FOGGING VALIDATION PROTOCOL

FOR

MICROBIOLOGY LAB

DATE OF VALIDATION	
SUPERSEDES PROTOCOL No.	

FOGGING VALIDATION PROTOCOL FOR MICROBIOLOGY LAB

PROTOCOL CONTENTS

FOGGING VALIDATION PROTOCOL FOR MICROBIOLOGY LAB

1.0 PROTOCOL APPROVAL

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (MICROBIOLOGY)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

FOGGING VALIDATION PROTOCOL FOR MICROBIOLOGY LAB

2.0 OBJECTIVE:

- The objective of this study is to provide the document evidence of effectiveness of fogging using 20 % Virosil by fogger.
- To establish the document evidence of residual study of hydrogen peroxide in environment after completion of fogging contact time.

3.0 SCOPE:

- This Validation study is applicable for performing fogging validation by using 20 % Virosil in Microbiology Lab.

4.0 RESPONSIBILITY:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review & Pre Approval of Validation Protocol. • Co-ordination with Microbiology lab and Engineering execute the Validation Activity. • Monitoring of Validation Activity. • Verification of Tests & Results.
Microbiology Lab	• Review of Validation Protocol. • To Execute of Validation study as per protocol. • Analytical Support (Microbiological Testing / analysis).
Engineering	• Review of Validation Protocol. • Responsible for Trouble shooting (if occurs during execution).

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5.0 EQUIPMENT DETAILS

Equipment Name	Fogger Machine
Equipment ID.	
Manufacturer's Name	
Model No.	
Capacity	5.0 Liter
Flow rate	45 ml/ min.
Dead Volume	450 ml

6.0 FREQUENCY OF STUDY:

- One time study.
- Active Ingredient changed in used fogging solution.
- Concentration change of fogging solution.
- Change in fogging method.

7.0 REASON FOR VALIDATION:

To validate the fogging procedure.

8.0 SITE OF STUDY:

Microbiology Lab.

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9.0 PRE-REQUIREMENTS

9.1 Training details:

Training of Approved Protocol shall be provided to all the persons who are participating in study. The Details of training should be mentioned in Report.

9.2 Selection of fogging solution:

Following fogging solution is being used in microbiology lab for fogging.

Sr. No.	Chemical Composition	Concentration	Contact time	Application rate
1.0	Hydrogen Peroxide 10 % Silver Nitrate 0.01 %	20 %	60 minutes	1000 ml /1000 ft^3

Combination of Hydrogen Peroxide and Silver Nitrate is a clear solution with characteristic peroxide odour. It is universal disinfectant based on a complex of silver ions and hydrogen peroxide as a strong oxidizing agent that can be used for aerial fogging.

Benefits:

- Eco friendly & Safe to human & environment
- Residue free
- Broad Spectrum- kills all pathogens including spore
- Silver and hydrogen peroxide have synergistic effect
- No corrosive properties below 50°C
- Nontoxic / without causing any irritation to the eyes, nose and skin.
- Non foaming
- Non Staining

Activity:

- Bactericidal
- Fungicidal
- Virucidal
- Sporicidal

Residual Properties: There is no requirement to re-wash equipment and surfaces disinfected since it is H_2O_2 based and decompose into water and oxygen and no other toxic residue.

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9.3 Selection of worst case room for study:

Sr. No.	Room Name	Room ID.	AHU No.	Grade	Room Volume (Ft^3)	Fogging Solution Required (ml)	Room Selection justification
Sterility Area							
1.0	Entry A/L-1			D	165	165	• Buffer Zone (ID. No.) considering the worst case room for fogging validation study due to maximum room volume. • MLT-2 Room (ID. No.) considering the worst case room for fogging validation study due to higher microbial count limit of grade C as compare to grade B and determine the reduction in microbial population.
2.0	Entry A/L-2			C	183	183	
3.0	Entry A/L-3			B	189	189	
4.0	Buffer Zone			B	610	610	
5.0	Cooling Zone			B	512	512	
6.0	Sterility Room			B	486	486	
7.0	Return A/L-1			C	198	198	
8.0	Return A/L-2			D	241	241	
MLT Area							
9.0	Entry A/L-1			D	136	136	
10.0	Entry A/L-2			C	132	132	
11.0	Entry A/L-3			C	110	110	
12.0	Buffer Zone			C	437	437	
13.0	MLT-1			C	403	403	
14.0	Micro Assay			C	408	408	
15.0	MLT-2			C	573	573	
16.0	Return A/L-1			C	132	132	
17.0	Return A/L-2			D	136	136	
Total						5051	

9.4 Quantity of fogging solution required for selected room:

Following equation shall be used to calculate the fogging solution quantity

Total quantity of disinfectant solution (ml) = Volume of Area x Application Rate

Application rate = 1000 ml / 1000 ft^3 (Considering the Vendor Recommendation)

Room Name	Room Volume (Ft3)	Calculation	Required Qty.
Buffer Zone	610	610 X 1000 ml /1000 ft3	610 ml
MLT-2	573	573 X 1000 ml /1000 ft3	573 ml

9.5 Fogging time required for selected room:

Following equation shall be used to calculate the fogging time

Total fogging time (Min.) = Total quantity to be fogged / Flow Rate

Room Name	Fogging Solution Required Qty.	Fogger Flow Rate	Calculation	Fogging Time
Buffer Zone	610 ml	45-50 ml/min.	610 / 45	13.55 min ≈ 14 min.
MLT-2	573 ml	45-50 ml/min	573 / 45	12.73 min ≈ 13 min.

9.6 Material Requirement:

- Hydrogen Peroxide Chemical Indicator
- Fumigant to be validated (Virosil 20%)
- 90 mm sterile disposable Petriplates with SCDA media
- Air sampler
- Fogger

9.7 Growth Promotion Test

Soybean casein digest medium shall be subjected growth promotion test prior to study which shall be used for active air sampling.

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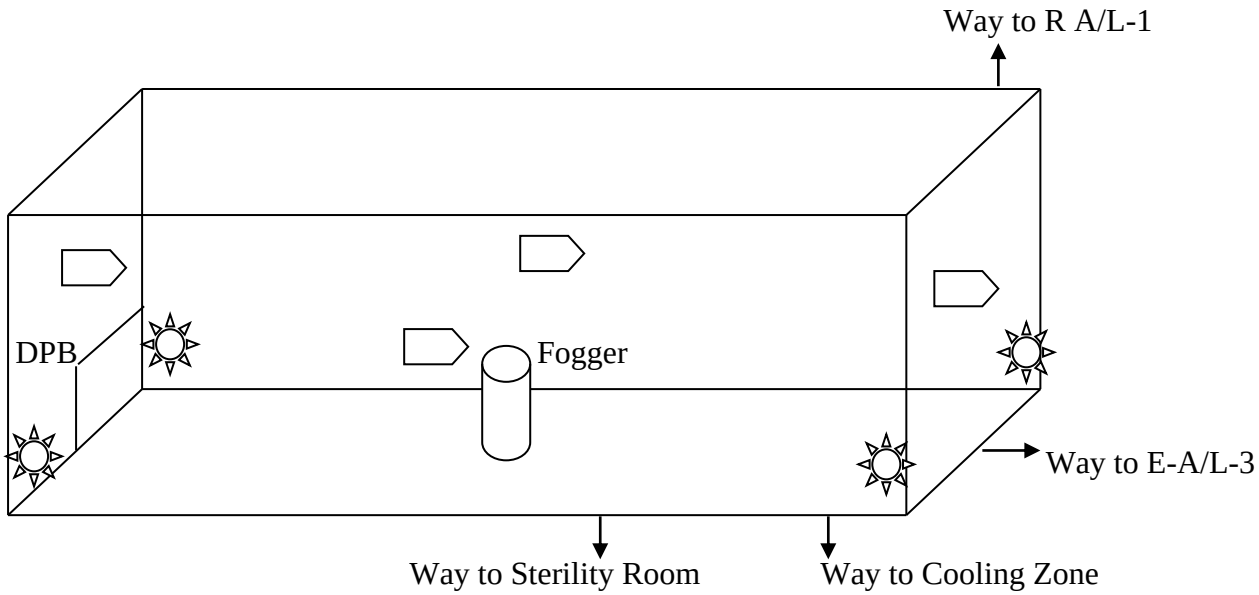
10.0 TEST & CHECKS:

10.1 Fogging in Buffer Zone

10.1.1 Procedure

- Prepare the fogging solution of 20 % Virosil as per the SOP No. title “Procedure for Disinfectants Preparation”.
- Perform the active air sampling by air sampler before fogging study as per SOP no. …….. at four locations as mentioned below diagram.



Air Sampling Location = 04 nos. Hydrogen Peroxide Chemical Indicator location = 04 nos.

Buffer Zone (Sterility Area)

- Place the fogger on steady place at center of room and ensure it does not fall down during the fogging process.
- Positioning lock set: Direct the motor housing & nozzle to approx. 40-50 degree & tighten the two knobs on the sides.
- Plug in fogger power cord to the main power supply.
- Pour the fogging solution into the fogger more than the quantity specified in section no. 9.4 and also consider the dead volume i.e. 450 ml (Maximum 5 Liter).
- Switch off the AHU no. PC/QC/AHU-003.
- Press the START button and fogger will start.
- Fogging shall be done for specified time period i.e. 14 minutes as mention in section 9.5.
- Hold the area for 60 minutes after fogging.

- After completion of fogging contact time perform the active air sampling by air sampler after as per SOP no. ……. at four locations as mentioned above diagram.
- Simultaneously after completion of fogging contact time place the hydrogen peroxide chemical indicator at four locations as mentioned in above diagram for 10 minutes.
- Observe the color change in the chemical indicator as vendor recommended and record the observation in report.
- Incubate the plates at the specified temperature and period as per SOP NO. …….
- This study shall be perform for one time.

10.1.2 Hydrogen Peroxide Chemical Indicator Location

Sr. No.	Location	Rationale
1.0	Center of wall (DPB Side)	These locations are closest to fogger and fog direct fall down the on the wall where probability of maximum concentration of hydrogen peroxide so that consider the worst location for this study.
2.0	Center of wall (Way to E A/L-3 Side)	
3.0	Center of wall (Way to R A/L-1 Side)	
4.0	Center of wall ((Way to Sterility Room Side))	

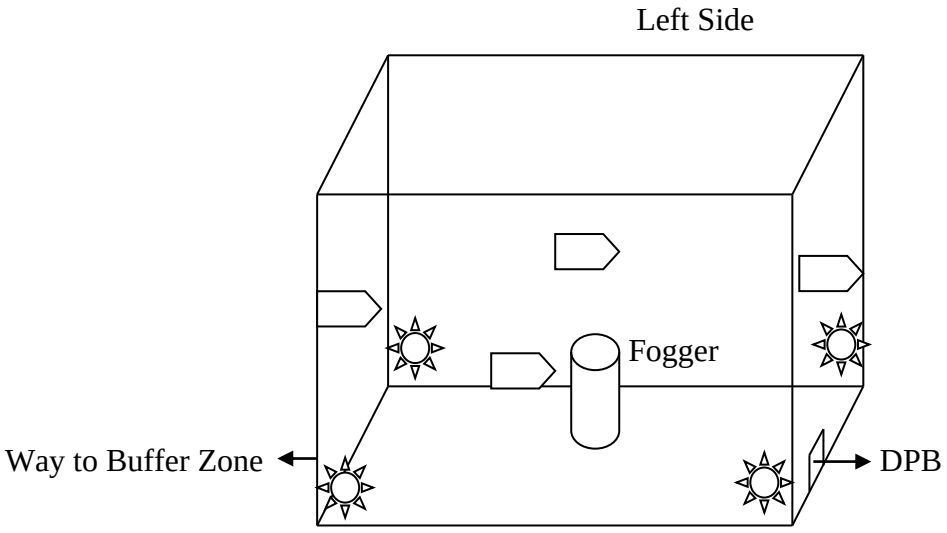
10.1.3 Active Air Sampling Location:

Sr. No.	Location	Rationale
1.0	Left corner (DPB Side)	These locations are far away from the fogger and fog not reached easily in the corner side so that consider the worst location for this study.
2.0	Right corner (DPB Side)	
3.0	Left corner (A/L Side)	
4.0	Right corner (A/L Side)	

10.2 Fogging in MLT-2 Room

10.2.1 Procedure

- Prepare the fogging solution of 20 % Virosil as per the SOP No. …….. title "Procedure for Disinfectants Preparation".
- Perform the active air sampling by air sampler before fogging study as per SOP no. …… at four locations as mention below diagram.



Air Sampling Location = 04 nos. Hydrogen Peroxide Chemical Indicator location = 04 nos.

MLT-02 Room (MLT Area)

- Place the fogger on steady place at center of room and ensure it does not fall down during the fogging process
- Positioning lock set: Direct the motor housing & nozzle to approx. 40-50 degree & tighten the two knobs on the sides.
- Plug in fogger power cord to the main power supply.
- Pour the fogging solution into the fogger more than the quantity specified in section no. 9.4 and also consider the dead volume i.e. 450 ml (Maximum 5 Liter).
- Switch off the AHU no. ……...
- Press the START button and fogger will start.
- Fogging shall be done for specified time period i.e. 13 minutes as mention in section 9.5.
- Hold the area for 60 minutes after fogging.
- After completion of fogging contact time perform the active air sampling by air sampler after as per SOP no. …….. at four locations as mentioned above diagram.

- Simultaneously after completion of fogging contact time place the hydrogen peroxide chemical indicator at four locations as mentioned in above diagram for specific time for 10 minutes.
- Observe the color change in the chemical indicator as vendor recommended and record the observation in report.
- Incubate the plates at the specified temperature and period as per SOP NO. ……...
- This study shall be perform for one time.

10.2.2 Hydrogen Peroxide Chemical Indicator Location

Sr. No.	Location	Rationale
1.0	Center of wall (DPB Side)	These locations are closest to fogger and fog direct fall down the on the wall where probability of maximum concentration of hydrogen peroxide so that consider the worst location for this study.
2.0	Center of wall (Way to E A/L-3 Side)	
3.0	Center of wall (Way to R A/L-1 Side)	
4.0	Center of wall ((Way to Sterility Room Side))	

10.2.3 Active Air Sampling Location:

Sr. No.	Location	Rationale
1.0	Left corner (DPB Side)	These locations are far away from the fogger and fog not reached easily in the corner side so that consider the worst location for this study.
2.0	Right corner (DPB Side)	
3.0	Left corner (A/L Side)	
4.0	Right corner (A/L Side)	

11.0 ACCEPTANCE CRITERIA :

11.1 Residual Limit of hydrogen Peroxide

- Hydrogen Peroxide should not more than 0.5 mg/L in environment after completion of fogging contact time (by interpretation of color change of Hydrogen Peroxide chemical indicator as per vendor recommendation).

11.2 Microbial Limit of Active Air Sampling

Area Name	Grade	Limits
Buffer Zone	Grade B	NMT 10 CFU
MLT-02 Room	Grade C	NMT 100 CFU

12.0 DEVIATIONS:

In case of any deviation observed during fogging study, same shall be handled through SOP for Handling of Deviation (SOP NO. ……..-Current Version).

13.0 CHANGE CONTROL:

If any change is required during fogging study, same shall be handled through SOP for Change Management (SOP NO. ……-Current Version).

14.0 CONCLUSION:

Validation Data shall be written on Validation Report, clearly stating the achievement or Non-compliance of the Acceptance Criteria, effect of the deviations made during the Validation and in case of failure, Investigation carried out and their findings.

15.0 REFERENCES:

- SOP No. ……. title “Procedure for Disinfectants Preparation”.
- SOP No. …….. title “Fogging in Microbiology Section”.
- SOP No. …… title “Environmental Monitoring of Microbiological Section”.
- Report No. ……. “Test Report provided by Virosil Pharma”
- Virosil Solution Literature.

16.0 DOCUMENTS TO BE ATTACHED :

- Chemical Indicator Certificate.
- Fogging Solution Preparation Record.
- Growth Promotion test for Used Media.
- AHU Operation Record.
- Fogging Record.
- Air Sampler Record.
- Microbiological Analysis Reports.

17.0 ABBREVIATIONS:

QA	:	Quality Assurance
QC	:	Quality control
SOP	:	Standard Operating Procedure
ID No.	:	Identification Number
GPT	:	Growth Promotion Test
^{o} C	:	Degree Centigrade
LAF	:	Laminar Air Flow
CFU	:	Colony forming unit
AHU	:	Air Handing Unit
Ft^3	:	Cubic Feet
%	:	Percentage
$H_2 O_2$	:	Hydrogen Peroxide
ml	:	Milliliter
Min.	:	Minute
DPB	:	Dynamic Pass box
L	:	Liter
mg	:	Milligram