



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Microbiological Environmental Monitoring of Raw Material Store	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Microbiological Environmental Monitoring of Raw Material Store in "I" Block.

2.0 SCOPE:

This SOP is applicable for Microbiological Environmental Monitoring (Settle Plate, Air Sampling, Swab Test, and Contact Plate) of Raw Material Store in "I" Block.

3.0 RESPONSIBILITY:

Officer / Executive – Microbiologist

4.0 ACCOUNTABILITY:

Head – QC

5.0 PROCEDURE:

- 5.1 Sanitize the external surface of the pre incubated plate & Aluminum foil with 70% filtered (0.2 μ) IPA. Make the set of 10 plates and wrap 2 times in the aluminum foil.
- 5.2 Transfer the plates to the respective area and label the plate with location, date of exposure and shift as follows.

L/M/PC/DD/MM/OS

Where,

- 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.
- PC - Plate Code
- DD - Date
- MM - Month
- OS - Operating Shift A or B

- 5.3 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.
- 5.4 Place all the materials in cleaned SS container.
- 5.5 Sanitize the air sampler and other materials carefully with 70% IPA filtered with (0.2 μ).
- 5.6 Transfer the SS container into Dry Powder Injection Facility.



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5.7 BY SETTLE PLATE METHOD:

- 5.7.1** Transfer the plates inside the RM Store of Dry Powder Injection by removing the wrapping of aluminum foil.
- 5.7.2** Expose the SCDA plates at each specified location as per the format by opening the upper lid of the Petri plate.
- 5.7.3 Exposure Time:** Expose the SCDA plate as mentioned in table.

Grade	Exposure Time of Settle Plate
A	NLT 4Hrs
B	NLT 4Hrs
C	NLT 4Hrs
D	NLT 4Hrs

- 5.7.4** 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.
- 5.7.5** Incubate all the plates first at 20⁰C to 25⁰C for 72 hours and then at 30⁰C to 35⁰C for 48 hours in inverted position. For negative control incubate SCDA plate as it is without streaking or exposing.

5.8 BY AIR SAMPLER :

- 5.8.1** Sanitize the air sampler with lint free cloth previously wetted with filtered 70% IPA.
- 5.8.2** Transfer the air sampler in raw material store of dry powder injection facility and again sanitize with lint free cloth previously wetted with (0.2 μ) filtered 70% IPA.
- 5.8.3** 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.
- 5.8.4** 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



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with lint free cloth previously wetted with filtered 70% IPA and carry out the air sampling for other specified locations.

5.8.5 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 microbiology lab for incubation.

5.8.6 Incubate all the plates first at 20⁰C to 25⁰C for 72 hours and then at 30⁰C to 35⁰C for 48 hours in inverted position. For negative control incubate SCDA plate as it is without streaking / exposing. Also carry out positive control.

5.9 BY SWAB METHOD:

5.9.1 Transfer the swab inside the raw material store of dry powder injection by removing the last wrapping of aluminum foil.

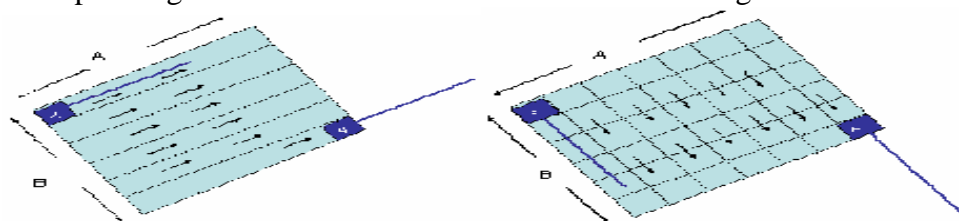
5.9.2 Remove the swab stick and rub on the specified location in unidirectional to cover approx 5x5 cm area which is to be monitored. During swabbing swab should not be overlapped, it should be discontinuous. After sampling sanitize the sampled area 70% IPA.

5.9.3 After sampling, aseptically Streak the swab on pre incubated SCDA plates with swab sticks under LAF in concern area and Label the SCDA Plate.

5.9.4 Carry out the sampling for all locations. After completion of work transfer the swabs and streaked SCDA Plates to microbiology lab.

5.9.5 SCDA plates incubate at 20⁰C to 25⁰C for 72 hours and then at 30⁰C to 35⁰C for 48 hours.

5.9.6 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.



5.10 BY CONTACT PLATE METHOD:

5.10.1 Transfer the DNA contact plates inside raw material store of dry powder injection by removing the last wrapping of aluminum foil.

5.10.2 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.



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- 5.10.3** During surface sampling press the contact plates with uniform pressure to make contact of the entire media surface.
- 5.10.4** Sanitize the sampled area with 70% IPA. Ensure that there is no agar media traces left over the contact surface sampled.
- 5.10.5** After sampling transfer the contact plates to microbiology lab for incubation.
- 5.10.6** Incubate the contact plates at 20 to 25⁰C for 72 hours and then at 30 to 35⁰C for 48 hours.
- 5.10.7** Perform the Personnel Monitoring Staff, Operator & Helper at the end of filling / work.

5.11 ACCEPTANCE CRITERIA FOR TOTAL AEROBIC MICROBIAL COUNT:

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

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

5.11.2 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 cfu
Grade B	6 cfu	8 cfu	10 cfu
Grade C	60 cfu	80 cfu	100 cfu
Grade D	120 cfu	160 cfu	200 cfu

5.11.3 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

- 5.11.4** Any bacterial count observed in first three days, it shall be recorded on 4th day observation. Fungal count shall be denoted as 'F'.



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5.12 CORRECTIVE AND PREVENTIVE ACTIONS:

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

S.No.	Observation	Corrective action
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.).

5.13 REQUENCY OF MICROBIOLOGICAL ENVIRONMENTAL MONITORING:

5.13.1 Environmental monitoring of aseptic area shall be during operation as per given table:

Grade	Area	Air Monitoring By Settle Plate	Air Monitoring By Active Air Sampler	Surface Monitoring	Plate Exposure Time
A	Under LAF & RLAF	Daily	Daily / Shift	Daily/ Shift	4 Hours
B	Surrounding of Grade A	Daily	Twice in Weekly	Weekly	4 Hours
C	Change Room	Daily	Weekly	Weekly	4 Hours
D	Change Room	Weekly	Weekly	Twice in Month	4 Hours



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9.0 ABBREVIATIONS:

%	Percentage
μ	Micron
IPA	Isopropyl Alcohol
No.	Number
Q.A.	Quality Assurance
QC	Quality Control
S.S.	Stainless Steel
SOP	Standard Operating Procedure
SCDA	Soyabean Casein Digest Agar

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE – I MICROBIOLOGICAL ENVIRONMENTAL MONITORING REPORT OF RAW MATERIAL STORE

A.R. 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 ⁰ C – 25 ⁰ C for 72 hrs	2nd Incubation Temp & Time.	30 ⁰ C – 35 ⁰ C for 48 hrs
Incubator ID No.		Incubator ID No.	

OBSERVATION TABLE:

Grade	Area	Location	Plate code	Observation		Total Count
				Incubation at 20 ⁰ C -25 ⁰ C for 72 hrs	Incubation at 30 ⁰ C - 35 ⁰ C for 48 hrs	
D	Corridor	Near Return Riser	SP-01			
		Near Return Riser	SP-02			
		Near Return Riser	SP-03			
		Near Return Riser	SP-04			
		Near Return Riser	SP-05			
		Near Return Riser	SP-06			
		Near Return Riser	SP-07			
		Near Return Riser	SP-08			
		Near Return Riser	SP-09			
		Near Return Riser	SP-10			
D	Approved Raw Material Store	Near Return Riser	SP-11			
		Near Return Riser	SP-12			
		Near Return Riser	SP-13			
		Near Return Riser	SP-14			
		Near Return Riser	SP -15			
D	Under Test Material Store	Near Return Riser	SP -16			
		Near Return Riser	SP -17			
		Near Return Riser	SP -18			
		Near Return Riser	SP -19			
D	Sterile Raw Material Store	Near Return Riser	SP -20			
		Near Return Riser	SP -21			
		Near Return Riser	SP -22			
C	Air lock -1	Near Return Riser	SP -23			



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C	Air lock -2	Near Return Riser	SP -24			
B	Dispensing Room	Near Return Riser	SP -25			
		Near Return Riser	SP -26			
Near Return Riser		SP -27				
A		RLAF	SP-28			
		Dynamic Pass Box	SP-29			
		Dynamic Pass Box	SP-30			
D	Air lock -1	Near Return Riser	SP-31			
C	Air lock -2	Near Return Riser	SP-32			
B	Non Sterile Sampling Area	Near Return Riser	SP -33			
		Near Return Riser	SP -34			
		Near Return Riser	SP -35			
A		RLAF	SP -36			
D	Rejected	Near Return Riser	SP -37			
D	PM Sampling Air lock	Near Return Riser	SP-38			
D	PM Sampling Area	Near Return Riser	SP-39			
		Near Return Riser	SP-40			
D	Approved PM Store	Near Return Riser	SP-41			
		Near Return Riser	SP-42			
		Near Return Riser	SP-43			
		Near Return Riser	SP-44			
		Near Return Riser	SP-45			
		Near Return Riser	SP-46			
D	Air lock -1	Near Return Riser	SP -48			
C	Air lock -2	Near Return Riser	SP -49			
A		Dress Cabinet	SP -50			
B	Air lock -3	Near Return Riser	SP -51			
C	Return Air Lock-1	Near Return Riser	SP -52			
D	Return Air Lock-2	Near Return Riser	SP -53			
B	Sampling Sterile Raw Material	Near Return Riser	SP-54			
		RLAF	SP-55			
		Dynamic Pass Box	SP-56			
D	Material A/L	Near Return Riser	SP-57			
D	Quarantine	Near Return Riser	SP-58			
		Near Return Riser	SP-59			

Remarks: The environmental monitoring result of settle plate for above locations Complies/Does Not Comply as per prescribed limits.



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MICROBIOLOGICAL ENVIRONMENTAL MONITORING OF AIR BY ACTIVE AIR SAMPLING OBSERVATION TABLE:

Grade	Area	Location	Plate code	Observation		Total Count
				Incubation at 20° C -25°C for 72 hrs	Incubation at 30°C - 35°C for 48 hrs	
D	Corridor	Near Return Riser	AS-01			
		Near Return Riser	AS -02			
		Near Return Riser	AS -03			
D	Approved Raw Material Store	Near Return Riser	AS-04			
D	Under Test Material Store	Near Return Riser	AS-05			
		Near Return Riser	AS-06			
D	Sterile Raw Material Store	Near Return Riser	AS-07			
C	Air lock -1	Near Return Riser	AS-08			
C	Air lock -2	Near Return Riser	AS-09			
B	Dispensing Room	Near Return Riser	AS-10			
A		RLAF	AS-11			
		Dynamic Pass Box	AS-12			
		Dynamic Pass Box	AS-13			
D	Air lock -1	Near Return Riser	AS-14			
C	Air lock -2	Near Return Riser	AS-15			
B	Non Sterile Sampling Area	Near Return Riser	AS-16			
A		RLAF	AS-17			
D	Rejected	Near Return Riser	AS-18			
D	PM Sampling Air lock	Near Return Riser	AS-19			
D	PM Sampling Area	Near Return Riser	AS-20			
D	Approved PM Store	Near Return Riser	AS-21			
		Near Return Riser	AS-22			
D	Air lock -1	Near Return Riser	AS-23			
C	Air lock -2	Near Return Riser	AS-24			
A		Dress Cabinet	AS-25			
B	Air lock -3	Near Return Riser	AS-26			
C	Return Air Lock-1	Near Return Riser	AS-27			
D	Return Air Lock-2	Near Return Riser	AS-28			
B	Sampling Sterile Raw Material	Near Return Riser	AS-29			
A		RLAF	AS-30			
		Dynamic Pass Box	AS-31			
D	Material A/L	Near Return Riser	AS-32			
D	Quarantine	Near Return Riser	AS-33			

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



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MICROBIOLOGICAL ENVIRONMENTAL MONITORING OF SURFACE BY SWAB METHOD

OBSERVATION TABLE:

Grade	Area	Location	Plate code	Observation		Total Count
				Incubation at 20 ^o C -25 ^o C for 72 hrs	Incubation at 30 ^o C - 35 ^o C for 48 hrs	
D	Corridor	Floor Coving	SW- 01			
		Wall Corner	SW-02			
D	Approved Raw Material Store	Floor Coving	SW- 03			
		Wall Corner	SW-04			
D	Under Test Material Store	Floor Coving	SW- 05			
		Wall Corner	SW-06			
D	Sterile Raw Material Store	Floor Coving	SW- 07			
		Wall Corner	SW-08			
C	Air lock -1	Floor Coving	SW- 09			
C	Air lock -2	Floor Coving	SW-10			
B	Dispensing Room	Floor Coving	SW- 11			
		Wall Corner	SW-12			
RLAF		SW- 13				
Dynamic Pass Box		SW-14				
Dynamic Pass Box		SW- 15				
D	Air lock -1	Floor Coving	SW-16			
C	Air lock -2	Floor Coving	SW- 17			
B	Non Sterile Sampling Area	Floor Coving	SW-18			
		Wall Corner	SW- 19			
A		RLAF	SW-20			
D	PM Sampling Area	Floor Coving	SW- 21			
		Wall Corner	SW-22			
D	Approved PM Store	Floor Coving	SW- 23			
		Wall Corner	SW-24			
D	Air lock -1	Floor Coving	SW- 25			
C	Air lock -2	Floor Coving	SW-26			
		A	Dress Cabinet	SW- 27		
B		Air lock -3	Near Return Riser	SW-28		
C	Return Air Lock-1	Floor Coving	SW- 29			
D	Return Air Lock-2	Floor Coving	SW-30			
B	Sampling Sterile Raw Material	Floor Coving	SW- 31			
		Wall Corner	SW-32			
A		RLAF	SW- 33			
Dynamic Pass Box		SW-34				
D	Material A/L	Floor Coving	SW- 35			
D	Quarantine	Floor Coving	SW-36			
		Wall Corner	SW- 37			

Remarks: The surface monitoring result of Swab sampling for above locations Complies/Does Not Comply as per prescribed limits.



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MICROBIOLOGICAL ENVIRONMENTAL MONITORING OF SURFACE BY CONTACT PLATE METHOD

OBSERVATION TABLE:

Grade	Area	Location	Plate code	Observation		Total Count
				Incubation at 20 ⁰ C -25 ⁰ C for 72 hrs	Incubation at 30 ⁰ C - 35 ⁰ C for 48 hrs	
D	Corridor	Floor	CP- 01			
D	Approved Raw Material Store	Floor	CP -02			
D	Under Test Material Store	Floor	CP -03			
D	Sterile Raw Material Store	Floor	CP -04			
C	Air lock -1	Wall	CP -05			
C	Air lock -2	Wall	CP -06			
B	Dispensing Room	Floor	CP -07			
A		RLAF	CP -08			
		Dynamic Pass Box	CP -09			
		Dynamic Pass Box	CP -10			
D	Air lock -1	Wall	CP -11			
C	Air lock -2	Wall	CP -12			
B	Non Sterile Sampling Area	Floor	CP -13			
A		RLAF	CP -14			
D	PM Sampling Area	Floor	CP -15			
D	Approved PM Store	Floor	CP -16			
D	Air lock -1	Wall	CP -17			
C	Air lock -2	Wall	CP -18			
A		Dress Cabinet	CP -19			
B	Air lock -3	Near Return Riser	CP -20			
C	Return Air Lock-1	Wall	CP -21			
D	Return Air Lock-2	Wall	CP -22			
B	Sampling Sterile Raw Material	Floor	CP -23			
A		RLAF	CP -24			
		Dynamic Pass Box	CP -25			
D	Material A/L	Wall	CP -26			
D	Quarantine	Floor Covine	CP -27			

Remarks: The surface monitoring result by Contact Plates for above locations Complies / Does Not Comply as per prescribed limits.



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PERSONNEL MONITORING BY CONTACT PLATE

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
			Chest			
			Forehead			
			Armpits			
			Chest			
			Forehead			
			Armpits			
			Chest			
			Forehead			
			Armpits			
			Chest			
			Forehead			
			Armpits			
			Chest			
			Forehead			
			Armpits			
Observed By						

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			
			Left hand			
			Right hand			
			Left hand			
			Right hand			
Observed By						

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



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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

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

Done By:
Date:

Checked By:
Date:

Approved By:
Date:



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ANNEXURE-II ENVIRONMENTAL MONITORING REPORT OF PASSIVE AIR SAMPLING

Date of Sampling		Date of Observation	
Sampled By		Area Status	Static / Dynamic
Media Used For Settle Plate	Soybean Casein Digest Agar	Plate Exposure Time	
Autoclave Media Ref. No		Grade	
1st Incubation Temp & Time.	20 ⁰ C – 25 ⁰ C for 72 hrs	2nd Incubation Temp & Time.	30 ⁰ C – 35 ⁰ C for 48 hrs
Incubator ID No.		Incubator ID No.	
Area			

S.No.	Area	Plate Code	Observation at 20° to 25°C for 72 hrs	Observation at 30° to 35°C After 48 hrs	Total Microbial Count
1.					
2.					
3.					
4.					
5.					
6.					

-ve control

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

Done By:
Date:

Checked by:
Date:

