PHARMA DEVILS

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		

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.:**

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

PHARMA DEVILS

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.:**

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)