Annexure III : Document distribution, retrieval and destruction record Format No. IPC/PvPI/QA/001-F03

Annexure IV: Document requisition form: Format No. IPC/PvPI/QA/001-F04

Annexure V : List of Stamps with Impression: Format No. IPC/PvPI/QA/001-F05

Annexure VI : List of Revision history detail: Format No. IPC/PvPI/QA/001-F06

Annexure VII: List of division wise distribution of SOP Issued copy no detail Format No. IPC/PvPI/QA/001-F07

Annexure VIII: Master list of record file: Format No.IPC /PvPI/QA/001-F08

Annexure IX: Log Book Issue Format: Format No.IPC/PvPI/QA/001-F01-09

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| Prepared by | Saurabh Kr Jain | PV Associate | Saurabh | 19/10/2016 |
| Reviewed by | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| Approved by | Dr. Kalaiselvan | PSO | | 26/10/2016 |

| | |
|---|---|
| सत्यमेव जयते IPC | **INDIAN PHARMACOPOEIA COMMISSION**<br>**National Coordination Centre-Pharmacovigilance Programme of India**<br>**Annexure-I**<br>**FORMAT FOR STANDARD OPERATING PROCEDURE** |

**Format No. IPC/PvPI/QA/001-F01-01**

| | | | | |
|---|---|---|---|---|
| **a** | **b** | | | |
| | **c** | | **d** | |
| | | | **e** | |
| | **f** | | **g** | |
| | **h** | | **i** | |
| **j** | | | | |

**Body**

**1.0 OBJECTIVE**

**2.0 SCOPE**

**3.0 RESPONSIBILITY**

**4.0 ACCONTABILITY**

**5.0 PROCEDURE**

**6.0 SAFETY AND PRECAUTION**

**7.0 REFRENCES**

**8.0 ABBREVIATION**

**9.0 ANNEXURE**

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | | | | |
| **Reviewed by** | | | | |
| **Approved by** | | | | |

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saurabh Kr. Jain | PV Associate | Saurabh | 15/10/2016 |
| **Reviewed by** | Dr. Pawan K. Saini | S.O. | | 25/10/2016 |
| **Approved by** | Dr. Ilcalaiselvan | PSO | | 26/10/2016 |

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Sign PW Dt 26/10/2016

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

**Annexure-II**
**DOCUMENT REVIEW COMMENT FORMAT**

**Format No. IPC/PvPI/QA/001-F02-01**

| | | | |
|---|---|---|---|
| **Title** | | | |
| **Document No.** | | **Division** | |

| S. No. | Comment | Reviewed by |
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*** Attach details (if applicable)**

**QA assessment:** Feasible: Yes ☐ No ☐

**(QA-Representative)**

**(Sig/Date)**

**(Officer Incharge -PvPI )**

**(Sig/Date)**

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saurabh Kr Jain | PV Associate | Saurabh | 19/10/2016 |
| **Reviewed by** | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| **Approved by** | Dr. V. Kalaiselvan | PSO | | 26/10/2016 |

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Sign. ..... Dt. 26/10/2016

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

**Annexure-III**
**DOCUMENT DISTRIBUTION,RETRIEVAL AND DESTRUCTION RECORD**

**Format No. IPC/PvPI/QA/001-F03-01**

| **Document No.** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Title** | | | | | | | | |
| **Controlled Copy No.** | **Issue Details** | | | **Retrieval details (QA)** | | **Destruction details (QA)** | | **Remarks** |
| | **Issued to (Division Code)** | **Issue by/on** | **Received by/on** | **Returned by/on** | **Received by/on** | **Destroyed by/on** | **Verified by/on** | |
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| | **Name** | **Designation** | **Signature** | **Date** |
|---|---|---|---|---|
| **Prepared by** | Saurabh Kr Jain | PV Associate | Saurabh | 19/10/2016 |
| **Reviewed by** | Dr Pawan K. Saini | S.O. | PKS | 25/10/2016 |
| **Approved by** | Dr. Kalaiselvan | PSO | KS | 26/10/2016 |

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INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme of India

## Annexure-IV
## DOCUMENT REQUISITION FORM

Format No. IPC/PvPI/QA/001-F04-01

| | |
|---|---|
| **Title** | **Document No.** |
| **No of copies required** | **Controlled / Uncontrolled copy** |
| **Division** | |
| **Reasons for request:** | |
| **Initiated by:** | **Sign / Date:** |
| **DOCUMENT REQUEST APPROVAL** | |
| **The request is Approved or Rejected :** | |
| **By Name:** _____ | **Signature and date:** _____ |
| **No. of copies issued :** | |
| **By: Name:** _____ | **Signature and Date:** _____ |
| **No. of copies received By: Name:** _____ | **Signature and Date:** _____ |

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saurabh Kr Jain | PV Associate | Saurabh | 19/10/2016 |
| **Reviewed by** | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| **Approved by** | Dr. Kalaiselvan | PSO | | 26/10/2016 |

MASTER COPY
Sign..... Dt.....

CONTROLLED COPY
Sign..... Dt.....

| | INDIAN PHARMACOPOEIA COMMISSION<br>National Coordination Centre-Pharmacovigilance Programme of India | Page No. |
|---|---|---|
| सत्यमेव जयते<br>IPC | Annexure-V<br>LIST OF STAMPS WITH IMPRESSION | 1 of 2 |

**Format No. IPC/PvPI/QA/001-F05-01**

| SR. NO. | NAME OF THE STAMP | INK USE | LOCATION ON PAGE | IMPRESSION OF STAMP |
|---|---|---|---|---|
| 01 | DRAFT COPY | RED | On top right hand corner of front page only | |
| 02 | MASTER COPY | Green | Middle Centre top of page | |
| 03 | CONTROLLED COPY | BLUE | Right top corner | |
| 04 | ISSUED COPY No..... | BLUE | On bottom centre of front page only | |
| 05 | UNCONTROLLED COPY | BLUE | Right top corner | |

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saurabh Ku Jain | Pv Associate | Saurabh | 19/10/2016 |
| **Reviewed by** | Dr. Pawan K. Saini | S.O | | 25/10/2016 |
| **Approved by** | Dr. Kalaiselvan | PSO | | 26/10/2016 |

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Sign ... Dt 25/10/2016

CONTROLLED COPY
Sign ... Dt 26/10/2016

| | INDIAN PHARMACOPOEIA COMMISSION<br>National Coordination Centre-Pharmacovigilance Programme of India | Page No. |
|---|---|---|
| सत्यमेव जयते<br>IPC | Annexure-V<br>LIST OF STAMPS WITH IMPRESSION | 2 of 2 |

**Format No. IPC/PvPI/QA/001-F05-01**

| | | | | |
|---|---|---|---|---|
| 06 | DISPLAY COPY | BLUE | Right bottom corner | |
| 07 | CANCELLED COPY | RED | Impress the cross stamp on middle of the front page | |
| 08 | OBSOLETE COPY | RED | Impress the cross stamp on middle of the front page | |
| 09 | QA (IPC-NCC-PvPI) | GREEN | According to requirements | |

| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saurabh Kr Jain | PV Associate | Saurabh | 19/10/2016 |
| **Reviewed by** | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| **Approved by** | Dr. Kakiselvan | PSO | | 26/10/2016 |

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

**Annexure-VI**
**SOP REVISION HISTORY DETAIL**

**Format No. IPC/PvPI/QA/001-F06-01**

| SOP No. | | | |
|---|---|---|---|
| **S. No.** | **SOP Revision No.** | **Effective Date** | **Reason for Revision** |
| | | | |
| | | | |
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| | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Saurabh Ku. Jain | PV Associate | Saurabh | 19/10/2016 |
| **Reviewed by** | Dr Pawan K. Saini | S.O. | | 25/10/2016 |
| **Approved by** | Dr. V. Kalaiselvan | PSO | | 26/10/2016 |

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| | |
|---|---|
| | **INDIAN PHARMACOPOEIA COMMISSION**<br>**National Coordination Centre-Pharmacovigilance Programme of India** |
| | **Annexure-VII**<br>**LIST OF DIVISION WISE DISTRIBUTION OF DOCUMENT ISSUED COPY No DETAIL** |

**Format No. IPC/PvPI/QA/001-F07-01**

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