



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Preparation & Consumption of Decontamination Solution	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 OBJECTIVE:**

The objective of this Standard Operating Procedure (SOP) is:

- 1.1 To describe the procedure for preparation and consumption of decontamination Solution used for decontaminating crates, SS containers, and polybags of process waste and for decontamination for change room procedure.

**2.0 SCOPE:**

- 2.1 This SOP is applicable in Beta-lactum Block for Preparation & Consumption of Decontamination Solution.

**3.0 RESPONSIBILITY:**

- 2.1 Housekeeping workmen shall be:
  - 2.1.1 Responsible for preparation of the decontamination solution as per the below mention procedure.

**4.0 ACCOUNTABILITY:**

Executive-Production.

**5.0 PROCEDURE FOR PREPARATION OF DECONTAMINATION SOLUTION:**

**5.1 Preparation of Decontamination solution (2.0 % w/v Sodium Hydroxide)**

- 5.1.1 Check for the cleanliness of the containers before preparation.
- 5.1.2 Take required quantity of Sodium Hydroxide & mix Purified) water in order to have 2 % w/v solution. Stir it until it dissolves completely.
- 5.1.3 Put Status label on the container mentioning Name of Solution with Concentration, date of Preparation & Prepared by.

**PRECAUTIONS: Always wear hand gloves while preparing decontamination Solution.**

**5.2 Consumption:**

- 5.2.1 Transfer the decontamination solution into respective containers for decontamination of HDPE crates, SS containers, poly bag of process waste etc.



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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5.2.2 Discard all the excess decontamination solution at the end of the shift and record in the daily preparation and consumption record as per Annexure I.

**NOTE:** Quantity of solution prepared can be increased by proportionately increasing the Quantity of Sodium hydroxide (NaOH) and water as per requirement.

### 6.0 TRAINING:

Trainer	--	Head - Production
Trainee	--	All Departmental Executives, Officers and related workmen
Period	--	One day

### 7.0 DISTRIBUTION:

Certified Copy No. 1	:	Head of Department
Certified Copy No. 2	:	Head – Plant Operations
Reference Copy No. 3	:	For Display – Loading /Unloading bay
Reference Copy No. 4	:	For Display – House keeping area
Original Copy	:	Head – Quality Assurance

### 7.0 ANNEXURE:

Annexure 1: Format for Decontamination solution preparation and consumption record.

### 9.0 REFERENCE:

In-House and SOP

## REVISION HISTORY

Revision Number	Effective Date	Revision Details	Reason for Revision	Authorized By



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**ANNEXURE - 1**

**FORMAT FOR PREPARATION AND CONSUMPTION OF DECONTAMINATION SOLUTION**

<b>REF. SOP No.:</b>	<b>Version No.:</b>	<b>Page No.:</b> 01 of 01
	<b>Effective Date:</b>	

<b>Preparation &amp; Consumption Record of Decontamination Solution</b>					<b>Department: House Keeping</b>	
					<b>Ref. SOP No: .....</b>	
<b>Date</b>	<b>Quantity of 2% NaOH Prepared by</b>	<b>Prepared By</b>	<b>Checked By</b>	<b>Quantity of 2% NaOH Consumed</b>	<b>Checked By</b>	<b>Remarks</b>

<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>	<b>Authorized By</b>