DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Regulatory Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. **PURPOSE:**
   To define the procedure for handling of Regulatory Inspection.

2. **SCOPE:**
   The procedure is applicable to ……

3. **RESPONSIBILITY:**
   Head- QC & A/GM-Operations/Department Heads.

4. **PROCEDURE:**

4.1. On receipt of information regarding regulatory inspection, Head – QC & A shall send inter-office communication to all department heads indicating the purpose of inspection and checklist if any.

4.2. Concerned department heads shall ensure that the relevant documents and other requirements are made available before the date of inspection.

4.3. Team comprises the following members shall review the requirements for inspection as per checklist given by inspection authorities or as per details given in Annexure I. Any corrective action shall be taken as per pre - approved document procedures.

4.3.1. GM-Operations, Manager- Production, Manager- QA, Manager- QC, Manager- Engineering.

4.4. Before the date of inspection, Head- QC & A shall circulate an inter-office communication, indicating the persons need to attend open meeting on inspection day as per details in Annexure II. Any corrective action shall be taken as per pre – approved document procedures.

4.5. Once the inspectors reached the factory, Head- QC & A and GM-Operations shall invite and bring them to conference room for opening meeting.

4.6. The persons already notified shall be present for the opening meeting. Head- QC & A or GM-Operations shall brief about company profile to the inspectors.

4.7. The day's agenda shall be discussed with the inspectors and arrangements shall be made based on inspector's requirements.

4.8. Head- QC & A shall coordinate the inspection and only the following representatives shall interact with the inspectors on any query, as and when required.

4.8.1. GM-Operations.
4.8.2. Manager- Production.
4.8.3. Manager- QA.
4.8.4. Manager- QC.
4.8.5. Manager- Engineering.

4.9. While interaction with the inspector, the representative shall understand the query completely and present only the relevant documents within reasonable time. Explanations shall be given only on demand.

4.10. At the end of the inspection, closing meeting shall be arranged and the members who were present in opening meeting shall be represented.

4.11. After receipt of the inspection report from inspectors, Head – QC & A shall initiate corrective action in consultation with the department heads. A copy of report shall be forwarded to Director & Executive Vice President.

4.12. The corrective action plan shall include timelines and person responsible to complete the activity.

4.13. The corrective action plan shall be sent to the regulatory authorities through Director and Executive Vice President.

4.14. The concerned department heads shall ensure that corrective actions are implemented within the timelines.

5 ENCLOSURES:
Annexure-I: Checklist for preparation before Regulatory Inspection.

Annexure- II: Inter office communication

6. MASTER SOP – Retained by Head – QC & A/Management Representative.

7. NUMBER OF CONTROLLED COPIES: 06

8. DISTRIBUTION LIST:

Copy No.	Distributed To
01	Manager – QC & A
02	GM- Operations
03	In-charge – Warehouse
04	Manager- Production
05	Manager – Maintenance
06	Manager - HR

9. REVISION HISTORY:

Date of Preparation	Revision History	Change Details	Reason for Revision
	00	New SOP	Not applicable