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INDIAN PHARMACOPŒIA COMMISSION
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National Coordination Centre-Pharmacovigilance Programme of India

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		SOP No.	IPC/PvPI/QA/002
Section	All section	Revision No.	00
Effective Date	01/02/2016	Review Date	31/01/2019

Title: Procedure for Specimen signature

1.0 OBJECTIVE

1.1 To lay down the procedure for maintaining the Specimen signature record of employees all the sections at NCC-PvPI.

2.0 SCOPE

2.1 This SOP shall be applicable to all sections of NCC-PvPI.

3.0 RESPONSIBILITY

- 3.1 The personnel's engaged in the PvPI activity shall be responsible for adhering to this SOP.
- 3.2 HR section shall be responsible for maintain the specimen signature record .
- 3.2 Quality-Manager/Technical-Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

4.1 Officer Incharge - Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 Specimen signature is a Signature of an employee to proof authenticity of a person who is signing the documents. Specimen signatures shall provide documentary evidence for signing the particular documents and performing particular jobs.

	Name	Designation	Signature	Date
Prepared by	Saurabh K Jain	Tech-Associate	[Signature]	19/01/2016
Reviewed by	Dr. Parvati K. Bainsi	Scientific officer	[Signature]	20/01/2016
Approved by	[Signature] Dr. Kalishen	PS O	[Signature]	20/01/2016

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- 5.2 Specimen signature shall provide a traceability of the documents signed by that particular employee.
- 5.3 Specimen signature of each & every employee, who is responsible for signing the documents, shall be maintained.
- 5.4 Specimen signature shall be taken from all the employees at the time of joining and shall be updated whenever a new employee is joining the organization.
- 5.5 Employee shall provide his/her initial as well as full signatures for specimen signatures record along with the details like name of employee, designation & date of joining.

(Refer to Annexure I : Format no. IPC/PvPI/QA/002-F01)

- 5.6 Employee shall have to use the signature as per specimen signature record for signing the documents (Note: Specimen signatures can be change with prior approval of Officer Incharge).
- 5.7 When any employee resigns or transfers to other location, record of specimen signatures (Refer to Annexure I) shall be updated in the remark column by writing resigned or transferred & mention the date of relieving.
- 5.8 An updated original copy of the specimen signature list shall be maintained by the HR section.

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 outside the organization.

	Name	Designation	Signature	Date
Prepared by	<i>Suresh K. Jain</i>	<i>Tech. Associate</i>	<i>Suresh</i>	<i>19/01/2016</i>
Reviewed by	<i>Dr. Pawan K. Saini</i>	<i>S.O.</i>	<i>PWS</i>	<i>20/01/2016</i>
Approved by	<i>Dr. Kalai Selvan</i>	<i>PSO</i>	<i>KS</i>	<i>20/1/2016</i>

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7.0 REFERENCES: In house

8.0 ABBREVIATIONS

- SOP : Standard Operating Procedure
NCC : National Coordination Centre
PvPI : Pharmacovigilance Programme of India
HR : Human Resource
QA : Quality Assurance

9.0 ANNEXURE(s):

Annexure I : Specimen signature Record Format No. IPC/PvPI/QA/002-F01

	Name	Designation	Signature	Date
Prepared by	Saurabh Kr Jain	Tech Associate	Saurabh	19/01/2016
Reviewed by	Dr Pawan K. Saini	S.O.	MW	20/01/2016
Approved by	Dr. Kalu Sehwan	PSO	Ky	20/01/2016



Format No. IPC/Pv/PI/QA/002-F01-00

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Annexure-I

SPECIMEN SIGNATURE RECORD

S. No.	Name of Employee	Designation	Signature		Date of Joining	Date of Relieving	Remarks
			Initial	Full			

	Name	Designation	Signature	Date
Prepared by	Sankesh Kr. Jain	Tech. Associate	<i>Sankesh</i>	19/01/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>P.K. Saini</i>	20/01/2016
Approved by	Dr. Kalraj Selvan	P.S.O.	<i>Uy</i>	20/01/2016

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