PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Environmental Monitoring of Microbiology Laboratory

SOP No.:		**Department:**	Microbiology	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 26	

1.0 OBJECTIVE

To lay down procedure for environmental monitoring of microbiology laboratory.

2.0 SCOPE

This SOP is applicable for environmental monitoring of 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 Viable Monitoring

4.1.1 Passive air sampling (Settle plate exposure technique)

4.1.1.1 Prepare and qualify Soyabean casein digest agar / Potato dextrose agar media plates of 90 mm dia as per SOP .

4.1.1.2 Alternatively ready to use agar media plates can be use for monitoring.

4.1.1.3 Perform the growth promotion test of ready to use plates as per SOP.

4.1.1.4 Transfer the media plates to sampling area in a closed container to avoid any contamination.

4.1.1.5 Label the plates with the details given below -

Monitoring type / Plate No. / Media Load No. / Sampling Date / Sign

4.1.1.6 Frequency, exposure time and recommended limits of passive air sampling (Settle plate exposure technique) are given in table - I.

Table - I

Grade	Recommended Limits ** (cfu / 4 hours)	Media Used / Frequency of Exposure	Time of Exposure
A	1	SCDA / Daily PDA / Once in a week SCDA (Anaerobic monitoring)/ Monthly	4 hours
B	3		
C	5		
D	50	SCDA / Once in a week PDA / Monthly SCDA (Anaerobic monitoring)/ Monthly	

** **In-house Limits:** To be revised after 6 months trend data.

4.1.1.7 Remove the plates from the container and place the media plates on the petri plate stand, provided at each of the designated locations.

4.1.1.8 Expose the plates for a period of 4 hours.

4.1.1.9 After completion of exposure time, cover the lid of each plate and transfer to micro lab for incubation.

4.1.1.10 Incubate the Soyabean casein digest agar plates along with one unexposed plate (Negative control) of the same media load or of the same batch/lot, if using ready to use plate, at 30°C-35°C for 2 days for aerobic bacterial counts followed by 20°C-25°C for 3 days for fungal, Yeast and molds counts in the inverted position.

4.1.1.11 Incubate the potato dextrose agar plates along with one unexposed plate (Negative control) of the same media load or of the same batch/lot, if using ready to use plate 20°C-25°C for 5 days for fungal, yeast and molds counts in the inverted position.

4.1.1.12 For anaerobic environmental monitoring incubate the Soyabean casein digest agar plates along with one unexposed plate (Negative control) of the same media load or of the same batch/lot, if using ready to use plate, at 30°C-35°C for 3 days for anaerobic bacterial counts in the inverted position under anaerobic condition.

4.1.1.13 After completion of incubation period count the number of colonies per plate and record the observations as cfu/4 hrs.

4.1.1.14 Negative control (Unexposed Plate) should not show any growth.

4.1.1.15 Record the results in Annexure - I and V.

4.1.2 Active air sampling (Volumetric Air Sampling)

4.1.2.1 Operate the volumetric air sampler for active air sampling.

4.1.2.2 Ready to use Soyabean casein digest agar plates / cassettes are to be used for sampling.

4.1.2.3 Perform the growth promotion test of ready to use plates / cassettes as per SOP.

4.1.2.4 Transfer the media plates / cassettes to sampling area in a closed container to avoid any contamination.

4.1.2.5 Label the plates / cassettes with the details given below -

Monitoring type / Plate/cassette No. / Media Load No. / Sampling Date / Sign

4.1.2.6 Remove the plates / cassettes from the container and carry out the air sampling at the designated locations.

4.1.2.7 Operate the volumetric air sampler as per SOP and sample 1000 lit or one mt^3 air per location.

4.1.2.8 After completion of sampling cover the lid of each plates / cassettes and transfer to micro lab for incubation.

4.1.2.9 Incubate the Soyabean casein digest agar plates / cassettes along with one unexposed plate (Negative control) of the same media load or of the same batch/lot, if using ready to use plates / cassettes, at 30°C-35°C for 2 days for aerobic bacterial counts followed by 20°C-25°C for 3 days for fungal, yeast and molds counts in the inverted position.

4.1.2.10 After completion of incubation period count the number of colonies observed per plate and calculate the cfu/m^3.

4.1.2.11 Negative control (Unexposed Plate) should not show any growth.

4.1.2.12 Record the results in Annexure – II and VI.

4.1.2.13 Frequency, volume of air sampled and recommended limits of active air sampling (Volumetric air sampling) are given in table - II.

Table - II

Grade	Recommended Limits ** (cfu / m^3)	Media Used / Frequency of Air Sampling	Volume of air Sampled (In liter)
A	1	SCDA / Daily	1000
B	7		
C	10		
D	100	SCDA / Weekly	

** **In-house Limits:** To be revised after 6 months trend data.

4.1.3 Personal Monitoring

4.1.3.1 Prepare and qualify the RODAC plates by pouring sufficient Soyabean casein digest agar media as per SOP.

4.1.3.2 Pour the plates in such a way that the surface of the medium is slightly raised in comparison to the edge of the plate.

4.1.3.3 Alternatively ready to use agar media plates (RODAC Plates) can be use for monitoring.

4.1.3.4 Perform the growth promotion test of ready to use plates (RODAC Plates) as per SOP.

4.1.3.5 Transfer the RODAC plates to sampling area in a closed container to avoid any contamination.

4.1.3.6 Label the RODAC plates with the details given below -

Monitoring type / Plate No. / Media Load No. / Sampling Date / Sign

4.1.3.7 Remove the RODAC plates from the container open the lid of plate and gently contact (touch) the plate over the location to be monitored.

4.1.3.8 Perform the personnel monitoring at specified area as given in Annexure - VIII.

4.1.3.9 After monitoring replace the lid of the RODAC plate and transfer to micro lab for incubation.

4.1.3.10 After monitoring decontaminate the sampled area with the help of a sterile cloth soaked in sterile 70% IPA.

4.1.3.11 Incubate the Soyabean casein digest agar RODAC plates along with one unexposed plate (Negative control) of the same media load or of the same batch/lot, if using ready to use plate, at 30°C-35°C for 2 days for aerobic bacterial counts followed by 20°C-25°C for 3 days for fungal, yeast and molds counts in the inverted position.

4.1.3.12 After completion of incubation period count the number of colonies per plate and record the observations as cfu/plate.

4.1.3.13 Negative control (Unexposed Plate) should not show any growth.

4.1.3.14 Record the results in Annexure - IV.

4.1.3.15 Frequency and recommended limits of personal monitoring are given in table - III.

Table - III

Personal Monitoring	Recommended Limits ** (cfu / contact plate)	Media Used / Frequency of Personal Monitoring
Garment	5	SCDA / After every operation
Gloves	3	SCDA / After every operation

** **In-house Limits:** To be revised after 6 months trend data.

4.1.4 Surface Monitoring (RODAC Plate Technique)

4.1.4.1 Prepare and qualify the RODAC plates by pouring sufficient Soyabean casein digest agar media as per SOP.

4.1.4.2 Pour the plates in such a way that the surface of the medium is slightly raised in comparison to the edge of the plate.

4.1.4.3 Alternatively ready to use agar media plates (RODAC Plates) can be use for monitoring.

4.1.4.4 Perform the growth promotion test of ready to use plates (RODAC Plates) as per SOP.

4.1.4.5 Transfer the RODAC plates to sampling area in a closed container to avoid any contamination.

4.1.4.6 Label the RODAC plates with the details given below -

Monitoring type / Plate No. / Media Load No. / Sampling Date / Sign

4.1.4.7 Remove the RODAC plates from the container open the lid of plate and gently contact (touch) the plate over the location to be monitored.

4.1.4.8 Perform the surface monitoring at specified areas.

4.1.4.9 After monitoring replace the lid of the RODAC plate and transfer to micro lab for incubation.

4.1.4.10 After monitoring decontaminate the sampled area with the help of a sterile cloth soaked in sterile 70% IPA.

4.1.4.11 Incubate the Soyabean casein digest agar RODAC plates along with one unexposed plate (Negative control) of the same media load or of the same batch/lot, if using ready to use plate, at 30°C-35°C for 2 days for aerobic bacterial counts followed by 20°C-25°C for 3 days for fungal, yeast and molds counts in the inverted position.

4.1.4.12 After completion of incubation period count the number of colonies per contact plate and record the observations as cfu/plate.

4.1.4.13 Negative control (Unexposed Plate) should not show any growth.

4.1.4.14 Record the results in Annexure - III and VII.

4.1.4.15 Frequency and recommended limits of surface monitoring are given in table - IV.

Table - IV

Grade	Location	Recommended Limits ** (cfu / 24 - 30cm^2)	Media Used / Frequency of surface monitoring
A	Wall	1	SCDA / Daily
	Floor	1	
B	Wall	3	
	Floor	3	
C	Wall	5	
	Floor	10	
D	Wall	50	SCDA / Weekly
	Floor	50	

** **In-house Limits:** To be revised after 6 months trend data.

4.1.5 Surface Monitoring (Swab Testing Technique)

4.1.5.1 Carry out the surface monitoring by using swab testing in case where surface monitoring is not possible by using RODAC plate technique.

4.1.5.2 Prepare the swabs as per SOP.

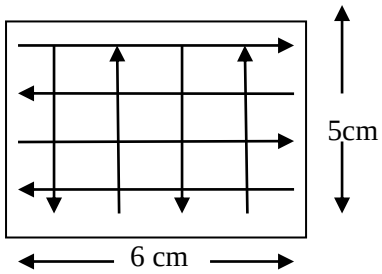
4.1.5.3 Transfer the swabs to sampling area in a closed container to avoid any contamination.

4.1.5.4 Remove the swab stick from the tube and move the head of the swab slowly over the area to be sampled.

4.1.5.5 Rub the swab slowly and thoroughly back and forth over the desired surface of 30 cm^2. Repeat this procedure by flipping of the swab over the same surface area in 90° from the earlier swabbing direction.

4.1.5.6 Rotate the swab throughout the procedure.

4.1.5.7 Cover an area of approximately 24 - 30 cm sq.



4.1.5.8 Using the same swab, go back over the same area using strokes perpendicular to the first.

4.1.5.9 After monitoring decontaminate the sampled area with the help of a sterile cloth soaked in sterile 70% IPA.

4.1.5.10 Aseptically transfer the swab back into tube, plug the tubes and bring to micro lab for plating.

4.1.5.11 Add 10 ml of sterile 0.1% Peptone water into each tube containing the swab.

4.1.5.12 Gently vortex the tubes and transfer the solution to a sterile filtration funnel fitted with a membrane of nominal pore size of 0.45 µm.

4.1.5.13 Twice rinse the swab with 10 ml 0.1% Peptone water, each time gently vortexing the tube and filter the rinsate through the same membrane.

4.1.5.14 After filtration, place the membrane on the pre poured plate of Soyabean casein digest agar media.

4.1.5.15 Prepare Soyabean casein digest agar media plate as per SOP.

4.1.5.16 Incubate the Soyabean casein digest agar plate at 30°C-35°C for 2 days for aerobic bacterial counts followed by 20°C-25°C for 3 days for fungal, yeast and molds counts in the inverted position.

4.1.5.17 Incubate a negative control that has been treated in a similar way as test, without sampling the surface.

4.1.5.18 After completion of incubation period count the number of colonies per plate and record the observations as cfu/24 - 30cm^2.

4.1.5.19 Negative control (without sample) should not show any growth.

4.1.5.20 Record the results in Annexure - III and VII.

4.1.5.21 Surface monitoring is to be carried out on rotational basis (weekly) by using RODAC Plate method and swab testing method alternatively.

4.2 Non Viable Monitoring (Particle Count)

4.2.1 Use air borne particle counter for monitoring of non-viable particle count in the microbiology laboratory.

4.2.2 Sample the locations under laminar airflow unit and in the room at working height.

4.2.3 In grade A & B area minimum volume of 1 m^3 to be sampled, and in grade C & D area minimum volume of 1 CFM is to be sampled.

4.2.4 Operate the air born particle counter as per SOP and after completion of sampling attach the print out generated by particle counter.

4.2.5 Record the results in Annexure - IX.

4.2.6 Frequency and recommended limits Non Viable Monitoring are given in table - V.

Table - V

Grade	Frequency of Non Viable Monitoring	Maximum permitted number of Particle / m3 equal to above			
		At Rest (Static)		In Operation (Dynamic)	
		0.5 µm	5.0 µm	0.5 µm	5.0 µm
A	Every six month	3500	1	3500	1
B	Every six month	3500	1	350000	2000
C	Every six month	350000	2000	3500000	20000
D	Every six month	3500000	20000	Not determine	Not determine

4.3 Physical monitoring (Monitoring of Temperature and Relative Humidity)

4.3.1 Temperature and relative humidity monitoring is to be carried out daily morning and in the evening.

4.3.2 Incase of media storage room only temperature is to be monitored.

4.3.3 Record the monitoring observation results in Annexure - X.

4.3.4 Frequency and acceptance criteria for monitoring of temperature and relative humidity are given in table - VI.

Table - VI

Physical Parameter	Frequency of Monitoring	Acceptance Criteria
Temperature (^{0}C)	Daily Twice (Morning / Evening)	23 ± 2^{0}C
Relative Humidity (%)	Daily Twice (Morning / Evening)	Not more than 55 %
Media Storage Room Temperature (^{0}C)	Daily Twice (Morning / Evening)	Not more than 25^{0}C

4.4 Trends of results

4.4.1 Identify the colonies present on the plate based on colony characteristics.

4.4.2 If any new colonies other then routine micro flora observed, Isolate and identify the organism as per SOP.

4.4.3 Establish the micro flora information data as per SOP.

4.4.4 Monthly prepare the trends of monitoring results in the form of graph and chart.

4.4.5 Annually prepare a review report on environmental monitoring based on the available trends data.

5.0 SAFETY & PRECAUTIONS

5.1 Follow the entry, exit procedure of respective areas to enter in areas.

5.2 Use proper apparel such as shoe-covers, nose mask, and sterile garments before entering in production areas in order to avoid microbial contamination.

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
S.S.	:	Stainless Steel
IPA	:	Iso Propyl alcohol
CFU	:	Colony Forming Unit
No.	:	Number
LAF	:	Laminar Air Flow
mm	:	Millimeter
µ	:	Micron
mL	:	Milliliter
%	:	Percentage
cm	:	Centimetre
°C	:	Degree Centigrade

9.0 ANNEXURES

Annexure - I	**:**	Passive air sampling by settle plate exposure in grade A, B & C areas
Annexure - II	**:**	Active air sampling report in grade A, B & C areas
Annexure - III	**:**	Surface monitoring report in grade A, B & C areas
Annexure - IV	**:**	Personal monitoring report
Annexure - V	**:**	Passive air sampling by settle plate exposure in grade D area
Annexure - VI	**:**	Active air sampling report in grade D area
Annexure - VII	**:**	Surface monitoring report in grade D area
Annexure - VIII	**:**	Locations of personal monitoring
Annexure - IX	**:**	Non - viable monitoring report (Particle count)
Annexure - X	**:**	Physical Monitoring (Temperature & Relative Humidity)

ANNEXURE - I

PASSIVE AIR SAMPLING BY SETTLE PLATE EXPOSURE IN GRADE A, B & C AREA OF MICROBIOLOGY LABORATORY

Date of monitoring: _____ **Report date:** _____

Media used: _____ **Sterilized medium lot no.:** _____

Time of exposure: _____**Exposure done by:** _____

Incubation temperature: 2 days30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

S. No.	Name of the Room	Plate No.	Name of the Location	Grade	Limit (cfu/plate /4 hrs)	Observation (cfu/plate /4 hrs)
1.	Media Preparation room		Inside dynamic pass box	A	1	
2.	Change room - 2		Near return air riser	C	5	
			Near return air riser			
			Inside garment cubicle	A	1	
3.	Change room - 3		Near return riser	B	3	
			Center of the room			
4.	Sterile corridor		Near return air riser	B	3	
			Near return air riser			
			Near return air riser			
			Inside dynamic pass box of MLT	A	1	
			Inside pass box of Incubator room			

Sr. No.	Name of the Room	Plate No.	Name of the Location	Grade	Limit (cfu/plate /4 hrs)	Observation (cfu/plate /4 hrs)
5.	Cooling zone		Near return air riser	B	3	
			Near return air riser			
			Near return air riser			
			Inside static pass box of sterility testing room			
			Under vertical LAF in front of autoclave	A	1	
			Under vertical LAF in front of DHS			
6.	Sterility testing room		Near return air riser	B	3	
			Near return air riser			
			Near return air riser			
			Near return air riser			
			Inside LAF	A	1	
7.	Change room - 4		Near return air riser	C	5	
			Center of the room			
8.	LAL Room		Inside LAF	A	1	
9.	MLT Room		Inside LAF	A	1	
			Inside dynamic pass box of Incubator room			
10.	Negative control		NA	NA	Nil	

NA: Not Applicable

Remarks: The area complies / does not comply with the laid down limits.

Observation Done By: **Checked By:**

Date: **Date:**

ANNEXURE - II
ACTIVE AIR SAMPLING REPORT IN GRADE A, B & C AREA OF MICROBIOLOGY LABORATORY

Date of monitoring: _____ **Report date:** _____

Media used: _____ **Sterilized medium lot no.:** _____

Time of exposure: _____**Done by:** _____

Incubation temperature: 2 days 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for Fungal count.

S.No.	Name of the Room	Plate No.	Name of the Location	Grade	Limit (cfu/m^3)	Observation (cfu/m^3)
1.	Media preparation room		Inside dynamic pass box	A	1	
2.	Change room - 2		Center of change room	C	10	
			Inside garment cubicle	A	1	
3.	Change room - 3		Center of change room	B	7	
4.	Sterile corridor		Near door of sterility testing room	B	7	
			Near door of change room - 3			
			Inside dynamic pass box of Incubator room	A	1	
			Inside dynamic pass box of MLT room			
5.	Cooling zone		Center of the room	B	7	
			Under vertical LAF in front of autoclave	A	1	
			Under vertical LAF in front of DHS			
6.	Sterility testing room		Under LAF	A	1	
			Center of the room	B	7	
7.	Change room - 4		Center of change room	C	10	
8	LAL Room		Under LAF	A	1	
9.	MLT Room		Under LAF	A	1	
			Inside dynamic pass box of Incubator room			
10.	Negative control		NA	NA	Nil	

NA: Not Applicable

Remarks: The area complies / does not comply with the laid down limits.

Observation Done By: **Checked By:**

Date: **Date:**

ANNEXURE - III

SURFACE MONITORING REPORT IN GRADE A, B & C AREA OF MICROBIOLOGY LABORATORY

Date of monitoring: _____ Report date: _____

Media used: _____Sterilized medium lot no.: _____

Membrane Filter Lot No.: _____ Monitoring done by: _____

Method: CONTACT PLATE / SWAB

Incubation temperature: 2 days 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

Sr. No.	Name of the Room	Plate No.	Name of the Location	Grade	Limit (cfu/Contact plate / 24 -30cm^3)	Observation (cfu/Contact plate / 24-30cm^3)
1.	Media preparation room		Inside dynamic pass box	A	1	
2.	Change room - 2		Surface of wall / floor / door	C	5 / 10 / 5	
			Inside garment cubicle	A	1	
3.	Change room - 3		Surface of wall / floor / door	B	3	
4.	Sterile corridor		Surface of wall / floor / door	B	3	
			Inside dynamic pass box (MLT Rom)	A	1	
			Inside dynamic pass box (Incubator room -I)			

Sr. No.	Name of the Room	Plate No.	Name of the Location	Grade	Limit (cfu/Contact plate / 24 -30cm^3)	Observation (cfu/Contact plate / 24-30cm^3)
5.	Cooling zone		Surface of wall / floor / door	B	3	
			Outer surface of Autoclave			
			Outer surface of DHS			
			Inside dynamic pass box (Media preparation room)	A	1	
6.	Sterility testing room		Surface of wall / floor / door	B	3	
			Surface of LAF bench	A	1	
			Inside static pass box	B	3	
7.	Change room - 4		Surface of wall / floor / door	C	5 / 10 / 5	
8.	LAL room		Surface of LAF bench	A	1	
9.	MLT room		Surface of LAF bench	A	1	
10.	Negative Control	SM10.1	NA	NA	Mil	

NA: Not Applicable

Remarks: The area complies / does not comply with the laid down limits.

Observation Done By:
Date:

Checked By:
Date:

ANNEXURE - IV

PERSONAL MONITORING REPORT OF MICROBIOLOGY LABORATORY

Date of monitoring: _____ Report date: _____

Media used: _____Sterilized medium lot no.: _____

Monitoring done by: _____

Incubation temperature: 2 days 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

Sr. No.	Name of the Person	Plate No.	Name of the Sampling Location	Limit (cfu/Contact plate)	Observation (cfu/Contact plate)
1.			Forhead	5	
			Chest		
			Right hand gloves	3	
			Left hand gloves		
			Right arm pit	5	
			Left arm pit		
			Left inner Fore hand		
			Right inner Fore hand		
2.			For head	5	
			Chest		
			Right hand gloves	3	
			Left hand gloves		
			Right arm pit	5	
			Left arm pit		
			Left inner Fore hand		
			Right inner Fore hand		

Sr. No.	Name of the Person	Plate No.	Name of the Sampling Location	Limit (cfu/Contact plate)	Observation (cfu/Contact plate)
3.			For head	5	
			Chest		
			Right hand gloves	3	
			Left hand gloves		
			Right arm pit	5	
			Left arm pit		
			Left inner Fore hand		
			Right inner Fore hand		
4.			For head	5	
			Chest		
			Right hand gloves	3	
			Left hand gloves		
			Right arm pit	5	
			Left arm pit		
			Left inner Fore hand		
			Right inner Fore hand		
5	Negative Control		NA	Nil	

NA: Not Applicable

Remarks: The area complies / does not comply with the laid down limits.

Observation Done By: **Checked By:**

Date: **Date:**

ANNEXURE - V

PASSIVE AIR SAMPLING BY SETTLE PLATE EXPOSURE IN GRADE D AREA OF MICROBIOLOGY LABORATORY

Date of monitoring: _____ **Report date:** _____

Media used: _____ **Sterilized medium lot no.:** _____

Time of exposure: _____**Exposure done by:** _____

Incubation temperature: 2 days 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

Sr. No.	Name of the Room	Plate No.	Name of the Location	Limit (cfu/plate /4 hrs)	Observation (cfu/plate/4 hrs)
1.	A/L for media preparation room		Near riser	50	
			Center of the room		
2.	Media preparation room		Near riser - 1	50	
			Near riser - 2		
			Center of the room		
3.	Change room - 1		Near riser	50	
			Center of the room		
4.	A/L for MLT / LAL room		Near return riser	50	
			Center of the room		
5.	LAL room		Center of the room	50	
			Above LAF		

Sr. No.	Name of the Room	Plate No.	Name of the Location	Limit (cfu/plate /4 hrs)	Observation (cfu/plate/4 hrs)
6.	MLT Room		Near riser - 1	50	
			Near riser - 2		
7.	A/L for incubator room		Center of the room	50	
8.	Incubator room - I		Between Pass box of sterile corridor & MLT room	50	
			Near door		
9.	Incubator room - II		Center of the room	50	
			Near door		
			Near View Panel		
10.	Negative control		NA	Nil	

NA: Not Applicable

Remarks: The area complies / does not comply with the laid down limits.

Observation Done By:
Date:

Checked By:
Date:

ANNEXURE - VI

ACTIVEE AIR SAMPLING REPORT IN GRADE D AREA OF MICROBIOLOGY LABORATORY

Date of monitoring: _____ **Report date:** _____

Media used: _____ **Sterilized medium lot no.:** _____

Time of exposure: _____**Done by:** _____

Incubation temperature: 2 days 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

Sr. No.	Name of the Room	Plate No.	Name of the Location	Limit (cfu/m^3)	Observation (cfu/m^3)
1.	A/L for media preparation room		Center of the air lock	100	
2.	Media preparation room		Center of change room	100	
3.	Change room - 1		Center of change room	100	
4.	A/L for MLT / LAL room		Center of the air lock	100	
5.	LAL room		Center of the room	100	
6.	MLT Room		Center of the room	100	
7.	A/L for incubator room		Center of the air lock	100	
8.	Incubator room - I		Center of the room	100	
9.	Incubator room - II		Center of the room	100	
10.	Negative control		NA	Nil	

NA: Not Applicable

Remarks: The area complies / does not comply with the laid down limits.

Observation Done By: **Checked By:**

Date: **Date:**

ANNEXURE - VII

SURFACE MONITORING REPORT IN GRADE D AREA OF MICROBIOLOGY LABORATORY

Date of monitoring: _____ Report date: _____

Media used: _____Sterilized medium lot no.: _____

Membrane Filter Lot No.: _____ Monitoring done by: _____

Method: CONTACT PLATE / SWAB

Incubation temperature: 2 days 30°C- 35°C for bacterial count followed by 3 days at 20°C- 25°C for fungal count.

Sr. No.	Name of the Room	Plate No.	Name of the Location	Limit (cfu/Contact plate / 24 -30cm^3)	Observation (cfu/Contact plate / 24-30cm^3)
1.	A/L for media preparation room		Surface of wall / floor	50	
2.	Media preparation room		Surface of wall / floor	50	
			Surface of Autoclave		
			Surface of DHS		
3.	Change room - 1		Surface of wall / Floor / door	50	
4.	A/L for MLT / LAL room		Surface of wall / floor	50	
5.	LAL room		Surface of wall / floor	50	
6.	MLT Room		Surface of wall / floor	50	

Sr. No.	Name of the Room	Plate No.	Name of the Location	Limit (cfu/Contact plate / 24 -30cm^3)	Observation (cfu/Contact plate / 24-30cm^3)
7.	A/L for incubator room		Surface of wall / floor	50	
8.	Incubator room - I		Surface of wall / floor	50	
			Surface of Incubator		
9.	Incubator room - II		Surface of wall / floor	50	
			Surface of Incubator		
10.	Negative control		NA	Nil	

NA: Not Applicable

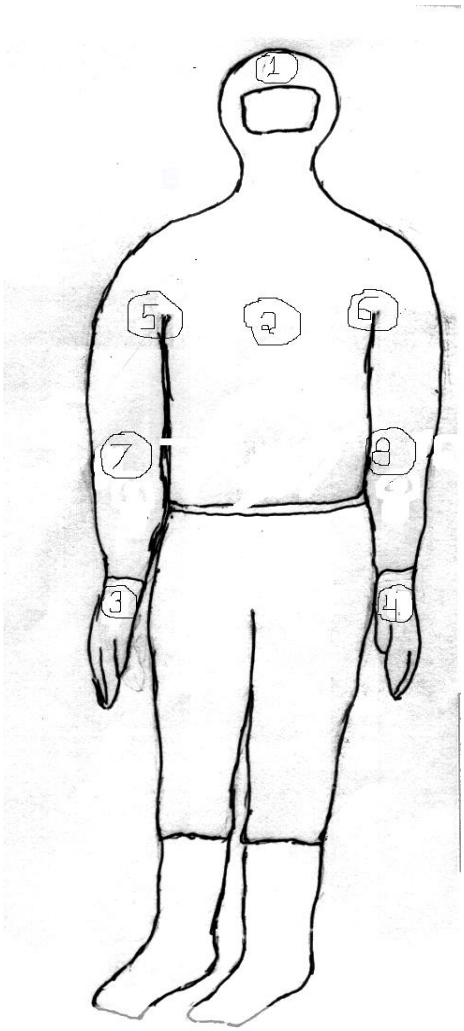
Remarks: The area complies / does not comply with the laid down limits.

Observation Done By:
Date:

Checked By:
Date:

ANNEXURE - VIII

LOCATIONS OF PERSONAL MONITORING



Sampling Location	No.
For head	1
Chest	2
Right hand gloves	3
Left hand gloves	4
Right arm pit	5
Left arm pit	6
Right inner for hand	7
Left inner for hand	8

ANNEXURE - IX

NON - VIABLE MONITORING REPORT OF MICROBIOLOGY LABORATORY

Date of monitoring: _____Particle Counter ID No.: _____

Monitoring done by: _____Monitoring performed in: Static / Dynamic condition

Sr. No.	Name of the Room	Location No.	Grade	Maximum permitted number of Particle / m3 equal to above				Observation	
				At rest		In operation		0.5 µm	5.0 µm
				0.5 µm	5.0 µm	0.5 µm	5.0 µm		
1.	A/L for media preparation room		D	3500000	20000	Not determine			
2.	Media preparation room		D	3500000	20000	Not determine			
3.	Change room - 1		D	3500000	20000	Not determine			
4.	Change room - 2		C	350000	2000	3500000	20000		
5.	Change room - 3		B	3500	1	350000	2000		
6.	Sterile corridor		B	3500	1	350000	2000		

Sr. No.	Name of the Room	Location No.	Grade	Maximum permitted number of Particle / m3 equal to above				Observation	
				At rest		In operation		0.5 µm	5.0 µm
				0.5 µm	5.0 µm	0.5 µm	5.0 µm		
6.	Sterile corridor		B	3500	1	350000	2000		
7.	Cooling zone		B	3500	1	350000	2000		
			A	3500	1	3500	1		
8.	Sterility testing room		B	3500	1	350000	2000		
			A	3500	1	3500	1		
9.	Change room - 4		C	350000	2000	3500000	20000		
10.	A/L for MLT / LAL room		D	3500000	20000	Not determine			
11.	LAL room		D	3500000	20000	Not determine			

Sr. No.	Name of the Room	Location No.	Grade	Maximum permitted number of Particle / m3 equal to above				Observation	
				At rest		In operation		0.5 µm	5.0 µm
				0.5 µm	5.0 µm	0.5 µm	5.0 µm		
11.	LAL room	PC11.4 (LAF)	A	3500	1	3500	1		
12.	MLT room	PC12.1	D	3500000	20000	Not determine			
		PC12.2							
		PC12.3							
		PC12.4 (LAF)	A	3500	1	3500	1		
13.	A/L for incubator room	PC13.1	D	3500000	20000	Not determine			
		PC13.2							
14.	Incubator room - I	PC14.1	D	3500000	20000	Not determine			
		PC14.2							
		PC14.3							
15.	Incubator room - II	PC15.1	D	3500000	20000	Not determine			
		PC15.2							
		PC15.3							
		PC15.4							

NA : Not applicable

Remarks: The area complies / does not comply with the laid down limits.

Observation Done By: **Checked By:**

Date: **Date:**

ANNEXURE - X

PHYSICAL MONITORING (TEMPERATURE AND RELATIVE HUMIDITY) OF MICROBIOLOGY LABORATORY

Date	Location	Morning			Evening			Checked by (Date& Sign)
		Time - ____________ (hrs)			Time - ____________ (hrs)			
		Temperature (^{0}C)	RH (%)	Done By (Date&Sign)	Temperature (^{0}C)	RH (%)	Done By (Date&Sign)	
	MLT Room							
	LAL Room							
	Sterility Testing Room							
	Media Storage Room		NA			NA		
	MLT Room							
	LAL Room							
	Sterility Testing Room							
	Media Storage Room		NA			NA		
	MLT Room							
	LAL Room							
	Sterility Testing Room							
	Media Storage Room		NA			NA		
	MLT Room							
	LAL Room							
	Sterility Testing Room							
	Media Storage Room		NA			NA		
	MLT Room							
	LAL Room							
	Sterility Testing Room							
	Media Storage Room		NA			NA		