.

DISINFECTANT VALIDATION PROTOCOL & REPORT

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

DISINFECTANT VALIDATION PROTOCOL AND REPORT

1.0 DETAIL OF DISINFECTANT USE FOR VALIDATION:

NAME OF DISINFACTANT	COMPOSITION	BATCH. NO.	CONCENTRATION USE FOR VALIDATION
ISO-PROPYL ALCOHOL	Propan-2-ol	L143841501	70% V/V
DETTOL	i) Chloroxylenol I.P. 4.8 % W/V ii) Terpineol B.P. 9.0 % V/V iii) Alcohol Absolute (Denatured) 13.1 % V/V	D4739	2.5% V/V
SAVLON	i) Chlorhexidine Gluconate Solution I.P.1.5 % V/V ii) Strong Cetrimide Solution equivalent to Cetrimide 3.0 % W/V	KN4034	2.5% V/V
MICROLYSE	i) Benzalkonium Chloride Solution I.P. 4.0 % W/V	MLE14058	1.5% V/V
ACTALL	i) Chloroxylenol I.P 2.4 % W/V ii) Triclosan U.S.P. 0.5 % W/V iii)Terpineol B.P. 9 % W/V iv)Iso-Propyl Alcohol I.P. 12% V/V	AAL14004	2.5% V/V
SAVINOX	i) Chlorhexidine Gluconate Solution I.P.1.5% V/V ii) Cetrimide I.P. 3.0% W/V	SNP14007	3.0% V/V
ENDOMAX	i) Glutaraldehyde 2.45% W/V	EMX14029	2.5% V/V
SILVICIDE	i) Silver Nitrate I.P. 0.01% W/V ii) Hydrogen Peroxide I.P. 10% W/V	SCE5000	5.0% V/V
FORMALDEHYDE	i) Formaldehyde Solution (37-41% W/V)	P12F100982	40% V/V

DISINFECTANT VALIDATION PROTOCOL AND REPORT

2.0 PROTOCOL APPROVAL:

Particulars	Name	Signature	Date
Prepared By (Sr. Executive-QC)			
Checked By Head-QC			
Approved By Head-QA			

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DISINFECTANT VALIDATION PROTOCOL AND REPORT

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DISINFECTANT VALIDATION PROTOCOL AND REPORT

3.0 OBJECTIVE: To provide a procedure for disinfectant validation, for the surfaces and area sanitization of controlled and clean rooms.

4.0 SCOPE: This Protocol is applicable for disinfectant validation to establish the "Minimum effective concentration of disinfectant solution" and its effectiveness duration after application in controlled and clean areas at ……..

5.0 RESPONSIBILITIES:

DEPARTMENT	RESPONSIBILITIES
Quality Control	• Responsible for follow the procedure. • Responsible for preparation of validation protocol, summary report and supervise the microbiology officer during the disinfectant validation activity. • Responsible for review and technical correction of validation protocol.
Quality Assurance	• To Monitor all Validation Activities and ensuring the Validation as per the Protocol. • To monitor Protocol completeness and Technical Accuracy • To Review the Data & Approve the Validated Procedure, if found satisfactory.

DISINFECTANT VALIDATION PROTOCOL AND REPORT

6.0 REQUIREMENTS: Before proceeding for validation following material are required.

6.1 CULTURES:

6.1.1 *Staphylococcus aureus* ATCC 6538

6.1.2 *Pseudomonas aeruginosa* ATCC 9027

6.1.3 *Bacillus subtilis ATCC* 6633

6.1.4 *Escherichia coli* ATCC 8739

6.1.5 *Salmonella abony* NCTC 6017

6.1.6 *Shigella boydii* ATCC 8700

6.1.7 *Candida albicans* ATCC 10231

6.1.8 *Aspergillus brasiliensis* ATCC 16404

6.1.9 Environmental isolate

6.2 DISINFECTANT:

6.2.1 Disinfectant for validation as per given table above on page no. 2.

6.2.2 Disinfectant validation study shall be carried out on below mentioned surfaces

Table-1

Sr. No.	Surface Selection
1.0	Stainless steel
2.0	Plastic
3.0	Epoxy
4.0	Tiles
5.0	Glass
6.0	Aluminium
7.0	silicon

6.3 MEDIA AND OTHER REQUIREMENT:

6.3.1 Soyabean Casein Digest Agar (Hi- media MH290 or equivalent).

6.3.1.1 Preparation: Suspend 40 g in 1000 ml of purified water. Add 1 g per liter of polysorbate 80 into the media. Sterilize the culture media by autoclaving at 15 psi, 121.1°C for 15 minutes. After sterilization pH should be 7.3 ± 0.2 at 25°C.

6.3.2 Buffered Sodium Chloride Peptone Solution pH 7.0 (Hi- media MH1275 or equivalent) as Diluent.

6.3.2.1 Preparation: Suspend 14.64 g in 1000 ml of purified water. Add 1 g per liter of polysorbate 80 into the media. Sterilize the culture media by autoclaving at 15 psi, 121.1°C for 15 minutes. After sterilization pH should be 7.0 ± 0.2 at 25°C.

6.3.3 Vortex Mixture

6.3.4 Sterile membrane filters

6.3.5 Auto pipette and sterile tips

6.3.6 Sterilized Petri plates

6.3.7 Forceps

6.3.8 Vaccum pump

6.3.9 Test Tubes Sterile.

7.0 VALIDATION TEST PROCEDURE FOR ESTABLISHMENT OF MINIMUM EFFECTIVE CONCENTRATION OF DISINFECTANT:

7.1 DISINFECTANT VALIDATION USE DILUTION STUDY:

7.1.1 Culture concentration control

7.1.2 Inoculate 1 ml of culture suspension having more than 1,00,000 cfu in 10 ml of diluent.

7.1.3 Shake the tube gently and carry out serial dilutions in such a way to get less than 100 cfu count on a filter paper.

7.1.4 Filter the dilution (giving less than 100 cfu) through 0.45 µ membrane filter by applying Vaccum .Rinse twice the membrane filter with 100 ml diluent.

7.1.5 Aseptically transfer the membrane on the surface of sterile Soyabean casein Digest Agar with Tween 80.

7.1.6 For bacterial culture incubate the plate at 30-35°C for 3-5 days and fungal culture at 20-25°C for 5-7 days.

7.1.7 Count the actual number of inoculated cfu in the diluent as follow:

Actual No. of inoculated cfu = Observed cfu x Dilution factor.

7.2 MICROORGANISMS RECOVERY AFTER DISINFECTANT

7.2.1 Aseptically dispense required amount of disinfectant into sterile measuring cylinder (quantity to be dispensed based on the concentration and volume to be prepared) and make up the volume with sterile purified water to the required volume.

7.2.2 Distribute 10 ml of above prepared disinfectant into sterile test tubes and mark the tubes in such a way mentioned below:

I test tube - 0 minutes contact time.

II test tube - 5 minutes contact time.

III test tube - 10 minutes contact time.

7.2.3 Inoculate 1 ml of culture suspension having more than 10000 cfu in to I tube (0 minutes)

7.2.4 Immediately shake the tube gently and carry out serial dilution in such a way to get less than 100 cfu count on a filter paper.

7.2.5 Filter the dilution (giving less than 100 cfu) through 0.45 µ membrane filter by applying Vaccum .Rinse the filter paper twice with the 100 ml diluent.

7.2.6 Aseptically transfer the membrane on the surface of sterile Soyabean casein Digest Agar with Tween 80.

7.2.7 In II test tube (5 min contact time), inoculate 1 ml of cultures suspension having more than 10000 cfu and allow it to stand for 5 minutes with intermediate shaking.

7.2.8 After 5 min carry out serial dilution in such a way to get less than 100 cfu count on a filter paper.

7.2.9 Filter the dilution (giving less than 100 cfu) through 0.45 µ membrane filter by applying Vaccum .Rinse the filter paper twice with the 100 ml diluent.

7.2.10 Aseptically transfer the membrane on the surface of sterile Soyabean Casein Digest Agar with Tween 80.

7.2.11 Repeat the above procedure for 10 minutes

7.2.12 Repeat the above procedure for different culture suspension as required.

7.2.13 For bacterial cultures incubate the plates at 30-35° C for 3-5 days and fungal culture at 20-25 °C for 5-7 days.

7.2.14 Count the actual number of inoculated cfu in the diluent as above.

7.2.15 **Negative Control:** Carry out negative control by filtering the serial diluent through 0.45 µ membrane filter paper and incubate the plate at 30-35°C for 3-5 days.

7.3 DISINFECANT VALIDATION SURFACE STUDY

7.3.1 CULTURE CONCENTRATION CONTROL

7.3.1.1 Take 50 -100 cm^2 sterile surface area of above mentioned (Table-1) material surface under LAF and mark 25 cm^2 on it.

7.3.1.2 Aseptically inoculate evenly 1 ml (having more than 10000 cfu) with any one of the culture suspension inside the marked 25 cm^2 surface area of the material.

7.3.1.3 Under Laminar Air flow (LAF), dry the inoculated culture suspension material.

7.3.1.4 After completion of time period, inoculate the material in to sterile tube or beaker containing sterile diluent and aseptically wipe the surface of material with sterile swab gently to recover the organisms.

7.3.1.5 Shake the tube gently and carry out serial dilution in such a way to get less than 100 cfu count on a filter paper.

7.3.1.6 Filter the dilution (giving less than 100 cfu) through 0.45 µ membrane filter by applying Vaccum .Rinse the filter paper twice with the 100 ml diluent.

7.3.1.7 Aseptically transfer the membrane on the surface of sterile Soyabean casein Digest Agar with Tween 80.

7.3.1.8 For bacterial cultures incubate the plates at 30-35° C for 3-5 days and fungal culture at 20-25 °C for 5-7 days.

7.3.1.9 Count the actual number of inoculated cfu in the diluent as above.

7.4 MICROORGANISMS RECOVERY AFTER DISINFECTANT:

7.4.1 Take 50 -100 cm^2 sterile surface area of above mentioned (Table-1) material surface under LAF and mark 25 cm^2 on it.

7.4.2 If material is autoclavable, sterilize the above material in steam sterilizer.

7.4.3 After sterilization aseptically transfer sterilized materials to Laminar Air flow (LAF).

7.4.4 If material is not autoclavable, carryout disinfection with approved disinfectant and rinse with sterile purified water to remove disinfectant debris if any, before usage for validation studies.

7.4.5 Aseptically inoculate evenly 1 ml (having more than 10000 cfu) with any one of the culture suspension inside the marked 25 cm^2 surface area of the material.

7.4.6 Under Laminar Air flow (LAF), dry the inoculated culture suspension material.

7.4.7 After drying, apply disinfectant on the inoculated culture suspension and leave for time period which is already determined in dilution study for particular disinfectant.

7.4.8 After completion of time period, inoculate the material in to sterile tube or beaker containing sterile diluent and aseptically wipe the surface of material with sterile swab gently to recover the organisms.

7.4.9 Shake the tube gently and carry out serial dilution in such a way to get less than 100 cfu count on a filter paper.

7.4.10 Filter the dilution (giving less than 100 cfu) through 0.45 µ membrane filter by applying Vaccum .Rinse the filter paper twice with the 100 ml diluent.

7.4.11 Aseptically transfer the membrane on the surface of sterile Soyabean casein Digest Agar with Tween 80.

7.4.12 For bacterial cultures incubate the plates at 30-35° C for 3-5 days and fungal culture at 20-25 °C for 5-7 days.

7.4.13 Count the actual number of inoculated cfu in the diluent as above.

7.4.14 Repeat the above procedure for other remaining organisms and surfaces as mentioned in Table-1based on the requirement.

7.4.15 Negative Control

7.4.15.1 Take 50 -100 cm^2 sterile surface area of above mentioned (Table-1) material surface under LAF and mark 25 cm^2 on it.

7.4.15.2 Aseptically inoculate evenly 1 ml of sterile diluent inside the marked 25 cm^2 surface area of the material.

7.4.15.3 Under Laminar Air flow (LAF), dry the inoculated diluent on the surface of the material.

7.4.15.4 After drying, aseptically wipe the surface of material with sterile swab and transfer it into 10 ml diluent.

7.4.15.5 Filter the diluent through 0.45 µ membrane filter by applying Vaccum .Rinse the membrane filter twice with the 100 ml diluent.

7.4.15.6 Aseptically transfer the membrane on the surface of sterile Soyabean casein Digest Agar with Tween 80.

7.4.15.7 Incubate the plate at 30-35°C for 3-5 days.

7.4.15.8 Repeat the above procedure for other remaining surfaces as mentioned in Table- I based on the requirement.

7.4.15.9 Acceptance Criteria: No growth should observed after incubation.

7.5 LOG REDUCTION CALCULATION:

Log Reduction = (Log N0 (Actual Number of inoculated organisms) – Log N (Number of organisms recovered after disinfectant).

For example, if 12500 cfu of microorganisms are inoculated and recovered 05 cfu after disinfectant application, the calculation shall be = log (12500) – log (5)

= 4.09 – 0.69

= 3.94 log reduction

8.0 VALIDATION TEST PROCEDURE FOR ESTABLISHMENT OF EFFECTIVENESS DURATION OF DISINFECTANT SOLUTION AFTER APPLICATION IN CONTROLLED AND CLEAN AREA:

8.1 Use the environmental testing flexi plates (55 mm) to monitor the environmental microorganisms after the application of disinfectant solution from the surfaces of floor of granulation area, Capsule Filling room, Compression Room, Coating Room, Tablet Capsule inspection area, Solution preparation room, Blister packing room and main corridor in the manufacturing area and floor and doors of MLT Room in microbiology area.

8.2 Collect the sample from the above area after the application of disinfectant solution and then at different location in the same area at a time interval of 02 hours, 04 hours, 06 hours and 08 hours.

8.3 Incubate the plates at 30-35°C for pre incubation to ensure that they are sterile before the test is carried out.

8.4 On the day of monitoring, select the uncontaminated plates and mark the plates with location details.

8.5 Carefully open the plate and take the sample by pressing agar surface at specified location for a period of 5- 10 seconds for each plate.

8.6 Wipe the sampled area with 70 % filtered IPA solution immediately to remove the media traces from the sampled area.

8.7 Incubate all the plates after testing at 20-25°C for a minimum of 72 hours. Further incubate all the plates in inverted position for a period of 48 hours at 30-35°C.

8.8 ACCEPTANCE CRITERIA

8.8.1 VALIDATION TEST PROCEDURE FOR ESTABLISHMENT OF MINIMUM EFFECTIVE CONCENTRATION OF DISINFECTANT

8.8.1.1 Minimum three log reduction of microorganisms should be obtained after disinfectant application.

8.8.1.2 No growth should be observed in negative control.

8.8.2 VALIDATION TEST PROCEDURE FOR ESTABLISHMENT OF EFFECTIVENESS DURATION OF DISINFECTANT SOLUTION AFTER APPLICATION IN CONTROLLED AND CLEAN ROOM AREA

8.8.2.1 Total aerobic microbial count on the plate should not be more than 50 cfu/plate.

9.0 REFERENCES:

9.1 USP chapter <1072>

10.0 EVALUATION OF RESULTS

10.1 The decrease in the bacterial load to exposed disinfectant indicates that the disinfectant is capable of reducing the contaminant when used in the area.

11.0 CONCLUSION

11.1 A summary report shall be prepared that contain discussion and conclusion with clearly state the successful achievement of objective of validation studies.

12.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
Ltd.	:	Limited
cfu	:	Colony Forming Unit
DV	:	Disinfectant Validation
W/V	:	Weight/ Volume
V/V	:	Volume/volume
QCD	:	Quality Control Department
LAF	:	Laminar Air Flow
IPA	:	Isopropyl alcohol
°C	:	Degree Centigrade
%	:	Percentage

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ANALYTICAL WORKSHEET FOR VALIDATION OF DISINFECTANT SOLUTIONS – DILUTION METHOD

ANNEXURE I

Name of the Disinfectant		Active Ingredient	
Disinfectant Manufacturer		Batch No./ Lot No. of Disinfectant	
Disinfectant Concentration Used		Membrane filter Lot No.	
Media Used		Media Lot No.	
Diluent Used		Media Lot No.	
Incubator ID (32.5 ±2.5°C)		Incubation Period	
Incubator ID (22.5 ±2.5°C)		Incubation Period	
Date of Test		Date of Report	

OBSERVATION TABLE:

1. **CULTURE CONCENTRATION CONTROL (DILUENT + MICROBIAL CULTURE)**

Sr. No	Name of Organisms	Stock Culture Concentration	Stock culture concentration dilution times	Organism Recovery After Incubation			Actual No. of Inoculated Cfu (Average cfu x Dilution Factor)
				Plate 1	Plate 2	Average	

ANALYTICAL WORKSHEET FOR VALIDATION OF DISINFECTANT SOLUTIONS – DILUTION METHOD

2.0 TEST OBSERVATION
MICROORGANISMS RECOVERY AFTER DISINFECTANT (DILUENT + DISINFECTANT + MICROBIAL CULTURE)

Sr. No	Name of Organisms	Stock Culture Concentration	Contact Time	Organism Recovery After Incubation (1:10)			Organism Recovery After Incubation (1:100)			Organism Recovery After Incubation (1:1000)			Actual No. of Inoculated Cfu (Average cfu x Dilution Factor)
				Plate 1	Plate 2	Average	Plate 1	Plate 2	Average	Plate 1	Plate 2	Average	
			0 min										
			5 min										
			10 min										
			0 min										
			5 min										
			10 min										
			0 min										
			5 min										
			10 min										
			0 min										
			5 min										
			10 min										
			0 min										
			5 min										
			10 min										

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Sr. No	Name of Organisms	Stock Culture Concentration	Contact Time	Organism Recovery After Incubation (1:10)			Organism Recovery After Incubation (1:100)			Organism Recovery After Incubation (1:1000)			Actual No. of Inoculated Cfu (Average cfu x Dilution Factor)
				Plate 1	Plate 2	Average	Plate 1	Plate 2	Average	Plate 1	Plate 2	Average	
			0 min										
			5 min										
			10 min										
			0 min										
			5 min										
			10 min										
			0 min										
			5 min										
			10 min										
			0 min										
			5 min										
			10 min										

3.0 NEGATIVE CONTROL (DILUENT)

OBSERVATION:_____

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4. CALCULATION FOR LOG REDUCTION:

Sr. No	Name of Organism	Contact Time	Actual No. of Inoculated Cfu (Average cfu x Dilution Factor) (N0)	No. of cfu Recovered After Disinfectant (Average cfu x Dilution Factor) (N)	Log Reduction = Log N0 – Log N
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			

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S. No	Name of Organisms	Contact Time	Actual No. of Inoculated Cfu (Average cfu x Dilution Factor) (N0)	No. of cfu Recovered After Disinfectant (Average cfu x Dilution Factor) (N)	Log Reduction = Log N0 – Log N
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			

	ANALYSED BY	CHECKED BY	APPROVED BY
Name:			
Designation:			
Signature :			
Date:			

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ANALYTICAL WORKSHEET FOR VALIDATION OF DISINFECTANT SOLUTIONS – SURFACE METHOD

ANNEXURE II

Name of the Disinfectant		Active Ingredient	
Disinfectant Manufacturer		Batch No./ Lot No. of Disinfectant	
Disinfectant Concentration Used		Membrane filter Lot No.	
Media Used		Media Lot No.	
Diluent Used		Media Lot No.	
Incubator ID (32.5 ±2.5°C)		Incubation Period	
Incubator ID (22.5 ±2.5°C)		Incubation Period	
Date of Test		Date of Report	
Surface Used			

OBSERVATION TABLE:

1. **CULTURE CONCENTRATION CONTROL (DILUENT + MICROBIAL CULTURE)**

Sr. No	Name of Organisms	Stock Culture Concentration	Stock culture concentration dilution times	Organism Recovery After Incubation			Actual No. of Inoculated Cfu (Average cfu x Dilution Factor)
				Plate 1	Plate 2	Average	

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2. TEST OBSERVATION

MICROORGANISMS RECOVERY AFTER DISINFECTANT (DILUENT + DISINFECTANT + MICROBIAL CULTURE)

S. No	Name of Organisms	Stock Culture Concentration	Contact Time	Organism Recovery After Incubation (1:10)			Organism Recovery After Incubation (1:100)			Organism Recovery After Incubation (1:1000)			Actual No. of Inoculated Cfu (Average cfu x Dilution Factor)
				Plate 1	Plate 2	Avg.	Plate 1	Plate 2	Avg.	Plate 1	Plate 2	Avg.	
1			0 min										
			5 min										
			10 min										
2			0 min										
			5 min										
			10 min										
3			0 min										
			5 min										
			10 min										
4			0 min										
			5 min										
			10 min										
5			0 min										
			5 min										
			10 min										

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Sr. No	Name of Organisms	Stock Culture Concentration	Contact Time	Organism Recovery After Incubation (1:10)			Organism Recovery After Incubation (1:100)			Organism Recovery After Incubation (1:1000)			Actual No. of Inoculated Cfu (Average cfu x Dilution Factor)
				Plate 1	Plate 2	Avg.	Plate 1	Plate 2	Avg.	Plate 1	Plate 2	Avg.	
6			0 min										
			5 min										
			10 min										
7			0 min										
			5 min										
			10 min										
8			0 min										
			5 min										
			10 min										
9			0 min										
			5 min										
			10 min										

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3. NEGATIVE CONTROL (DILUENT)

OBSERVATION:

S.No.	Surface Details	Observation

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ANALYTICAL WORKSHEET FOR VALIDATION OF DISINFECTANT SOLUTIONS – SURFACE METHOD

4.0 CALCULATION FOR LOG REDUCTION

Sr. No	Name of Organism	Contact Time	Actual No. of Inoculated Cfu (Average cfu x Dilution Factor) (N0)	No. of cfu Recovered After Disinfectant (Average cfu x Dilution Factor) (N)	Log Reduction = Log N0 – Log N
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			

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Sr. No	Name of Organism	Contact Time	Actual No. of Inoculated Cfu (Average cfu x Dilution Factor) (N0)	No. of cfu Recovered After Disinfectant (Average cfu x Dilution Factor) (N)	Log Reduction = Log N0 – Log N
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			
		0 min			
		5 min			
		10 min			

	ANALYSED BY	CHECKED BY	APPROVED BY
Name:			
Designation:			
Signature :			
Date:			

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ANALYTICAL WORKSHEET FOR DISINFECTANT VALIDATION

ANNEXURE III

Name of the Disinfectant			
Active Ingredient			
Batch No./ Lot No. of Disinfectant		Disinfectant Concentration Used	
Name of Area		Sampled By	
Date of Sampling		Time of Sampling	
Name of Media	Soyabean Casein digest Agar	Media Lot No	
Incubation Temperature	22.5 ± 2.5°C	Incubation Period	
Incubation Temperature	32.5 ± 2.5°C	Incubation Period	
Incubator ID (22.5 ± 2.5°C)		Incubator ID (32.5 ± 2.5°C)	
Date of Report			

Sr. No	Name of Location	Sampled Area	Total Aerobic Microbial Count (cfu/plate)

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S.No	Name of Location	Sampled Area	Total Aerobic Microbial Count (cfu/plate)
	Negative Control		
Total Aerobic Microbial Count Limit			
TAMC Limit NMT 50 cfu/Plate			

Remark:_____

	ANALYSED BY	CHECKED BY	APPROVED BY
Name:			
Designation:			
Signature :			
Date:			