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## 1.0 OBJECTIVE

To lay down a procedure for cleaning and disinfection of general Microbiology laboratory.

## 2.0 SCOPE

This Procedure is applicable to cleaning and disinfection of general Microbiology laboratory other than sterility testing area at Pharma Micro Hub pvt Ltd.

## 3.0 RESPONSIBILITY

- 3.1 Microbiologist is responsible to perform the cleaning activity as per the procedure.
- 3.2 Senior-Microbiology is responsible for ensuring compliance of the activity as per the procedure.

## 4.0 ACCOUNTABILITY

- 4.1 Head– Microbiology/ designee is accountable for overall compliance of this SOP.

## 5.0 PROCEDURE

### 5.1 Precautions:


- 5.1.1 Personnel involved in cleaning activity shall check the use before date of disinfectant solution before starting the cleaning activity.
- 5.1.2 Keep the cleaning equipment and accessories in a dedicated area with proper labelling.
- 5.1.3 All the cleaning accessories shall be clean at the end of the activity.
- 5.1.4 Do not perform the cleaning activity in the rooms during the testing activity.
- 5.1.5 Ensure that water should not go inside the electrical panel / machine panel during cleaning activity.
- 5.1.6 Dry mopping should be performed for electrical panel / machine panel.
- 5.1.7 Wear personnel protective equipment's (PPE) like gloves, nose mask and goggles etc., during disinfectant preparation and cleaning the area.

### 5.2 Receipt and Storage of disinfectants :

- 5.2.1 Receive and store the disinfectants as per the SOP.
- 5.2.2 Enter the details of the disinfectants in the 'Disinfectant inventory and issuance Record' as per Annexure- I.

### 5.3 Preparation of Disinfectant Solutions:

- 5.3.1 Prepare the disinfectant in controlled area.
- 5.3.2 The disinfectant solutions such as (Bacilloid special 1% v/v), sanihygine (1% v/v) and Korsolex Rapid (3% v/v) solutions shall be prepared with Water for Injection (WFI) in a container.

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- 5.3.3 After preparation of required disinfectant, record the details in ‘Disinfectant preparation record’ as per Annexure-II
- 5.3.4 Use the Sterile 70% Isopropyl alcohol (IPA) in all testing areas for LAF cleaning and for hand disinfection.
- 5.3.5 Label the prepared disinfectant containers as per the specimen label given Annexure-V (Dilute disinfectant solution label).
- 5.3.6 Place the label in a polythene sheet and tag it to the spray containers to prevent washout of the label information by alcohol.
- 5.3.7 The Sterile IPA containers shall be used as per the manufacturer COA and labeled as per the Annexure-VI.
- 5.3.8 Hold time of prepared disinfectants and Sterillium shall be followed as per Appendix-I

5.4 **In-house lot number Allotment for prepared diluted disinfectant:**

- 5.4.1 Assign the In-house lot number to the prepared dilute disinfectant solution as per the below format.

DS/YY/XX/NNN

Where,

DS: Denotes Disinfectant

YY: Denotes last two digits of current year

XX: Denotes name of the disinfectant for example

Sanihygine-SH

Korsolex- KL

Bacilloid special-BS.

70% Isopropyle Alcohol-IP


Minnicare - MC

NNN: Denotes current serial number of prepared disinfectant starting from 001.

5.5 **Cleaning and Disinfection Procedure:**

- 5.5.1 Housekeeping person shall enter into the microbiology clean rooms as per the SOP
- 5.5.2 General Microbiology laboratory other than sterility testing area shall be cleaned once in a day, before to start of the daily activity with the scheduled disinfectant solution.
- 5.5.3 Sterility area shall be cleaned at the end of the activity with the scheduled disinfectant solution.

**Note:** In case of unscheduled holiday cleaning activity shall be performed on next working day. Ceilings and walls of general microbiology shall be cleaned weekly once.

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5.5.4 Perform the cleaning and disinfection sequentially from the rooms of highest criticality to least criticality areas (Highest criticality Least Criticality).

**Sequence I** : MLT Room → Culture Handling Room → Change Room

**Sequence II** : Media store room → Media preparation room

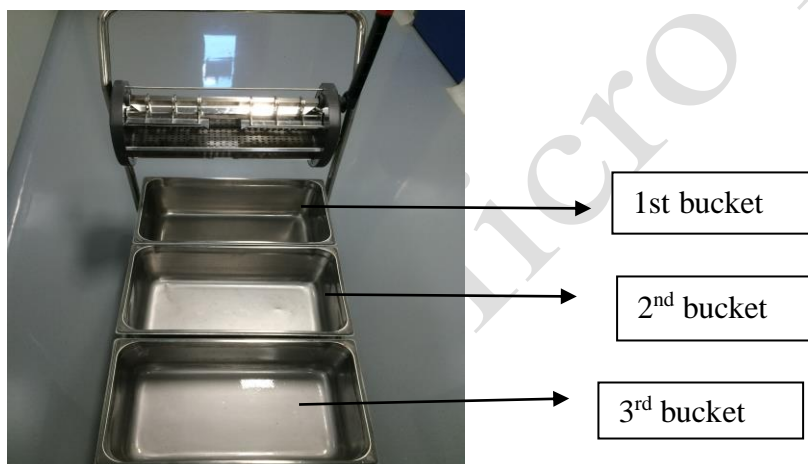
**Sequence III** : Autoclave area → Change room

**Sequence IV**: BET testing room → Incubators room →  
Material store room → Microbiology documentation room

**Sequence V**: Change Room → Microbiology corridor →  
Washing area → Decontamination area.

5.5.5 **Cleaning of areas by using three bucket system:**

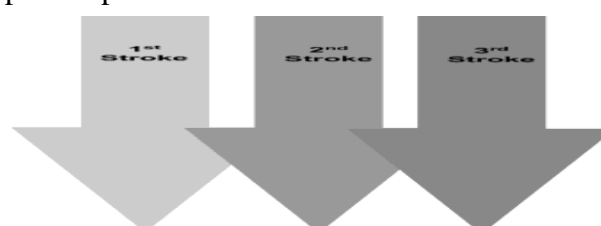
5.5.5.1 First clean the area using dry mop followed by wet mop using three bucket system and pictorial photograph of three bucket system as shown in below figure.




5.5.5.2 Cleaning of area shall be done daily before start the routine activities.

5.5.5.3 Ensure that cleaning shall start from farthest end to nearest end with reference to entrance of the room, top to bottom in one direction only.

5.5.5.4 Clean the area by pull lift method: 1<sup>st</sup> stroke - lift the mop and place it in manageable distance and pull towards the person. 2<sup>nd</sup> stroke – Lift the mop again and place it down at the start of first stroke and pull towards to the person with partial overlapping (overlapping 10 – 20% of first stroke) for effective cleaning. Follow the same procedure as that of 2<sup>nd</sup> stroke for the 3<sup>rd</sup> stroke refer the diagram below. Cleaning of entire room should be done as per the pull lift method.




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- 5.5.5.5 Use three bucket mopping technique for cleaning the floors, walls and Ceilings. Perform the cleaning and disinfection as per below steps.
- 5.5.5.6 Collect the required quantity of WFI in the middle bucket and scheduled disinfectant solution in the 3<sup>rd</sup> bucket of three bucket system.
- 5.5.5.7 Dip the mopping pad using mop rod in disinfectant solution and squeeze the mopping pad in the 1<sup>st</sup> bucket.
- 5.5.5.8 Use the dipped mop and clean the area as per pull lift method as per point no.5.5.5.4.
- 5.5.5.9 After cleaning dip the mopping pad in the bucket of WFI for removal of particle and squeezes it in middle empty bucket.
- 5.5.5.10 Repeat the same procedure from point no.5.5.5.7 to 5.4.5.9 to complete entire area cleaning.
- 5.5.5.11 After each stroke examine the mopping pad for visible contamination and change the mop if required.
- 5.5.5.12 Clean the equipment surfaces and other SS accessories first and then the floors.
- 5.5.5.13 Clean the surfaces of equipment, cross over benches, SS accessories LAF units and any other utility lines and window panels, etc. with lint free mop moistened with scheduled diluted disinfectant.
- 5.5.5.14 Clean all the surfaces (handle, frame, and glass) of door from top to bottom using lint free mop moistened with scheduled diluted disinfectant.
- 5.5.5.15 Before cleaning of the waste bins empty out the contents from the bins.
- 5.5.5.16 Use the below disinfectant solutions on weekly (Monday-Sunday) rotation basis for cleaning.

Rotation of Week	Name of the disinfectant	Concentration of Disinfectant	Category	Minimum Contact Time	Hold Time of Disinfectant
Week I	Sanihygine	1%	Bactericidal	10 min	48Hours
Week II	Korsolex Rapid	3%	Sporicidal	10 min	48Hours
Week III	Bacilloid special	1%	Bactericidal	10 min	48 Hours
Week IV	Korsolex Rapid	3%	Sporicidal	10 min	48 Hours

**Note:** in case of 5 weeks in a month, the rotation of disinfectant shall be follow in sequence mentioned in the above table.

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5.5.5.17 Allow the disinfectant solutions for contact time as per validation. After the specific contact time, clean the area with cooled water for injection as per the above defined flow. Start any activity after the completion of the cleaning activity.

**Note:-**The contact time shall be given based on the validation studies.

5.5.5.18 Frequency of cleaning other areas in Microbiology.

Areas/Equipment and cleaning flow	Cleaning Frequency
Equipments surfaces ,SS accessories and Floor	Daily
Ceilings, Walls, Equipment's surfaces, SS accessories and Floor	Weekly

5.5.5.19 At the end of day House keeping personnel shall clear the waste bins.

5.5.5.20 Incase of cleaning performed on daily basis, enter the cleaning details in "Microbiology area Daily cleaning record –Annexure-III.

5.5.5.21 In case of cleaning performed on weekly basis, enter the cleaning details in "Microbiology area Weekly cleaning record– Annexure-IV.

## 6.0 ABBREVIATIONS

6.1 WFI : Water for Injection.

6.2 SOP : Standard operating procedure.

6.3 SS : Stainless steel

6.4 LAF : Laminar Air flow.

6.5 MLT : Microbial limit test

6.6 BET : Bacterial endotoxin test

## 7.0 ANNEXURE (S) / APPENDIX (S)

7.1 ANNEXURE- I : Disinfectant Inventory and Issuance Record

7.2 ANNEXURE- II : Disinfectant Preparation Record


7.3 ANNEXURE- III : Microbiology area Daily cleaning record

7.4 ANNEXURE- IV : Microbiology area Weekly cleaning record

7.5 ANNEXURE- V : Dilute disinfectant solution label

7.6 ANNEXURE- VI : Ready to use disinfectant solution label

## 8.0 REFERENCES

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8.1 USP monograph <1072>- Antiseptics and disinfectants.

**9.0 CHANGE HISTORY**


9.1 New SOP.

**END OF DOCUMENT**

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**ANNEXURE-III  
MICROBIOLOGY AREA- DAILY CLEANING RECORD**

Date of Cleaning		Disinfectant Name/ In-house Lot Number	
Cleaning Activity Start Time		Cleaning Activity End Time	
Area		Cleaning Status: Cleaning Done (√) / Cleaning Not Done (X)	
MLT Room			
Culture handling room			
Change Room			
Autoclave room			
Change room			
Media store room			
Media preparation room			
BET testing room			
Incubators room			
Microbiology documentation room			
Microbiology corridor			
Washing area			
Decontamination area			
Change Room			
Material store room			
Remarks			
Done By (Sign/Date):			
Reviewed By: (Sign/Date):			

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**ANNEXURE-IV  
MICROBIOLOGY AREA – WEEKLY CLEANING RECORD**


Date of Cleaning		Disinfectant Name/ In-house Lot Number	
Cleaning Activity Start Time		Cleaning Activity End Time	
Area		Cleaning Status: Cleaning Done(√) / Cleaning Not Done(X)	
MLT Room			
Culture handling room			
Change Room			
Sterilization area			
Change room			
Media store room			
Media preparation room			
BET testing room			
Incubators room			
Microbiology documentation room			
Microbiology corridor			
Washing area			
Decontamination area			
Change Room			
Material Storage room			
Remarks			
Done by (sign & Date):			
Reviewed By(sign & Date):			

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**ANNEXURE-V  
DILUTE DISINFECTANT SOLUTION LABEL**

<b>DILUTE DISINFECTANT SOLUTION LABEL</b>	
Name of Disinfectant & Concentration	
Date of preparation & Time	
Use before date & Time	
Prepared by sign & date	
Checked by sign & date	

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**ANNEXURE-VI  
READY TO USE DISINFECTANT SOLUTION LABEL**

<b>READY TO USE DISINFECTANT SOLUTION LABEL</b>	
Name of the disinfectant	
Opened on date	
Use before date	
Opened by sign & date	

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