



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Department:** Microbiology

**SOP No.:**

**Title:** Aseptic Area Practices

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

### 1.0 Objective

To lay down a procedure to evaluate efficacy fumigating solution used for fumigation in Microbiology lab.

### 2.0 Scope

This Standard Operating Procedure is applicable for formulation plant.

### 3.0 Responsibility

Executive/Officer-Microbiology : Shall be responsible to follow the fumigation efficacy testing procedure.

Head - QC/Designee : Shall be responsible for the compliance of this SOP.

### 4.0 Abbreviations And Definitions

QC : Quality Control

SOP : Standard Operating Procedure

cfu : Colony Forming unit

### 5.0 Procedure

5.1 Prepare plates of Soyabean casein digest agar and Sabouraud chloramphenicol agar

5.2 Preincubate the plates for 24 hours to check for contamination.

5.3 Carry out environmental monitoring by settle plate technique in the Microbiology testing area, before fumigating the area.

5.4 Incubate the Soyabean casein digest agar plates at 30 to 35°C for 72 hours and Sabouraud chloramphenicol agar at 20 to 25°C for 5 days in the inverted position.

5.5 Simultaneously inoculate 100 cfu of *Bacillus subtilis* in the plates and pour 15-20 ml of Soyabean Casein digest medium, mix well and allow the plates for solidification.

5.6 After solidification expose the plates in Microbiology testing area.

5.7 Carry out fumigation and defumigation in area as per the procedure.

5.8 Incubate the plates inoculated with bacillus subtilis on 30-35°C for 72 hrs.

5.9 Incubate an unexposed plate inoculated with *Bacillus subtilis* for 72 hrs as control.



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5.10 After completion of incubation count the cfu observed and record in the format as Annexure-1.

5.11 Carryout the environmental monitoring by settle plate technique in microbiology testing area and under laminar air flow unit after defumigation.

5.12 Incubate the Soyabean casein digest agar plates at 30 to 35°C for 72 hours and Sabouraud chloramphenicol agar at 20 to 25°C for 5 days in the inverted position.

5.13 Count the number of colonies observed and record the results in the format as Annexure-1.

*NOTE: Reduction in no of cfu after fumigation indicates the effectiveness of fumigation.*

### 6.0 Forms and Records

6.1 Report for Evaluation of Fumigation Efficiency : Annexure-1

### 7.0 Distribution

7.1 Master Copy : Documentation cell (Quality Assurance)

7.2 Controlled Copies : Quality Control, Quality Assurance

### 8.0 History

Date	Revision Number	Reason for Revision