



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Fogging Operation in Clean Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 10

1.0 OBJECTIVE:

To lay down the procedure for operation, cleaning and maintenance of fogger and fogging of ampoule section.

2.0 SCOPE:

This SOP is applicable for operation, cleaning and maintenance of fogger and fogging of ampoule section Machine.

3.0 RESPONSIBILITY:

Officer / Executive-Concern Department

4.0 ACCOUNTABILITY:

Head-Concern Department

5.0 ABBREVIATIONS:

Cu. ft.	Cubic Feet
Ltd.	Limited
MI	Millie Liter
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE :

6.1 FOGGER PRECAUTIONS:

6.1.1 Never fog near or toward an open flame.

6.1.2 Do not dispense flammable liquids.

6.1.3 Do not switch of the blower head while unit is in operation .Wait 15minutes after fogger switch off.

6.1.4 Do not fog non approved disinfectant which can damage the machine parts and accelerate motor wear.

6.1.5 Do not switch on the fogger in absence of intake air filters.

6.1.6 Do not restrict the air intake of the fogger by blocking the hand.

6.1.7 Do not insert any instrument, wire cloth or any tool in to the fogger machine.

6.1.8 Always use 3-wire grounded electrical system.



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6.1.9 Do not immerse fogger in water or liquid to clean it.

6.1.10 Do not swing fogger in running condition.

6.1.11 Do not block air outlets.

6.2 INSTRUCTION AND OPERATION

6.2.1 The equipment's should be completely closed without any vent /opening and ensure no any operational activity should be carried out.

6.2.2 Ensure the equipment sanitization and area cleaning with scheduled disinfectant as per sop.

6.2.3 Ensure the online particle counters are closed.

6.2.4 Ensure the temperature and RH of the clean room.

6.2.5 Ensure 20% Virosil disinfectant shall be prepared as per sop and available for usage.

6.2.6 Use 20% Virosil solution for fogging and pour in to the fogger through funnel provided on the tank as per Annexure.

6.2.7 Place the fogger on a table or surface mounted at height of 2-3 feet and keeps the angle of the nozzle at 40-50 degrees with the help of adjustment knobs.

Note: *Ensure that it does not fall down during running condition.*

6.2.8 Fogger direction should be towards the top of the Roof.

6.2.9 Adjust the timer switch of the fogger according to the volume of the dilution added as per Annexure.

6.2.10 Connect the electrical cord of the fogger to the power supply and then switch of the mains.

6.2.11 Move out of the room and close the door completely and do not enter the room for 60 minutes after the fogging has completed.

6.3 FREQUENCY:

6.3.1 B- Area –Once in a day at the end of Operation or whenever required.

6.3.2 C- Area –Twice in a Week.

6.3.3 D - Area –Weekly



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6.3.4 Fogging shall be carried out based on the trend of environmental excursions or whenever required.

6.4 CLEANING AND MAINTENANCE OF THE FOGGER:

6.4.1 FOGGER TANK CLEANING:

6.4.1.1 Separate the tank by unscrew the two wing nuts on the tank lid and lift the blower head.

6.4.1.2 Clean the fogger tank with purified water followed by WFI after every fogging operation.

6.4.1.3 Thoroughly wipe the outer body of the fogger with lint free cloth dipper with scheduled disinfectant after successive fogging.

Note: Do not leave the fogging solution in the tank. Ensure the tank empty before storage.

6.4.2 METERING TIP CLEANING:

6.4.2.1 Clean the nozzle hole with the help of the pin provided on the tank cover to clean the residue present in the nozzle after every fogging operation.

6.4.2.2 Run the machine with cooled WFI to clean the nozzle to prevent it get from choked.

6.4.2.3 Intake air filter Wash the suction air filter after every fogging operation provided on the both side of machine, dried thoroughly and used.

Note: To clean remove profilers by rotate anti clock wise direction.

6.4.2.4 Do not touch the blower head while the fogger is in operation as its gets warmed up.

6.4.2.5 Record the cleaning details as per Annexure V.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Fogging Solution Usage Record	
Annexure-II	Fogging Record (Class B-Area)	
Annexure-III	Fogging Record (Class C- Area)	
Annexure-IV	Fogging Record (Class D- Area)	
Annexure-V	Fogger usage and cleaning Record	

ENCLOSURES: SOP Training Record



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8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE – I FOGGING SOLUTION USAGE RECORD

Block: Injection

Section:

S.No.	Area	Volume of Area in Cubic Feet	Volume of Fogging to be Used(ml)	Fogging Duration (In Minutes)
1.	Solution Filtration Room			
2.	Ampoule Filling & Sealing Room			
3.	Change Room-3 (Aseptic Area)			
4.	Aseptic Corridor (Passage-1)			
5.	Aseptic Corridor (Passage-2)			
6.	Tools Room			
7.	Disinfectant Filtration Room			
8.	Autoclave Unloading (Cool Zone)			
9.	Change Room-2 (Aseptic Area)			
10.	Return Change Room-1 (Aseptic Area)			
11.	Airlock-2 (Unit Preparation)			
12.	Unit Preparation Room			
13.	Equipment Washing			
14.	Disinfectant Preparation Room			
15.	Personnel Airlock-2 (Amp. Washing & Sterilization Room)			
16.	Ampoule Washing & Sterilization Room			
17.	Personnel Airlock-2 (Manufacturing)			
18.	Manufacturing Room			
19.	Ampoule Hold Room			
20.	Airlock-2 Ampoule Hold Room			
21.	CIP & SIP Room			
22.	Garment Washing & Preparation			
23.	Change Room-1 (Aseptic Area)			
24.	Return Change Room-2 (Aseptic Area)			



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Annexure II FOGGING RECORD (CIASS-B AREA)

Block :

Department:

Month /Year:

Frequency: Once in a day at the end of operation or whenever required. **Fogging Agent:**

Date	Area	Fogging Duration (In Minutes)	Fogging Time		Done By Sign& Date	Checked By Sign& Date	Remarks
			From	To			
	Solution Filtration Room	8					
	Ampoule Filling & Sealing Room	15					
	Change Room-3 (Aseptic Area)	2					
	Aseptic Corridor (Passage-1)	12					
	Aseptic Corridor (Passage-2)	2					
	Tools Room	5					
	Disinfectant Filtration Room	4					
	Autoclave Unloading (Cool Zone)	8					



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ANNEXURE – III

FOGGING RECORD (CLASS C AREA)

Block :

Department:

Month /Year:

Frequency: Twice in a Week.

Fogging Agent:

Date	Area	Fogging Duration (In Minutes)	Fogging Time		Done By Sign & Date	Checked By Sign & Date	Remarks
			From	To			
	Change Room-2 (Aseptic Area)						
	Return Change Room-1 (Aseptic Area)						
	Airlock-2 (Unit Preparation)						
	Unit Preparation Room						
	Equipment Washing						
	Disinfectant Preparation Room						
	Personnel Airlock-2 (Amp. Washing & Sterilization Room)						
	Ampoule Washing & Sterilization Room						
	Personnel Airlock-2 (Manufacturing)						
	Manufacturing Room						
	Ampoule Hold Room						
	Airlock-2 Ampoule Hold Room						



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ANNEXURE – IV FOGGING RECORD (CLASS D AREA)

Block : I-Block

Department:

Month /Year:

Frequency: Weekly

Fogging Agent:

Date	Area	Fogging Duration (In Minutes)	Fogging Time		Done By Sign& Date	Checked By Sign& Date	Remarks
			From	To			
	CIP & SIP Room						
	Garment Washing & Preparation						
	Change Room-1 (Aseptic Area)						
	Return Change Room-2 (Aseptic Area)						
	Scrap Out						
	Decartoning Room						
	Production & QA office						
	Outer Corridor (Passage-1)						
	Outer Corridor (Passage-2)						
	Outer Corridor (Passage-3)						
	Personnel Airlock (Disinfectant Preparation)						
	Airlock-I (Unit Preparation)						
	Material Entry (Manufacturing)						
	Personnel Airlock-I						



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	(Manufacturing)						
	Personnel Airlock-1 (Amp. Washing & Sterilization Room)						
	Personnel Airlock-1 (Ampoule Hold Room)						
	Machine Part Room						
	Day Store PPM-1						
	Day Store PPM-2						
	Airlock Day Store						
	RM Day Store						

