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INDIAN PHARMACOPOEIA COMMISSION
 National Coordinating Centre Pharmacovigilance Programme of India

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 Date: 26/08/2016

STANDARD OPERATING PROCEDURE

Page No.	1 of 3
SOP No.	IPC/PvPI/QA/019
Revision No.	00
Review Date	31/08/2019

Section	All sections
Effective Date	01/09/2016

Title: SOP for Archiving of documents

1.0 OBJECTIVE

1.1 To lay down a procedure for archival of essential documents related to PvPI.

2.0 SCOPE

2.1 This SOP shall be applicable to all 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 implementation of this SOP.

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

4.0 ACCOUNTABILITY

4.1 Officer In charge – Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 All essential documents shall be archived i.e. Quality documents, Technical documents and HR related documents etc.

5.2 All essential documents shall be retained for at least 3 years after the completion of work or for a longer period where so required by other applicable requirements e.g. ADR reporting form and other source documents related to Patient.

5.3 Documents shall be stored in a way that preserves their integrity and readability and restricts access to authorized individuals only.

5.4 Based on the request of the staff, auditor, committee, or regulatory authority, the documents shall be available for direct access prior permission of officer in-charge.

	Name	Designation	Signature	Date
Prepared by	Sansabh Kr Jain	Pr Associate		24/08/2016
Reviewed by	Dr Pawan K. Saini	Scientific officer		25/08/2016
Approved by	Dr. Kalaise Wan	PSO		26/08/2016



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Any transfer of ownership of the data or of the documents shall be documented. The new owner shall assume responsibility for archiving.

- 5.5 Access to archives shall be restricted to the named individuals responsible for the archives.
- 5.6 Any alteration of records shall be traceable. All essential documents shall be legible and accurate.
- 5.7 All essential documents shall be boxed and labelled with the specific title with reference number and the date they were archived, and date to be destroyed (if applicable).
- 5.8 The department administrator (or equivalent) shall maintain a record of details of archived documents. Records shall include details of the Quality/technical and others, archiving location and person authorized to access these documents, the date they were archived, and date to be destroyed (if applicable).
- 5.9 The documents shall be archived in an appropriate room or locked cupboard (consider fire protection without water sprinkler systems, water protection, for humid conditions, pests etc). The room or cupboard shall be secure with access only by authorised personnel. If appropriate, an external archive site shall be utilized.

6.0 SAFETY AND PRECAUTION (If Any)

- 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
Prepared by	Saurabh Kr Jain	Pv Associate		24/08/2016
Reviewed by	Dr Pawan K Saini	S.O.		25/08/2016
Approved by	Dr. Kalisehwar V	PSO		26/08/2016



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7.0 REFERENCES In-house

8.0 ABBREVIATION

ADR	:	Adverse Drug Reaction
SOP	:	Standard Operating Procedure
NCC	:	National Coordinating Centre
PvPI	:	Pharmacovigilance Programme of India

9.0 Annexure

Annexure I	:	Archival Record (Format No. IPC/PvPI/QA/019-F01)
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	Name	Designation	Signature	Date
Prepared by	Saunabh Kr Jadhav	Pv Associate		24/08/2016
Reviewed by	Dr Pawan K. Saini	S.O.		25/08/2016
Approved by	Dr. V. Kalaniselvan	PSO		26/08/2016

