# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Quality Assurance | **SOP No.:** |
| **Title:** Procedure for Handling of Regulatory Communication | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

## 1.0 OBJECTIVE:

To lay down a procedure for Handling of Regulatory Communication.

## 2.0 SCOPE:

This SOP is applicable for Handling of Regulatory Communication at …….

## 3.0 RESPONSIBILITY:

Officer/Executive –Licensing and Legal

## 4.0 ACCOUNTABILITY :

Quality-Head

## 5.0 DEFINITION:

Not Applicable

## 6.0 PROCEDURE:

**6.1** For regulatory communication from State drugs inspectors/Government testing laboratory /CDSCO/Railway board /Institutions/Doctors/Medical college/NPPA/End users etc. all letters shall be received by Licensing & Legal department.

**6.2** Once communication received at legal department at Skymap , legal department will assess the requirement /Complaints /Non compliances/Noticed for further compliance & requirement fulfillment of State drugs inspectors/ Government testing laboratory /CDSCO/Railway board /Institutions/Doctors/Medical college/NPPA/End users etc.

**6.3** Licensing & Legal department shall forward the letter to Quality Assurance department.

**6.4** After receiving of the regulatory related letter from the Licensing & Legal department letter shall be log in Annexure –I of this SOP by Officer/Executive of Quality Assurance Department.

**6.5** Quality assurance shall check the regulatory requirements.

**6.6** If any reference standard/working standard with COA and Method of analysis required, Quality assurance shall inform to Quality control department for the same.

**6.7** Quality assurance shall provide control sample of the respective batch for analysis in in-house laboratory for confirmation of Quality of the product.

**6.8** After confirmation of the Quality of the product from Quality Control department, Quality assurance shall collect the reference standard/Working standards with COA and method of analysis.

**6.9** Quality assurance shall review the documents.

**6.10** Licensing and Legal department shall inform to Customer as per Annexure –II of this SOP and take comment from the customer if any. (Within 5 Working days)

**6.11** Quality assurance shall provide Reference standards /Working standards with COA and Method of analysis to licensing and legal department.

**6.12** After review of the documents licensing and Legal department will initiate the reply to regulatory body consulting with Quality Head along with supportive documents & working standards etc.

**6.13** Licensing and Legal department shall sent documents and working/reference standards to the respective place /department as per address mention on the letter within time line framed on letter.

**6.14** For any legal activity shall be handle by Licensing & legal department.

**6.15** Respective letter received shall be maintained in the Separate file in Licensing and Legal department along with document sent to regulatory body.

**6.16** All the legal communication must be done through registered post & acknowledgment must be kept in to record.

**6.17** Reply shall be communicated to customer /party for their acknowledgement.

## 7.0 ABBREVIATIONS:

SOP : Standard Operating Procedure

QA : Quality Assurance

Ltd. : Limited

No. : Number

COA : Certificate of Analysis

CDSCO : Central Drugs Standard Control Organization

NPPA : National Pharmaceutical Pricing Authority

## 8.0 ANNEXURES:

| ANNEXURE No. | TITLE OF ANNEXURE | FORMAT No. |
|---|---|---|
| Annexure-I | Log of regulatory letter | |
| Annexure-II | Customer Information Form | |

## 9.0 DISTRIBUTION:

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

## 10.0 REFERENCES:

Not applicable

## 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

## LOG OF REGULATORY LETTER

| S.No. | Date | Letter Reference No. | Received from | Description of regulatory communication | Received by | Communicated to Customer/ Party on | Replied on | Checked By | Remarks |
|---|---|---|---|---|---|---|---|---|---|
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## ANNEXURE –II

## CUSTOMER INFORMATION FORM

| | |
|---|---|
| **Date of Letter received** | |
| **Letter received from** | |
| **Name of Customer/Party** | |
| **Subject** | |
| **Product Name** | |
| **Batch No** | |
| **Mfg Date** | |
| **Exp Date** | |
| **Corrective action planned** | |
| **Feedback from customer/Party** | |

**Note: Customer feedback must be shared within 5 working days.**

**Sign and date:**
**(Quality-Head)**

**Signature and date:**
**(Customer)**