



Attachment-3
Template for EC monitoring report

Name and address of site	Name:
Study No.	
Name of Principal Investigator	
Name and Address of EC	
Name and Address of Sponsor	
Site Personnel attended Monitoring activity	1. 2.
EC Personnel conducted Monitoring activity	1. 2.
*Date(s) of monitoring activity	DD-MMM-YYYY
*Date of monitoring report	DD-MMM-YYYY
*Monitoring report release Date	
Report Prepared/Reviewed by (EC monitor details):	Signature and date
	Name:
Report Approved by (Member secretary/Chairperson of the site):	Signature and date:
	Name:



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Disclaimer:

The EC monitoring activity was based on the sampling methodology and hence observations mentioned in this report are limited to documents, processes and systems reviewed during conduct of monitoring activity. It is responsibility of the site to review rest of the data in general to ensure compliance to study documents, applicable SOPs, guidelines and regulations.

Confidentiality:

- Distribution of this monitoring report is limited to maintain confidentiality of report.

Observations:

1. Category of Observation:

A. Critical Observation:

Observation	
Root Cause	
Corrective Action	
Preventive Action	
Impact assessment	

B. Major Observation:

Observation	
Root Cause	



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Corrective Action	
Preventive Action	
Impact assessment	

C. Minor Observations:

Observation	
Response	

D. Recommendations:

Sr. No.	Recommendations for site

Response provided by:

	Name	Role	Sign and Date (DD-MMM-YYYY)
Response provided by (Site staff)			
Response approved by (Principal Investigator/designee)			



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Compliance reviewed by:

	Name	Role	Sign and Date (DD-MMM-YYYY)
Compliance reviewed by (EC monitor)			
Compliance approved by (Member Secretary/Chairperson)			

***Note:** Follow date convention process as per institution/hospital in the entire document.