



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Microbial Monitoring of Cyto OSD manufacturing facility

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 5

1.0 PURPOSE:

To lay down the procedure for microbial monitoring of Cyto OSD manufacturing facility.

2.0 SCOPE:

The scope is for microbial monitoring of Cyto OSD manufacturing facility by passive air sampling and active air sampling method.

3.0 RESPONSIBILITY:

Microbiology personnels.

4.0 PROCEDURE:

4.1 Pre operational checks for Microbiological area monitoring

4.1.1 Two days pre incubated petriplates shall be used.

4.1.2 Check the plates for any microbial contamination and physical observation of the plates.

4.1.3 Outer surface of the plates shall be santized with lint free mop soaked in filtered disinfectant.

4.1.4 Check the expiry / Use before date of the media (which ever applicable).

4.1.5 Inner and outer surface of SS containers shall be santized with lint free mop soaked in filtered disinfectant.

4.1.6 Check the cleaning status of the area where plates are to be exposed.

4.2 PRECAUTIONS TO BE TAKEN DURING AREA MONITORING

4.2.1 Expose and collect the plate in such a way to avoid personnel interference.

4.2.2 Open the lid in such a way that fingers does not touch the surface of the media.

4.2.3 Do not lean on plate while exposing and collecting the plate.



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4.3 MICROBIOLOGICAL ENVIRONMENTAL MONITORING SHALL BE CARRIED OUT BY TWO METHODS

- **Passive air sampling (settle plate) method**
- **Active air sampling method**

4.3.1 PASSIVE AIR SAMPLING (SETTLE PLATE METHOD)

Procedure

- 4.3.1.1 Prepare the Soyabean casein digest agar plates as per SOP “Procedure for Storage and Preparation of Microbiological Culture Media” SOP.
- 4.3.1.2 Aseptically check the pre-incubated plates for any evidence of microbiological contamination under laminar airflow.
- 4.3.1.3 Discard the plates having any microbiological growth.
- 4.3.1.4 Sanitize the external surface of the petriplates with the help of lint free sterile mop soaked in filtered disinfectant.
- 4.3.1.5 Mark the petriplates with the following details.

For negative control plate	For all the other plates
Media lot No	Name of the location
Date of use	Date of sampling
Used by	

- 4.3.1.6 Wrap the required number of petriplates with sanitized aluminum foil and keep the wrapped plates in a sanitized SS container, close the lid of the SS container.
- 4.3.1.7 Carry the container and enter the respective area as per the respective areas Entry Exit procedure.
- 4.3.1.8 Withdraw the plates from SS containers and take the petriplates to the location to be monitored. As per Appendix – I



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4.3.1.9 Place the petriplates on the plate exposure stands and remove the upper lid of the petriplates and keep it in inverted position on resting stand.

(**Note:** Inclined petriplate stand in front of riser and straight petriplates stand at all other location) if there is no stand available expose the plates on floor at the specified location

4.3.1.10 Expose the plates at all the locations for 4 hours at the locations mentioned in Appendix – I.

4.3.1.11 After completion of 4 hours of the plate exposure, close the petriplate with lid.

4.3.1.12 Collect all the exposed plates in the S.S. containers and transfer the plates to microbiology laboratory incubators / walk in-incubators for incubation.

4.3.1.13 Incubate all the exposed plates in inverted position at $32.5 \pm 2.5^{\circ}\text{C}$ for 5 days. (Keep each set not more than 10 plates in Stack)

4.3.1.14 After incubation observe and count the number of colonies on the colony counter or in the light source with the help of marker.

4.3.1.15 Note down the observation in Annexure –I.

4.3.1.16 If the counts are more than the limits, follow the SOP. Handling of out of limits results in environmental monitoring and water analysis SOP.

Frequency of Monitoring

Once in 15 days.

Note: Whenever there is no production activity monitoring shall be performed before / concurrent with the batch activity.

Acceptance criteria

Limit: Action: 100 CFU / plate

4.3.2 ACTIVE AIR SAMPLING

Procedure

4.3.2.1 Proceed all the steps as mentioned in point No. 4.4.1.1 to 4.4.1.7

4.3.2.2 Withdraw the plates from the container and take the petriplates to the location to be monitored.



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- 4.3.2.3 Place the petriplates on the active air sampler and operate the instrument as per SOP “Procedure for Operation of Air samplers”.
- 4.3.2.4 Take the instrument to the location where the air is to be sampled, hold it with the plate facing at the required working height.
- 4.3.2.5 Perform air sampling at the locations as mentioned in Appendix-I
- 4.3.2.6 Sample the air from each location about 1000 liter.
- 4.3.2.7 Mark the petriplates with the following details,

For negative control plate	For all the other plates
Media lot No	Name of the location
Date of use	Date of sampling
Used by	

- 4.3.2.8 Collect the petriplates in the S.S. container and transfer the sampled plates to microbiology laboratory incubators / walk in-incubators for incubation.
- 4.3.2.9 Proceed all the steps as mentioned in point Nos 4.4.1.13 to 4.4.1.14
- 4.3.2.10 Note down the observation in the format attached as Annexure –II.

Frequency of Monitoring

Once in 15 days.

Note: Whenever there is no production activity monitoring shall be performed before/ incuncurent with the batch activity.

Acceptance criteria

Limit: Action: 200 CFU / plate.



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5.0 ABBREVIATIONS AND DEFINITIONS

SOP : Standard Operating Procedure

QCM : Quality Control Microbiology

QAD : Quality Assurance Department

Rev. : Revision

No. : Number

Settle Plate: This method is still widely used as a simple and inexpensive way to qualitatively assess the environments over prolonged exposure time.

6.0 REFERENCE DOCUMENTS

SOP: Procedure for Operation of Air samplers

SOP: Procedure for Storage and Preparation of microbiological Culture Media

SOP: Handling of out of trend results in environmental monitoring and water analysis.

SOP: Operation and Cleaning of Air Sampler SAS 180 L

USP chapter No.<61> Microbiological examination of non sterile products

USP chapter No.<1116> Microbiological evaluation of clean rooms and other controlled environments

7.0 ANNEXURE / ATTACHMENTS

Appendix-I: Layout of environmental monitoring.

Annexure I: Form 2 – Passive air sampling (Settle Plate) Cyto OSD.

Annexure II: Form 3 – Active air sampling Cyto OSD.

8.0 REVISION LOG

Revision Number	Effective Date	Reason for Revision