



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Operation of Millipore M Air T Air Sampler

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 Objective

To lay down a procedure for Operating of Millipore M Air T Air Sampler.

2.0 Scope

This Standard Operating Procedure is applicable for formulation plant.

3.0 Responsibility

Executive/Officer-Microbiology : Responsible for following the Operating Procedure of Millipore M Air T Air Sampler.

Head - QC/Designee : Shall be responsible for the compliance of SOP.

4.0 Abbreviations and Definitions

QC	:	Quality Control
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
IPA	:	Isopropyl Alcohol
SCDA	:	Soyabean Casein Digest Agar
GPT	:	Growth Promotion Test
SS	:	Stainless Steel
CFU	:	Colony Forming Unit
psi	:	Pound Per Square Inch

5.0 Procedure

- 5.1 Sterilize the Stainless steel impaction head assembly by autoclaving at 121°C for 15 minutes at 15psi pressure in Microbiology Laboratory.
- 5.2 Disinfect the whole body of the air sampler by mopping with 0.45µ filtered 70% IPA.
- 5.3 Microbiologist should follow the gowning procedure applicable in the area where the sampling shall be done and then wearer hand gloves rinsed with 0.45µ filtered 70% IPA before handling the Air Sampler.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Operation of Millipore M Air T Air Sampler

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

- 5.4 Sample the air at each specified locations of area as per the sampling plan laid down as per the Annexure-1.
- 5.5 Transfer the pre filled media plates or prepared agar, pre incubated media plate as well as the Air Sampler to the sampling location.
- 5.6 Growth promotion test of pre filled SCDA media air sampling cassette or prepared agar pre incubated media plate should be done before subjecting it for air sampling as per SOP for GPT.
- 5.7 Set the Volume of air to be sampled to 1000 liters and then place either SCDA medium pre filled or prepared agar pre incubated media plate on the plate holder of the instrument. Close the agar plate with sterilized perforated stainless steel head adapter immediately; adopting least exposure to the environment.
- 5.8 Start air sampling by pressing twice the start key present on the operation panel of the equipment.
- 5.9 After completion of air sampling; remove the plate and close the lid of the plate immediately. Ensure similar sampling procedure to be followed for all the sampling points.
- 5.10 After sampling at each location, mop the SS sieve with the disinfectant mop provided along with the equipment and then proceed for next location sampling taking care in order to prevent contamination of the sieve.
- 5.11 Place all the Air sampled plates in a clean, 0.45 μ filtered 70% IPA mopped SS container with lid and transfer the SS Container to the Microbiology Laboratory.
- 5.12 Incubate all the plates first at 30 - 35°C for 48 hours and later at 20 - 25°C for 72 hours.
- 5.13 After completion of incubation count the number of colonies and report the number of cfu per cubic meter.
- 5.14 Record all the observations properly in the format of Compressed Air Monitoring Report as per Annexure-1.
- 5.15 Discard all the plates along with media after autoclaving properly as per the SOP for Disposal of used Microbiological Culture and Media.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Operation of Millipore M Air T Air Sampler

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

6.0 Forms and Records

6.1 Compressed Air Monitoring Report for Viable Microbial Counts: Annexure-1

7.0 Distribution

7.1 Master Copy : Documentation Cell (Quality Assurance)

7.2 Controlled Copies: Quality Control, Quality Assurance

8.0 History

Date	Revision Number	Reason for Revision