



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Fogging in Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Fogging in Microbiology Section.

2.0 SCOPE:

This SOP is applicable for Fogging in Microbiology Section.

3.0 RESPONSIBILITY:

Operating Person – Microbiology

4.0 ACCOUNTABILITY:

Head – QC

5.0 ABBREVIATIONS:

AHU	Air Handling Unit
IPA	Isopropyl Alcohol
Ltd.	Limited
ml	Milliliter
MLT	Microbial Limit Test
No.	Number
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

- 6.1** Switch off the AHU system of concerned area which has to be fogged.
- 6.2** For fogging in sterility and MLT area of microbiology laboratory transfer Virosil/Silvicide solution through Dynamic Pass Box for sterility area and Dynamic pass Box for MLT area.
- 6.3** Enter into the sterility testing area or Enter into the MLT and bio- assay area as per respective area SOP.
- 6.4** After surface sanitization of Virosil/Silvicide container with 0.2 μ filtered 70% IPA transfer it into the Dynamic Pass Box for sterility testing area and Dynamic pass Box for MLT area.
- 6.5** Open the door of Dynamic Pass Box of aseptic area corridor and take Virosil/Silvicide solution inside the area and close the door. Check the fogger for proper cleaning.
- 6.6** Prepare the 20% Virosil/Silvicide as per SOP title “Procedure for Disinfectants Preparation” and Transfer the Virosil/Silviside solution in fogger as per requirement.
- 6.7** Place the fogger at center of room and ensure it does not fall down during the fogging process.



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- 6.8** Positioning lock set: Direct the motor housing & nozzle to approximately 40-50 degree & tighten the two knobs on the sides.
- 6.9** Application rate = 1000 ml / 1000 ft³.
- 6.10** Connect the fogger to power supply and select the room number and Press the START button and fogger will start and write the start time of fogger on sterile petri plate lid of first room and write the end time of last room, same shall be transcribe in respective annexure.
- 6.11** After fogging in Airlock-V, person should be out from the respective area and perform the fogging in Airlock –I of sterility area and MLT & bioassay area.
- 6.12** Allow fogging to take place for each area as mentioned below table-1.

Table-1

Room No.	Room Name	Room Volume (Ft ³)	Fogging Solution Required (ml)	Fogger Flow Rate	Calculation	Fogging Time
Sterility Area						
1.0	Sterility Room	486	486	45 ml/min	486X1000 ml/1000ft ³ /45	10.80 min ≈ 11 min.
2.0	Unloading room	512	512	45 ml/min	512X1000 ml/1000ft ³ /45	11.37 min ≈ 12 min.
3.0	Corridor	610	610	45 ml/min	610X1000 ml/1000ft ³ /45	13.55 min ≈ 14 min.
4.0	Entry airlock-III	189	189	45 ml/min	189X1000 ml/1000ft ³ /45	4.20 min ≈ 5 min.
5.0	Entry airlock -II	183	183	45 ml/min	183X1000 ml/1000ft ³ /45	4.06 min ≈ 5 min.
6.0	Entry airlock -IV	198	198	45 ml/min	198X1000 ml/1000ft ³ /45	4.40 min ≈ 5 min.
7.0	Exit airlock-V	241	241	45 ml/min	241X1000 ml/1000ft ³ /45	5.35 min ≈ 6 min.
8.0	Exit airlock-I	165	165	45 ml/min	165X1000 ml/1000ft ³ /45	3.66 min ≈ 4 min.
Total		2584	2584			62 min.
MLT Area						
1.0	MLT room -1	403	403	45 ml/min	403X1000 ml/1000ft ³ /45	8.95 min ≈ 9 min.
2.0	MLT room -2	573	573	45 ml/min	573X1000 ml/1000ft ³ /45	12.73 min ≈ 13 min.
3.0	Corridor	437	437	45 ml/min	437X1000 ml/1000ft ³ /45	9.71 min ≈ 10 min.



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Room No.	Room Name	Room Volume (Ft ³)	Fogging Solution Required (ml)	Fogger Flow Rate	Calculation	Fogging Time
4.0	Entry airlock -III	110	110	45 ml/min	110X1000 ml/1000ft ³ /45	2.44 min ≈ 3 min.
5.0	Entry airlock -II	132	132	45 ml/min	132X1000 ml/1000ft ³ /45	2.93 min ≈ 3 min.
6.0	Bioassay room	408	408	45 ml/min	408X1000 ml/1000ft ³ /45	9.06 min ≈ 10 min.
7.0	Exit airlock -IV	132	132	45 ml/min	132X1000 ml/1000ft ³ /45	2.93 min ≈ 3 min.
8.0	Exit airlock -V	136	136	45 ml/min	136X1000 ml/1000ft ³ /45	3.02 min ≈ 4 min.
9.0	Entry airlock -I	136	136	45 ml/min	136X1000 ml/1000ft ³ /45	3.02 min ≈ 4 min.
Total		2467	2467			59 min.

6.13 Calculation for fogging solution preparation:

6.13.1 Sterility area:

- Fogger run time – 62 minute
- Fogger flow rate- 45 ml/min.
- Fogger dead volume 450 ml
- Calculation = Fogger run time × Fogger flow rate + Fogger dead volume
= 62 × 45 + 450
= 3240 ≈ 3300
- Total fogging solution = 3300 ml

6.13.2 MLT area:

- Fogger run time – 59 minute
- Fogger flow rate- 45 ml/min.
- Fogger dead volume 450 ml
- Calculation = Fogger run time × Fogger flow rate + Fogger dead volume
= 59 × 45 + 450
= 3105 ≈ 3200
- Total fogging solution = 3200 ml



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6.14 Follow the fogging sequence as follow

6.14.1 Sterility Area: sterility test room → unloading room → corridor → airlock-III
→ airlock-II → airlock-IV → airlock-V → airlock-I

6.14.2 MLT and Bioassay Area: MLT-1 → MLT-2 → corridor → airlock-III
→ airlock-II → bioassay room → airlock-IV → airlock-V → airlock-I

6.15 Record the fogging details of MLT and bioassay Area in annexure-I and sterility area in annexure-IV.

6.16 Hold the area for approx. 60 minutes after fogging.

6.17 Record the fogging details in respective annexure.

6.18 Drain the remaining fogging solution of fogger in drain sink after fogging.

6.19 Clean and sanitize the fogger with filtered 70% IPA solution.

6.20 FREQUENCY:

Sterility Area: Once in a working day or after any maintenance work

MLT and Bio-assay Area: Once in a week or after any maintenance work

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Fogging Record for MLT and bioassay Area	
Annexure – II	Fogging Record for sterility area	

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Microbiology
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

