PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

EFFICACY OF FUMIGATION

1. Unit Operation:
To ensure that the fumigation is effective in reducing the bioload of the working environment.

2. Objective:
To determine that the fumigation procedure effectively reduces the bio-load of ……

3. Site of Study:
Microbiology laboratory

4. Validation Team:
Representatives from Quality Control : _____

Quality Assurance : _____

5. Area to be validated: _____

6. SOP for the study:
i. SCA, SCDA plates are prepared as per _____.
ii. Plate exposure done as per _____
iii. Fumigation and defumigation done as per_____.

7. Control:
a) Pre-incubated Soyabean Casein Digest agar plates and Sabouraud's chloramphenicol agar plates are used.
b) Unexposed spore strip of *Bacillus subtilis* var niger ATCC 9372.

8. Materials and Equipments Used:
Prepare the media from dehydrated media using purified water. Test the media for pH, Growth promotion ability and pre-incubation.

9. Experimental Results:
Carry out the experiment as per validation protocol.

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10. OBSERVATIONS:

I)

Date of fumigation : Date of De-fumigation:

Residual formaldehyde content:

A) Time of plate exposure before fumigation: Date/sign:

Incubation started at:……..hrs. Incubator No.

Location	Bacterial cfu/plate before fumigation Load no.	Fungal count before fumigation Load no.
Date /sign		

Incubation completed at: hrs.

B) Time of plate exposure after defumigation: Date/sign:

Incubation started at: hrs Incubator No.

Location	Bacterial cfu/plate after fumigation Load no.	Fungal cfu/plate after fumigation Load no.
Date /sign		

Incubation completed at: hrs.

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II) **Viable count of biological Indicators:**

Viable count of biological Indicators (unexposed strips)	
Viable count of biological Indicators after fumigation (exposed strips)	

11. Conclusion:

12. Recommendation:

13. Team approval:

_____ _____

Quality Control Quality Assurance

Date:

14. Review (inclusive of follow up action, if any):

15. Approved by:

_____ _____

QUALITY ASSURANCE UNIT HEAD

Date:

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MICROBIOLOGY DEPARTMENT

EFFICACY OF FUMIGATION

1. **Unit Operation:**
   To ensure that the fumigation is effective in reducing the bioload of the working environment

2. **Objective:**
   To determine that the fumigation procedure effectively reduces the bio-load of Microbiology laboratory.

3. **Site of Study:**
   Microbiology Laboratory

4. **Validation Team:**
   Representatives from: Quality Control
   Quality Assurance

   (Individuals to be named in validation report.)

5. **SOP for the study:**

i. SCA, SCDA plates are prepared as per SOP.
ii Environment count by settle plate technique as per SOP.
iii Fumigation and de-fumigation of the area as per SOP.

6. **Control:**

c) Pre-incubated Soyabean Casein Digest agar plates and Sabouraud's chloramphenicol agar plates are used.
d) Unexposed spore strip of Bacillus subtilis var niger ATCC 9372.

7. **Materials and Equipments Used:**
   Prepare the media from dehydrated media using purified water. Test the media for pH, Growth promotion ability and pre-incubation.

8. **Experimental details:**

a) Prepare the Soyabean casein digest agar and Sabouraud chloramphenicol agar and pour plates as given. Pre-incubate the plates for 48 hours to check for contamination.

b) Carry out the environmental control by settle plate technique in the micro testing area before fumigating the areas as per the SOP.

c) Expose the at least three spore strips of Bacillus subtilis var niger ATCC 9372 in sterile petri plate before starting the fumigation activity in the testing area.

d) Carry out fumigation and defumigation of the area as per the procedure given.

e) After defumigation check for residual formaldehyde content and then carryout the environmental control by settle plate technique in micro testing area as per SOP.

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

g) Count the number of colonies observed and record it in the test data sheet.

EFFICACY OF FUMIGATION

h) Carry out the viable count of exposed and unexposed biological indicator strips as per SOP.

9. Acceptance Criteria

a) The environment count in the area should show reduction in bacterial and fungal count after fumigation

b) Formaldehyde content in the area after defumigation for I hour should not be more than 1 ppm

c) There should be reduction in the viable count of exposed spore strips as compared to the unexposed strips.

COMPILED BY	APPROVED BY	AUTHORISED BY
Unit - Quality Assurance	**Corporate – Quality Assurance**	**Unit head**
Date :	**Date :**	**Date :**