![emblem]	**INDIAN PHARMACOPOEIA COMMISSION** National Coordinating Centre-Pharmacovigilance Programme of India			
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Title: SOP for Data integrity

1.0 OBJECTIVE

1.1 To lay down a procedure for operation, maintenance, security & backup of computerized system meant for storage & data integrity.

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 IT section shall be responsible for implementation of this SOP.

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

4.0 ACCONTABILITY

4.1 Officer In charge – Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 General criteria

5.1.1 The computer installation shall be given due consideration in terms of physical location of computer hardware, peripheral components and communication equipments etc.

5.1.2 The computer shall be handled by designated computer operator professionally qualified and appropriately trained and experienced in operational and maintenance criteria.

5.1.3 All type of software shall be validated before its installation in computer with their specific application.

	Name	Designation	Signature	Date
Prepared by	DEEPAK MALIK	IT-Associate	Malik	24/08/2016
Reviewed by	Dr Pawan K. Saini	Scientific officer		26/08/2016
Approved by	Dr. Kalaiselvan	PIO		26/08/2016

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5.1.4   Any change in the computer system shall be brought out with prior approval from officer in-charge.

5.1.5   Any change initiated by IT personnel shall suppose to retain the integrity of already stored data and to avoid hard disk crash or software malfunctioning in central server.

5.1.6   Backup copies of all data shall be maintained to allow for the recovery of the system in case of any failure to maintain the integrity of the data.

5.1.7   The integrity of computer system related to generation and application of data shall be password protected in order to avoid any loss/damage or change in original data and shall be secured by authorized access only.

5.1.8   The person authorized for the handling the provided computer system shall also be responsible for the storage and maintenance of the data.

5.1.9   Any change or recovery procedure necessary to revalidate the system shall be able to entail any change to hardware or software pertaining to system.

5.2   Information sent or received via e-mail

5.2.1   The e-mail received at NCC-PvPI shall be monitored on daily basis.

5.2.2   Printout of all the relevant e-mails shall be taken and handed over to the concerned person for taking appropriate action.

5.2.3   All the information shall be stored in the hard disk to retain the data for a long period of time.

5.2.4   The information shall be reviewed periodically and the undesired e-mail/correspondence shall be deleted after consultation with the concern person.

	Name	Designation	Signature	Date
Prepared by	DEEPAK MALIK	IT-ASSOCIATE	Malik	24/08/2016
Reviewed by	Dr. Pawan K. Sahni	S.O.		25/08/2016
Approved by	Dr. Kalaiselvan	PtO		26/08/2016

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

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

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5.3 Generation of data after acquiring, its processing, recording, reporting, storing and its retrieval

5.3.1 All documents i.e. quality manual, standard operating procedures, formats, tables, lists etc. shall generated electronically by using IT tool.

5.3.2 Hard copies shall be generated for all these prepared documents (if required).

5.3.3 These documents are electronically generated through a person with designated authority for the same. The data generated by means of direct computer input is identified at the time of entry by the person designated for the same.

5.3.4 All the data shall be stored in the specific folder for its easy retrieval and its integrity and confidentiality shall be ensured.

5.3.5 The designated person shall authorize to make amendment in the prepared document and the hard copy shall be generated for that amended document.

5.3.6 All these documents shall be stored, password protected with the knowledge of IT and authorized person only.

5.3.7 The password shall be changed at fixed interval of time with the consent of officer in-charge to avoid unauthorized access.

5.3.8 Besides obtaining hard copies of all these documents, the backup is additionally generated in compact disk/hard disk depending upon the quantum of generated data.

5.3.9 The access to offline storage device or server shall be permitted only to the authorised personnel so that the confidentiality and security of data shall be maintained.

5.4 Nondisclosure agreement

Nondisclosure agreement shall be signed by each employee working under the PvPI to protect the confidential information i.e.; user name, password details of software and any Pharmacovigilance data of ADR monitoring centres under PvPI.

	Name	Designation	Signature	Date
Prepared by	DEEPAK MALIK	IT-Associate	Malik	24/08/2016
Reviewed by	Dr Pawan K. Sachu	S.O.		25/08/2016
Approved by	Dr. V. Kalaiselvan	PJo		26/08/2016

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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.

7.0 REFRENCES : In-house

8.0 ABBREVIATION

ADR : Adverse Drug Reaction

SOP : Standard Operating Procedure

NCC : National Coordinating Centre

AMC : Adverse Drug Reaction Monitoring Centre

PvPI : Pharmacovigilance Programme of India

9.0 Annexure

Annexure I : Nondisclosure agreement (Format no. IPC/PvPI/IT/001-F01)

	Name	Designation	Signature	Date
Prepared by	DEEPAK MALIK	IT-Associate	Malik	24/08/2016
Reviewed by	Dr Pawan K. Saini	S.O.		25/08/2016
Approved by	Dr. V. Kalaiselvan	PIO		26/08/2016

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre-Pharmacovigilance Programme of India

Annexure-I

Nondisclosure - Agreement

Format No. IPC/PvPI/IT/001-F01-00

To,

Dr. G. N. Singh,

Secretary-cum-Scientific Director,

Indian Pharmacopoeia Commission,

Sector-23, Raj Nagar, Ghaziabad

Date:

I _____ agree at all times during the term of my employment and thereafter, I will not disclose or make available to anyone of the confidential information i.e.; user name, password details of Vigiflow and any Pharmacovigilance data of ADR monitoring centres under Pharmacovigilance Programme of India.

Any breach of the above will result in punitive measures or the right to may expose me to a suit for damage in a court of law.

Name of the ADR Monitoring Centre with full Address:

(   )   (   )

Name of Pharmacovigilance Associate   Name of the Coordinator

Signature   Signature

	Name	Designation	Signature	Date
Prepared by	DEEPAK MALIK	IT-Associate	Malik	24/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		26/08/2016
Approved by	Dr. V. Kalaiselvan	PIO		26/08/2016