INSTITUTIONAL ETHICS COMMITTEE-CHARUSAT

GCP INSPECTION CHECKLIST

Central Drugs Standard Control Organization

I. General		
1.	Name and address of the clinical trial site	
2.	Date of Inspection	
3.	Inspection Team Members:	
4.	Personnel present during Inspection (with name and role/designation.)	
5.	Address & Contact details of Investigator:	
6.	Name & address of the Sponsor	
7.	Name & address of clinical trial NOC holder	
8.	Name & address of EC	
9.	Protocol Title	
10.	Protocol Number Version/date Protocol amendments, if any.	
11.	Investigational Product	

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12	Stage of study: (Mark the relevant)	(A) Before Trial Commencement ☐ (B) During Conduct of the trial ☐ (C) After Completion of Trial ☐
13	Type of Inspection:	Surveillance ☐ For Cause ☐

II.LEGAL & ADMINISTRATIVE ASPECTS:					
S. no.	**Item**	**Yes**	**No**	**NA**	**Remark**
1	Clinical trial NOC from O/o DCGI (Note: mention along with Protocol no., Ver., date)				
2	NOC for subsequent protocol amendments, if any from O/o DCGI				
3	Ethics Committee approval date (Note: mention along with Protocol no., Ver., date)				
3	Appendix VII as per Sch.-Y (mention revision(s) and notification to O/oDCGI, if any)				
4	Whether valid financial agreement between the Sponsor, Investigator & Institution available.				
5	Whether liability of involved parties (Investigator, Sponsor and Institution) clearly agreed.				
6	Is the valid clinical trial Insurance available?				
7	Site Initiation date				
8	Date of screening of first subject,				
9	Date of signing ICF by the first subject				
10	Date of Last Patient-Last Follow-Up (if applicable)				

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11	Whether SOP for various activities are established and documented.				
12	Verify, whether the hospital/institute/site has adequate emergency care facilities to handle emergency situation.				
III Organization & Personnel					
1	Assure that signed & dated, Curriculum Vitae is available for the Investigator, Sub Investigator /Co-Investigator				
2	Confirm the educational qualification of the Investigator with registration by Medical Council of State/India.				
3	Confirm the GCP, Schedule Y and protocol specific training of Investigator, Sub-Investigator/Co-Investigator and its team.				
4	Determine whether authority for conducting various clinical trial activities were delegatedproperly by Investigator to competent personnel (obtain the list of personnel and duty delegation log).				
5	Check whether the person whom the authority is delegated is adequately qualifiedand trained for the activity/activities assigned.				
6	Obtain the list of all clinical trials performed by Investigator (Preferably for last three years)				
7	Ensure that the Investigator is involved in conduct of not more than three clinical trialsat a time.				
IV Conduct of Trial					
A.	**Screening of subjects:**				
1	Check and review the informed consent for the screening of the subjects.				
2	Check site screening log & enrolment logand obtain authenticated copy.				
3	**Check whether the subjects are meeting the inclusion/exclusion criteria as per the approvedprotocol w.r.t review of source documents &/or CRF.**				

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3.1	Clinical Examination by Investigator (Check patient file/Source documents)				
3.2	Verify ,Clinical Laboratory Evaluation (Check Blood Cell Counts, Biochemical test, Urine analysis etc.as required by protocol)				
3.3	Verify X-Ray, MRI, ECG, USG or any other technique required to ascertain the inclusion/exclusion criteria.				
3.4	Verify, Whether all conditions of Clinical trial NOC are followed or not?				
B. Subject record and Informed consent:					
1	Whether ICF have all the elements enlisted in Appendix V of Schedule Y.				
	Whether ICF is approved by Ethics Committee prior to consent process.				
2	Whether IC has been obtained from each subject prior to participation of the subject inthe study.				
3	Whether signature/thumb impression of thesubjects/legal representative have been affixed with date.				
4	Whether in case of illiterate subjects or illiterate representative of a subject, there are signature and details of an impartial witness.				
5	Have witness/ signature being personallydated. (If applicable).				
6	Have patient/witnesssignature been personally dated?				
7	Has the dated signature of the designated person for administering informed consent(IC) been affixed?				
8	Is the designated person for administering ICmedically qualified?				

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9	If IC has been administered by a designated person who is not medically qualified, is there evidence that subject's queries of a medical nature were answered by a medically qualified person or the investigator?				
10	Is the completed ICF signed and dated by the investigator?				
11	Check weather re-consenting is done for changes in ICF, if any.				
B.1	**Audio-Visual recording of Informed Consent Process(For 'vulnerable population' in 'New Chemical Entities (NCEs) clinical trial' only & Anti HIV & Anti-Leprosy patients only Audiorecording)** (Verify as per GSR 611(E) dated 31.07.2015)				
1	Whether audio-visual recording is performedfor all subjects, independently.				
2	Is audio-visual recording conducted in a room conducive to recording of disturbance free audio and video of the consent process?				
3	Check whether the video recording is free from disturbance to ensure that the image is recognizable and the audio is clearly audible.				
4	Check whether the recording of informed consent process is preserved safely.				
C. Source Documents and Case Record Form					
1	Verify condition, completeness, legibility, accessibility of the investigators source data file. (source data includes study subject's files, recording from automated instruments,tracings, X-ray and other films, laboratory notes, photograph negatives, magnetic media, hospital records, clinical and office charts, subject's diaries, evaluation checklistsand pharmacy dispensing records)				

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2	Whether subject received the test drug with respect to dose and frequency according to the protocol;				
3	Determine whether safety/ efficacy end pointdata(Clinical, laboratory examination results) were collected and reported in accordance with the protocol				
4	Does medical record mentions subject ID/ name /hospital registration number / and indication that subjects are participating in aclinical trial				
5	Compare the source document with CRF and determine whether source data have been correctly transcribed in CRF;				
6	Verify the drop-outs and reason for drop-out of subject is appropriately recorded.				
7	Whether the withdrawal of subject from the study is recorded and appropriately justified in accordance with approved protocol.				
8	Verify whether Standard Operating Procedure of handling of Serious Adverse Event occurred in clinical trial is available.				
9	Verify whether all SAE's have been reported to the sponsor, EC and Licensing authority as per the timelines in accordance with Schedule Y. (Verify as per GSR 53(E) dated 30.01.2013 & GSR 889 (E) dated 12.12.14 effective from 12.06.2015)				
10	Verify Whether SOP for medical care during serious adverse event is available or not.				

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11	Verify whether adequate medical care have been given to the subject especially in the event of inter current illness, adverse events including abnormal lab parameters;				
12	Verify whether all study related activities are performed at site approved by O/o DCGI.				

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VI. Sponsor					
1	Whether investigator maintain copies of allreport submitted to the sponsor;				
2	Whether all CRF were submitted to sponsorafter completion of study;				
3	Determine whether all dropout and reasonthereof were reported to sponsor;				
4	Determine the method and frequency of monitoring the progress of the study by thesponsor and corrective action by site.				
5	Whether sponsor appointed a monitor with appropriate qualification and experience to monitor trial at the site.				
6	Whether a log of onsite monitoring visit is maintained at the site.				
7	Is monitor submits visit report with deviations if any to the sponsor.				
8	Whether sponsor performed an audit as a part of QA in order to independent and separate from routine monitoring of quality control function.				
9	In case the investigator and sponsor agrees to prematurely terminate or suspend the study for any reason, whether it was promptly informed to study subjects, Ethics Committee and Licensing Authority.				

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VII. Investigational Product					
1	Review individual subject record to verify the correct dose administration with respect to dose, frequency, route of administration				
2	Determine whether unqualified /unauthorised persons administered/dispensed the test drug				
3	Determine whether adequate record of quantity of test drug received , dispensed is maintained.(Check the test drug reconciliation and verify the leftover drug or balance on the day of inspection).				
4	Determine whether storage condition/monitoring method are as per protocol/recommendation;				
5	Whether trial medication are maintained in secured manner with controlled access;				
6	Have un-used trial medications been returned to the sponsor or disposed of according to protocol?				
7	Are the drugs dispensing records being maintained properly?				
8	Whether the records for reconciliation of all IP's are maintained?				
9	Are electronic or hand-written temperature logs available for the storage area of the investigational products?				
10	Verify that investigation product is appropriately labelled. (For clinical trial use only).				

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VIII. Ethics Committee					
1	Identify the name, address of the EC/ IEC in the approval letter and compare it with one stated in Investigator Undertaking.				
2	Verify the Status of EC-whether Institutional or Independent, Check Registration certificate (Verify as per GSR 72(E) dated 08.12.2013)				
2	Verify if EC approval letter mention study code , title and version number of the protocol, list of other documents reviewed, list of members present at the meeting, quorum of five members as specified in Schedule Y satisfied, date, time , venue of the meeting, signature and date of member secretary / Chairman.				
3	Verify whether the EC recorded minutes of meeting.				
4	Verify whether EC is performed on site monitoring of the clinical trial approved. (Frequency and SOP)				
5	Verify whether EC members have conflict of interest in the approved trial, if yes then the member should abstain from such approval meeting.				
6	Verify whether the communications between Investigator and EC are available for changes, Serious Adverse Event and deviations occurred in clinical trial.				

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7	Verify whether EC is function in accordance with conditions of registration by LA.				
IX Pathology Laboratory (for Screening/ Assessment)					
1	Name and address of the clinical laboratory used in the study. (Local and Outside).				
2	Whether financial & Confidentiality agreement with Investigator and concerned laboratory (ies) in place.				
3	Is investigator/Sponsor verified the accreditation status and adequacy of the facilities to perform the specified tests as per protocol.				
4	Verify whether the SOP for sample preparation, handling and transportation is available. Verify the appropriateness of the SOP.				
X Quality Assurance					
1	Verify whether SOP for all procedures conducted at site are available i.e. have a copy of Site Specific and Trial specific SOPs				
2	Verify the essential components of SOP like who prepared, checked, authorized and when, frequency of SOP revision				
3	Whether SOPs for all operation likescreening and Informed consent Process, AVrecording of ICP of vulnerable population in NCE-CTs, SAEs & its Management, Communication with EC/Sponsor/CDSCO, GCP/Sch.Y, training to trial team, training assessment				
4	Whether SOPs for all operation like IP handling and distribution to study subjects, blood samples collection, processing preservation and transportation to local laboratory.				
5	Whether SOPs for all operation of storage cabinets, refrigerators/deep freezers used to store samples and IP are available.				

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6	Verify, whether records for job description/responsibilities, qualification and training for all personnel involved in the clinical trial is maintained and stored.				

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7	Verify whether the activities performed are in compliance with duty delegated by Investigator.				
8	Verify whether concern staff is adequately trained and records maintained there of				
9	In case of vaccines, are a spillage SOP available and the study team trained to handle such an incidence?				
XI	**Record keeping and data handling**				
1	Is adequate space available for document retention?				
2	Determine whether documents are maintained properly and for the period as specified.				
3	Whether necessary measures have been taken to prevent accidental or premature destruction.				
4	Whether the archival access controlled or restricted to authorized personnel.				
5	Weather SOP available to document all steps in data management in order to allow step by step retrospective assessment of data quality and study performance.				
6	Whether corrections in documents carry the date and initials of Investigators and authorized person.				
XI-a	**Electronic data processing**				
1	Is electronic data processing is done by authorized person?				
2	Verify whether list of authorized persons to make changes is maintained				
3	Verify if provision for recording of trail of changes and deletions made is available.				

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4	Whether the hardware and software use for data recording and processing is validated				

Collect authenticated copies as exhibit wherever any Critical &/or Major non-compliance has been observed.