DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of External Audits at the Site	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for handling of external audits or inspections from Regulatory agency, Customer.

2.0 SCOPE:

This SOP is applicable for handling of external audits or inspections from Regulatory agency, Customer at ……..

3.0 RESPONSIBILITY:

3.1 QA (Officer/ Executive): Preparation, Distribution (to Respective Departments), Revision, Retrieval & Destruction of this SOP.

4.0 ACCOUNTABILITY:

4.1 Head QA: Approval, ensure Training and Implementation of this SOP.

5.0 DEFINITIONS:

NA

6.0 PROCEDURE:

Note: The contents of the audit compliance reports shared with external agency/party/regulatory agency in response to the observations noticed during inspection are confidential and revelations of these observations to other external auditors is restricted as per management decision.

6.1 Preparing for an Inspection or Audit

6.1.1 Head QA/Designee shall confirm with the external agency (auditor/party, as applicable) regarding the agreed dates and times of the inspection/audit, and verify the purpose of the inspection/audit and the inspection/audit plan and procedures.

6.1.2 Head QA/Designee shall inform all the concerned Department Heads about the audit plan & purpose.

6.1.3 Head QA/Designee shall review the inspection/audit procedures with all the concerned Department Heads and conduct a thorough review of the required documentation.

6.1.4 Head QA/Designee shall ensure arrangement and ease for access to the appropriate documents for the inspector/auditor.

6.2 Participating in an Inspection or Audit

6.2.1 Head QA/Designee shall meet with the inspector/auditor as scheduled.

6.2.2 Prior to being granted access to the documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit.

6.2.3 Head QA/Designee shall provide a brief orientation to the inspector/auditor of …….. procedures.

6.2.4 Head QA/Designee shall accompany the inspector/auditor at all times while in confidential areas of the site.

6.2.5 Head QA/Designee shall ensure that the inspector/auditor's questions are answered by the most appropriate personnel. Plant Personnel must make every reasonable effort to be available and to accommodate the requests of the inspector/auditor.

6.2.6 Head QA/Designee shall request meetings with the inspector/auditor at the end of each day, as needed, to discuss any observations. If questions are asked or observations are made during the daily meetings, Head QA/Designee research the issues and provide the inspector/auditor with clarification as soon as possible once the information is available.

6.2.7 Head QA/Designee shall ensure that observations are understood before the inspector/auditors leave the facility.

6.2.8 Head QA/Designee shall record any observations of the inspector/auditor and any discussion and ascertain when/if a written response is required.

6.3 Follow-up after an Inspection or Audit

6.3.1 After receiving the Audit Non compliance report from any source (Customer/Regulatory Bodies), Executive/Manager QA shall prepare (write/copy) the Audit Compliance report in respective format as shown in **Annexure-I** or in the customer/Regulatory format (If requested by them).

6.3.2 QA shall circulate the copy of prepared report (in Microsoft word format) to concerned department Head through mails for their compliance and reply.

6.3.3 Concerned Department Heads shall revert back the same report after writing their reply in **"CAPA Plan"** column of the report, along with target completion date.

6.3.4 QA Officer/Executive shall combine the replies with consultation & guidance of Manager/Head QA.

6.3.5 Head QA/Designee shall verify the compliance status and if found satisfactory shall reply to Customer/Regulatory bodies.

6.3.6 If work for any compliance is under progress, then Head QA shall get a target date from respective department Head and shall reply to Customer/Regulatory Body accordingly.

6.3.7 If observations are Classified/Categorized by the Auditor, Audit Compliance Report shall contain Class/Category and in case Classification/Categorization not defined by auditor then the **"Observation Category"** column of the format **"Audit Compliance Report"** as shown in **Annexure-I**, shall be omitted during compilation.

6.3.8 Wherever Corrective and/or Preventive Action are provided as compliance for reported observation, correspondingly CAPA (Corrective and Preventive Action) may be filed.

6.3.9 If any compliance require time frame, Target date shall be mentioned in **"Target Completion Date''** column. QA department shall take follow ups for completion of such compliances and send the status to respective Customer/Regulatory Body after completion or as and when required by auditor.

6.3.10 QA Officer/Executive shall compile replies of all departments in a single report.

6.3.11 Printout of this common compiled report shall be taken and Executive/ Manager QA shall put signature with date in Prepared By & this report shall be approved by Head QA or his/her designee.

6.3.12 Scan copy of this signed report shall be sent to respective customer / Regulatory Body and Hard copy shall be kept for reference.

6.3.13 If Hard copy of the compliance report is required by Customer / Regulatory Body, Xerox copy or printout from scan copy of original compliance report shall be kept for reference.

6.4 Numbering System of Audit Compliance Report:

6.4.1 Officer/Executive-QA shall assign a tracking number to the Audit Compliance Report (in Microsoft word format). The tracking numbers to be assigned sequentially based on the order in which the audit report is received from external agency/customer/regulatory agency, as mentioned below.

QA/COMP/YY/ZZZ

Where,

QA – stands for Quality Assurance
/ – separator
COMP – stands for Audit Compliance Report
YY – stands for last digit of the year (i.e. 19 stands for Year 2019 and so on.
/ – separator
ZZZ – stands for the continuous serial number of the audit compliance report of the respective year (i.e. 001, 002, 003,…….)

6.4.2 Audit compliance report sent to concerned party/customer/regulatory body shall be recorded as per **Annexure-II**.

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
No.	Number

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Audit Compliance Report	
Annexure-II	Record of Audit Compliance Report	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department

10.0 REFERENCES:

In House

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I

Audit Compliance Report

Name of Plant **:** .....

Address **:** .....

Date of Audit **:**

Auditor(s) **:**

Auditee(s) **:**

Observation Category	Observation No.	Details of Observation	CAPA	Target Completion Date	Remark

Prepared By
Sign & Date:

Checked By
Sign & Date:

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ANNEXURE-II

RECORD OF AUDIT COMPLIANCE REPORT

S.No.	Date of Audit	Name of external Agency/Customer/Regulatory	Compliance Report Number