



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Transferring of Environment Monitoring aids From Microbiology Laboratory to Production Areas

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 3

1.0 OBJECTIVE

To lay down procedure for transferring Environment monitoring aids from Microbiology laboratory to production area.

2.0 SCOPE

This SOP is applicable for manufacturing.

3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE

4.1 Transferring media plates for passive air sampling

- 4.1.1 Prepare media plates as per SOP.
- 4.1.2 After solidification transfer them to the incubator room through dynamic pass box for preincubation.
- 4.1.3 After pre incubation take out the plates as per requirement and transfer them in the MLT LAF through dynamic pass box.
- 4.1.4 Surface sanitize the plates with 70% IPA or any other approved disinfectant under LAF.
- 4.1.5 Label the plates with the details as given in per SOP.
- 4.1.6 Double wrap the plates with sterilized aluminium foil.
- 4.1.7 Plates to be expose in grade A, B, C and D area to be wrap separately.
- 4.1.8 Transfer the double wrapped plates in sanitized SS container.
- 4.1.9 Transfer SS container in the pass box of production area.
- 4.1.10 Enter the production area as per entry exit procedure and take out the SS container from the pass box.
- 4.1.11 Transfer this container to the dynamic pass box of change room - 2 of bulk mfg -1, having opening in sterile area. Follow the entry exit procedure of the area.
- 4.1.12 Enter in the sterile corridor by following the entry exit procedure of the area.
- 4.1.13 Open the pass box and surfaces sanitize the SS container before opening.



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4.1.14 Take out the plates from the container and do the environment monitoring as per SOP.

4.2 Transferring contact plates for surface monitoring and personnel monitoring

4.2.1 Prepare and preincubate the contact plates as per SOP.

4.2.2 To transfer them in the production area and do monitoring follow step 4.1.3 to 4.1.16.

4.3 Transferring media cassettes for air sampling

4.3.1 Take out a packet of media cassettes containing 10 cassettes per packet.

4.3.2 Transfer this packet in a sanitized SS container.

4.3.3 Transfer this container to the pass box of production area.

4.3.4 To transfer plates inside the production area follow step 4.1.11 to 4.1.16.

4.3.5 After sanitizing the container in the sterile area surface sanitize the packet cover.

4.3.6 With the help of sterile blade cut the outer cover of the packet and take out the plates, wrapped in second sterile layer.

4.3.7 Take this packet to the sampling location cut it with the help of a sterile blade take out a cassette and do regular monitoring as per SOP.

4.4 Transferring swabs for surface monitoring

4.4.1 Transferring ready to use sterile swabs -

4.4.1.1 Transfer required number of swab in the LAF.

4.4.1.2 Surface sanitizes the individual swab.

4.4.1.3 Double wrap the swabs in sterilized aluminium foil.

4.4.1.4 Transfer these wrapped packets in ss container and transfer this container to the production pass box.

4.4.1.5 To take out the swabs for monitoring follow step 4.1.11 to 4.1.15.

4.4.2 Transferring non sterile swabs -

4.4.2.1 Transfer required number of non-sterile swabs in the LAF.

4.4.2.2 Prepare the swabs as per SOP.

4.4.2.3 Double wrap the swabs in butter paper.

4.4.2.4 Sterilize them in an autoclave.



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4.4.2.5 Transfer these sterilized wrapped packets in ss container and transfer the container to the production pass box.

4.4.2.6 To take out the swabs for monitoring follow step 4.1.11 to 4.1.15.

5.0 SAFETY & PRECAUTIONS

Not applicable.

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

No. : Number

LAF : Laminar Air Flow

MLT : Microbial Limit Test

QC : Quality Control

% : Percentage

IPA : Isopropyl Alcohol

SS : Stainless Steel

9.0 ANNEXURES

Not applicable.