

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

| Department: Production | SOP No.: |
|---|-----------------|
| Title: Procedure for On line Rejection of Raw material and Packing material | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a procedure for On line Rejection of Raw material and Packing material.

2.0 SCOPE:

The procedure is applicable for On line Rejection of Raw material and Packing material.

3.0 RESPONSIBILITY:

Operator/Officer /Executive/Assistant Manager Head Production: To ensure execution & compliance. Head QA: To ensure the compliance.

4.0 **PROCEDURE:**

- 4.1 This procedure is applicable to all materials issued to the production which are found abnormal in the quality before taking for processing / partially consumed.
- 4.2 Inform to shift in-charge, QA and HOD whenever any abnormality observed in the material prior to start the batch, for any abnormality observed in the material partially consumed in batch, Segregate the rejected material and affix on line rejection label as per SOP.
- 4.3 Fill the batch returned material disposition report (BRMDR) as per the Annexure-I of SOP.
- 4.4 Issue additional material in additional material requisition slip as per SOP from store for the issue of same quantity for process.
- 4.5 Provide copy of BRMDR as per SOP and copy of AMR as per SOP to store for issuing material against line rejection qty to production.
- 4.6 After approval from QA Head, receive the new material from store and take for processing.

5.0 ANNEXURE (S):

Nil

6.0 **REFERENCE** (S):

SOP: Disposition of Batch Returned material.



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SOP: Status labeling in production department.

SOP: Procedure for issuance of Additional raw material and Packing material from store.

7.0 ABBREVIATION (S) /DEFINITION (S) :

BRMDR: Batch return Material Disposition Report

- AMR : Additional material requisition
- QA : Quality Assurance
- SOP : Standard Operating Procedure
- QAD : Quality Assurance Department
- HOD : Head of Department

REVISION CARD

| S.No. | REVISION No. | REVISION DATE | DETAILS OF REVISION | REASON (S) FOR REVISION | REFERENCE CHANGE CONTROL No. |
|-------|-----------------|------------------|------------------------|----------------------------|------------------------------------|
| 1 | 00 | | | New SOP | |