



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Decontamination of Scrap for 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 Decontamination of Scrap for Cyclosporine Products.

2.0 SCOPE:

This SOP is applicable for Decontamination of Scrap for Cyclosporine Products in Three Piece Area.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR Batch Manufacturing Record
Ltd. Limited
No. Number
Pvt Private
QA Quality Assurance
SOP Standard Operating Procedure

6.0 PROCEDURE:

- 6.1 Collect the rejected vials, dropper and cap during filling and packing at the end of the activity.
- 6.2 Record the rejected quantity of vials, dropper & caps in respective BMR.
- 6.3 Open the rejected vials with the help of opener.
- 6.4 Dip the rejected vials, dropper and caps into container having 2.5 % Sodium Hypochlorite solution for 30 minute.
- 6.5 Drain this Solution from container in the drain existing in equipment wash room of unit preparation area.
- 6.6 Then send the scrap i.e. rejected vials, dropper and cap as per SOP of "Handling and Destruction of In-Process Rejections" to scrap yard after decontamination.
- 6.7 Cleaning & sanitization of drain point shall be done after drain off the solution as per SOP "Cleaning & sanitization of drain traps in production area" SOP.

7.0 ANNEXURE :

Not applicable.

ENCLOSURE: SOP Training Record

8.0 DISTRIBUTION:



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- 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