| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Quality Assurance | **SOP No.:** |
| **Title:** Role and Responsibility of Quality Assurance Department | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

## 1.0 OBJECTIVE:

To lay down a Procedure to define Role and Responsibilities of Quality Assurance Department.

## 2.0 SCOPE:

This SOP is applicable to define the Role and Responsibilities of Quality Assurance Department at …….

## 3.0 RESPONSIBILITY:

QA (Officer/ Executive): Preparation, Review, Distribution, Revision, Retrieval and Destruction of this SOP.

## 4.0 ACCOUNTABILITY:

**Head QA:** Approval

## 5.0 DEFINITION:

Not Applicable

## 6.0 PROCEDURE:

### 6.1 Responsibilities of Quality Assurance is given below:

**6.1.1** To impart cGMP, GLP, Behavioral, Motivational and other kinds of Training ensuring Compliance of the specified procedure/guidance's.

**6.1.2** Handling of Quality Management System, Including Change Controls, Deviations, Incidents, Control of Non-Conforming Materials/Products, Monthly Reports, Analytical Method Validations, Analytical Method Transfers, Vendor Audits and Updating the Approved Vendor List (s), OOS, OOT, CAPA, etc.

**6.1.3** Co-ordination with various Departments to implement cGMP in Plant.

**6.1.4** Destruction, Review, Approval and Rejection of Documents.

**6.1.5** in-Process Control.

**6.1.6** Handling of Rework & Reprocess.

**6.1.7** Handling of Yield Variations.

**6.1.8** Monitoring and Control of Manufacturing Environment.

**6.1.9** Designing and Monitoring the Storage conditions for Materials and Products.

**6.1.10** Monitoring of Utility like HVAC, Water System etc.

**6.1.11** Training.

**6.1.12** Documents Control.

**6.1.13** Qualification and Validation Activities.

**6.1.14** Handling of Validation Failure.

**6.1.15** Vendor Audit/Approval.

**6.1.16** Preparation, Handling and ensuring compliance of various Regulatory Agencies & Customer Audits.

**6.1.17** Investigation and Collection of Samples.

**6.1.18** Annual Product Review.

**6.1.19** Co- ordination with Regulatory Department.

**6.1.20** Handling of Market Complaints.

**6.1.21** Document Numbering System.

**6.1.22** Batch Release / Rejection

**6.1.23** Product Recall.

**6.1.24** Handling of Return Goods.

**6.1.25** Stability Studies of Products.

**6.1.26** Management of Control Sample.

**6.1.27** Reference Sample Management.

**6.1.28** Preparation, Approval of SOP’s, BMR, BPR and Protocols.

**6.1.29** Preparation of Calibration Policy and Implementation.

**6.1.30** Internal audit.

**6.1.31** Handling of ID. labels.

**6.1.32** Analysis on contract basis.

**6.1.33** Handling of OOS in stability.

**6.1.34** Signature authorization in QA & QC department.

**6.1.35** Handling of rounding of figures in QA & QC.

**6.1.35** Artwork Approval

**6.2** In the absence of respective designated as assigned, responsibility shall be carry forward to his or her designee.

## 7.0 ABBREVIATIONS:

**BMR** Batch Manufacturing Record

**BPR** Batch Packing Record

**cGMP** Current Good Manufacturing Practices

**CAPA** Corrective and Preventive Action

**GLP** Good Laboratory Practices

**HVAC** Heating Ventilation and Air Conditioning

**OOS** Out of Specification

**OOT** Out of Trend

**WHO** World Health Organization

**TRS** Technical Report Series

**SOP** Standard Operating Procedure

**QA** Quality Assurance

**QC** Quality Control

**SOP** Standard Operating Procedure

**ID** Identification

## 8.0 ANNEXURES:

Not Applicable

## 9.0 DISTRIBUTION:

 Master Copy Quality Assurance Department.

 Controlled Copy No. 01 Quality Assurance Department.

## 10.0 REFERENCES:

WHO TRS

PIC/S

## 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 | | |