



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Maintenance of Sterile Area

Effective Date:

Supersedes: Nil

Review Date:

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1.0 OBJECTIVE:

To lay down the procedure for Maintenance of Sterile (Aseptic) Area.

2.0 SCOPE:

This SOP is applicable in injectable department for the Maintenance of Sterile Area.

3.0 RESPONSIBILITY:

Production Supervisor.

4.0 ACCOUNTABILITY:

Production Executive / Asst. Production Manager.

5.0 PROCEDURE :

5.1 Enter the sterile area follows SOP for gowning procedure for sterile area personnel.

5.2 Cleaning of the area (Daily)

5.2.1 Clean the floor of the area for any glass pieces and other waste materials using a mop.

5.2.2 Using a plastic scoop collects the waste in a plastic basket and sends it Outside the sterile area.

5.2.3 Clean the ceilings and walls using a sponge mop and disinfectant solution as per **Annexure –I**.

5.3 WEEKLY CLEANING OF STERILE AREA.

5.3.1 Clean the ceilings, walls and fixtures like laminar stations, tube lights and U.V. lamp covers in once in a week day prior to the weekly holiday as follows:

5.3.2 Clean the ceilings and walls using a sponge mop and disinfectant solution as per **Annexure –I**.

5.3.3 Open the pre-filters of all laminar flows and pressure modules and send them outside the sterile area for cleaning. Assemble these parts after cleaning.

5.3.4 Clean the tube lights and U.V. lights one by one by initially switching them off and then cleaning



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with a clean dry sterilized **NYLON** cloth.

5.4 FUMIGATION OF ASEPTIC AREA :

- 5.4.1 Ensure that air handling unit (AHU) is switched off.
- 5.4.2 Ensure that the all containers containing sterile material are closed.

5.5 FUMIGATION:

- 5.5.1 Generate the formalin gas by heating 200 ml. of formaldehyde solution kept in a beaker by heating, in different areas in the sequence given below.
 - 5.5.2 Filling Room.
 - 5.5.3 Buffer Zone.
 - 5.5.4 Air-Lock II.
 - 5.5.5 Switch Off the light of respective rooms.
 - 5.5.6 Leave the area immediately after closing the door properly.
 - 5.5.7 After fumigating the Air-lock –II. Leave the Air-lock – I. Close the door adjacent to the corridor tightly.
 - 5.5.8 Place a sign board indicating “**Fumigation in process**” on the outside of first entry door.
Temperature should be maintained at **NLT 25°C** and relative humidity of **NMT 55%**.
 - 5.5.9 **De-fumigation** – De-fumigation the area after at least 8 hours.

6.0 ABBREVIATIONS:

- 6.0 SOP – Standard Operating Procedure.
- 6.1 NLT - Not Less than
- 6.2 NMT - Not More Than



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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7.0 ANNEXURES

7.1 Annexure-I : Disinfectant solution

7.2 Annexure-II : Location for plate exposure

CHANGE HISTORY

Supersedes SOP No.	Change Control No.	Changes made
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