DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling inspections by the International Regulatory Agencies	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To establish responsibilities and guidelines for proper conduct in handling inspections by the International Regulatory Agencies.

2.0 SCOPE:

This procedure is applicable for proper conduct in handling inspections by the International Regulatory Agencies.

3.0 RESPONSIBILITY:

3.1 The Quality Assurances Department is responsible for communicating the inspection schedule to various departments in the plant and to receive the Inspectors from external Regulatory agencies.

3.2 The Quality Assurance Department is responsible to facilitate the inspection in the plant.

4.0 ACCOUNTABILITY:

Head-QA/ his designee.

5.0 PROCEDURE:

5.1 Receiving the Inspector

5.1.1 Properly credentialed Inspector bearing a notice of inspection/accompanied by Company representative shall be allowed into the plant by the security staff.

5.1.2 Security shall direct the inspector to a comfortable area and contact Plant head/Head QA in charge.

5.1.3 The Plant head/Head QA in charge shall accept the written notice of inspection from the inspectors, in appropriate form if any else accept based on production of appropriate credentials.

5.2 Handling the Inspection

5.2.1 The Company representative shall document the minutes of the inspectors investigation points during the inspection and periodically communicate to the management. The representative of the Company shall always accompany the inspector during the inspection.

5.2.2 The inspector questions shall be answered honestly and completely without speculation. If one does not know the answer, the same shall be noted and answers shall be given after verification

5.2.3 If the Inspector needs to see records, determine exactly what is required and supply the records/ information as appropriate.

5.2.4 If copies of records are required, supply the copies and retain a duplicate.

5.2.5 During the inspection company representative shall provide responsible and knowledgeable persons to the inspectors, who can give accurate answers to questions.

5.2.6 Because the company policy generally prohibits the taking of photographs, inform the Inspector of the policy.

5.2.7 At the end of each working day, request the Inspectors to discuss with you any concerns they may have developed during the course of their inspection.

5.2.8 Company representative shall discuss the observation with all Head's of Departments.

5.3 **Wrap up Inspection**

5.3.1 When the inspection is complete, company representative shall return with the Inspector to the conference area for an exit interview.

5.3.2 Accept the Inspection Report from the Inspector of Regulatory Agency, if one is given and discuss the findings with the Inspector.

5.3.3 If there is disagreement with any of the findings, point the matter out to the Inspector with a view to having it removed or corrected, but do not be argumentative.

5.4 **Close out of Inspection**

5.4.1 As soon as possible after the inspection/investigation, company representative shall convene a meeting with the persons responsible for taking corrective action on the alleged deficiencies.

5.4.2 Quality Assurance Department shall coordinate and prepare appropriate responses with a time table for corrective action.

5.4.3 Regulatory Affairs shall submit written responses to Inspectors of Regulatory Agencies promptly for actions required, and assure that the required actions are implemented.

5.5 **Retention Samples**:

5.5.1 If Inspectors of Regulatory Agencies request product samples, Quality Assurance shall arrange to provide and retain duplicate sample amounts of those provided.

6.0 ABBREVIATIONS:

SOP - Standard Operating Procedure

QA - Quality Assurance

7.0 CROSS REFERENCES:

NA

8.0 REFERENCES:

In-House

9.0 ATTACHMENTS:

NA

10.0 CIRCULATION LIST:

Quality Assurance

Production

Engineering

Quality Control

Warehouse

Personnel & Administration

Purchase

Account

11.0 REVISION HISTORY:

SOP NUMBER	REASON FOR CHANGE	VERSION NUMBER	SUPERSEDES	CHANGE CONTROL No.
	New SOP	01	NIL	NA