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IPC

INDIAN PHARMACOPOEIA COMMISSION  
National Coordination Centre-Pharmacovigilance Programme of India

STANDARD OPERATING PROCEDURE

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SOP No.

IPC/PvPI/QA/012

Section

QA Section

Revision No.

04

Effective Date

01/04/2016

Review Date

31/03/2019

Title: SOP to perform Causality Assessment

### 1.0 OBJECTIVE

1.1 To lay down a procedure to perform and establish a causal relationship between a suspected adverse event(s) reported and the suspected drug(s).

### 2.0 SCOPE

2.1 This SOP shall be applicable to Causality Assessment Committee at AMC's under PvPI.

### 3.0 RESPONSIBILITY

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

3.2 All AMC's Co-ordinators and Causality Assessment Committee who works for Pharmacovigilance Programme of India at their respective AMCs shall be responsible for adhering to this SOP.

3.3 Quality Manager, Technical Manager, Section-In-charge & AMC Coordinator shall ensure overall implementation of this SOP.

### 4.0 ACCOUNTABILITY:

4.1 Officer Incharge -Pharmacovigilance Programme of India

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Technical Associate		14/03/2016
Reviewed by	Dr. Prabhat Mohan	SA		15/03/2016
Approved by	Dr. Kalai Selvan	PSO		16/03/16

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**5.0 PROCEDURE:**

- 5.1 The Causality Assessment shall be performed by using WHO-UMC Causality Scale as per Format No. IPC/PvPI/QA/012-F01.
- 5.2 All AMCs of PvPI are required to constitute a Causality Assessment Committee to assess a causal relationship between adverse event/ adverse drug reaction and drug of the reported cases.
- 5.3 Causality Assessment Committee shall be responsible for Causality Assessment of each adverse event /adverse drug reaction /case reported from the respective AMCs/Peripheral hospital.
- 5.4 Ensure that the ADR form contains all mandatory information as per 'SOP to fill Suspected ADR Reporting Form'.
- 5.5 Ensure that the information of dechallenge and rechallenge have been provided.
- 5.6 Check for laboratory data, concomitant medicaments and pre-existing medical history for assessing causal relationship.
- 5.7 Perform the Causality Assessment for all serious, non-serious, suspected, expected and unexpected events reported.
- 5.8 After Causality Assessment, the Coordinator/Technical Associate shall mention the causal relationship category in the Suspected ADR reporting Form.

**6.0 SAFETY AND PRECAUTION**

Not Applicable

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate	<i>[Signature]</i>	14/03/2016
Reviewed by	Dr. Pradeep Sharma	S.A	<i>[Signature]</i>	15/03/2016
Approved by	Dr. Kalai selvan	P.S.O	<i>[Signature]</i>	16/03/16

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**Title:** SOP to perform Causality Assessment**7.0 REFERENCES**

## 7.1 URL:

[http://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/WHOCausality\\_assessment.pdf?ua=1](http://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOCausality_assessment.pdf?ua=1) (Assessed on 10/03/ 2016)

**8.0 ABBREVIATIONS**

SOP	:	Standard Operating Procedure
PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
AMC	:	Adverse Drug Reaction Monitoring Centre
WHO-UMC	:	World Health Organisation- Uppsala Monitoring Centre
ADR	:	Adverse Drug Reaction
CAC	:	Causality Assessment Committee

**9.0 ANNEXURE**

Annexure I : WHO-UMC Causality Scale Format No. IPC/PvPI/QA/012-F01

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/03/2016
Reviewed by	Dr. Kalai Selvan	S.A		15/03/2016
Approved by	Dr. Kalai Selvan	PSU		16/03/16



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Annexure I

WHO-UMC Causality Scale

Format No. IPC/PvPI/QA/012-F01-00

Causality term	Assessment criteria
<b>Certain</b>	<ol style="list-style-type: none"> <li>1. Event or laboratory test abnormality, with plausible time relationship to drug intake.</li> <li>2. Cannot be explained by disease or other drugs.</li> <li>3. Response to withdrawal plausible (pharmacologically, pathologically).</li> <li>4. Event definitive pharmacologically or phenomenological (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon).</li> <li>5. Rechallenge satisfactory, if necessary.</li> </ol>
<b>Probable/ Likely</b>	<ol style="list-style-type: none"> <li>1. Event or laboratory test abnormality, with reasonable time relationship to drug intake.</li> <li>2. Unlikely to be attributed to disease or other drugs.</li> <li>3. Response to withdrawal clinically reasonable.</li> <li>4. Rechallenge not required.</li> </ol>
<b>Possible</b>	<ol style="list-style-type: none"> <li>1. Event or laboratory test abnormality, with reasonable time relationship to drug intake.</li> <li>2. Could also be explained by disease or other drugs.</li> <li>3. Information on drug withdrawal may be lacking or unclear.</li> </ol>
<b>Unlikely</b>	<ol style="list-style-type: none"> <li>1. Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible).</li> <li>2. Disease or other drugs provide plausible explanations.</li> </ol>
<b>Conditional/ Unclassified</b>	<ol style="list-style-type: none"> <li>1. Event or laboratory test abnormality.</li> <li>2. More data for proper assessment needed, or additional data under examination.</li> </ol>
<b>Unassessable/ Unclassifiable</b>	<ol style="list-style-type: none"> <li>1. Report suggesting an adverse reaction.</li> <li>2. Cannot be judged because information is insufficient or contradictory data cannot be supplemented or verified.</li> </ol>

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/03/2016
Reviewed by	Dr. Prasad Indira	S.A		15/03/2016
Approved by	Dr. Kalai Selvan	PSO		16/3/16