Annexure 10

Format for Site Monitoring Report
INSTITUTIONAL ETHICS COMMITTEE -CHARUSAT

SITE MONITORING VISIT REPORT [Clinical Trial]

(Please tick the box corresponding to the answer)

IEC project no.	Date of Visit:
Study Title:	
Principal Investigator & Department:	
Type of Study:	Investigator Initiated/Phrama/Govt. Agency/Others_____
Date of IEC Approval:	
Date of Initiation of study:	
Duration of study:	
Reason of Monitoring:	Routine/for cause/Protocol violation or deviation/ SAE reporting/ Recruitment rate/ others ____
Last Monitoring done, If any	Yes/NO Date of Monitor:
Project Status:	1. Ongoing 2. Completed 3. Recruitment Completed 4. Follow-up, extension study 5. Suspended 6. Terminated
In case of the response to the above question is option 5 or 6, kindly provide reason/s:	
Recruitment Status: Total participants to be recruited: Screened: Screen Failures: Enrolled: Withdrawn: Reason:	

Discontinued: Reason: Completed: Active:	
Are the present study team members as per the list approved by the IEC? Yes/ No	Comment:
Are site facilities appropriate? Yes/ No	
Is intimation and approval from participant noted in the source document with regards to current risk benefit information? Yes/ No	
Is the recent version of Informed Consent Document (ICD), after IEC approval, used? Yes/ No	
Whether appropriate vernacular consent has been taken from all patients? Yes/ No	
Any other findings noted about the ICDs? Yes/ No	
Is recent IEC approved version of protocol used? Yes/ No	
Has the eligibility, inclusion exclusion criteria been adhered to? Yes/ No	
Any adverse events found? Yes/ No	
Any SAEs found? Yes/ No	
Were the SAEs informed to IEC within timelines specified by CDSCO? Yes/ No	
No. of deaths reported:	

-Death unrelated to the participation in trial: - Death possibly related to the participation in trial: - Death related to the participation in trial: Any other non-death study related injury	_____ _____ Yes/ No/ NA Comments (If Any) _____ _____
Compensation paid for study related injury or death Yes/ No/ NA	Comments (If any)
Is there any protocol non-compliance? Deviations/violations? Yes/ No	
Have the protocol non-compliance deviations/violations been informed to IEC? Yes/ No	
Are all Case Record Forms up to date? Yes/ No	
Are storage of data and investigating products locked? Yes/ No	
How well are the participants protected? Good/ Fair/ Not good	
Any other remarks	Give details:
Duration of visit:_____ hours	Starting from: Finish:
Name of the study team member/s present: Signatures _____	Date:
Name of IEC members and representatives who attended monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the IEC meeting held on:

Signature with date
Chairperson, IEC