STANDARD OPERATING PROCEDURE

Title: Handling of Spillage of Cyclosporine Products

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 handling of spillage of Cyclosporine products.

2.0 SCOPE:

This SOP is applicable for Handling of spillage of Cyclosporine products at Three Piece area.

3.0 RESPONSIBILITY:

Officer / Executive Production /Warehouse

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
ETP	Effluence Treatment Plant
Ltd	Limited
MSDS	Material Safety Data Sheet
No.	Number
PM	Packing Material
Pvt	Private
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 If possible collect & check the weight of the spilled RM / Product Bulk / Packaging Material.

6.3 Record the loss of quantity in respective BMR followed by its further approval from QA personnel.

6.4 In the event of bulk spillage during Manufacturing, Filtration and Filling, stop the spillage by closing the valves of vessels having the bulk product.

6.5 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 house-keeping personnel after proper Status Labeling.

6.6 Dilute the spilled RM / Product Bulk with sufficient quantity of 2.5% Sodium hypochlorite solution (Refer MSDS if required).

6.7 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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6.8 Perform the cleaning of the area as per relevant SOP.

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

6.10 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 ANNEXURE:
Not Applicable
ENCLOSURE: SOP Training Record

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

9.0 REFERENCE:
In House

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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