



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**FOGGING VALIDATION REPORT FOR MICROBIOLOGY LAB**

**FOGGING VALIDATION REPORT**  
**FOR**  
**MICROBIOLOGY LAB**

<b>DATE OF VALIDATION</b>	
<b>SUPERSEDES REPORT No.</b>	<b>NIL</b>



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**1.0 REPORT PRE- APPROVAL**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

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

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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## FOGGING VALIDATION REPORT FOR MICROBIOLOGY LAB

### 2.0 OBJECTIVE:

- The objective of this study is to establish the document evidence of effectiveness of fogging by using 20 % Virosil in fogger.
- To establish the document evidence of residual study of hydrogen peroxide by chemical indicator 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 RESPONSIBILITIES

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Compilation &amp; Approval of Validation Report.</li><li>• Co-ordination with Microbiology lab and Engineering execute the Validation Activity.</li><li>• Monitoring of Validation Activity.</li><li>• Verification of Tests &amp; Results.</li></ul>
<b>Microbiology Lab</b>	<ul style="list-style-type: none"><li>• Review of Validation Report.</li><li>• To Execute of Validation study as per protocol.</li><li>• Analytical Support (Microbiological Testing / analysis)</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Validation Report.</li><li>• Responsible for Trouble shooting (if occurs during execution).</li></ul>



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**5.0 EQUIPMENT DETAILS**

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

**6.0 FREQUENCY OF STUDY:**

\_\_\_\_\_

**7.0 REASON OF VALIDATION:**

\_\_\_\_\_

**8.0 PRE –REQUISITES:**

**8.1 Training Record of Validation Team:**

Training shall be imparted to persons involved in performance re-qualification activity and shall be recorded as follows;

S. No.	Name of Trainee	Department	Designation	Trainee (Sign. / Date)	*Training Evaluation (Satisfactory / Not Satisfactory)

**Training Given By:  
Sign & Date**

*\*Note: Training evaluation shall be done on the basis of oral assessment*

*Remark: if additional page is required during execution, then issue the required no. of copies.*



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**8.2 Fogging solution preparation Record:**

Sr. No.	Brand Name	Chemical Composition	Qty. taken for fogging solution	Water Qty.	Total Qty. of fogging solution (20 %)

**Inference:**

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**Checked By**  
(Microbiologist)

Sign/Date: \_\_\_\_\_

**Verified By**  
(Quality Assurance)

Sign/Date \_\_\_\_\_



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**8.3 Room selected for study:**

Sr. No.	Room Name	Room ID.	AHU No.	Grade

**Inference:**

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**Checked By**

(Microbiologist)

Sign/Date: \_\_\_\_\_

**Verified By**

(Quality Assurance)

Sign/Date \_\_\_\_\_



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**8.4 Quantity of fogging solution required for selected room**

Sr. No.	Fogger ID.	Qty. taken for fogging

**Inference:**

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**Checked By**  
(Microbiologist)

**Sign/Date:** \_\_\_\_\_

**Verified By**  
(Quality Assurance)

**Sign/Date**\_\_\_\_\_





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**8.5 Chemical Indicator Detail:**

Detail	Observation
Name	
Lot Number / Type	
Scale	
Manufacturing Date	
Expiry Date	
Manufactured by	

**Inference:**

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**Checked By**  
(Microbiologist)

Sign/Date: \_\_\_\_\_

**Verified By**  
(Quality Assurance)

Sign/Date \_\_\_\_\_



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**8.6 Growth Promotion Test Report of Media Plate**

Name of Media :  
Media Lot No. :  
GPT Results (Complies/ Not Complies) :

**Inference:**

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**Checked By**

**(Microbiologist)**

**Sign/Date:** \_\_\_\_\_

**Verified By**

**(Quality Assurance)**

**Sign/Date**\_\_\_\_\_



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**9.0 TEST & CHECKS**

**9.1 Buffer Zone**

**9.1.1 Fogging Details**

Items	Observation
Date of fogging	
Fogging start time	
Fogging end time	
Total fogging time	
Contact time start	
Contact time end	
Total contact time	

**Inference:**

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**Checked By**  
(Microbiologist)

Sign/Date: \_\_\_\_\_

**Verified By**  
(Quality Assurance)

Sign/Date \_\_\_\_\_



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**9.1.2 Residual Observation of Hydrogen Peroxide by Chemical Indicator:**

CI Exposure Time Start	CI Exposure Time End		
Location No.	Color Change Observation		Result
1.			
2.			
3.			
4.			

**Acceptance Criteria:** 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).

**Inference:**

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**Checked By**  
(Microbiologist)  
Sign/Date: \_\_\_\_\_

**Verified By**  
(Quality Assurance)  
Sign/Date \_\_\_\_\_



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**9.1.3 Active Air Sampling Results:**

Location No.	Sampling Stage	Observation		TAMC	Reduction in Microorganism	
		TBC	TFC		Numbers	%
1.	Before Fogging					
	Post 60 min. (Contact Time) of Fogging					
2.	Before Fogging					
	Post 60 min. (Contact Time) of Fogging					
3.	Before Fogging					
	Post 60 min. (Contact Time) of Fogging					
4.	Before Fogging					
	Post 60 min. (Contact Time) of Fogging					

**Acceptance Criteria:** Microbial Limit of Active Air Sampling.

Area Name	Grade	Limits
Buffer Zone	Grade B	NMT 10 CFU

**Inference:**

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**Checked By**

(Microbiologist)

Sign/Date: \_\_\_\_\_

**Verified By**

(Quality Assurance)

Sign/Date \_\_\_\_\_



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**9.2 MLT-2 Room**

**9.2.1 Fogging Details**

Items	Observation
Date of fogging	
Fogging start time	
Fogging end time	
Total fogging time	
Contact time start	
Contact time end	
Total contact time	

**Inference:**

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**Checked By**

(Microbiologist)

Sign/Date: \_\_\_\_\_

**Verified By**

(Quality Assurance)

Sign/Date \_\_\_\_\_



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**9.2.2 Residual Observation of Hydrogen Peroxide by Chemical Indicator:**

CI Exposure Time Start	CI Exposure Time End		
Location No.	Color Change Observation		Result
1.			
2.			
3.			
4.			

**Acceptance Criteria:** 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).

**Inference:**

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**Checked By**

(Microbiologist)

Sign/Date: \_\_\_\_\_

**Verified By**

(Quality Assurance)

Sign/Date \_\_\_\_\_



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### 9.2.3 Active Air Sampling Results:

Location No.	Sampling Stage	Observation		TAMC	Reduction in Microorganism	
		TBC	TFC		Numbers	%
1.	Before Fogging					
	Post 60 min. (Contact Time) of Fogging					
2.	Before Fogging					
	Post 60 min. (Contact Time) of Fogging					
3.	Before Fogging					
	Post 60 min. (Contact Time) of Fogging					
4.	Before Fogging					
	Post 60 min. (Contact Time) of Fogging					

### Acceptance Criteria: Microbial Limit of Active Air Sampling

Area Name	Grade	Limits
MLT-02 Room	Grade C	NMT 100 CFU

### Inference:

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Checked By  
(Microbiologist)

Sign/Date: \_\_\_\_\_

Verified By  
(Quality Assurance)

Sign/Date \_\_\_\_\_





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**9.3 Summary of Results**

**9.3.1 Residual of Hydrogen Peroxide**

<b>Buffer Zone</b>	<b>Day 1<sup>st</sup></b>
Location 1	
Location 2	
Location 3	
Location 4	
<b>MLT-02 Room</b>	
Location 1	
Location 2	
Location 3	
Location 4	

**9.3.2 Reduction in Microbial Population (%)**

<b>Buffer Zone</b>	<b>Day 1<sup>st</sup></b>
Location 1	
Location 2	
Location 3	
Location 4	
<b>MLT-02 Room</b>	
Location 1	
Location 2	
Location 3	
Location 4	





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**10.0 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.

**11.0 DEVIATION (IF ANY):**

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**12.0 NON COMPLIANCE:**

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**13.0 CHANGE CONTROL (IF, ANY):**

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**14.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY) :**

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**FOGGING VALIDATION REPORT FOR MICROBIOLOGY LAB**

**17.0 ABBREVIATIONS:**

SOP	:	Standard Operating Procedure
ID No.	:	Identification Number
GPT	:	Growth Promotion Test
CFU	:	Colony forming unit
AHU	:	Air Handling Unit
%	:	Percentage
ml	:	Milliliter
Min.	:	Minute
L	:	Liter
mg	:	Milligram
CI	:	Chemical indicator
Qty.	:	Quantity
TBC	:	Total Bacterial Count
TFC	:	Total Fungal Count
TAMC	:	Total Aerobic Microbial Count
NMT	:	Not More Than



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**18.0 REPORT POST 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)			