



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Environmental Monitoring of Microbiology Section

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Environmental Monitoring in Microbiology Laboratory.

2.0 SCOPE:

This SOP is applicable for Environmental Monitoring in Microbiology Laboratory of Quality Control Area.

3.0 RESPONSIBILITY:

Officer / Executive – Microbiologist

4.0 ACCOUNTABILITY:

Head – QC

5.0 PROCEDURE:

5.1 After pre-incubation, label SCA plates as per given below Petron, transfer all labeled plates in dynamic pass box of concern area

L/M/SN/DD/MM/OS/NN

L - Location

M - Method of monitoring such as **SP** for settle plate, **AS** for air sampling, **SC** for surface monitoring by contact plate, **SW** for swab test, **FD** for finger Dab, **PC** for personnel monitoring by contact plate.

SN - Sr. No. of plates exposed

DD - Date

MM - Month

OS - Operating Shift A or B

NN - Frequency of air monitoring by Settle Plate during operation

For example: - ST/ SP/AL-01/27/11/01

ST - Sterility area

SP - Settle plate

AL-01- Sr. No. of plates exposed

27 - Date

11 - Month

01 - Exposure number

5.2 Take a swab tubes and aseptically pour 1 ml of sterile 0.9 %w/v saline solution, prepare the required number of swabs. Similarly prepare the individual pack of 10 swabs and wrap it two times with sanitized aluminum foil.

5.3 Place all the materials in cleaned Dynamic Pass Box.

5.4 Sanitize the air sampler and other materials carefully with 70% IPA filtered with (0.22 μ).



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.5 Place the containers having materials into Dynamic pass box of Solution preparation room. Enter into the sterility area through air locks. Expose the SCA plates at the specified location as per Format for 4 hours. At the time of exposure write down the time of exposure on to the wrapped aluminium foil.

5.6 ENVIRONMENTAL MONITORING OF AIR BY SETTLE PLATE METHOD:

5.6.1 Transfer the Media plates inside the sterility area, Biological Assay room and MLT Room By dynamic pass box.

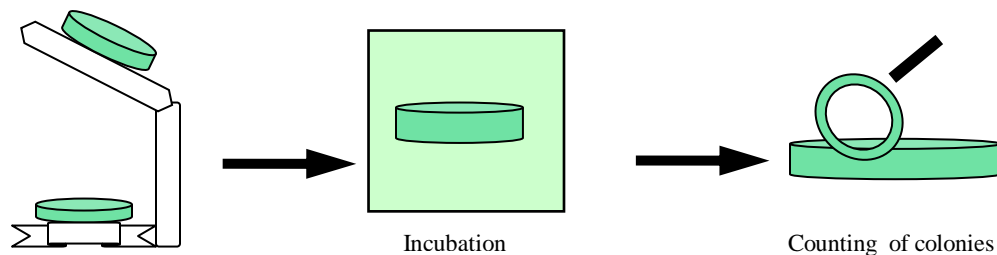
5.6.2 Expose the SCA plates at each specified location as per the format by opening the upper lid of the Petri plate for 4 hours.

5.6.3 After completion of exposure time close the lids of plate in the same sequence used for plates expose and collect all exposed plates and wrap with same single aluminum foil. Place the plates in SS container and transfer the plates to microbiology lab for incubation.

5.6.4 Incubate all the plates first at 20 to 25⁰C for 72 hours and then at 30 to 35⁰C for 48 hours in inverted position. For negative control incubate SCA plate as it is without streaking or exposing.

5.6.5 Incubate all the plates firstly a 20⁰ to 25⁰C for 72 hours and then at 30⁰C to 35⁰C for 48 hours in inverted position. For negative control incubate SCA Plate without streaking or exposing.

5.6.6 Generally the height of Passive air sampling should not be not more than 1 feet below the working height. (Remark: Plates should never be exposed directly on the floor).



Diagrammatic representations of Plate Exposure

5.7 ENVIRONMENTAL MONITORING OF AIR BY SAS 180 AIR SAMPLERS:

5.7.1 Sanitize the air sampler with lint free cloth previously wetted with filtered 70% IPA.



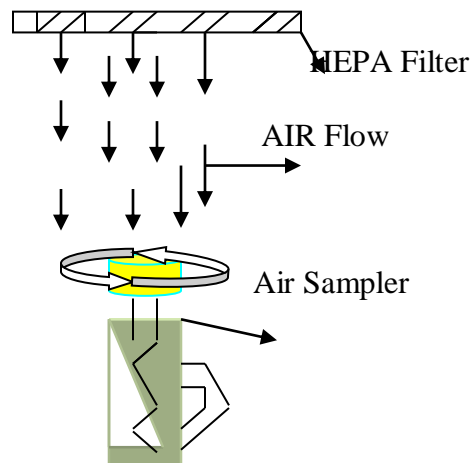
PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.7.2** Transfer the air sampler in sterility room by dynamic pass box of sterility Area and again sanitize with lint free cloth previously wetted with (0.22 μ) filtered 70% IPA.
- 5.7.3** At the location of air sampling open the top lid of pre incubated SCDA plate immediately remove the aluminum foil or butter paper of perforated sieve and set it with head of air sampler over the SCDA plate. Vertically put the air sampler at the location and carry out the air sampling of 1000 Liter.
- 5.7.4** After air sampling, remove the plate (in the same area where it is exposed) from air sampler, close the lid immediately and place aside. Immediately clean the head cone of air sampler with lint free cloth previously wetted with filtered 70% IPA and carry out the air sampling for other specified locations.



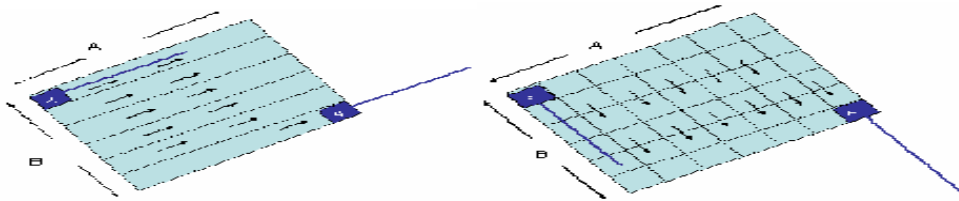
- 5.7.5** After air sampling collect, all the plates and wrap with same single aluminum foil. Place the plates in SS container and transfer the plates to incubation room.
- 5.7.6** Incubate all the plates first at 20 to 25⁰C for 72 hours and then at 30 to 35⁰C for 48 hours in inverted position. For negative control incubate SCA plate as it is without streaking.
- 5.7.7** Incubate all the plates first at 20 to 25⁰C for 72 hours and then at 30 to 35⁰C for 48 hours in inverted position. For negative control incubate SCA plate as it is without streaking. Incubate the plate as per above define.
- 5.8 ENVIRONMENTAL MONITORING OF SURFACE BY SWAB METHOD:**
- 5.8.1** Remove the swab stick and rub on the specified location in unidirectional to cover approx. 5x5 cm area which is to be monitored. During swabbing swab should not be overlapped, it should be discontinuous. After sampling sanitize the sampled area 70% IPA.



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.8.2** After sampling, aseptically Streak the swab on pre incubated SCA plates with swab sticks under LAF in concern area and Label the SCA Plate.
- 5.8.3** Carry out the sampling for all locations. After completion of work transfer the swabs and streaked SCA Plates to Incubation room.
- 5.8.4** SCA plates incubate at 20 to 25⁰C for 72 hours and then at 30 to 35⁰C for 48 hours.
- 5.8.5** Perform the sampling at the end of filling and cover the maximum location which is not cover by contact plate e.g. corner of SS stool. Door handle and coving of floor.



5.9 ENVIRONMENTAL MONITORING OF SURFACE BY CONTACT PLATE METHOD:

- 5.9.1** Open the lid of contact plate take the sample by pressing the plate smoothly on the surface which has to be monitor, after sampling, close the lid of plates.
- 5.9.2** During surface sampling press the contact plates with uniform pressure to make contact of the entire media surface.
- 5.9.3** Sanitize the sampled area with 70% IPA. Ensure that there is no agar media traces left over the contact surface sampled.
- 5.9.4** After sampling transfer the contact plates to incubation Room.
- 5.9.5** Incubate the contact plates at 20 to 25⁰C for 72 hours and then at 30 to 35⁰C for 48 hours.

5.10 Acceptance Criteria for Total Aerobic Microbial Count:

5.10.1 Settle plate (Diameter 90mm) (cfu/4Hours)

Grade	Alert Level	Action Level	Limits
Grade A	<1 cfu	<1 cfu	<1 cfu
Grade B	3 cfu	4 cfu	5 cfu
Grade C	30 cfu	40 cfu	50 cfu
Grade D	60 cfu	80 cfu	100 cfu



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Environmental Monitoring of Microbiology Section

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

5.10.2 For Viable Particles (Active Air Sampler – per meter³ or (1000 liter) of air)

Grade	Alert Level	Action Level	Limits
Grade A	<1 cfu	<1 cfu	<1
Grade B	6 cfu	8 cfu	10 cfu
Grade C	60 cfu	80 cfu	100 cfu
Grade D	120 cfu	160 cfu	200 cfu

5.10.3 Surface monitoring by Contact plate and Swab Method (Sampling Area approx. – 25 cm²)

Grade	Alert Level	Action Level	Limits
Grade A	<1 cfu	<1 cfu	<1 cfu
Grade B	3 cfu	4 cfu	5 cfu
Grade C	15 cfu	20cfu	25 cfu
Grade D	30 cfu	40 cfu	50 cfu

5.11 CORRECTIVE AND PREVENTIVE ACTIONS:

5.11.1 If count goes up to alert level and action level take the preventive action as per mention below.

S.No.	Observation	Corrective action
		Alert Level
1.	If count goes up to alert level.	Perform the localize cleaning by schedule disinfectant.
2.	Repeatedly in the same area. For the three consecutive day.	Through cleaning for that area and select the disinfectant based on the type of organism which we have found.
3.	Multiple locations on any day.	Through cleaning for that area by schedule disinfectant.
4.	Repeatedly in the same area along with other area for the three consecutive.	Stop production and through cleaning (wall, ceiling, floor, door and machine etc.)
5.	If count goes up to action level.	Through cleaning for that area.
6.	Repeatedly for the three consecutive same.	Stop production and through cleaning (wall, ceiling, floor, door and machine etc.).

5.12 FREQUENCY OF ENVIRONMENTAL MONITORING:

Grade	Air Monitoring By Settle Plate	Air Monitoring By Active Air Sampler	Surface Monitoring
A	Daily / shift	Daily / shift	Operation/shift
B	Daily	Operation	Operation



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Environmental Monitoring of Microbiology Section

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

C	Once in week	Once in week	Once in week
D	Twice in month	Twice in month	Twice in month

5.13 JUSTIFICATION OF LOCATIONS

LOCATION	CLASS	JUSTIFICATION
Near Entry	B, C & D	At the time of entry or exit in room which may increase the bio Burdon at that particular point.
Risers	B, C & D	As these are return air riser location and there is probability of maximum count of these location.
Centre of room	B, C & D	To verify the probability of excess viable count. Hence to ensure the area is well within the acceptable Bioburden level.
Static Pass box	C	To verify the grade C condition for transferring the material in aseptic area.
Dynamic Pass box	A	To verify the grade A condition for transferring the material in aseptic area
Dynamic Garment Storage Cabinet	A	To verify the grade A condition for storage sterile garments.
Laminar Air Flow Left, Right, Middle, Front side and Back side	A	Process activity is carried out under this location this is very important to know viable count at this location to verify grade A condition.
Near Glass Window Left	B, C & D	Mention plates location is decided on the basis of less air sweep at these locations

6.0 REFERENCES:

EU-GMP

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Microbiological Environmental Monitoring Report of Sterility Area	
Annexure-II	Microbiological Environmental Monitoring Report of Biological Assay & MLT Room	
Annexure-III	Microbiological Environmental Monitoring Report	

ENCLOSURES: SOP Training Record



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Environmental Monitoring of Microbiology Section

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance Department
- Controlled Copy No. 02 Quality Control Department
- Master Copy Quality Assurance Department

9.0 ABBREVIATIONS:

Ltd. Limited
No. Number
QA Quality Assurance
QC Quality Control
SOP Standard Operating Procedure

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE-I

MICROBIOLOGICAL ENVIRONMENTAL MONITORING REPORT OF STERILITY AREA

Report No.			
Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle plate, Swab Sampling, Air Monitoring & Finger Dab	Soybean Casein Digest Agar	Media Used For Surface and Personnel Monitoring by Contact Plate	Dey Englay Neutralizing Agar
Autoclave Media Ref. No		Autoclave Media Ref. No	
Plate Exposure Time: Std. 4 hrs for settle plate		Area Covered for surface monitoring	24 – 30 cm ²
Shift		Area Covered for Finger Dab	5 Finger of Each Hand
1st Incubation Temp & Time.	20 – 25 ^o for 72 hrs	2nd Incubation Temp & Time.	30 – 35 ^o C for 48 hrs
Incubator ID No.		Incubator ID No.	
Air Sampler ID for Air monitoring			

AIR MONITORING BY SETTLE PLATE METHOD

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 01	Near Riser				
C	Air lock 02	Near Riser				
A		Dress Cabinet				
B	Air lock 03	Centre of air lock - 3				
C	Air lock 04	Near Riser				
D	Air lock 05	Near Riser				
B	Corridor	Near Entry Riser				
		Near Pass box Riser				
A		Dynamic Pass Box Incubation Room				
		Dynamic Pass Box Corridor				
		Dynamic Pass Box Pre Incubation Room				
B	Cooling zone	Near autoclave				
		Near riser				
		Near riser				
B	Sterility Room	Near entry				
		Near LAF right side				
		Near LAF left side				
A		Under LAF - Middle				
Observed By						

-ve control



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Remarks: The environmental monitoring result of settle plate for above locations complies / does not comply as per prescribed limits.

MONITORING OF AIR BY ACTIVE AIR SAMPLER

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 01	Centre of air lock -1				
C	Air lock 02	Centre of air lock -2				
A		Dress Cabinet				
B	Air lock 03	Centre of air lock -3				
C	Air lock 04	Centre of air lock -4				
D	Air lock 05	Centre of air lock -5				
B	Corridor	Centre				
A		Dynamic Pass box incubation room				
		Dynamic Pass box corridor				
		Dynamic Pass box Pre incubation room				
B	Cooling zone	Centre of room				
B	Sterility Room	Near LAF				
A		Near entry				
		Under LAF Middle				
Observed By						

-ve control

Remarks: The environmental monitoring result of Air Sampling for above locations complies / does not comply as per prescribed limits.

SURFACE MONITORING BY SWAB SAMPLING

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 01	Wall corner				
		Floor Coving				
C	Air lock 02	Wall corner				
		Floor Coving				
A		Dynamic Garment Cabinet corner				
B	Air lock 03	Wall corner				
		Floor Coving				
C	Air lock 04	Wall corner				
		Floor Coving				



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 05	Wall corner				
		Floor Coving				
B	Sterility Room	Wall corner				
		Floor Coving Edge				
		Door Handle				
A		Under LAF corner				
Observed By						

-ve control

Remarks: The surface monitoring result of Swab sampling for above locations complies / does not comply as per prescribed limits.

SURFACE MONITORING BY CONTACT PLATE

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 01	Wall				
		Floor				
C	Air lock 02	Wall				
		Floor				
A	Air lock 02	Garment Cabinet				
B	Air lock 03	Wall				
		Floor				
C	Air lock 04	Wall				
		Floor				
D	Air lock 05	Wall				
		Floor				
B	Cooling zone	Wall				
		Floor				
B	Sterility Room	Wall				
		Floor				
A		LAF working floor				
Observed By						

-ve control

Remarks: The surface monitoring result of contact plate for above locations complies / does not comply as per prescribed limits.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

PERSONNEL MONITORING BY CONTACT PLATE

Grade	Working Location	Name of Person	Sampling Location	Observation		Total Microbial Count
				Incubation at 20°C to 25°C for 72 hrs	Incubation at 30°C to 35°C for 72 hrs	
			FOREHEAD			
			CHEST			
			RIGHT ARMPIT			
			LEFT ARMPIT			
			RIGHT ELBOW			
			LEFT ELBOW			
			WAIST			
			RIGHT THIGH			
			LEFT THIGH			
			RIGHT BOOTY			
			LEFT BOOTY			
			FOREHEAD			
			CHEST			
			RIGHT ARMPIT			
			LEFT ARMPIT			
			RIGHT ELBOW			
			LEFT ELBOW			
			WAIST			
			RIGHT THIGH			
			LEFT THIGH			
			RIGHT BOOTY			
			LEFT BOOTY			
			LEFT BOOTY			
			FOREHEAD			
			CHEST			
			RIGHT ARMPIT			
			LEFT ARMPIT			
			RIGHT ELBOW			
			LEFT ELBOW			
			WAIST			
			RIGHT THIGH			
			LEFT THIGH			
			RIGHT BOOTY			
			LEFT BOOTY			
			LEFT BOOTY			
Observed By						



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

-ve control

Remarks: The Personal monitoring result for above locations complies / does not comply as per prescribed limits

PERSONNEL MONITORING BY FINGER DAB

Grade	Working Location	Name of Person	Sampling Location	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
			Left hand			
			Right hand			
			Left hand			
			Right hand			
			Left hand			
			Right hand			
Observed By						

-ve control

Remarks: The Personal monitoring result for 5 finger (Finger Dab) complies / does not comply as per prescribed limits

LIMITS FOR SETTLE PLATE METHOD: Total Aerobic Microbial Count

Grade	Alert Limits	Action Limits	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	3 cfu	4 cfu	5 cfu
C	30 cfu	40 cfu	50 cfu
D	60 cfu	80 cfu	100 cfu

LIMITS FOR ACTIVE AIR SAMPLING METHOD: Total Aerobic Microbial Count:

Grade	Alert Level	Action Level	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	6 cfu	8 cfu	10 cfu
C	60 cfu	80 cfu	100 cfu
D	120 cfu	160 cfu	200 cfu

LIMITS FOR SWAB SAMPLING METHOD: Total Aerobic Microbial Count

Grade	Alert Level	Action Level	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	3 cfu	4 cfu	5 cfu
C	15 cfu	20cfu	25 cfu
D	30 cfu	40 cfu	50 cfu

LIMITS FOR CONTACT PLATE METHOD: Total Aerobic Microbial Count



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Environmental Monitoring of Microbiology Section

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Grade	Alert Level	Action Level	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	3 cfu	4 cfu	5 cfu
C	15 cfu	20cfu	25 cfu
D	30 cfu	40 cfu	50 cfu

LIMITS FOR PERSONNEL MONITORING BY FINGER DAB AND CONTACT PLATE: Total Aerobic Microbial count

Grade	Alert Level	Action Level	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	3 cfu	4 cfu	5 cfu

Microbiologist:
Date:

Checked by:
Date:

Approved by:
Date



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE-II

MICROBIOLOGICAL ENVIRONMENTAL MONITORING REPORT OF MLT & ASSAY ROOM

Report No.			
Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle plate, Swab Sampling, Air Monitoring & Finger Dab	Soybean Casein Digest Agar	Media Used For Surface and Personnel Monitoring by Contact Plate	Dey Englay Neutralizing Agar
Autoclave Media Ref. No		Autoclave Media Ref. No	
Plate Exposure Time: Std. 4 hrs for Settle Plate		Area Covered for surface monitoring	24 – 30 cm ²
Shift		Air Sampler ID for Air Monitoring	
1st Incubation Temp & Time.	20 – 25 ⁰ for 72 hrs	2nd Incubation Temp & Time.	30 – 35 ⁰ C for 48 hrs
Incubator ID No.		Incubator ID No.	

AIR MONITORING BY SETTLE PLATE METHOD

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 01	Near Riser				
C	Air lock 02	Near Riser				
A	DGSC	Dress Cabinet				
B	Air lock 03	Centre of air lock - 3				
C	Air lock 04	Near Riser				
D	Air lock 05	Near Riser				
B		Near Entry				
		Near Dynamic Pass box				
A	Corridor	Dynamic Pass box incubation room				
		Dynamic Pass box Solution preparation room				
B	Assay Room	Near LAF left side				
		Near LAF right side				
A	LAF	Under LAF				
B	MLT Room	Near LAF left side				
		Near LAF right side				
A	LAF	Under LAF				
Observed By						



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

-ve control

Remarks: The environmental monitoring result of settle plate for above locations complies / does not comply as per prescribed limits.

MONITORING OF AIR BY ACTIVE AIR SAMPLER

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 01	Near riser				
C	Air lock 02	Near riser				
A		DGSC				
B	Air lock 03	Near riser				
C	Air lock 04	Near riser				
D	Air lock 05	Near riser				
B	Assay Room	Near Entry				
		Near LAF				
A		Under LAF Middle				
B	MLT Room	Near entry				
A		Under LAF				
B	Corridor	Near Entry				
		Near Dynamic Pass box				
A		Dynamic Pass box incubation room				
		Dynamic Pass box Solution preparation room				
Observed By						

-ve control

Remarks: The environmental monitoring result of Air sampling for above locations complies / does not comply as per prescribed limits.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

SURFACE MONITORING BY SWAB SAMPLING

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 01	Wall corner				
		Floor Coving				
C	Air lock 02	Wall corner				
		Floor Coving				
A		DGSC				
B	Air lock 03	Wall corner				
		Floor Coving				
C	Air lock 04	Wall corner				
		Floor Coving				
D	Air lock 05	Wall corner				
		Floor Coving				
B		Wall corner				
		Floor Coving				
A	Corridor	Dynamic Pass box incubation room				
		Dynamic Pass box Solution preparation room				
B	Assay Room	Wall corner				
		Floor Coving Edge				
		Door Handle				
A		Under LAF corner				
B	MLT Room	Wall corner				
		Floor Coving Edge				
		Door Handle				
A		Under LAF corner				
Observed By						

-ve control

Remarks: The surface monitoring result of Swab sampling for above locations complies / does not comply as per prescribed limits.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

SURFACE MONITORING BY CONTACT PLATE

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count
D	Air lock 01	Wall				
		Floor				
C	Air lock 02	Wall				
		Floor				
A		DGSC				
B	Air lock 03	Wall				
		Floor				
C	Air lock 04	Wall				
		Floor				
D	Air lock 05	Wall				
		Floor				
B	Corridor	Wall corner				
		Floor Coving				
A	Corridor	Dynamic Pass box incubation room				
		Dynamic Pass box Solution preparation room				
		Dynamic Pass box Pre-incubation room				
B	MLT Room	Wall				
		Floor				
A		LAF working floor				
B	Assay Room	Wall				
		Floor				
A		LAF working floor				
Observed By						

-ve control

Remarks: The surface monitoring result of contact plate for above locations complies / does not comply as per prescribed limits.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Environmental Monitoring of Microbiology Section

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

LIMITS FOR SETTLE PLATE METHOD: Total Aerobic Microbial Count

Grade	Alert Limits	Action Limits	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	3 cfu	4 cfu	5 cfu
C	30 cfu	40 cfu	50 cfu
D	60 cfu	80 cfu	100 cfu

LIMITS FOR ACTIVE AIR SAMPLING METHOD: Total Aerobic Microbial Count

Grade	Alert Level	Action Level	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	6 cfu	8 cfu	10 cfu
C	60 cfu	80 cfu	100 cfu
D	120 cfu	160 cfu	200 cfu

LIMITS FOR SWAB SAMPLING METHOD: Total Aerobic Microbial Count

Grade	Alert Level	Action Level	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	3 cfu	4 cfu	5 cfu
C	15 cfu	20cfu	25 cfu
D	30 cfu	40 cfu	50 cfu

LIMITS FOR SURFACE MONITORING BY CONTACT PLATE METHOD: Total Aerobic Microbial Count

Grade	Alert Level	Action Level	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	3 cfu	4 cfu	5 cfu
C	15 cfu	20cfu	25 cfu
D	30 cfu	40 cfu	50 cfu

Microbiologist:

Checked By:

Approved By:

Date:

Date:

Date:



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE-III MICROBIOLOGICAL ENVIRONMENTAL MONITORING REPORT

Report No.			
Date of sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle plate, Swab Sampling, Air Monitoring & Finger Dab	Soybean Casein Digest Agar	Media Used For Surface and Personnel Monitoring by Contact Plate	Dey Englay Neutralizing Agar
Autoclave Media Ref. No		Autoclave Media Ref. No	
Plate Exposure Time: Std. 4 hrs for Settle Plate		Area Covered for surface monitoring	24 – 30 cm ²
Shift		Air Sampler ID for Air Monitoring	
1st Incubation Temp & Time.	20 – 25 ^o for 72 hrs	2nd Incubation Temp & Time.	30 – 35 ^o C for 48 hrs
Incubator ID No.		Incubator ID No.	

AIR MONITORING BY SETTLE PLATE METHOD

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count

-ve control

Remarks: The Air monitoring result of Settle plate for above locations complies / does not comply as per prescribed limits.

MONITORING OF AIR BY ACTIVE AIR SAMPLER

Grade	Area	Location	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs.	Total Microbial Count

-ve control



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Environmental Monitoring of Microbiology Section	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Remarks: The environmental monitoring result of Air sampling for above locations complies / does not comply as per prescribed limits.

LIMITS FOR SETTLE PLATE METHOD: Total Aerobic Microbial Count

Grade	Alert Limits	Action Limits	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	3 cfu	4 cfu	5 cfu
C	30 cfu	40 cfu	50 cfu
D	60 cfu	80 cfu	100 cfu

LIMITS FOR ACTIVE AIR SAMPLING METHOD: Total Aerobic Microbial Count:

Grade	Alert Level	Action Level	Specified Limits
A	<1 cfu	<1 cfu	<1 cfu
B	6 cfu	8 cfu	10 cfu
C	60 cfu	80 cfu	100 cfu
D	120 cfu	160 cfu	200 cfu

Microbiologist:
Date:

Checked By:
Date:

Approved By:
Date: