

PHARMA DEVILS QUALITY CONTROL DEPARTMENT

| STANDARD OPERATING PROCEDURE | | | | | | | | |
|---|---------------------|--|--|--|--|--|--|--|
| Department: Quality Control | SOP No.: | | | | | | | |
| Title: Sampling, Testing, Release and Rejection of Consumable Items | Effective Date: | | | | | | | |
| Supersedes: Nil | Review Date: | | | | | | | |
| Issue Date: | Page No.: | | | | | | | |

1.0 OBJECTIVE:

To lay down a procedure for Sampling, Testing, Release & Rejection of Consumable Item.

2.0 SCOPE:

This SOP is applicable to sampling, testing, release & rejection of consumable Item like sodium hydroxide and hydrochloric acids etc.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department Head – Quality Control Department

4.0 **DEFINITION(S):**

NA

5.0 **PROCEDURE**:

5.1 Sampling of consumable items:

- 5.1.1 Sampling of consumable item shall be initiated after receiving the "GRN" from warehouse.
- 5.1.2 Quality control personnel shall enter the material details in consumable inward record as per Annexure-I, and shall assign A.R. No. for each batch /lot.
- 5.1.3 Quality control personnel shall prepare Under test label.
- 5.1.4 Quality control personnel shall perform the sampling of the items as per $\sqrt{n+1}$ and paste under test label on each pack and paste sample label on sampled pack.

5.2 Testing of consumable items:

- 5.2.1 Quality control personnel shall perform the analysis as per respective specification and standard test procedure.
- 5.2.2 Raw data shall be recorded in the respective work sheet.



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- 5.2.3 After completion of analysis, all data shall be reviewed and certificates of analysis for each batch shall be prepared.
- 5.24 Incase of items which cannot be tested in-house, they will be approved on the basis of manufacturers COA

5.3 Release/Reject of consumable items:

- 5.3.1 If materials is approved prepare Approved labels for each containers and affix on each packs of the particular batch above the "Under test label".
- 5.3.2 If materials is rejected prepare Rejected labels and affix on each packs of the particular batch above the "Under test label". Initiate the "Rejection Note" for respective consignment.
- 5.3.3 Send the rejection note to warehouse and ensure that the item is transferred to rejected area.

6.0 **ABBREVIATION(S):**

QCD - Quality Control Department

SOP - Standard Operating Procedure

7.0 **REFERENCE(S):**

NA

8.0 ANNEXURE(S):

Annexure-I: Consumable Item Inward record.

9.0 **REVISION CARD:**

| S.No. | REVISION No. | REVISION DATE | DETAILS OF REVISION | REASON (S) FOR REVISION |
|-------|-----------------|------------------|------------------------|----------------------------|
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| CONSUMABLE ITEM INWARD RECORD | | | | | | | | | | | | | | |
|-------------------------------|-----------------------|-------------------------------|--------|-----------|-----------|------------------|------------------------------|---------------|--------------------|------------|-----------|-------------------|---------|---------|
| S.No | Date of Intimation | Name of Consumable item | B. No. | Mfg. Date | Exp. Date | Qty. Received | Suppliers / Manufacturers | Sampled By | Challan No/Date | GRN No. | AR No. | Date of Report | Analyst | Remarks |
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