



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.



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.:

- 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.



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.:

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



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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.:

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		