

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Fogging in Different Locations at FFS Section						
SOP No.:		Department:	Production			
SOP No.:		Effective Date:				
Revision No.:	00	Revision Date:				
Supersede Revision No.:	Nil	Page No.:	1 of 7			

1.0 OBJECTIVE:

To lay down a procedure for Fogging in different locations at FFS section.

2.0 SCOPE:

This SOP is applicable Fogging in different locations in FFS section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head-Production

5.0 ABBREVIATIONS:

- cu. ft. Cubic Feet
- Ltd. Limited
- ml Milliliter
- No. Number
- QA Quality Assurance
- SOP Standard Operating Procedure

6.0 **PROCEDURE**:

- 6.1 Check & ensure that the area intended for fogging is completely closed.
- 6.2 Virosil shall be used as Fogging Agent in ULV fogger m/c.
- 6.3 ULV fogger m/c details (ID:-) Make:-BIOSTAR

Sr. No.:-....

Liquid discharge:- 200 ml per minute (3 Trail taken with 20% V/V Solution of Virosil)

Dead volume:-100-150 ml

Tank capacity:-5 Lit.

Input power supply:- 220 V, 4 AMP, 50/60 Hz

- 6.4 20 % Solution of Virosil in WFI shall be used as Fogging Solution. (For 1000 cu. ft. Area to be fogged with Fogger 200 ml of Virosil in 800 ml WFI to be used).
- 6.5 Fogging with 20 % Virosil Solution shall be performed in the particular Area.
- 6.6 After Fogging, leave the Area in Static Condition up to 60 minutes for complete sanitization.
- 6.7 Clean the Area and Equipment before starting of any activity with scheduled Disinfectant Solution for the day.



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- 6.8 Run the fogger in respective area as time defined in Annexure-I.
- 6.9 Record the Fogging details in Annexure-II, Titled "Fogging Record (Grade B)", Annexure-III, Titled "Fogging Record (Grade C)" and Annexure-IV, Titled "Fogging Record (Grade D)".

6.10 FREQUENCY:

6.10.1 For Grade B : Daily (At the End of the Activity / At the End of the Shift)

6.10.2 For Grade C : Twice in a Week

6.10.3 For Grade D : Weekly

Fogging frequency may be increased on the basis of Environmental Monitoring Report of the said Area.

- Shut Down
- Microbial Count (Beyond Limit)

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Fogging Time/Volume Required in FFS Area	
Annexure-II	Fogging Record (Grade B)	
Annexure-III	Fogging Record (Grade C)	
Annexure-IV	Fogging Record (Grade D)	

ENCLOSURES: SOP Training Record

8.0 **DISTRIBUTION:**

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

9.0 **REFERENCES:**

Not Applicable



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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE – I FOGGING TIME/VOLUME REQUIRED IN FFS AREA

Block:

Section: FFS

S.No.	Area	Volume of Area (In Cubic Feet)	Volume of Fogging solution to be Used (In ml)	Fogging Duration (In minutes)
1.	CIP/SIP ROOM			
2.	WASHING AREA			
3.	CIP/SIP A/L			
4.	A/L-01 (MFG)			
5.	A/L-02 (MFG)			
6.	MFG ARAE			
7.	BUFFER ZONE			
8.	RM OTHER			
9.	RM BIO			
10.	GRANULE DEY STORE			
11.	A/L-01 (FILLING) ENTRY			
12.	A/L-02 (FILLING) ENTRY			
13.	A/L-03 (FILLING) ENTRY			
14.	A/L-01 (FILLING) EXIT			
15.	A/L-02 (FILLING) EXIT			
16.	FILLING ROOM			
17.	HOLD AREA			
18.	COMMON CORRIDORE (outside)			
19.	COMMON CORRIDORE (Inside)			
20.	COMMON CHANGE ROOM			
21.	JANITOR ROOM			



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:.. D:ff.

PHARMA DEVILS

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ANNEXURE – II FOGGING RECORD (GRADE B)

Block:

Department: Production

Section:

Month:

Year:

Fogging Agent:

Frequency: Daily (At the End of the Activity / At the End of the Shift)

Date	A 1000	Fogging Time		Done By	Checked By	Remarks
	Area	From	То	Sign & Date	Sign & Date	Nemarks
	A/L-03 (FILLING) ENTRY					
	FILLING ROOM					
	HOLD AREA					
	BUFFER ZONE					



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ANNEXURE III FOGGING RECORD (GRADE C)

Block:

Department: Production

Section:

Month:

Year:

Fogging Agent:

Frequency: Twice in a Week

Date	Area	Fogging Time		Done By	Checked By	Remarks
	Alta	From	То	Sign & Date	Sign & Date	Kemarks
	MFG AREA					
	A/L-02 (MFG)					
	A/L-02 (FILLING) ENTRY					
	A/L-01 (FILLING) EXIT					



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ANNEXURE – IV FOGGING RECORD (GRADE D)

Block:

Department: Production

Line:

Month:

Year:

Fogging Agent:

Frequency: Weekly

Date	Area	Foggin	g Time	Done By	Checked By	Domoniza
Date	Area	From	То	Sign & Date	Sign & Date	Kemarks
	CIP/SIP ROOM					
	WASHING AREA					
	CIP/SIP A/L					
	A/L-01 (MFG)					
	A/L-02 (FILLING) EXIT					
	A/L-01 (FILLING) ENTRY					
	COMMON CORRIDOR (Inside)					
	JANITOR ROOM					
	COMMON CHANGE ROOM					
	RM BIO					
	RM OTHER					
	COMMON CORRIDOR (outside)					
	GRANULE DEY STORE					