

	TITLE Procedure for Preparing GCP Inspection		Division Name.	QMS Monitoring Division	
			Document No.	QMS-INS-007	
			Revision No.	00	
			Effective Date	30/12/2022	
			Page No.	1 of 5	
Prepared By		Approved By		Authorized By	
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Designation	Drugs Inspector	Designation	ADC(I)	Designation	DCG(I)
Sign		Sign	V. Rajappan	Sign	
Date	14/12/22	Date	15/12/22	Date	23/12/22

Control Status

1.0 Purpose

To lay down a procedure for preparing GCP inspection and to provide directions to inspectors for conducting inspection at clinical trial site.

2.0 Scope

This document is applicable to the concerned division of CDSCO to set a uniform procedure for preparing GCP inspection.

3.0 Responsibility

3.1 The Inspector/ ADC(I)/ DDC(I) shall be responsible for implementation of the SOP.

3.2 The DDC(I) and ADC(I) of concerned division shall be responsible for overall compliance of the SOP.

4.0 Accountability

DCG (I) or his designee

5.0 Procedure**5.1 Central Inspection Plan**

5.1.1 CDSCO-HQ shall prepare tentative central inspection plan (Annexure-I) on risk based approach taking in to account the clinical trial permission issued, number of clinical trial at particular site, number of enrolment of subjects, date of initiation of trial at a particular site, nature of investigational SAEs, AEs reported product, nature of study, vulnerability of subjects, previous data, compliance history of the investigator/ sponsor/ ethics committee, etc. if any.

5.1.2 Based on the tentative central inspection plan, the inspections shall be conducted by the Zonal/ Sub-Zonal Office during the conduct of clinical trial or after completion of clinical trial as the case may be for verification of GCP compliance. Inspections during conduct of clinical trials give more appropriate information. Accordingly, based on

	TITLE Procedure for Preparing GCP Inspection		Division Name	QMS Monitoring Division	
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			Page No.	2 of 5	
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evaluation of risk/ criticalities involved in product under study or trial itself, such inspection may be carried out.

- 5.1.3 The Zonal/Sub Zonal office may also plan inspection depending on the complaints/ media reports or any other situations which warrants unannounced inspections.

5.2 Inspection Initiation

- 5.2.1 Inspection shall be planned for surveillance/ to verify compliance to GCP to take regulatory decisions or any specific cause(s).
- 5.2.2 The site and date of inspection may be planned by CDSCO (HQ) or Zonal/Sub-Zonal Head on the basis of tentative central inspection plan.
- 5.2.3 Before initiation of inspection, Zonal/ Sub-Zonal Head may take information about status of the trial (Ongoing, completed etc.) from the Sponsor/ Investigator or CDSCO-HQ.
- 5.2.4 The Inspector shall be deputed from the CDSCO Head Quarter or Zonal/Sub-Zonal offices of CDSCO, who may be accompanied by an officer from State Drugs Control Authority & subject expert.
- 5.2.5 The mode of inspection may be hybrid where CDSCO (HQ)/ expert may join virtually or physically.
- 5.2.6 Divisional/ Zonal /Sub-Zonal Head may ask for documents/ information from the sponsor/ CRO/ Investigator or Ethics Committee, if required by Inspector.
- 5.2.7 Routine inspection may need less detail than for cause inspections, or inspections for specific products or systems.
- 5.2.8 Inspector shall review protocol and other relevant documents before Inspection.
- 5.2.9 Inspector shall prepare a comprehensive inspection plan and communicate to the inspection site or concern.

5.3 Review of documents and information

- 5.3.1 Essential information and documentation is identified, obtained and reviewed. This obtained/ collected information is reviewed and evaluated by the inspection team.

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			Revision No.	00	
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			Page No.	3 of 5	
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Results of this review are incorporated into the inspection plan.

- 5.3.2 Necessary information needed which is used to evaluate the essential aspect to be included in the conduct of the inspection, may be derived from a number of sources: Dossier, reference documents, guidelines, legislation, inspection SOPs etc. A guide to the documentation that may be reviewed whichever is available/ gathered prior to the start of an inspection is listed in the Annexure-II of the SOP and in CDSCO guidance document for GCP inspection.

5.4 Inspection plan

- 5.4.1 Inspector shall prepare the inspection plan based on the scope of inspection and reviewed documents.
- 5.4.2 The inspection plan shall be general in outline and define the relevant aspects of the clinical trial sites and scope that are to be covered during the inspection with various aspects of GCP.
- 5.4.3 The inspection plan shall include timelines for the inspection.
- 5.4.4 Inspection shall be planned as per CDSCO Guidance on Clinical Trial Inspection & GCP inspection checklist published on website & Guidance document for functions and responsibilities of Zonal, Sub-Zonal and Port Offices of CDSCO (along with additional points as per current rules and requirements of clinical trial). Accordingly, the inspection checklist shall include all points as per current regulations, Indian GCP guidelines and other applicable guidelines.

NOTE: Rules and checklist update may not be concurrent in some cases; rules shall take the precedence over the checklist

5.5 Inspection announcement

- 5.5.1 The Zonal/ Sub-Zonal or CDSCO-HQ announces the inspection to the Sponsor/ Investigator/ Ethics Committee contact address.
- 5.5.2 The responsible personnel at the selected sites are informed of the forthcoming inspection except in case of unannounced inspection.

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			Page No.	4 of 5	
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5.5.3 Inspection dates for the selected sites are communicated to the sites, in accordance with the timelines in the site inspection plans.

5.5.4 The Inspector(s) shall ensure that the relevant parts of the inspection plans are communicated to the responsible personnel at the site.

5.6 Practical preparation

5.6.1 The need for preparation may differ between inspections, depending on the type of inspection, type of trial, therapeutic area and product, location of the inspection, number of selected sites, etc.

5.7 Other responsibilities of Inspector(s) shall be:

- The verification of the location of the sites and for the co-ordination of the inspection team.
- Keeping the inspection documentation up to date and secure.
- Checking that the confidentiality requirements are adhered.
- To conduct the inspection at the site in accordance with the legal requirements and SOPs.
- Adhering to the timelines

6.0 Annexure / Format

Annexure/Format No.	Title
Annexure-I (QMS-INS-007/F01)	Tentative Central Inspection Plan for Clinical Trial Inspections (Vaccines) for year XXXX
Annexure-II (QMS-INS-007/F02)	Documents/ information used for review prior to the start of the GCP inspection

7.0 References

Doc. No.	Title
1	The Drugs and Cosmetics Act, 1940.
2	New Drugs and Clinical Trial (NDCT) Rules, 2019

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3	CDSCO Guidance on Clinical Trial Inspection
4	Guidance document for functions and responsibilities of Zonal, Sub-Zonal and Port Offices of CDSCO
5	Good Clinical Practices (GCP) Guidelines
6	Guideline for Good Clinical Practice ICH E6(R2)

8.0 Abbreviation

Acronym	Full Form
CDSCO	Central Drugs Standard Control Organization
DCGI	Drugs Controller General (India)
QMS	Quality Management System
DDC (I)	Deputy Drugs Controller, India
ADC (I)	Assistant Drugs Controller, India
DI	Drugs Inspector
GCP	Good Clinical practices
SOP	Standard Operating Procedure
INS	Inspection

9.0 Revision History

Revision No.	Reason(s) for Revision
00	New SOP



Annexure-1 of QMS-INS-007

Tentative Central Inspection Plan for Clinical Trial Inspections (Vaccines) for year XXXX

Central Drugs Standard Control Organization

Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India

FDA Bhawan, ITO, Kotla Road, New Delhi -110002

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Tentative Central Inspection Plan for Clinical Trial Inspections (Vaccines) for year XXXX

S. No.	Name of Sponsor /CT permission holder	Name of Investigational product	Protocol no. and study title	Name of Investigator / Address of clinical trial site	CT approval with date	Remarks

Note: 1) This is a dynamic inspection plan based on the clinical trials approval and may be updated as and when required.

2) Inspections may be planned by Zonal/Sub-Zonal offices as per the specific situation which may be arise from time to time.



Annexure-II of QMS-INS-007

‘Documents/ information used for review prior to the start of the GCP inspection’

Central Drugs Standard Control Organization

Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India
FDA Bhavan, ITO, Kotla Road, New Delhi -110002

DOCUMENTS / INFORMATION FOR REVIEW PRIOR TO THE START OF THE GCP INSPECTION WHICHEVER AVAILABLE

1. Overview of the conduct of the study:

S.No	Contents
1	Total number of sites/ locations
2	Inclusion rate, screening, randomization, etc.
3	SAEs, ADRs
4	Drop out frequency
5	Time frame of trial
6	Annual reports, final report
7	Presence of a similar/extension protocol

2. Sites

S.No	Contents
1	Investigator(s)/ co-investigator(s) CVs and qualifications
2	Information on sites involved/selected (including e.g. pharmacy clinical departments X-ray, MRI, Echo, ECG, CT, CROs)

3. Lab

S.No	Contents
1	Local/ Central
2	Type of labs involved
3	Type of examinations/ tests
4	Special equipment/ procedures

4. Sponsor

S.No	Contents
1	Responsibilities defined in contracts
2	CRO(s) involved
3	Protocol, amendments, investigator's brochure
4	CRFs
5	Printout (of parts) of the clinical database
6	Quality management (QC, QMS)
7	Sponsor SOPs related with the scope of the inspection



Annexure-II of QMS-INS-007

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5. Trial Medication

	Contents
1	GMP
2	Manufacturing
3	Labelling
4	Blinding procedures
5	Randomization list
6	Quality documentation

6. Ethics

	Contents
1	Patient information/informed consent
2	Patient recruitment
3	Insurance
4	Updates of safety information
5	IEC opinion

7. Local inspectorate

	Contents
1	Availability of qualified inspectors
2	Availability of qualified GMP inspectors (if the scope of the inspection covers IMP)
3	Recruitment of external experts
4	Time schedule

8. Local legal regulations

	Contents
1	Applicable GCP and legal requirements
2	Notification/ approval of protocol
3	Importation of investigational products
4	Announcement of inspection to the competent authority
5	Trial medication: import license, labeling, storage, destruction
6	SAE reporting