



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Decontamination & Cleaning of Beta-Lactam Facility	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 OBJECTIVE:**

To lay down the procedure for decontamination and cleaning of Beta-Lactam facility.

**2.0 SCOPE:**

This SOP is applicable to old Beta- Lactam Facility.

**3.0 RESPONSIBILITY:**

- 3.1 External Contract agency shall be responsible for carrying out decontamination and cleaning of Beta-Lactam facility.
- 3.2 Associate Officer and above of concerned dept. shall be responsible for verification of decontamination and cleaning activity of Beta-Lactam facility.
- 3.3 Head Project / Head QA shall be responsible for the implementation of this SOP.

**4.0 ACCOUNTABILITY:**

Head QA

**5.0 SAFETY REQUIREMENTS:**

- 5.1 Personal involved in decontamination and cleaning shall undergo medical checkup and medical report shall be attached with Final summary report.
- 5.2 Personal shall use all personal protective equipment (PPE) and appropriate gowning during decontamination and cleaning of Beta- Lactam facility.
- 5.3 Tools used during decontamination & cleaning shall be dedicated for Beta – Lactam facility.
- 5.4 After decontamination and cleaning tools must be decontaminated and cleaned adequately and stored separately in dedicated and identified place.

**6.0 PROCEDURE:**

- 6.1 For entry and exit into Beta- Lactam facility follow proper gowning procedure.
- 6.2 Sufficient quantity of 0.5 % NaOCl, 0.1 % NaOH and 1.0% SDS will be prepared and make the solution in ratio of 1:1:1 of each.
  - 6.2.1 **Preparation of 0.5 %w/v NaOCl:**



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Take 100 gm of NaOCl & dissolve in 20 Liters. of Purified water.

**6.2.2 Preparation of 0.1 % w/v NaOH:**

Take 20 gm of NaOH & dissolve in 20 Liters. of Purified water.

**6.2.3 Preparation of 1.0 % w/v SDS:**

Take 200 gm of SDS & dissolve in 20 Liters. of Purified water

6.3 Spray the solution on all the surfaces, holes, crevices and the all the equipments surfaces.

6.4 Keep the area/Equipment as such for validated contact time.

6.5 Thoroughly rinse all the area/equipments surfaces with purified water/WFI and

6.6 Allow to area / Equipment to get air dry.

6.7 The area/equipment should be swabbed for detection of proper decontamination.

6.8 Swab samples shall be sent to approved testing laboratory for testing of Ampicilin, Cloxacillin and Sulbactum as per the approved procedure.

6.9 The acceptance criteria for polled Beta compound (Ampicilin, Cloxacillin and Sulbactum) is - NMT 2.5 ng/ 100 cm<sup>2</sup>.

6.10 In case any of the swab does not complies the acceptance criteria, re-clean the area as per above mentioned procedure and take another swab until clean.

6.11 All metrical use for decontamination and cleaning should be treated as chemical waste and after decontamination shall be sent to ETP.

**7.0 REFERENCES:**

Not Applicable

**8.0 ANNEXURES:**

Not Applicable



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**9.0 ABBREVIATIONS:**

Abbreviations	Full Forms
SOP	Standard Operating Procedures
QA	Quality Assurance
SDS	Sodium Dodecyl Sulfate
NaOCl	Sodium Hypo Chlorite
NaOH	Sodium Hydroxide
ETP	Effluent Treatment Plant
ng	Nano Gram
%	Percentage

**10.0 REVISION HISTORY LOG:**

REVISION LOG			
Revision Number	Effective Date	Details of Change	Reason for Revision
00		Not Applicable	New Introduction