



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Spillage Handling

| | | | |
|--------------------------------|-----|------------------------|------------|
| SOP No.: | | Department: | Production |
| | | Effective Date: | |
| Revision No.: | 00 | Revision Date: | |
| Supersede Revision No.: | Nil | Page No.: | 1 of 2 |

1.0 OBJECTIVE:

To lay down a procedure for Spillage Handling.

2.0 SCOPE:

This SOP is applicable for Spillage Handling in production area.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

| | |
|------|------------------------------|
| BMR | Batch Manufacturing Record |
| ETP | Effluent Treatment Plant |
| MSDS | Material Safety Data Sheet |
| PM | Packaging Material |
| QA | Quality Assurance |
| QC | Quality Control |
| RM | Raw Material |
| SOP | Standard Operating Procedure |

6.0 PROCEDURE:

- 6.1 As soon as spillage is observed, "**Hold**" the said Processing / Packing Operation and take needful corrective action to restrict further loss of RM / Product Bulk / Packaging Material.
- 6.2 Inform the shift In-charge about the same, further they will intimate to the Department Head and Head-QA.
- 6.3 If possible collect & check the weight of the spilled RM / Product Bulk / Packaging Material.
- 6.4 Record the loss of quantity in respective BMR followed by its further approval from QA personnel.
- 6.5 In the event of bulk spillage during Manufacturing, Blending, Filtration and Filling, stop the spillage by closing the valves of vessels having the bulk product.
- 6.6 In the event of product container's breakage at the time of filling & collect the broken containers in a Poly Bag. Handover the glass waste & paper waste to housekeeping personnel after proper Status Labeling.
- 6.7 Dilute the spilled RM / Product Bulk with sufficient quantity of Water (Refer MSDS if required).
- 6.8 Drain the diluted Solution / Suspension / Slurry in the Drain System from specified Drain Points and intimate ETP Personnel for its final disposal.



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6.9 Perform the cleaning of the area as per relevant SOP.

6.10 Raise the requisition for additionally required quantity of RM or PM (if any) on Material Requisition note followed by approval from QA.

6.11 Proceed for further processing of the said batch. Prior to proceeding for filling and sealing send the sample to QC and get its compliance reports as per relevant stage's specification.

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01: Quality Assurance
- Controlled Copy No.02: Production
- Master Copy: Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

| Revision No. | Change Control No. | Details of Changes | Reason for Change | Effective Date | Updated By |
|--------------|--------------------|--------------------|-------------------|----------------|------------|
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