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 – Microbiology

4.0 ACCOUNTABILITY:

Head – QC

5.0 ABBREVIATIONS:

Ltd.	Limited
QA	Quality Assurance
QC	Quality Control
RHFD	Right hand finger dab
LHFD	Left hand finger dab
FH	Forehead
CH	Chest
RA	Right Armpit
LA	Left Armpit
TFC	Total fungal count
TBC	Total bacterial count
TAMC	Total Aerobic microbial count
NA	Not applicable
CFU	Colony forming unit
ML	Microbiology laboratory
SCA	Soyabean Casean Digest Agar
DNA	Dey Englay Neutralizing Agar

6.0 PROCEDURE:

6.1 After pre-incubation, label SCA/DNA plates under LAF as per given below pattern.

L/M-PC/DD/MM/OS/G

L - Location

M - Method of monitoring such as **SP** for settle plate, **AS** for air sampling, **SM** for surface monitoring by contact plate, **FD** for finger Dab, **PM** for personnel monitoring by contact plate.

PC - Sr. No. of plate code

DD - Date

MM - Month
OS - Operating Shift A,B,C
G - Grade

For example: - ST/SP-01/27/11/I/A
ST - Sterility area
SP - Settle plate
01 - Sr. No. of exposed plate
27 - Date
11 - Month
I - Shift
A - Grade

6.2 Sanitize the surface of aluminum foil with 0.22µ filtered 70% IPA and wrap in aluminum foil.

6.3 Put the set of plates in cleaned SS Container sanitized with 0.22µ filtered 70% IPA

6.4 Place the containers having materials into Dynamic pass box of respective area (Sterility area/MLT and bioassay area. Enter into the sterility area as per sop number HML/052 and enter into the MLT and bioassay area as per sop number.

6.5 Transfer the air sampler in pass box of respective area and sanitize with lint free cloth previously wetted with 0.22µ filtered 70% IPA wherever applicable.

6.6 ENVIRONMENTAL MONITORING BY SETTLE PLATE METHOD:

6.6.1 Transfer the Media plates inside the sterility area through the dynamic pass box, MLT and Bioassay area through dynamic pass box.

6.6.2 Expose the SCA plates at each specified location as per the respective format by opening the upper lid of the Petri plate for 4 hours and write the start time on the first plate and end time on last plate.

6.6.3 After completion of exposure time close the lids of plate in the same sequence used for plates expose and write the start time on the first plate and end time on the last plate and collect all exposed plates. Place the plates in SS container and transfer the plates for incubation and ensure that container should not open during transit and same time shall be transcribed on report.

6.6.4 Incubate all the plates first at 20 to 25^{0}C for NLT 72 hours in inverted position.

6.6.5 After completion of 72 hours at 20 to 25°C then transfer the plates at 30 to 35^{0}C for NLT 48 hours in inverted position. For negative control incubate SCA plate as it is without exposing.

6.6.6 After completion of incubation; observed the microbial count with colony counter from both sides of plates and record in Annexure-I of Microbiological Environmental Monitoring Report of Sterility Area, Annexure-II of Microbiological Environmental Monitoring Report of Microbiological Assay & MLT Room and Annexure-IV Microbiological Environmental Monitoring Report of general microbiology.

6.6.7 Generally the height of Passive air sampling should not be not more than 1 feet below the working height.

6.6.8 Remark: Plates should never be exposed directly on the floor.

6.6.9 If there is a holiday on the day of release/transfer of media plates, take the observation/transfer of media plates on next working day.

6.7 ENVIRONMENTAL MONITORING BY ACTIVE AIR SAMPLING:

6.7.1 Transfer the air sampler in sterility area by dynamic pass box and MLT and bioassay area through dynamic pass box again sanitize with lint free cloth previously wetted with (0.22µ) filtered 70% IPA.

6.7.2 At the location of air sampling open the top lid of pre incubated SCA plate immediately, remove the aluminum foil or butter paper of perforated sieve and set it with head of air sampler over the SCA plate. Vertically put the air sampler at the location and carry out the air sampling of 1000 Liter and write the start time on first plate. Air sampling shall be done from high grade to low grade (first A grade than B grade, C grade so on)

6.7.3 After air sampling, remove the plate from air sampler, close the lid immediately and write the end time on last plate. 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.

6.7.4 After air sampling, place the plates in SS container and transfer the plates to incubation room for incubation.

6.7.5 Incubate all the plates first at 20 to 25^0C for NLT 72 hours in inverted position.

6.7.6 After completion of 72 hours at 20 to 25°C then transfer the plates at 30 to 35^0C for NLT 48 hours in inverted position. For negative control incubate SCA plate as it is without sampling.

6.7.7 After completion of incubation observed the microbial count with colony counter from both sides of plates and record the results as per Annexure-V, Titled **"MPN conversion table for SAS air samplers" and** Annexure-VI, Titled **"MPN conversion table for hi air flow air samplers**

(Himedia)" in annexure-I of Microbiological Environmental Monitoring Report of Sterility Area, annexure-II of Microbiological Environmental Monitoring Report of Microbiological Assay & MLT area and Annexure-IV Microbiological Environmental Monitoring Report of general microbiology.

6.7.8 If there is a holiday on the day of release/transfer of media plates, take the observation/transfer of media plates on next working day.

6.8 SURFACE MONITORING BY CONTACT PLATE METHOD:

6.8.1 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.

6.8.2 During surface sampling press the contact plates containing DNA media with uniform pressure for approximately 5 seconds to make contact of the entire media surface.

6.8.3 Sanitize the sampled area with 0.22µ filtered 70% IPA. Ensure that there is no agar media traces left over the contact surface sampled.

6.8.4 Perform the Monitoring at end of the sterility testing.

6.8.5 After sampling transfer the contact plates to incubation Room for incubation.

6.8.6 Incubate the contact plates at 20 to 25^0C for NLT 72 hours in inverted position.

6.8.7 After completion of 72 hours at 20 to 25°C then transfer the plates at 30 to 35^0C for NLT 48 hours.

6.8.8 After completion of incubation, observed the plates with colony counter and record in Annexure-I of Microbiological Environmental Monitoring Report of Sterility Area.

6.8.9 If there is a holiday on the day of release/transfer of media plates, take the observation/transfer of media plates on next working day.

6.9 PERSONNEL MONITORING BY CONTACT PLATE METHOD:

6.9.1 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.

6.9.2 During personal monitoring press the contact plates containing DNA media with uniform pressure for approximately 5 seconds to make contact of the entire media surface.

6.9.3 90 mm DNA plate shall be used for finger dab monitoring and 55 mm DNA plate shall be used for gown monitoring.

6.9.4 Sanitize the sampled area with 0.22µ filtered 70% IPA. Ensure that there is no agar media traces left over the contact surface sampled.

6.9.5 Perform the Personal Monitoring of gown at end of the environmental monitoring activity and end of the sterility testing during exit in corridor and finger dab monitoring shall be done under LAF (Grade A area) of following location.

- Right hand finger dab (RHFD)
- Left hand finger dab (LHFD)
- Fore head (FH)
- Chest (CH)
- Right Armpit (RA)
- Left Armpit (LA)

6.9.6 After sampling sanitize the sampled area with 0.22µ filtered 70% IPA. Ensure that there is no agar media traces left over the contact surface sampled.

6.9.7 After personal monitoring transfer the contact plates for incubation in incubation room.

6.9.8 Incubate the contact plates at 20 to 25^{0}C for NLT 72 hours followed by 30 to 35^{0}C for NLT 48 hours.

6.9.9 After completion of incubation; observe the plates with colony counter and record in Annexure-I of Microbiological Environmental Monitoring Report of Sterility Area.

6.9.10 If there is a holiday on the day of release/transfer of media plates, take the observation/ transfer of media plates on next working day.

6.10 Acceptance Criteria for Total Aerobic Microbial Count

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

6.10.1 Settle plate (Diameter 90 mm) (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

6.10.2 Active Air Sampling (per meter^3 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

6.10.3 Surface Monitoring by Contact Plate

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

6.10.4 Personnel Monitoring(Finger Monitoring and Gown Monitoring)

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

6.11 FREQUENCY OF ENVIRONMENTAL MONITORING:

Grade	Air Monitoring By Settle Plate	Air Monitoring By Active Air Sampler	Surface Monitoring	Personal monitoring
A	Once in a day/during activity in sterility room	Once in a day/during activity in sterility room	End of activity	End of activity
B	Once in a day/during activity in sterility room	Once in a day/during activity in sterility room	End of activity	During exit
C	Once in week	Once in week/Once in month in general microbiology	NA	NA
D	Once in month	Once in month	NA	NA

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

6.12 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.
Dynamic Pass box	B, C & D	To verify the grade A condition for transferring the material in aseptic area
Dynamic Garment Storage Cabinet	B	To verify the grade A condition for storage sterile garments.
Laminar Air Flow	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.

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 MLT & Bioassay Area	
Annexure-III	Microbiological Environmental Monitoring Report	
Annexure-IV	Microbiological Environmental Monitoring Report of general microbiology	
Annexure-V	MPN conversion table for SAS air Samplers	
Annexure-VI	MPN conversion table for hi air flow air samplers (Himedia)	
Annexure-VII	Microbiological Environmental Monitoring Schedule	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Microbiology
- Master Copy Quality Assurance

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

9.0 REFERENCES:

EU-GMP

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

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

Date of sampling		**Date of Observation**	
Sampled By		**Area Status**	Static / Dynamic
Media Used For Settle plate and Air Sampling	Soybean Casein Digest Agar	**Media Used For Surface and Personnel Monitoring**	Dey Englay Neutralizing Agar
Autoclave Media Ref. No.	SCA/	**Autoclave Media Ref. No.**	DNA/
Plate Exposure Time		**Air Sampler ID:**	
Plate collection Time			
Active Air Sampling Time		**Surface Monitoring Time**	
1st Incubation Temp & Time.	20 – 25^0 for NLT 72 hrs.	**2nd Incubation Temp & Time.**	30 – 35^{0}C for NLT 48 hrs.
Incubator ID No.		**Incubator ID No.**	

AIR MONITORING BY SETTLE PLATE METHOD

S.No.	Area	Location	Plate Code	GRADE	Observation		TAMC
					TBC	TFC	
1	Air lock 01	Near Riser	SP-01	D			
2	Air lock 02	Near Riser	SP-02	C			
3	Air lock 03	Near Riser	SP-03	B			
4	Corridor	Near Entry Riser	SP-04	B			
5		Near Pass box Riser	SP-05	B			
6	Sterility Room	Near entry riser	SP-06	B			
7		Under LAF	SP-07	A			
8	Air lock 04	Near Riser	SP-08	C			
9	Air lock 05	Near Riser	SP-09	D			
10	Cooling zone	Centre of hanging LAF	SP-10	A			
Observed By							

–ve control ……..

Remarks: The environmental monitoring result of settle 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.:**

MONITORING OF AIR BY ACTIVE AIR SAMPLING

S.No.	Area	Location	Plate Code	Grade	Observation		TAMC	Corrected Count (Feller correction)
					TBC	TFC		
1	Air lock 01	Centre of air lock -1	AS -01	D				
2	Air lock 02	Centre of air lock -2	AS -02	C				
3		Dress Cabinet	AS -03	B				
4	Air lock 03	Centre of air lock -3	AS -04	B				
5	Corridor	Centre of corridor	AS -05	B				
6		Dynamic Pass box incubation room	AS -06	B				
7		Dynamic Pass box corridor	AS -07	B				
8		Dynamic Pass box Pre incubation room	AS -08	B				
9	Cooling zone	Centre of room	AS -09	B				
10	Sterility Room	Centre of room	AS -10	B				
11		Under LAF	AS -11	A				
12	Air lock 04	Centre of air lock -4	AS -12	C				
13	Air lock 05	Centre of air lock -5	AS -13	D				
14	Cooling zone	Centre of hanging LAF	AS-14	A				
15	Mobile LAF	Under Mobile LAF	AS-15	A				
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 CONTACT PLATE

S.No.	Area	Location	Plate Code	Grade	Observation		TAMC
					TBC	TFC	
1	Corridor	Wall	SCP-01	B			
2		Floor	SCP-02	B			
3	Cooling zone	Wall	SCP-03	B			
4		Floor	SCP-04	B			
5	Sterility Room	Wall	SCP-05	B			
6		Floor	SCP-06	B			
7		LAF working floor	SCP-07	A			
Observed By							

–ve control ……..

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

PERSONNEL MONITORING

S.No.	Name of Person	Time of Monitoring	Sampling Location											
			RHFD		LHFD		FH		CH		RA		LA	
			TBC	TFC	TBC	TFC	TBC	TFC	TBC	TFC	TBC	TFC	TBC	TFC

Observed by/date:

–ve control ……..

Remarks: The Personal monitoring result 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

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

C	60 cfu	80 cfu	100 cfu
D	120 cfu	160 cfu	200 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

LIMITS FOR PERSONNEL MONITORING BY FINGER DAB AND GOWN MONITORING: 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:

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 & BIOASSAY AREA

Date of sampling		**Date of Observation**	
Sampled By		**Area Status**	Static / Dynamic
Media Used For Settle plate and Air Sampling	Soybean Casein Digest Agar	**Air Sampler ID**	
Autoclave Media Ref. No	SCA/	**Active Air Sampling Time**	
Plate Exposure Time:			
Plate collection Time:			
1st Incubation Temp & Time.	20–25^0 for NLT 72 hrs.	**2nd Incubation Temp & Time.**	30–35^{0}C for NLT 48 hrs.
Incubator ID No.		**Incubator ID No.**	

MONITORING BY SETTLE PLATE METHOD

S.No.	Area	Location	Plate Code	Grade	Observation		TAMC
					TBC	TFC	
1	Air lock 01	Near Riser	SP-01	D			
2	Air lock 02	Near Riser	SP-02	C			
3	Air lock 03	Near Riser	SP-03	C			
4	Corridor	Near riser	SP-04	C			
5	Assay Room	Near entry riser	SP-05	C			
6		Under Biosafety cabinet	SP-06	B			
7	MLT Room	Under LAF	SP-07	B			
8		Near entry riser	SP-08	C			
9	MLT Room 2	Under LAF	SP-09	B			
10		Near riser	SP-10	C			
11	Air lock 04	Near Riser	SP-11	C			
12	Air lock 05	Near Riser	SP-12	D			
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.:**

S.No.	Area	Location	Plate Code	Grade	Observation		TAMC
					TBC	TFC	

–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 SAMPLING

S.No.	Area	Location	Plate Code	Grade	Observation		TAMC	Corrected Count (Feller correction)
					TBC	TFC		
1	Air lock 01	Center of room	AS-01	D				
2	Air lock 02	Center of room	AS-02	C				
3		DGSC	AS-03	B				
4	Air lock 03	Center of room	AS-04	C				
5	Air lock 04	Center of room	AS-05	C				
6	Air lock 05	Center of room	AS-06	D				
7	Assay Room	Center of room	AS-07	C				
8		Under Biosafety Cabinet	AS-08	B				
9	MLT Room	Under LAF	AS-09	B				
10		Center of room	AS-10	C				
11	MLT Room 2	Under LAF	AS-11	B				
12		Dynamic Pass box	AS-12	C				
13		Center of room	AS-13	C				
14	Corridor	Center of corridor	AS-14	C				
15		Dynamic Pass box incubation room	AS-15	C				
Observed By								

–ve control ……

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
B	3 cfu	4 cfu	5 cfu

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

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
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:

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

Date of sampling		**Date of Observation**	
Sampled By		**Area Status**	Static / Dynamic
Media Used For Settle plate and Air Sampling	Soybean Casein Digest Agar	**Air Sampler ID**	
Autoclave Media Ref. No	SCA/	**Active Air Sampling Time**	
Plate Exposure Time:			
Plate collection Time:			
1st Incubation Temp & Time.	20 – 25^0 for NLT 72 hrs.	**2nd Incubation Temp & Time.**	30 – 35^{0}C for NLT 48 hrs.
Incubator ID No.		**Incubator ID No.**	

AIR MONITORING BY SETTLE PLATE METHOD

Grade	Area	Location	Plate Code	Observation		TAMC
				TBC	TFC	

–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 SAMPLING:

Grade	Area	Location	Plate Code	Observation		TAMC	Corrected Count (Feller correction)
				TBC	TFC		

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		TAMC	Corrected Count (Feller correction)
				TBC	TFC		

–ve control ……..

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:

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-IV

MICROBIOLOGICAL ENVIRONMENTAL MONITORING REPORT OF GENERAL MICROBIOLOGY

Date of sampling		**Date of Observation**	
Sampled By		**Area Status**	Static / Dynamic
Media Used For Settle plate, Air Sampling	Soybean Casein Digest Agar	**Autoclave Media Ref. No**	SCA/
Plate Exposure Time:		**Air Sampler ID**	
Plate collection Time:			
Active Air Sampling Time			
1st Incubation Temp & Time	20-25^0 for NLT 72 hrs	**2nd Incubation Temp & Time**	30-35^{0}C for NLT 48 hrs
Incubator ID No.		**Incubator ID No.**	

MONITORING BY SETTLE PLATE METHOD

Grade	Area	Location	Plate Code	Grade	Observation		TAMC
					TFC	TBC	
1	Garments washing room		SP-01	D			
2	Media preparation room	Near Entry Door	SP-02	D			
3	Autoclave room		SP-03	D			
Observed By							

–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 SAMPLING

S.No.	Area	Location	Plate Code	Grade	Observation		TAMC	Corrected Count (Feller correction)
					TFC	TBC		
1	Garments washing room	Center of room	AS-01	D				
2		Under DYP	AS-02	C				
3	Media preparation room	Center of room	AS-03	D				

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.:**

S.No.	Area	Location	Plate Code	Grade	Observation		TAMC	Corrected Count (Feller correction)
					TFC	TBC		
4	Autoclave room	Center of room	AS-04	D				
Observed By								

–ve control ……

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
D	60 cfu	80 cfu	100 cfu

LIMITS FOR ACTIVE AIR SAMPLING METHOD: Total Aerobic Microbial Count

Grade	Alert Level	Action Level	Specified Limits
C	60 cfu	80 cfu	100 cfu
D	120 cfu	160 cfu	200 cfu

Microbiologist:
Date:

Checked By:
Date:

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

ANNEXURE-V
MPN CONVERSION TABLE FOR SAS AIR SAMPLERS

r: number of Colony Forming Units found on the plate
Pr: Most Probable Number of microorganisms

55 mm contact plates – 90 mm Petri Plates - 219 holes 1,00 mm

r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr
1	1	38	42	75	92	112	156	149	249	186	412
2	2	39	43	76	93	113	158	150	252	187	418
3	3	40	44	77	95	114	160	151	255	188	425
4	4	41	45	78	96	115	162	152	258	189	432
5	5	42	46	79	98	116	165	153	261	190	439
6	6	43	48	80	99	117	167	154	265	191	447
7	7	44	49	81	101	118	169	155	268	192	455
8	8	45	50	82	102	119	171	156	271	193	463
9	9	46	51	83	104	120	173	157	275	194	471
10	10	47	53	84	106	121	176	158	278	195	480
11	11	48	54	85	107	122	178	159	282	196	489
12	12	49	55	86	109	123	180	160	286	197	499
13	13	50	57	87	110	124	182	161	289	198	508
14	14	51	58	88	112	125	185	162	293	199	519
15	15	52	59	89	114	126	187	163	297	200	530
16	17	53	60	90	116	127	189	164	301	201	542
17	18	54	62	91	117	128	192	165	305	202	554
18	19	55	63	92	119	129	194	166	309	203	567
19	20	56	64	93	121	130	196	167	313	204	580
20	21	57	66	94	122	131	199	168	317	205	595
21	22	58	67	95	124	132	201	169	322	206	611
22	23	59	69	96	126	133	204	170	326	207	627
23	24	60	70	97	128	134	206	171	331	208	646
24	25	61	71	98	130	135	209	172	335	209	666
25	26	62	73	99	131	136	212	173	340	210	687
26	28	63	74	100	133	137	214	174	344	211	712
27	29	64	76	101	135	138	217	175	349	212	739
28	30	65	77	102	137	139	220	176	354	213	770
29	31	66	78	103	139	140	222	177	359	214	807
30	32	67	80	104	141	141	225	178	365	215	851
31	33	68	81	105	142	142	228	179	370	216	905
32	34	69	83	106	144	143	231	180	375	217	978
33	36	70	84	107	146	144	234	181	381	218	1088
34	37	71	86	108	148	145	237	182	387	219	1307
35	38	72	87	109	150	146	240	183	393		
36	39	73	88	110	152	147	243	184	399		
37	40	74	90	111	154	148	246	185	405		

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

ANNEXURE-VI
MPN CONVERSION TABLE FOR HI AIR FLOW AIR SAMPLERS (HIMEDIA)

R: number of Colony Forming Units on the agar plates after incubation
Pr: Most Probable Number of micro-organisms in the volume of air sampled

r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr
1	3	46	51	91	106	136	171	181	249	226	347	271	480	316	686	361	1170
2	4	47	52	92	108	137	173	182	251	227	350	272	484	317	693	362	1192
3	5	48	54	93	109	138	174	183	253	228	352	273	487	318	699	363	1216
4	6	49	55	94	110	139	176	184	255	229	355	274	491	319	705	364	1242
5	7	50	56	95	112	140	178	185	257	230	358	275	495	320	712	365	1269
6	8	51	57	96	113	141	179	186	259	231	360	276	498	321	718	366	1298
7	9	52	58	97	115	142	181	187	261	232	363	277	502	322	725	367	1330
8	10	53	59	98	116	143	182	188	263	233	365	278	506	323	732	368	1364
9	11	54	60	99	117	144	184	189	265	234	368	279	510	324	738	369	1402
10	12	55	62	100	119	145	186	190	267	235	371	280	514	325	745	370	1444
11	13	56	63	101	120	146	187	191	269	236	373	281	517	326	753	371	1492
12	14	57	64	102	121	147	189	192	271	237	376	282	521	327	760	372	1546
13	15	58	65	103	123	148	190	193	273	238	379	283	525	328	767	373	1609
14	16	59	66	104	124	149	192	194	275	239	381	284	529	329	775	374	1685
15	17	60	68	105	125	150	194	195	277	240	384	285	533	330	783	375	1780
16	18	61	69	106	127	151	195	196	279	241	387	286	537	331	791	376	1907
17	19	62	70	107	128	152	197	197	281	242	390	287	542	332	799	377	2097
18	21	63	71	108	130	153	199	198	283	243	392	288	546	333	807	378	2477
19	22	64	72	109	131	154	200	199	285	244	395	289	550	334	815		
20	23	65	74	110	132	155	202	200	288	245	398	290	554	335	824		
21	24	66	75	111	134	156	204	201	290	246	401	291	559	336	833		
22	25	67	76	112	135	157	206	202	292	247	404	292	563	337	842		
23	26	68	77	113	137	158	207	203	294	248	407	293	567	338	851		
24	27	69	78	114	138	159	209	204	296	249	410	294	572	339	861		
25	28	70	80	115	140	160	211	205	298	250	413	295	576	340	871		
26	29	71	81	116	141	161	213	206	301	251	415	296	581	341	881		
27	30	72	82	117	143	162	214	207	303	252	418	297	586	342	891		
28	31	73	83	118	144	163	216	208	305	253	421	298	590	343	901		
29	32	74	85	119	145	164	218	209	307	254	425	299	595	344	912		
30	33	75	86	120	147	165	220	210	310	255	428	300	600	345	923		
31	34	76	87	121	148	166	221	211	312	256	431	301	605	346	935		
32	36	77	88	122	150	167	223	212	314	257	434	302	610	347	947		
33	37	78	90	123	151	168	225	213	316	258	437	303	615	348	959		
34	38	79	91	124	153	169	227	214	319	259	440	304	620	349	972		
35	39	80	92	125	154	170	229	215	321	260	443	305	625	350	985		
36	40	81	94	126	156	171	230	216	323	261	447	306	630	351	998		
37	41	82	95	127	157	172	232	217	326	262	450	307	635	352	1012		
38	42	83	96	128	159	173	234	218	328	263	453	308	641	353	1027		
39	43	84	97	129	160	174	236	219	330	264	456	309	646	354	1042		
40	44	85	99	130	162	175	238	220	333	265	460	310	652	355	1058		
41	46	86	100	131	163	176	240	221	335	266	463	311	657	356	1075		
42	47	87	101	132	165	177	242	222	338	267	466	312	663	357	1092		

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

43	48	88	103	133	167	178	243	223	340	268	470	313	669	358	1110		
44	49	89	104	134	168	179	245	224	342	269	473	314	674	359	1129		
45	50	90	105	135	170	180	247	225	345	270	477	315	680	360	1149		

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-VII
MICROBIOLOGICAL ENVIRONMENTAL MONITORING SCHEDULE

Area	Section	Grade	Settle Plate Monitoring	Active Air Monitoring	Surface Monitoring	Personal Monitoring
	Sterility area	A	Once in a day/during activity in sterility room	Once in a day/during activity in sterility room	End of activity	End of activity
		B	Once in a day/during activity in sterility room	Once in a day/during activity in sterility room	End of activity	During exit
		C	Every Monday	Every Monday		
		D	First Monday of month	First Monday of month		
	MLT area	B	Once in a day	Once in a day		
		C	Every Monday	Every Monday		
		D	First Monday of month	First Monday of month		
	General Microbiology area	C		First Sunday of month		
		D	First Sunday of month	First Sunday of month		
Perform the environmental monitoring ±2 days of weekly monitoring and ±5 days of monthly monitoring						