



STANDARD OPERATING PROCEDURE

Department: Production (Softgel)	SOP No.:
Title: Cleaning of Utensils and Accessories	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down the procedure for Fumigation of Production Area.

2.0 SCOPE:

This procedure is applicable for Fumigation of Production Area.

3.0 RESPONSIBILITY:

Technician / Officer / Executive / Manager-Production.

Head of Department : To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE

4.1 Safety Precautions

4.1.1 Use PPE's like hand gloves, nose mask and safety goggles during preparation and use of 20% Virosil solution.

4.1.2 Use freshly prepared solution.

4.1.3 Inform to engineering department to switch OFF the AHU's of respective area before fogging.

4.1.4 Perform the fumigation in the direction from the far end of the area to the entry of the area to protect from direct exposure to the person.

4.2 Preparation of 20 % v/v Virosil solution

4.2.1 To prepare 1 liter of 20% Virosil, take 200 ml of Virosil and make-up volume up to 1000 ml with Purified water and mix well.

4.2.2 Prepare the required quantity of solution and record the details in Annexure - II.

4.2.3 Dry clean all the equipments & accessories before starting the fumigation activity.(if applicable)

4.2.4 Load 20 % Virosil solution in to the fogger.



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- 4.2.5 Carry the 20% Virosil-loaded fogger in to the area and put the fogger at height about 2-3 feet with the help of table or chair and 2-3 feet distance from corner.
- 4.2.6 Set the fogger nozzle at upright position as much as possible.
- 4.2.7 Connect the fogger to the power plug.
- 4.2.8 Switch ON the fogger. Fog required quantity of fumigation material for specific period of time as per details mentioned in Annexure III.
- 4.2.9 After fogging is over collect the fogger from respective area and affix the “TO BE CLEANED” label duly signed with date by production person and update the area status “AREA IS UNDER FUMIGATION” and lock the door.
- 4.2.10 Drain the remaining quantity of 20% Virosil solution in the wash area and clean the fogger with sufficient amount of purified water and dry it. Put “CLEANED” Label on it.
- 4.2.11 Leave the area as it is for at least 1 hour.
- 4.2.12 After 1 hour inform to engineering department to start the AHU’s of respective area.
- 4.2.13 Clean the respective area after start of AHU.
- 4.2.14 Wipe all the equipment with 70% v/v IPA solution before starting next activity in the area.
- 4.2.15 Maintain the fumigation record as per Annexure-I.

4.3 Frequency:

For Soft gel Department: every 15 + 3 days

For Tablet and External Preparation Department: every 30 + 3 day

Note: Fumigation also applicable to following.

- After any major civil works
- After any major breakdown
- When microbial count exceed the specified limit in the production area.

5.0 ANNEXURE(S)

Annexure -I - Detail of fumigation record for production area.

Annexure -II - Preparation, Utilization and Destruction of 20% Virosil Solution.

Annexure -III - Flow rate calculation for 20% v/v Virosil solution.



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Annexure -IV - Calculation for consumption of 20% v/v Virosil solution and requirement of fogging time for production area.

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and Destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION(S)

- Virosil - Brand name of Fumigation Solution
- SGD - Soft Gelatin Department
- SOP - Standard Operating Procedure
- AHU - Air Handling Unit
- NA - Not Applicable
- PPE - Personal Protective Equipment
- v/v - Volume by Volume

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	----



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ANNEXURE III

FLOW RATE CALCULATION FOR 20%V/V VIROSIL SOLUTION

Calculate flow rate of 20% v / v Virosil Solution as per procedure given below

Step 1 : Fill the 1500 ml measured quantity of fogging solution in the Fogger

Step 2 : Run the fogger and measure time for consumption of 1500ml of 20% v / v Virosil Solution

Step 3 : Repeat the Step 2 for 10 times and Calculate average flow rate of 20% v / v Virosil Solution

S.No.	Qty. of 20% v / v Virosil Solution Taken (In ml)	Total time taken for Fogging of 20% v / v Virosil Solution(Minutes)	Flow Rate / Minute	Average Flow Rate/Minute (In ml)
1.	1500	33.50	44.78	46
2.	1500	33.42	44.88	
3.	1500	32.58	46.04	
4.	1500	32.49	46.17	
5.	1500	33.45	44.84	



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6.	1500	32.48	46.18	
7.	1500	33.15	45.25	
8.	1500	32.50	46.15	
9.	1500	32.58	46.04	
10.	1500	32.51	46.14	
Total	15000	-	456.48	



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ANNEXURE IV

CALCULATION FOR CONSUMPTION OF 20% V/V VIROSIL SOLUTION AND REQUIREMENT OF FOGGING TIME FOR PRODUCTION AREA

For Example:

1. Volume of the space to be Fogged = Length x Width x Height

Example: 20ft x 20 ft x 10 ft = 4000 cubic feet

2. Application rate recommended (Refer Dosage direction of the Virosil mentioned on the Label) : 400ml Virosil Solution (20% v/v) / 1000 cubic feet

3. Output flow rate of Fogger (As per above Calculation): 46 ml / Minutes

Step-1 Total volume of space to treated - 4000 cubic feet

Step-2 Calculate the total quantity of the Virosil Solution (20% v/v) needed for that Space

Step-3 Consumption of Virosil Solution (20% v/v) in ml= Volume (4000 cubic feet) x

Application Rate (400ml 20% v/v Virosil Solution / 1000 cubic feet)

= 1600 ml

Step-4 Calculate the Fogging Time

Time Required =Total Virosil Solution (20% v/v) to be fogged / Flow Rate

= 1600ml / 46 ml / min

= 34.78 minutes \approx 35 minutes



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S.No.	Area Name	Volume of Area (Feet ³)	Quantity of 20% v/v Virosil Solution requirement for area (In ml)	Fogging Time (In Minute)
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
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23.				