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सत्यमेव जयते IPC	**INDIAN PHARMACOPOEIA COMMISSION** **National Coordination Centre-Pharmacovigilance Programme of India**			
	STANDARD OPERATING PROCEDURE		**Page No.**	**1 of 3**
			SOP No.	**IPC/PvPI/QA/015**
	Section	All Sections	**Revision No.**	**01**
	Effective Date	03/05/2016	**Review Date**	02/05/2019
Title:	**SOP for documentation grading and Report Completeness of ICSRs**			

1.0 OBJECTIVE

1.1 To lay down a procedure for documentation grading and completeness score of ICSRs.

2.0 SCOPE

2.1 This SOP shall be applicable to NCC and AMC under PvPI.

3.0 RESPONSIBILITY

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

3.2 All the officers and section-In charge shall ensure that this SOP has been reflected in the sections.

3.3 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 To document and scoring of ICSRs from VigiFlow software the Coordinator and Vigiflow user at NCC have to log-in into VigiFlow with respective user id and password (as provided by NCC) from the web-page https://adr.who-umc.org.

5.2 After log-in, the menu page of VigiFlow will display:

	Name	Designation	Signature	Date
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Reviewed by	Dr. Rohit Tech	S.A		25/04/2016
Approved by	Dr. Kalaiselvan	PSO		26/04/2016

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5.3 Click on List Reports, enter the required dates in the specified column and select the AMC for which documentation grading and completeness is to be done.

5.4 Reports from selected AMC shall be displayed, then click on edit or view of the selected ICSRs and score as per documentation grading and completeness score document. (Annexure-I)

Note:- The documentation grading shall be applicable for the one time quality review of ICSR, It is not applicable to reverted ICSR except response to NCC.

6.0 SAFETY AND PRECAUTION

6.1 Scoring shall be done carefully for each step as it reflects the completeness of ICSRs and can affect the completeness score of Individual AMCs.

7.0 REFERENCES

7.1 SOP to fill Suspected ADR Reporting Form.

7.2 SOP to enter data from suspected ADR form into VigiFlow.

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

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IPC	:	Indian Pharmacopoeia Commission
PvPI	:	Pharmacovigilance Programme of India
AMC	:	Adverse Drug Reaction Monitoring Centre
NCC	:	National Coordination Centre
ICSR	:	Individual Case Safety Report
QA	:	Quality Assurance
ADR	:	Adverse Drug Reaction

9.0 ANNEXURE (s)

Annexure- I : Documentation Grading – Report Completeness of ICSRs

Annexure- II : Completeness Score format of ICSRs
Format No. IPC/PvPI/QA/015-F01

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What is Documentation grading?

Documentation grading is a system to measure the quality and quantity of the information provided on Individual Case Safety Reports (ICSRs) by the ADR Monitoring centres (AMCs).

Grading parameter

In grading parameter, *completeness* has been defined as *Completeness* is a quantitative measure determining to what extent an ICSR is complete.

Report Completeness Score

The *Report Completeness Score* is a score from 0 to 1 on an ICSR, calculated from the information provided in a structured format. The algorithm assigns a field score to specific data fields, such as *patient gender*, indicating whether the field has been filled or not. In addition to the field scores the algorithm also generates scores for pieces of information derived from multiple fields. The completeness score is calculated for each drug-ADR combination separately and the mean of these scores is the *Report Completeness Score*. Further details of the algorithm are given in Appendix 1.

Why do we need Documentation grading?

During the last few years, the National Coordination Centre (NCC) has received thousands of ICSRs from the AMCs for Pharmacovigilance Programme of India (PvPI). Unfortunately, the information provided on the ICSRs is not always sufficient for further analysis of the reports, including *signal detection*. To be able to perform analysis work more efficiently, a method to measure the information content of the ICSRs was needed. For this purpose the NCC has developed and implemented the documentation grading system. By communicating the result of the documentation grading to the AMCs, we hope that issues with quantity and quality of information in ICSRs will be identified and rectified.

What AMCs can do with this information?

Completeness scores show how much information sent to NCC through ICSRs and allow identification of changes in the amount of information on ICSRs over time. Although AMCs are dependent on their reporters for the quality of reports received, we believe that it is of

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interest for AMCs to know how report completeness has varied over time and to investigate possible reasons for this.

Details about calculation of scores

The total completeness score of an ICSR is calculated from several fields, description is mentioned in Table 1. This table provide the total no of fields and its scoring description.

Table 1: Field with score description

S. No.	Field	Score Description	Weightage given by NCC-PvPI
1	Report title	A full score is given if an allowed value has been entered.	**0.05**
2	Seriousness	A full score is given if an allowed value has been entered.	**0.1**
3	Primary Source	A change in score might be due to a change in Information of the following fields, Primary Source, Reporter's Qualification.	**0.1**
4	Patient Information	A change in Score might be due to a change in Information of the following fields, Age at time of onset, patient Initial.	**0.4**
5	Gender	A full score is given if an allowed value has been entered.	**0.35**
6	Free text	A change in score might be due to a change in information of the following fields,	**0.05**

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		Results of test and procedures, Relevant medical history, Reporter's comments, Is the ADR adequately labelled, Sender's Comment.	
7	Reaction(s)/Event (s)	A full score is given if an allowed value has been entered through WHO-ART.	**0.05**
8	Outcome	A full score is given if an allowed value has been entered.	**0.01**
9	Drug name	A full score is given if an allowed value has been entered through WHO-DD	**0.05**
10	Drug Information	A change in score might be due to a change in information of the following fields, Pharmaceutical form, Route of administration, Authorisation holder, Dose, Dosage regimen.	**0.05**
11	Action taken	A full score is given if an allowed value has been entered	**0.35**
12	Indication	A full score is given if an allowed value has been entered. Since indication is reported on drug level, the score per ICSR is the average score of all suspected/interacting	**0.5**

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		drugs.	
13	Time on set	A change in score might be due to a change in information of the following fields, Drug start date, ADR date of on set.	**0.15**
14	Causality assessment	A full score is given if an allowed value has been entered as per WHO-causality scale.	**0.05**
15	Case Narrative	A full score is given if an allowed value has been entered.	**0.05**
16	Compliance of in house SOPs	A full score is given if no query or resolve the query within 10 days by AMC.	**0.01**
17	Completeness	Completeness is calculated on the basis of formula given in equation 1	**C**

1. Calculation of the completeness score

The total completeness score of an ICSR is average calculated from several field scores. The data fields that are implemented in the completeness score are report title, seriousness, primary source, patient information, gender, free text, reaction term, outcome, drug name, drug information, action taken, indication, time onset, causality assessment, case narratives and response to NCC.

Only suspected and interacting drugs are included in the calculations.

Completeness is calculated from the information obtained from above mentioned 16 parameters by using a following multiplicative model.

$$C=\prod_{i=1}^{n}((1-w_i)+(w_i * f_i))$$

Where, C= Completeness score; i= field included in the score; w_i = field weight; f_i = is the field score.

An informative value is one that gives usable information. Non-informative values are represented by the values not specified, not available and unknown.

All informative responses generate a score 1, whereas non-informative values score 0. The description of each sixteen field scores is given as follows:

1.1. Report title

Report title is the first field in VigiFlow is also known as report header. Report title should be the combination of ADR- Drug. For example Haematoma:Clopidogrel The informative values are implemented in the score of report title according to Table 2.

Table2: Scores for Report title

Report Id	Report title	Score
R1	Haematoma: Clopidogrel	1
R2	Clopidogrel	0
R3	Haematoma	0
R4	-	0

Note: In the case of multiple drugs and ADRs, should write any one of the suspected drug-ADR combination from the report.

1.2. Seriousness

Seriousness is comprised of Yes or No, that means patient is serious then yes or non-serious then No. If "yes" have to specify the reason of seriousness. Reason of seriousness is mentioned in Table3.

The informative values are implemented in the score of seriousness according to Table 3.

Table3: Scores for Seriousness

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Report Id	Seriousness	Reason for Seriousness		Score
R1	Yes	Death	Any one should be marked	1
		Life threatening		
		Congenital anomaly		
		Hospitalization- initial or prolonged		
		Disability		
		Other		
R2	Yes	-		0
R3	No	-		1
R4	-	-		0

1.3. Primary source

Primary source is comprised of the primary source and reporter qualification. Since they all contain information of primary source they will not be seen as two separate fields and each carry equal weightage. Primary source is a detail of reporter/department from where report collect while reporter qualification is qualification of reporter.

The informative values are implemented in the score of primary source according to Table 4.

Table4:Primary source

Report Id	Primary source	Reporter Qualification	Primary Source Score
R1	Yes	Yes	1
R2	Yes	-	0.5
R3	-	Yes	0.5
R4	-	-	0

	Name	Designation	Signature	Date
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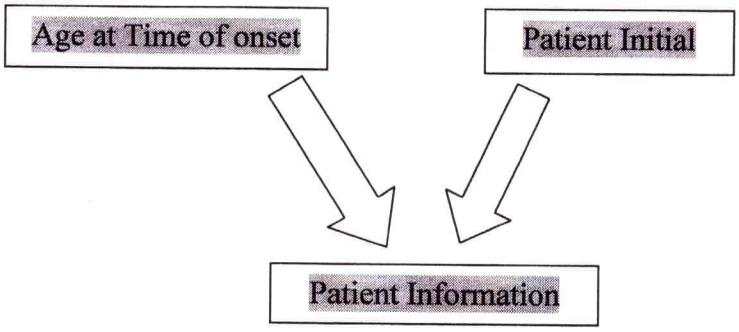
1.4. Patient information

Patient information is comprised of age at time of onset and patient initial. Since they all contain information of Patient information they will not be seen as two separate fields and each carry equal weightage.

Age at time of onset is the age of patient at reaction/event occurred.

Patient initial is initials of the patient name. The initials should be entered in the following order, given first alphabet of the name and surname without any sign or space between and it may be maximum 3 alphabets. For e.g.**R**am **K**umar **V**erma then initials should be as RKV.



The informative values are implemented in the score of patient information according to Table 5.

Table5:Patient information

Report Id	Age at time of onset	Patient initial	Score
R1	50	RKV	1
R2	-	RKV	0.5
R3	50	-	0.5
R4	-	-	0

1.5.Gender

The informative values are implemented in the score of gender according to Table 6.

Table 6:Gender

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Report Id	Gender	Score
R1	Male	1
R2	Female	1
R3	-	0
R4	Unknown	0

1.6. Free text

The score is generated from informative values in any free text field; see table7a.Almost all information in free text is considered informative. Only a few exceptions like. '#', '*' have been identified as non-informative.

A free text field has to contain at least 10 characters to be regarded as informative.

Table7a:Fields included in the free text

Field for free text	Description
Result of test procedure	This section should capture the tests and procedures performed to diagnose or confirm the reaction/event, including those tests done to investigate (exclude) a non-drug cause, (e.g., serologic tests for infectious hepatitis in suspected drug-induced hepatitis). Both positive and negative results should be reported.
Relevant medical history	This field should be used for providing information pertinent to understanding the case is desired such as diseases, conditions such as pregnancy, surgical procedures, psychological trauma, etc. and concurrent condition can be described in this section.

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Reporter's comments	This field should be used for comments from the primary source that are relevant for all reactions like diagnosis, causality assessment, treatment and other issues related to the reaction.
Is the ADR adequately labelled	Is the ADR adequately described in the Product Information for the reporting country (i.e. India) -Yes or -no
Sender Comment	This field should be used for any discussion or alternative diagnoses from the sender (person that sent the ICSR to the NCC). This section provides the sender with an opportunity to combine signs and symptoms that were reported into a succinct diagnosis and the reasoning.

The informative values are implemented in the score of free text according to Table 7b.

Table7b: Free text

Report Id	Free text					Score
	Result of test procedure	Relevant medical history	Reporter's comments	Is the ADR adequately labelled	Sender comment	
R1	Yes	Yes	Yes	Yes	Yes	1
R2	Yes	Yes	Yes	Yes	-	0.8
R3	Yes	Yes	Yes	-	-	0.6
R4	Yes	Yes	-	-	-	0.4
R5	Yes	-	-	-	-	0.2
R6	-	-	-	-	-	0

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		22/04/2016
Reviewed by	Dr. [illegible]	SA		25/04/2016
Approved by	Dr. Kalaiselvan	PSO		26/4/2016

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Note: if no information available regarding any of the free text, mention "**Not Applicable**".

1.7. Reaction(s)/Events

Reaction/Event should be coded from WHO-ART. The *informative values* are implemented in the score of reaction(s)/events according to Table 8.

Table8: Reaction(s)/Events

Report Id	Reaction/Event	WHO-ART	Score
R1	A1	0030 PT/HLT/IT	1
R2	A2	-	0
R3	A1	0030 PT/HLT/IT	0.5
	A2	-	
R4	-	-	0

Note: if Reaction/Event is not coded in WHO- ART, Describe the event in free text and suggest to WHO-ART.WHO-ART: WHO Adverse Reaction terminology, PT: Preferred term, HLT: high level term IT: Included term

1.8. Outcome

The score is generated from *informative values* in the field of *ADR outcome.* The *informative values* are implemented in the score of drugs according to Table

Table9: Outcome

Report Id	ADR	Outcome		Score
R1	A1	Recovered/resolved	Anyone have marked	1
		Recovering/resolving		
		Not recovered/not resolved		

	Name	Designation	Signature	Date
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		Recovered/resolved with sequelae		
		Fatal		
		Unknown#		
R2	A1	-		0
R3	A1	Anyone have marked		0.5
	A2	-		

the value Unknown is not considered an informative value

1.9. Drug Name

Suspected and concomitant drug should be coded from WHO-Drug Dictionary (WHO-DD). The informative values are implemented in the score of drugs according to Table 10.

Table10: Drug Name

Report Id	Suspected/Concomitant Drug	WHO-DD	Score
R1	D1	Coded	1
R2	D1	-	0
R3	D1	Coded	0.5
	D2	-	
R4	-	-	0

Note: If no matching drug exists in WHO-DD, it is possible to suggest a new drug to be added to the WHO Drug Dictionary. For this have must be provide Name of product, Pharmaceutical form, MA-holder, Active ingredient, and References, find out the same drug.

- A full score is given if above mentioned information has been given.

1.10. Drug Information

Drug information is comprised of pharmaceutical form, route of administration, authorization holder, dose, and dose regimen. Since they all contain information of drug information and they shall not be seen as five separate fields. Each sub field are carrying equal weightage.

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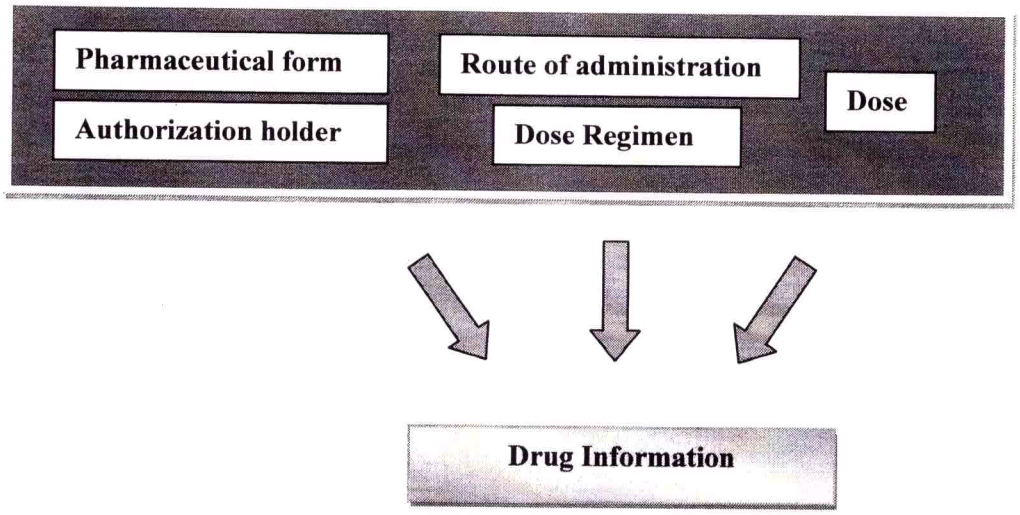

The informative values are implemented in the score of drugs information according to Table 11.

Table11: Drugs information

Report Id	Pharmaceutical form	Route of administration	Authorization holder	Dose	Regimen	Score
R1	Injection	IV	Cipla	250 mg	OD	1
R2	Injection	IV	Cipla	250 mg	-	0.8
R3	Injection	IV	Cipla	-	-	0.6
R4	Injection	IV	-	-	-	0.4
R5	Injection	-	-	-	-	0.2
R6	-	-	-	-	-	0

Note: In the case of serious (death/life threatening) and vaccination,Batch No must be provide.

1.11. Action Taken

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Prepared by	Rishi Kumar	Tech. Associate		22/04/2016
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The score is generated from *informative values* from any *action taken* field; see Table 12a.

Table 12a:

Action taken	Description
Drug withdrawn	It is the condition when the given drug therapy was stopped due to the occurrence of adverse reaction at current drug therapy
Dose reduced	It is a situation when the dose of the given drug therapy was reduced due to the occurrence of Adverse reaction at the given drug therapy.
Dose does not change	When the given drug therapy is continued
Not applicable	It should be used in circumstances such as if the patient death or the treatment had been completed prior to reaction/event.
Unknown	When the information about the drug therapy whether it is withdrawn or treatment is still continued is not available

The informative values are implemented in the score of action taken according to Table 12b.

Table12b: Action Taken

Report Id	Drug	Action taken		Score
R1	D1	Drug withdrawn	Any one should be marked	1
		Dose reduce		
		Dose does not change		
		Not applicable		
		Unknown#		0
R2	D1	-		0
R3	D1	Drug withdrawn	Any one should be	0.5
		Dose reduce		

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		22/04/2016
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Approved by	Dr. V. Kabilselvan	PSO		26/04/2016

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		Dose does not change	marked	
		Not applicable		
		Unknown#		**0**
	D2	-		

the value Unknown is not considered an informative value

1.12. Indication

The informative values implemented in the score for *indication* are generated from ICD8, ICD9 (including supplementary codes), ICD10.

The informative values are implemented in the score of indication according to Table 13.

Table13: Indication

Report Id	Drug	Indication Code	Score
R1	D1	486	1
R1	D1	-	0.67
	D2	486	
	D3	486	
R2	D1	3004	0.50
	D2	-	
R3	D1	#	0
R4	D1	-	0

is not considered as an informative value.

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1.13. Time Onset

Time Onsetis comprised of drug start date and ADR onset. Since they all contain information of time Onsetand they will not be seen as two separate fields.
The informative values are implemented in the score of time onset according to Table 14.

Table14: Time Onset

Report Id	Drug start date	ADR onset date	Time To Onset Score
R1	2010-08-08	2010-10-11	1.00
R2	2011-05-07	-	0
R3	-	2011-09-13	0
R4	2013-08-11	2010-11-11	0#
R5	-	-	0

#Date order can't be determined, the date type generating the lowest score (0)

1.14. Causality Assessment

Causality Assessment (relatedness of Drug and ADR) should be according to WHO-Causality scale. The *informative values* are implemented in the score of causality assessment according to Table 15.

Table15: Causality Assessment

Report Id	Drug	ADR	Perform Causality (WHO-Causality Scale)	Score
R1	D1	A1	Yes	1
R2	D1	A1	-	0
R3	D1	A1	Yes	1
	D2	A2		
	D1	A2		
	D2	A1		

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		22/04/2016
Reviewed by	Dr. Rashid Tenda	S.O		25/04/2016
Approved by	Dr. V. Kalaiselvan	PSO		26/04/2016

R4	D1	A1	Yes	0.5
	D2	A2	Yes	
	D1	A2	-	
	D2	A1	-	

Note: For detail of parameters see the WHO-Causality Assessment Scale.

1.15. Case narrative

The full score is generated from informative values in *case narrative* field, almost all information in case narrative is considered informative. Only a few exceptions like '#', '*'have been identified as non-informative. A case narrative field has to contain summary of report as per the following case narrative Format.

The Case Narrative in ICSRs should contains following details

1. Patient details (Male, female, Age, weight etc.)
2. Event name
3. Medical History
4. Suspected drug details with Indication
5. Dose and Onset Date
6. Concomitant Therapy
7. Event details
8. Outcome
9. Causality Assessment
10. Additional Information (e.g. Medical treatment, Lab Details etc.

The Above information should be included in the paragraph form.

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Approved by	Dr. Kalaiselvan	PS		26/04/2016

Example: The Following is the example of a clearly presented case narrative for a Adverse Event Case

PATIENT DETAILS: This case was considered medically important. Information was received from healthcare professional regarding a 29 year old male patient who received XXXXXXXXXX and experienced hypertension. MEDICAL HISTORY: Relevant medical history was XXXXXXXXXXXXXX. PRODUCT DETAILS: Indication for XXXXXXX was rheumatoid arthritis. Therapy began in Oct-2009 and was permanently discontinued in 4 April -2010. Dose regimen was 50 mg, frequency unknown. CONCOMITANT THERAPY: Concomitant medication included XXXXXXXX. EVENT DETAILS: The patient had been experiencing hypertension since he started the XXXXXXXXXXXX therapy in 15 Oct 2009. The decision was made to change his therapy to XXXXXXX. OUTCOME: The patient recovered from the events. CAUSALITY ASSESSMENT: The reporter suspected that the adverse events were related to the suspected drug (As per WHO Causality Scale). ADDITIONAL INFORMATION: No additional information was available at the time of this report.

1.16. Response to NCC

The full score is generated from informative values in the field of *response to NCC*, if no query or resolve the query related to ICSR within 10 days by concern AMCs.

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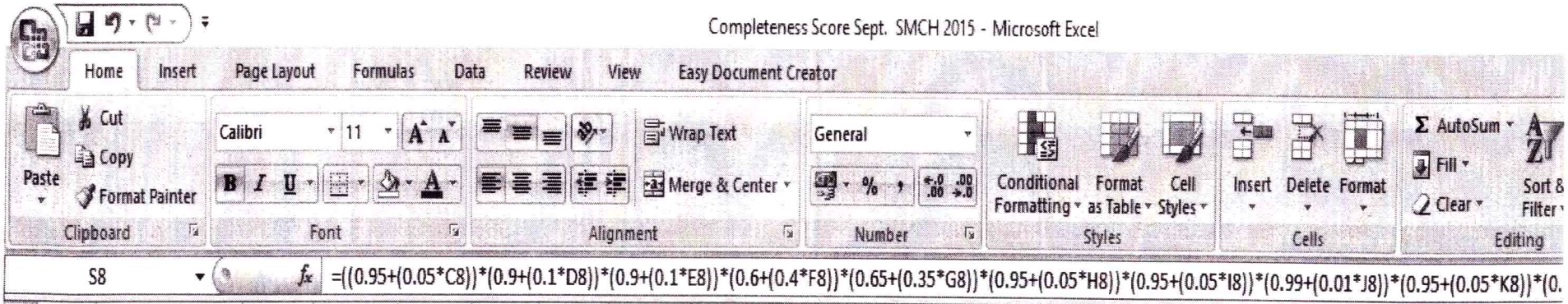
Annexure II

COMPLETENESS SCORE FORMAT OF ICSRs

Format No. IPC/PvPI/QA/015-F01-00



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	SMCH, Silchar (Sep-2015)																		
2	S.NO.	Case-ID	Report Title	Sender/ Primary Source	Seriousness	Patient Info	Gender	Free text	Reaction Term	Drug Name	Drug Information	Action taken	Indication	Time Onset	Outcome	Causality Assessment	Case Narrative	Response to NCC	
3	1	2015-36856	1	1	1	1	1	0.8	1	1	1	1	1	1	1	1	1	1	0.99
4	2	2015-36848	1	1	1	1	1	0.8	1	1	1	1	1	1	1	1	1	1	0.99
5	3	2015-36834	1	1	1	1	1	0.8	1	1	1	1	1	1	1	1	1	1	0.99
6	4	2015-36194	1	1	1	1	1	0.8	1	1	1	1	1	1	1	1	1	1	0.99

Note :- In the First Line of Excel Sheet the name of the AMC is to be mentioned e.g Silchar Medical College and Hospital (SMCH, Silchar)

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