



<b>STANDARD OPERATING PROCEDURE</b>		Page No.	1 of 2
		SOP No.	IPC/PvPI/IT/002
Division	Information Technology	Revision No.	00
Effective Date	15/11/2016	Review Date	14/11/2019

**Title: SOP for Vigiflow login distribution & Retrieval procedure**

**1.0 OBJECTIVE**

To lay down a procedure for Vigiflow login distribution & retrieval.

**2.0 SCOPE**

This SOP shall be applicable to the personnel working at NCC/AMCs of PvPI.

**3.0 RESPONSIBILITY**

- 3.1 The designated personnel at NCC/AMCs of PvPI shall be responsible for adhering to this SOP.
- 3.2 IT division of NCC-PvPI 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 IT division of NCC-PvPI shall provide Vigiflow Login details (user id and password) through email to the coordinator and Pharmacovigilance Associate of AMCs and personnel at NCC-PvPI after signing Non-Disclosure Agreement of PvPI as per Format No. IPC/PvPI/IT/001-F01.
- 5.2 After receiving VigiFlow Login Id and Password, the Coordinator or Pharmacovigilance Associate shall change the Vigiflow Login Password (if require) with intimation to IT division of NCC through e-mail.
- 5.3 In case of change of Coordinator, Coordinator shall be responsible to communicate to IT division of NCC via email to close/change the Vigiflow account.

	Name	Designation	Signature	Date
Prepared by	DEEPAK MAJIK	IT- Associate	<i>[Signature]</i>	03/11/2016
Reviewed by	Dr Pawan K. Saini	Scientific officer	<i>[Signature]</i>	04/11/2016
Approved by	Dr. Kalaiselvan	PSO	<i>[Signature]</i>	8/11/2016

**MASTER COPY****CONTROLLED COPY**

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

Sign: *[Signature]* Dt: 03/11/2016

**STANDARD OPERATING PROCEDURE**

Page No.	2 of 2
SOP No.	IPC/PvPI/IT/002
Revision No.	00
Review Date	14/11/2019

**Division Information Technology****Effective Date 15/11/2016****Title: SOP for Vigiflow login distribution & Retrieval procedure**

- 5.4 In case of resignation/transfer of Pharmacovigilance Associate at AMCs, the Coordinator shall have to change Vigiflow Login Password and communicate to IT division of NCC via email.
- 5.5 In case of transfer of Pharmacovigilance Associate at NCC to AMC or vice-versa, HR division shall inform to IT division. IT division shall inform to UMC to change the Vigiflow account as per requirement.
- 5.6 In case of resignation of Pharmacovigilance Associate at NCC, HR division shall inform to IT division. IT division shall inform to UMC to close the Vigiflow account.
- 5.7 Whenever a Coordinator/ Pharmacovigilance Associate are unable to change the login details, he/she can intimate to NCC-PvPI via email.

**6.0 SAFETY AND PRECAUTIONS (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.
- 6.4 The details of Vigiflow account shall be kept confidential.

**7.0 REFERENCES : In-house****8.0 ABBREVIATIONS**

- NCC : National Coordinating Centre
- AMC : Adverse Drug Reaction Monitoring Centre
- PvPI : Pharmacovigilance Programme of India
- UMC : Uppsala Monitoring Centre

**9.0 Annexure : Not applicable**

	Name	Designation	Signature	Date
<b>Prepared by</b>	DEEPAK MALIK	IT- Associate	<i>[Signature]</i>	03/11/2016
<b>Reviewed by</b>	Dr Pawan K. Saini	S.O.	<i>[Signature]</i>	04/11/2016
<b>Approved by</b>	Dr. Kabir Selvan	P.S.O.	<i>[Signature]</i>	8/11/2016