



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title:	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 Objective:

To lay down a procedure for fumigation and De-fumigation of aseptic area.

2.0 Scope:

This SOP is applicable for fumigation and De-fumigation of aseptic area.

3.0 Responsibility:

Officer and Above Production: Implementation of Procedure.

4.0 Accountability:

Production Head.

5.0 Procedure:

6.1 Fumigation

6.1.1 After Cleaning of whole sterile area every weekend/ whenever required perform the fumigation by using 37% Formaline in the Aseptic area

6.1.2 Switch off the entire machine in the sterile area and also switch off the LAF.

6.1.3 Consequently open the door filling, sealing, Cool zone, blending area, Air- lock I, II, III, except the entry door.

6.1.4 Switch off AHU system in the sterile area for 6 hours after fumigation is completed.

6.1.5 Hold the fumigation for minimum 6 hours.



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6.2 Defumigation

6.2.1 Start AHU of Sterile area and open the fresh air, exhaust and air damper and close return air damper. This operation continues till the formaldehyde fumes disappear. After completion of smell of formaldehyde close the exhaust and fresh air damper, open the return air damper.

7.0 Annexure:

Annexure –I: Fumigation and De-fumigation Record.

8.0 Reference:

NA

9.0 Abbreviation:

SOP : Standard Operating Procedure.

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