



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Fogger & Fogging Operation in Sterile and Non-Sterile Area

SOP No.:		Department:	Production
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1.0 OBJECTIVE:

To lay down a procedure for operation and cleaning of fogger & fogging operation in sterile and non-sterile area.

2.0 SCOPE:

This SOP is applicable for Fogging in Sterile & Non sterile area using Fogging Machine in Production & Warehouse department.

3.0 RESPONSIBILITY:

Operating Person- Production / Warehouse

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

%	Percent
cu. ft.	Cubic Feet
Ltd.	Limited
ml	Mille Liter
No.	Number
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
ULV	Ultra Low Volume
WFI	Water for Injection
Lit	Liter

6.0 PROCEDURE:

- 6.1 Clean the area and equipment and sanitize it with disinfectant solution scheduled for the day.
- 6.2 Close all the opening to ensure that the area to be fogged is completely closed.
- 6.3 Wear gloves and goggle while performing the fogging activity in the area.
- 6.4 Use 20 % solution of Virosil/ Silvicide as fogging agent for fogging the area as per defined frequency.
- 6.5 1000 cu. ft. area to be fogged with 1000 ml of 20 % Virosil/Silvicide solution (200 ml of Virosil/Silvicide in 800 ml of WFI) with the help of fogging machine. During fogging place the fogger at location mentioned in the **Annexure-I, Annexure-V and Annexure –IX**, based on the feasibility and movement of fogger from one area to another area.
- 6.6 After fogging with Virosil/Silvicide 20 %, leave the area in static condition upto one hour.



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6.7 Record the Fogging details in “**Fogging Record**” as per Format shown in **Annexure-II, Annexure-III & Annexure-VI** (For Sterile Area) and **Annexure – III, Annexure-VII & Annexure-VIII** (For Non Sterile Area) at facilities. Also record the usage of fogger is **Annexure-XIV** titled as “**Usage and Cleaning Record of Fogger**”.

6.8 Record the fogging details in “**Fogging Record**” as per Format shown in **Annexure-X** (Sterile area), **Annexure-XI** (For Grade C & D area), and **Annexure-XII** (For Grade D area) at facilities. Also record the usage of fogger is **Annexure-XIV** titled as “**Usage and Cleaning Record of Fogger**”.

6.9 Record the **Fogging solution usage Record** details in Warehouse Sterile & Non Sterile different area as per **Annexure-XV**.

6.10 Record the fogging details in “**Fogging Record**” as per Format show in **Annexure-IV**(for Sterile Area) and **Annexure-XVI**(For Non Sterile area), **Annexure-XVII** (For Non Sterile Sampling cum Dispensing area).

6.11 Frequency:

Sterile area-Daily at the end of Operation

Non Sterile Area (Grade C & D)-Weekly

Note: Fogging frequency may be shortened on the basis of environmental monitoring report of the said area.

6.12 Operation, Cleaning and Precautions during Use of Fogger:

6.12.1 ULV fogger can be used for atomizing light liquids into a heavy density fog/mist of very small droplets (in the form of liquid only).

6.12.2 ULV is defined as the ultra low volume application rate of chemical solution per unit space/surface area in aerosol state. Droplets in the ULV size range remains airborne of sufficient period of time.

6.12.3 Low flow rate 70-100 ml/minute produces a dry fog and fine droplets (6-10 microns) that float extensively and diffuse widely. Larger flow rate (150-200 ml/minute) produce progressively larger droplets (wet fog, heavy mist)

6.12.4 The flow rate of the liquid solution is regulated by adjusting the regulating valve.

6.13 Precautions:

6.13.1 During fogging always use goggles, gloves, facial masks and protective garments to avoid any contamination.

6.13.2 During fogging refer the material safety datasheet of respective chemical.

6.13.3 Do not use a non approved chemical which can damage machine parts and accelerate motor wear.



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6.13.4 Do not operate the machine without intake air filter. The fogger sucks the air from rear end through this air intake filter. Without filter, dirt or dust can enter into machine from rear end and can damage the fan blade, motor parts and accelerate the wear. Intake air filter is provided to prevent the entry of such substances. Always use intake filter and replace it when gets dirty and clogged.

6.13.5 After use of the fogger drain the remaining disinfectant solution and then clean the tank with water & dry. Turn the regulatory valve in clockwise direction to close completely.

6.13.6 If air intake filter is being washed make sure that it is reused only after it is completely dry. Do not place the wet filter on the machine.

6.14 Flow Control Valve Operation:

6.14.1 The valve ensures the precision regulation of liquid flow rotating the knob. Turn the valve knob in anti clockwise direction for higher flow (heavy fog) and clockwise direction for very fine droplets.

6.14.2 To generate fine fog keep the valve 1½-2 turn or less open from fully closed position i.e fully close the valve and then rotate in anticlockwise direction for 1½ -2 turn. For heavy fog rotate the valve for more than 2 turn upto maximum.

6.15 Dosage Instruction For Fogger:

6.15.1 Calibration of the fogger: Calibration is performed to determine the liquid flow rate. For this follow the below step.

6.15.1.1 Put some fogging liquid into a measuring cup and note the liquid level.

6.15.1.2 Unclamp the tank from fogger and dip the liquid intake tube in the cup.

6.15.1.3 Adjust the valve position for desired droplet size and operate the fogger for one minute and measure the volume dispensed. This used volume of liquid will be the flow rate of fogger per minute.

e.g. Liquid flow rate = 100 ml/minute.

6.15.2 Determination of the volume of space to be fogged:

Total space/volume to be fogged= Length x Width x Height

e.g. 20 feet x 20 feet x 10 feet = 4000 cubic feet.

If any object occupy the large volume than deduct the same from total volume.

6.15.3 Calculation of total quantity of the liquid required for that space:

6.15.3.1 For fogging 1000 cubic feet volume 1000 ml solution of Virosil/Silvicide 20 % is required.



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6.15.3.2 For fogging above 4000 cubic feet the required solution will be as:

$$\begin{aligned} & \text{Volume (4000 cu. ft.)} \times \text{Application rate (1000 ml/1000 cu. ft.)} \\ & = 4000 \text{ ml} \end{aligned}$$

6.15.4 Calculation of total fogging time:

$$\begin{aligned} \text{Time required} &= \text{Total liquid to befogged/Flow rate} \\ &= 4000 \text{ ml}/100 \text{ ml/minute} \\ &= 40 \text{ minutes} \end{aligned}$$

6.16 Cleaning of Fogger:

6.16.1 After completion of fogging activity is respective area as per frequency and requirement, transfer the fogger into equipment wash area.

6.16.2 Drain the remaining disinfectant solution from its tank. Clean the tank with purified water and WFI then dry.

6.16.3 Remove the intake air filter and clean with purified water and WFI then dry with filtered compressed air.

6.16.4 After drying place the intake air filter at its place.

6.16.5 Record the cleaning detail in respective log titled as “Usage and cleaning record of Fogger”.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Fogging Solution Usage Record	
Annexure-II	Fogging Record (Sterile Area)	
Annexure-III	Fogging Record (Non – Sterile Area)	
Annexure-IV	Fogging Record (Sterile Area) Warehouse	
Annexure-V	Fogging Solution Usage Record	
Annexure-VI	Fogging Record (Sterile Area Three Piece)	
Annexure-VII	Fogging Record (Unit Preparation Area Three Piece)	
Annexure-VIII	Fogging Record (Manufacturing Area Three Piece)	
Annexure-IX	Fogging solution usage record for Three Piece Line	
Annexure-X	Fogging record (Sterile area, Three Piece)	
Annexure-XI	Fogging record (Grade C & D area, Three Piece)	



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ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-XII	Fogging record (Grade D area, Three Piece)	
Annexure-XIV	Usage and Cleaning record of Fogger	
Annexure-XV	Fogging Solution Usage Record For Warehouse	
Annexure-XVI	Fogging Record (Non Sterile Area) Warehouse	
Annexure-XVII	Fogging Record (Non Sterile Area) Warehouse (Three piece)	
Annexure-XVIII	Fogger detail used for fogging	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Controlled Copy No. 04 Warehouse
- Master Copy Quality Assurance

9.0 REFERENCES:

Equipment manual

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE – I FOGGING SOLUTION USAGE RECORD

Block:

Line: DPI

S.No.	Area	Volume of Area in Cubic Feet	Volume of Fogging to be Used(ml)	Fogging Duration (In Minutes)	Location of Fogger
1.	Entry Air-lock I	203.16	203.16	2	Near door
2.	Entry Air-lock II	312.73	312.73	3	Near door
3.	Entry Air-lock III	203.16	203.16	2	Near door
4.	Filling Area	2171.68	2171.68	22	Near door and its opposite side
5.	Sealing Area	1209.80	1209.80	12	Near door and its opposite side
6.	Cool Zone	1400.49	1400.49	14	Near door
7.	Disinfectant filtration Room	413.43	413.43	4	Near door
8.	Blending Area	683.71	683.71	7	Near door
9.	Buffer Zone	514.37	514.37	5	Near door
10.	Sterile Corridor	2815.49	2815.49	28	Near door of Entry Air-lock III
11.	Return Air-lock I	336.11	336.11	3	Near door
12.	Return Air-lock II	203.16	203.16	2	Near door
13.	Sterile RM Sampling Area	2931.29	2931.29	30	Near door
14.	Vial Washing and Depyrogenation Area	3530.22	3530.22	35	Near door
15.	Air Lock-II of Vial Washing	144.16	144.16	2	Near door
16.	Air Lock-I of Vial Washing	144.16	144.16	2	Near door
17.	Vial De-cartoning Area	1117.57	1117.57	11	Near door
18.	Primary Packing Material Day Store	1006.89	1006.89	10	Near door
19.	Equipment Washing	423.92	423.92	4	Near door
20.	Unit Preparation Area	2164.24	2164.24	22	Near door
21.	Air Lock-II of Unit Preparation	214.53	214.53	2	Near door
22.	Garment Washing	1037.49	1037.49	11	Near door
23.	Air Lock-I of Unit	238.85	238.85	3	Near door



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	Preparation				
24.	Disinfectant Preparation Area	413.43	413.43	4	Near door
25.	Air Lock of Disinfectant Preparation	182.11	182.11	2	Near door
26.	Blender Drive Area	391.77	391.77	4	Near door
27.	Material Entry	296.57	296.57	3	Near door



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ANNEXURE – II FOGGING RECORD (STERILE AREA)

Block :

Department:

Month /Year :

Fogging Agent:

Frequency: Daily at the end of Operation

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			

Reviewed By QA:
(Sign & Date)



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ANNEXURE – III FOGGING RECORD (NON STERILE AREA)

Block :

Department :

Month /Year :

Frequency: Weekly

Fogging Agent:

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			

Reviewed By QA:
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ANNEXURE – IV FOGGING RECORD (STERILE AREA) WAREHOUSE

Block :

Department :

Month /Year :

Frequency: Daily at the end of Operation

Fogging Agent:

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	Sterile Sampling/Dispensing Room					
	Entry Air-lock II					
	Entry Air-lock III					
	Return Air-lock I					
	Return Air-lock II					
	Entry Air-lock I					

	Sterile Sampling/Dispensing Room					
	Entry Air-lock II					
	Entry Air-lock III					
	Return Air-lock I					
	Return Air-lock II					
	Entry Air-lock I					

Reviewed By QA:
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ANNEXURE – V FOGGING SOLUTION USAGE RECORD FOR THREE PIECE LINE

Block:

Line:

S.No.	Grade	Area	Volume of Ares in Cubic Feet	Volume of Fogging to be Used	Fogging Duration	Location of Fogger
1.	A & B	Filtration Room-I	1475	1475	15	Near door
2.		Filtration Room-II	1350	1350	14	Near door
3.		Filling Room	2696	2696	27	Near door & its opposite side
4.		Change Room-3 (Aseptic Area)	201	201	2	Near Door
5.		Aseptic Corridor	3160	3160	32	Near Door of change room -3
6.		Passage- 1	299	299	3	Near Door
7.		Machine Tools & Tubing Room	1479	1479	15	Near Door
8.		Disinfectant Filtration	670	670	7	Near Door
9.		Vials Staggering Room	1453	1453	15	Near Door
10.		Autoclave Unloading	1222	1222	12	Near Door
11.	C	Change Room-2 (Aseptic Area)	604	604	6	Near Door
12.		Return Change Room-1 (Aseptic Area)	291	291	3	Near Door
13.		Airlock-2 (Unit Preparation)	393	393	4	Near Door
14.		Unit Preparation Room	2155	2155	22	Near Door
15.		Passage	494	494	5	Near Door
16.		Equipment Washing	1107	1107	11	Near Door
17.		Disinfectant Preparation Room	842	842	8	Near Door
18.		Decartoning Room	672	672	7	Near Door
19.		Manufacturing Corridor	1103	1103	11	Near Door
20.		Personnel Airlock-2 (Manufacturing)	255	255	3	Near Door
21.		Manufacturing Room-I	2128	2128	21	Near Door
22.		Manufacturing Room-II	2077	2077	21	Near Door
23.	D	CIP & SIP Room	907	907	9	Near Door
24.		Garment Washing & Preparation	1006	1006	10	Near Door
25.		Change Room-1 (Aseptic Area)	518	518	5	Near Door
26.		Return Change Room-2	255	255	3	Near Door



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S.No.	Grade	Area	Volume of Ares in Cubic Feet	Volume of Fogging to be Used	Fogging Duration	Location of Fogger
		(Aseptic Area)				
27.		Scrap Out	403	403	4	Near Door
28.		Personnel Air Lock (De-cartoning)	218	218	2	Near Door
29.		Material Entry (De-cartoning)	270	270	3	Near Door
30.		Personnel Airlock (Disinfectant Preparation)	328	328	3	Near Door
31.		Sterile Material Entry	196	196	2	Near Door
32.		Airlock-I (Unit Preparation)	358	358	4	Near Door
33.		Material Entry (Manufacturing)	534	534	5	Near Door
34.		Personnel Airlock-I (Manufacturing)	256	256	3	Near Door
35.		Return Change Room (Manufacturing)	202	202	2	Near Door



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ANNEXURE – VI FOGGING RECORD (STERILE AREA THREE PIECE)

Block: I-Block

Department: Production

Line: Three Piece

Month:

Year:

Fogging Agent:

Frequency: Daily at the end of Operation

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	Filling Room					
	Filtration Room-I					
	Filtration Room-II					
	Autoclave Unloading					
	Machine Tools & Tubing Room					
	Disinfectant Filtration					
	Vials Staggering Room					
	Change Room-3 (Aseptic Area)					
	Passage- 1					
	Aseptic Corridor					
	Return Change Room-1 (Aseptic Area)					
	Return Change Room-2 (Aseptic Area)					
	Change Room-2 (Aseptic Area)					
	Change Room-1 (Aseptic Area)					

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ANNEXURE – VII FOGGING RECORD (UNIT PREPARATION AREA THREE PIECE)

Block:

Department: Production

Line: Three Piece

Month:

Year:

Fogging Agent:

Frequency: Weekly

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	Scrap Out					
	Sterile Material Entry					
	Decartoning Room					
	Personnel Air Lock (De-cartoning)					
	Material Entry (De-cartoning)					
	Disinfectant Preparation Room					
	Personnel Airlock (Disinfectant Preparation)					
	Equipment Washing					
	Unit Preparation Room					
	Passage					
	Airlock-2 (Unit Preparation)					
	Garment Washing & Preparation					
	Airlock-I (Unit Preparation)					

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ANNEXURE – VIII FOGGING RECORD (MANUFACTURING AREA THREE PIECE)

Block:.....

Department: Production

Line: Three Piece

Month:

Year:

Fogging Agent:

Frequency: Weekly

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	Manufacturing Room-I					
	Manufacturing Room-II					
	Manufacturing Corridor					
	Personnel Airlock-2 (Manufacturing)					
	Return Change Room (Manufacturing)					
	Personnel Airlock-I (Manufacturing)					
	Material Entry (Manufacturing)					
	CIP & SIP Room					

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ANNEXURE – IX

FOGGING SOLUTION USAGE RECORD FOR THREE PIECE LINE

Block:

Line: Three Piece

S.No.	Grade	Area	Volume of Area in Cubic Feet	Volume of Fogging to be Used(ml)	Fogging Duration (Minute)	Location of Fogger
1.	A & B	Filtration Room-I	2340	2340	24	Near door
2.		Filtration Room-II	2227	2227	23	Near door
3.		Filling Room	3595	3595	36	Near door & its opposite side
4.		Entry PAL-3 (Aseptic Area)	414	414	5	Near Door
5.		Aseptic-1.5 m wide Passage-B	1471	1471	15	Near door of cool zone
6.		Aseptic-1.5 m wide Passage-C	1224	1224	13	At corner
7.		Aseptic-1.2 m wide Passage-A	424	424	5	At corner
8.		Aseptic-2.37 m wide Passage	812	812	9	At corner
9.		Aseptic-1.985 wide Passage	1081	1081	11	Near door of Filtration 2
10.		Machine Tools & Tubing Room	839	839	9	Near door
11.		Disinfectant Filtration	572	572	6	Near door
12.		Vials Staggering Room	1642	1642	17	Near door
13.		Autoclave Unloading	1589	1589	16	Near door
14.		Return Change Room-1 (Aseptic Area)	417	417	5	Near door
15.	C	Entry PAL-2 (Aseptic Area)	552	552	6	Near door
16.		PAL-2 (Unit Preparation)	200	200	2	Near door
17.		Return Change Room-2 (Aseptic Area)	331	331	4	Near door
18.		Autoclave Loading Room	2173	2173	22	Near door
19.		PAL-2 (Mfg Area)	401	401	4	Near door
20.		Equipment Washing Room	728	728	8	Near door
21.		Disinfectant Preparation Room	500	500	5	Near door



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S.No.	Grade	Area	Volume of Area in Cubic Feet	Volume of Fogging to be Used(ml)	Fogging Duration (Minute)	Location of Fogger
22.		Decartoning Room	649	649	7	Near door
23.		Manufacturing Corridor	1378	1378	14	Near door
24.		Manufacturing Room-I	2072	2072	21	Near door
25.		Manufacturing Room-II	3057	3057	31	Near door
26.		PAL-2 (Visual inspection)	200	200	2	Near door
27.		Visual Inspection Room	1156	1156	12	Near door
28.		D	PAL-1 (Visual inspection)	200	200	2
29.	PAL-1 (Mfg Area)		375	375	4	Near door
30.	CIP Room		1376	1376	14	Near door
31.	PAL(De-cartoning)		191	191	2	Near door
32.	MAL (De-cartoning)		347	347	4	Near door
33.	PAL (Disinfectant Preparation)		186	186	2	Near door
34.	MAL (Disinfectant Preparation)		412	412	5	Near door
35.	Return PAL- 3 (Aseptic Area)		331	331	4	Near door
36.	Entry PAL-1 (Aseptic Area)		441	441	5	Near door
37.	Sterile Material Entry		286	286	3	Near door
38.	Material Receiving		758	758	8	Near door
39.	PAL-1(Unit Preparation)		179	179	2	Near door
40.	PAL(Garment Wash)		318	318	4	Near door
41.	Garment Washing		679	679	7	Near door
42.	Change Parts & Filters		586	586	6	Near door
43.	Janitor		323	323	4	Near door
44.	Change Room-2		1031	1031	11	Near door
45.	Production office		783	783	8	Near door
46.	2.25 m wide Passage Corridor(Grade D)		9369	9369	94	At middle and corner
47.	1.5 m wide Passage Corridor(Grade D)		2928	2928	30	At middle and corner



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ANNEXURE – X FOGGING RECORD (STERILE AREA, THREE PIECE)

Block:

Department: Production

Line: Three Piece

Month:

Year:

Fogging Agent:

Frequency: Daily at the end of Operation

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	Filtration Room-I					
	Filtration Room-II					
	Filling Room					
	Machine Tools & Tubing Room					
	Vials Staggering Room					
	Disinfectant Filtration					
	Autoclave Unloading					
	Aseptic-1.5 m wide Passage-B					
	Aseptic-1.5 m wide Passage-C					
	Aseptic-1.2 m wide Passage-A					
	Aseptic-2.37 m wide Passage					
	Aseptic-1.985 wide Passage					
	Entry PAL-3 (Aseptic Area)					
	Entry PAL-2 (Aseptic Area)					
	Return PAL-1 (Aseptic Area)					
	Return PAL-2 (Aseptic Area)					
	Return PAL- 3(Aseptic Area)					
	Entry PAL-1 (Aseptic Area)					

Reviewed By QA:
(Sign & Date)



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ANNEXURE – XI FOGGING RECORD (GRADE C & D AREA, THREE PIECE)

Block: Q-Block

Department: Production

Line: Three Piece

Month:

Year:

Fogging Agent:

Frequency: Weekly

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	Manufacturing Room-I					
	Manufacturing Room-II					
	Manufacturing Corridor					
	PAL-2 (Mfg Area)					
	PAL-1 (Mfg Area)					
	CIP Room					
	Visual Inspection room					
	PAL-2 (Visual inspection)					
	PAL-1 (Visual inspection)					
	Decartoning Room					
	Disinfectant Preparation Room					
	PAL-2 (Unit Preparation)					
	Autoclave loading room					
	Equipment washing room					

Reviewed By QA:
(Sign & Date)



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ANNEXURE – XII FOGGING RECORD (GRADE D AREA, THREE PIECE)

Block: Q-Block

Department: Production

Line: Three Piece

Month:

Year:

Fogging Agent:

Frequency: Weekly

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	MAL (De-cartoning)					
	PAL(De-cartoning)					
	MAL (Disinfectant Preparation)					
	PAL (Disinfectant Preparation)					
	Sterile Material Entry					
	Material Receiving					
	PAL-1(Unit Preparation)					
	Garment Washing					
	PAL(Garment Wash)					
	Change Parts & Filters					
	Janitor Room					
	Production office					
	Change Room-2					
	2.25 m wide Passage Corridor (Grade D)					
	1.5 m wide Passage Corridor (Grade D)					

Reviewed By QA:
(Sign & Date)



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ANNEXURE – XV FOGGING SOLUTION USAGE RECORD FOR WAREHOUSE

Block:

Area: Sterile & Non Sterile

S.No.	Area	Volume of Ares in Cubic Feet	Volume of Fogging to be Used	Fogging Duration (Minutes)	Location of Fogger
1.	Sterile Sampling/Dispensing Room	1319.84	1319.84	13	Near door and its opposite side
2.	Entry Air-lock I	147.6	147.6	2	Near door
3.	Entry Air-lock II	144.0	144.0	2	Near door
4.	Entry Air-lock III	176.4	176.4	2	Near Door
5.	Return Air-lock I	147.2	147.2	2	Near door
6.	Return Air-lock II	169.28	169.28	2	Near Door
7.	Non Sterile Sampling Room	1066.56	1066.56	11	Near door and its opposite side
8.	Air-lock I	200.0	200.0	2	Near Door
9.	Air-lock II	200.0	200.0	2	Near Door
10.	Non Sterile Dispensing Room	910.72	910.72	9	Near door and its opposite side
11.	Air-lock I	164.0	164.0	2	Near Door
12.	Air-lock II	164.0	164.0	2	Near Door
13.	Non Sterile Sampling Cum Dispensing Room	1494.0	1494.0	15	Near door and its opposite side
14.	Air-lock I	174.88	174.88	2	Near Door
15.	Air-lock II	187.08	187.08	2	Near Door



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ANNEXURE – XVI FOGGING RECORD (NON STERILE AREA) WAREHOUSE

Block :

Department :

Month /Year :

Frequency: Weekly

Fogging Agent:

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	Non Sterile Sampling Room					
	Air-lock II					
	Air-lock I					
	Non Sterile Dispensing Room					
	Air-lock II					
	Air-lock I					
	Non Sterile Sampling Room					
	Air-lock II					
	Air-lock I					
	Non Sterile Dispensing Room					
	Air-lock II					
	Air-lock I					

Reviewed By QA:
(Sign & Date)



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ANNEXURE – XVII

FOGGING RECORD (NON STERILE AREA) WAREHOUSE THREE PIECE

Block: Three Piece

Departments:

Month /Year:

Frequency: Weekly

Fogging Agent:

Date	Area	Fogging Time		Done By (Name)	Checked By Sign & Date	Remarks
		From	To			
	Non Sterile Sampling cum Dispensing Room					
	Air-lock II					
	Air-lock I					
	Non Sterile Sampling cum Dispensing Room					
	Air-lock II					
	Air-lock I					
	Non Sterile Sampling cum Dispensing Room					
	Air-lock II					
	Air-lock I					
	Non Sterile Sampling cum Dispensing Room					
	Air-lock II					
	Air-lock I					

Reviewed By QA:
(Sign & Date)



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ANNEXURE – XVIII FOGGER DETAIL USED FOR FOGGING ACTIVITY

Block/Line	Make	S.No	Flow rate	Dead Volume	Tank Capacity	Input power supply
Three Piece	BIOSTAR -ULV		100 ml/minute	100-150 ml	5 Lit.	220V,4 AMP, 50 Hz
I block/DPI	BIOSTAR -ULV		100 ml/minute	100-150 ml	5 Lit.	220V,4 AMP, 50 Hz