



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sanitization of Microbiology Laboratory

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 OBJECTIVE

To lay down procedure for Cleaning and Sanitization of microbiology laboratory.

2.0 SCOPE

This SOP is applicable for cleaning and sanitization in microbiology laboratory.

3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE

4.1 Prerequisites

- 4.1.1 Disinfectants.
- 4.1.2 Sterilized S.S bucket.
- 4.1.3 Sterile dusters and mops.
- 4.1.4 Water for injection.
- 4.1.5 Sterile garment.
- 4.1.6 Sterile gloves.
- 4.1.7 Nose mask.
- 4.1.8 Measuring cylinder.
- 4.1.9 Sterile screw cap bottles / aspirator bottle for storage of disinfectants.
- 4.1.10 Vacuum pump.
- 4.1.11 Sterile filter assembly with 0.22-micron membrane filter.

4.2 Preparation of Disinfectant Solutions

4.2.1 The disinfectant use for cleaning and sanitization are mentioned in Table - I.

4.2.2 Preparation of 5 liter Cadicide (2%) - (Area / surface disinfectant)

4.2.2.1 Collect 5 liters of Cadicide in to cleaned container.



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4.2.2.2 Add the contents of two activator vials in to container and mix well by shaking the container till colourless solution turns green. (Each activator vial is ment for 2.5 liter of solution).

4.2.2.3 Filter the above mixture of disinfectant solution through sterile 0.22 micron membrane filter and after filtration collect the filtered disinfectant solution into a sterile screw cap bottle / aspirator bottle.

4.2.2.4 Label the screw cap bottle / aspirator bottle as per Annexure - II.

4.2.2.5 Follow the above same procedure for preparation of other volume of disinfectants.

4.2.2.6 Use this filtered disinfectant solution on the day of preparation.

4.2.2.7 Maintain the disinfectant solution preparation record as per Annexure - I.

4.2.3 **Preparation of 5 liter Bacilloid (2%) - (Area / surface disinfectant)**

4.2.3.1 Collect 4900 mL of water for injection in to a cleaned container with the help of 1000 mL measuring cylinder.

4.2.3.2 Take 100 mL of Bacilloid with help of clean and dry measuring cylinder of 100 mL and mix in 4900 mL water for injection.

4.2.3.3 Filter the above mixture of disinfectant solution through sterile 0.22 micron membrane filter and after filtration collect the filtered disinfectant solution into a sterile screw cap bottle / aspirator bottle.

4.2.3.4 Label the screw cap bottle / aspirator bottle as per Annexure - II.

4.2.3.5 Follow the above same procedure for preparation of other volume of disinfectants.

4.2.3.6 Use this filtered disinfectant solution on the day of preparation.

4.2.3.7 Maintain the disinfectant solution preparation record as per Annexure - I.

4.2.4 **Preparation of 3 liter IPA (isopropyl alcohol) (70%) - (Hand disinfectant)**

4.2.4.1 Collect 900 mL of water for injection in to a cleaned container with the help of 1000 mL measuring cylinder.

4.2.4.2 Take 2100 mL IPA (isopropyl alcohol) with help of clean and dry measuring cylinder of 500 mL and mix in 900 mL water for injection.

4.2.4.3 Filter the above mixture of disinfectant solution through sterile 0.22 micron membrane filter and after filtration collect the filtered disinfectant solution into a sterile screw cap bottle / aspirator bottle.

4.2.4.4 Label the screw cap bottle / aspirator bottle as per Annexure - II.

4.2.4.5 Follow the above same procedure for preparation of other volume of disinfectants.

4.2.4.6 Use this filtered disinfectant solution on the day of preparation.

4.2.4.7 Maintain the disinfectant solution preparation record as per Annexure - I.



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Table - I

Name of the disinfectant	Concentration
Cadicide (Area /surface disinfections)	2 %
Bacillocid (Area /surface disinfections)	2 %
IPA (Hand disinfections)	70 %

4.3 Cleaning and Sanitization Schedule

Follow the cleaning and sanitization schedule as mentioned in Table - II.

Table - II

Area	Frequency of cleaning / sanitization	Schedule for use of Disinfectant solution
Floors / working bench	Daily	Rotate the disinfectant after every seven days.
Walls / window / doors / Fixtures	Weekly	
Ceiling	Monthly	

4.4 Cleaning Practices

- 4.4.1 The person who performs the cleaning activity should be familiar with entry and exit procedure of microbiology laboratory, preparation and usage of disinfectant solutions.
- 4.4.2 Cleaning should always be performed from more critical area to less critical area (for example sterility testing room, cooling zone, sterile corridor, change room - 4, change room - 3, change room - 2, and last in change room - 1).



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4.4.3 Always clean the ceiling first followed by walls and floor.

4.5 Procedure for use of clean room wipes

4.5.1 Fold the clean wiper in half and then fold it to half again.

4.5.2 For cleaning lightly dampen the clean room wipe with the disinfectant by using a spray pump. Do not saturate the wipe or dip the wipe in the disinfectant container.

4.5.3 Wipe the surface in a linear pattern from top to bottom or from side to side in a regular pattern of parallel strokes with enough overlap to ensure that no area is unwiped.

4.5.4 Use the other fold when the wipe becomes visually dirty.

4.5.5 For disinfection of the surface specially walls/floors use a nearly saturated wipe with enough pressure to leave a disinfection film.

4.6 Procedure for use of Twin bucket system and the clean room mopping

4.6.1 Fill approximately $\frac{3}{4}$ of both the buckets with the filtered disinfection solution.

4.6.2 Use the first bucket to rinse contaminants from the mop prior to rinsing in the final disinfectant in the (second bucket). This two-bucket method ensures that contaminants picked up on the mop are not redistributed to the clean room.

4.6.3 With the clean mop start cleaning the floor from extreme end and work your way back to the entrance.

4.6.4 Cleaning should be done in parallel strokes with enough overlap to ensure that no area remains uncleaned and one should avoid entering the area once cleaned to re-contaminate the cleaned area.

4.6.5 Use a "Pull and Lift" method with the mop, stroking in one direction only.

4.6.6 Rinse the mop after three cleaning strokes.

4.6.7 Replace both the disinfectant solution and the wipe when it becomes dirty.

4.7 Cleaning of Sterility Testing Area

4.7.1 Enter in to the Sterility testing area as per SOP.

4.7.2 Collect the all-waste materials in to the waste bin.

4.7.3 Remove the extraneous matter from the surface with a dry mop.

4.7.4 Follow twin-bucket system for cleaning.

4.7.5 Unload the sterilized cleaning accessories, i.e., S.S. buckets, moping dusters and water for injection from sterile side (Cooling zone) of autoclave.

4.7.6 Follow the step 4.2 for preparation of the disinfectants solution.



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4.7.7 Follow the step 4.5 and 4.6 for use of clean room wipes and use of twin bucket system.

4.7.8 Wet the sterilized mop dipping in the desired concentration of disinfectant solution and clean the surface.

4.7.9 Repeat the above step for cleaning of the remaining areas (i.e., cooling zone, sterile corridor, change room - 4, change room - 3, change room - 2, and last in change room - 1).

4.7.10 Record the cleaning details in Annexure - III.

4.8 Cleaning Procedure for Controlled area (MLT room, LAL room, Media preparation room and Incubator room)

4.8.1 Enter in to the respective area as per SOP.

4.8.2 Clean the main room first followed by airlocks. (For example Media preparation room first followed by airlock.)

4.8.3 Take separate mops for cleaning of each room and for each cleaning step.

4.8.4 Collect the all-waste materials in to the waste bin.

4.8.5 Remove the dust from the surface with a dry mop.

4.8.6 Follow the step 4.2 for preparation of the disinfectants solution.

4.8.7 Follow the step 4.5 and 4.6 for use of clean room wipes and use of twin bucket system.

4.8.8 Wet the sterilized mop dipping in the desired concentration of disinfectant solution and clean the surface.

4.8.9 Record the cleaning details in Annexure - III.

4.9 Fumigation of Sterility Testing Area

4.9.1 Before fumigation switch off the air handling unit, blower and laminar airflow unit.

4.9.2 Enter the sterility testing area as per SOP.

4.9.3 Before the fumigation cleaning should be completed as mentioned above.

4.9.4 Use aerosol fumigator (Fogger) for fumigation in sterility testing room.

4.9.5 Prepare 2 % Cadicide for fumigation as mentioned above.

4.9.6 Follow the step 4.2 for preparation of 2 % Cadicide.

4.9.7 Fill the fogger tank with required quantity of 2 % Cadicide.

4.9.8 Plug in the unit's main cord into a 3 pin 5 amps 230V, electrical socket with switch.

4.9.9 Set the time and volume of 2 % Cadicide required to fumigate the respective area by adjusting knob.



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4.9.10 Mount the fumigator 2 feet from the floor and keep the motor at 45 degree.

4.9.11 Operate the fogger as per SOP.

4.9.12 Keep the display board "AREA UNDER FUMIGATION-DO NOT ENTER" on the door of the change room - 1.

4.9.13 Allow the fumigant to remain overnight or for a minimum period of 12 hours.

4.9.14 Maintain the record of fumigation in Annexure - III.

4.9.15 Frequency - Fumigation of the sterility testing area once in a week.

4.10 De Fumigation Sterility Testing Area

4.10.1 Remove the fogger from the fumigated area after ensuring that there is no perceptible odour of fumes.

4.10.2 Check the fumes content of the fumigated area and it should be within limit.

4.11 Controlled Area Fumigation (MLT room/ LAL room)

4.11.1 Before fumigation switch off the Air handling unit, Blower and Laminar airflow unit.

4.11.2 Enter into the controlled area as per SOP.

4.11.3 Before the fumigation cleaning should be completed as mentioned above.

4.11.4 Use aerosol fumigator (Fogger) for fumigation in sterility testing room.

4.11.5 Prepare 2 % Cadicide for fumigation as mentioned above.

4.11.6 Follow the step 4.2 for preparation of 2 % Cadicide.

4.11.7 Fill the fogger tank with required quantity of 2 % Cadicide.

4.11.8 Plug in the unit's main cord into a 3 pin 5 amps 230V, electrical socket with switch.

4.11.9 Set the time and volume of 2 % Cadicide required to fumigate the respective area by adjusting knob.

4.11.10 Mount the fogger 2 feet from the floor and keep the motor at 45 degree.

4.11.11 Operate the fogger as per SOP.

4.11.12 Keep the display board "AREA UNDER FUMIGATION-DO NOT ENTER" on the door of airlock.

4.11.13 Allow the fumigant to remain overnight or for a minimum period of 12 hours.

4.11.14 Maintain the record of fumigation in Annexure - III.

4.11.15 Frequency - Fumigation of the control area of microbiology laboratory once in fifteen days.



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4.12 De Fumigation of Controlled Area

4.12.2 Remove the fogger from the fumigated area after ensuring that there is no perceptible odour of fumes.

5.0 SAFETY & PRECAUTIONS

5.1 All the disinfectant solutions are to be prepared by using dedicated equipments.

5.2 Wear hand gloves and nose mask while preparing and handling disinfectant solution.

5.3 Use water for injection for preparing disinfectant solution and sterile moping duster for cleaning of testing areas, change rooms and airlocks.

5.4 Wear sterile garments and gloves while cleaning in testing areas.

5.5 Always do the cleaning from more critical area to less critical area, i.e. from testing areas, change rooms, air locks, incubation area, media preparation room and washing area.

5.6 The disinfectant shall be used on rotational basis as given in Table - II.

5.7 Always use proper safety apparel such as gloves, safety goggles and nose mask during entire process of fumigation.

5.8 Prepared/filtered disinfectant is to be used on the day of filtration.

6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	First Issue	-----

7.0 REFERENCES

SOP.

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

QC : Quality Control

No. : Number

S.S : Stainless Steel

MLT : Microbial Limit Test



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LAL : Limulus Amoebocyte Lysate

mL : Milliliter

% : Percentage

IPA : Isopropyl Alcohol

NA : Not Applicable

9.0 ANNEXURES

Annexure - I : Disinfectant solution preparation record

Annexure - II : Disinfectant label

Annexure - III : Cleaning, sanitization and fumigation record



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ANNEXURE - II DISINFECTANT LABEL

Disinfectant Label

Name of disinfectant: _____

Date of preparation: _____

Concentration: _____

Use Before date: _____

Prepared by: _____



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ANNEXURE - III

CLEANING, SANITIZATION AND FUMIGATION RECORD

Date: _____

Name of the disinfectant (%) used: _____

Name of the Room	Cleaning and Sanitization							Fumigation Done On	Done by (Date & Sign)
	Daily		Weekly			Monthly	Done by (Date & Sign)		
	Floor	Working bench	Walls	Window/Door	Fixtures	Ceiling			
Media preparation room - Air lock									
Media Preparation room									
Change room - 1									
Change room - 2									
Change room - 3									
Change room - 4									
Cooling zone									
Sterile corridor									
Sterility testing area									
MLT room / LAL room - Air lock									
MLT room									
LAL room									
Incubator room - Air lock									
Incubator room -I									
Incubator room -II									

√ : Cleaning / Sanitization Done, NA: Not applicable

Checked by:
(Date & Sign)