



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Operation of Microbial Air Sampler	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE

1.1 To describe the procedure for Operation of Microbial Air Sampler Climet CL95.

2.0 SCOPE

2.1 This procedure is applicable for Microbiology Laboratory, Production and Warehouse.

3.0 RESPONSIBILITY

3.1 Microbiologist is responsible for operation of microbial air sampler.

4.0 ACCOUNTABILITY

4.1 Head Microbiology

5.0 EHS CONSIDERATIONS

5.1 Handle the microbial air sampler carefully.

5.2 Disinfect hands regularly while sampling.

5.3 Switch 'OFF' the microbial air sampler after completion of sampling.

6.0 PROCEDURE

6.1 Transportation of Microbial Air Sampler to Production Area:

6.1.1 Wipe the outer surface of the sampler with 70% IPA and then pack it into a sterile poly bag and the mouth of bag with an elastic band.

6.1.2 Take the sieve of the sampler which is wrapped in paper and sterilized and pack it with the sampler.

6.1.3 Take the required number of SCDA media plates which are pre-incubated and having no growth in the SS Petri plate carrier box.

6.1.4 Transfer the poly bag and plates into the pass box to container sealing room.

6.1.5 Open the poly bag and take out the sampler and also Petri plate rack, then close the door of the pass box and switch on the UV for 30 minutes.

6.1.6 Enter in to aseptic area as per entry exit procedure of the aseptic area.



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6.2 Operation of Microbial Air Sampler:

- 6.2.1 Take out the sampler, sieve and SCDA media plates from the pass box.
- 6.2.2 Go to the location of sampling point; fix the media plate onto the head of sampler.
- 6.2.3 Open the plate which is fitted in the sampler and cover it with the sterile sieve and tighten by rotating clockwise.
- 6.2.4 Switch on the air sampler by pressing the power button from the front panel.
- 6.2.5 Now press the “Start” button from the display.
- 6.2.6 Sampler will start sampling and display will show the sampling progress status.
- 6.2.7 Take a sample of 1000 liter per sampling point in 10 minutes at a sampling rate of 100 liter per minute.



- 6.2.8 After sampling the sampler beeps indicating the finishing of sampling.
- 6.2.9 Take out the media plate by the head of air sampler and close the plate.
- 6.2.10 Take the all samples from sampling points following the same procedure.
- 6.2.11 Sample should be done from critical to less critical zone.



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- 6.2.12 Wipe the sampler sieve with 70% IPA after one sample is over and dry it completely by running empty i.e. without culture media plate.
- 6.2.13 After sampling all points transfer the sampler, sieve and SCDA media plates to Microbiology department through pass box.
- 6.2.14 Incubate the plates at 20-25°C for 72 hours and 30-35°C for 48 hours and record the result as per environment monitoring SOP.
- 6.2.15 Recharge the battery of air sampler whenever required.

7.0 DEFINITIONS AND ABBREVIATIONS

- 7.1 SCDA – Soybean casein digest agar.
- 7.2 UV- Ultraviolet
- 7.3 IPA – Iso-propyl Alcohol
- 7.4 °C – Degree centigrade
- 7.5 SS – Stainless Steel

8.0 REFERENCE

- 8.1 NA

9.0 ANNEXURES

- 9.1 NA

10.0 DISTRIBUTION DETAILS

- 10.1 Controlled copy of this SOP shall be distributed to Quality Assurance, Microbiology and Production department.

11.0 REVISION HISTORY

Supersedes SOP No.	Change Control No.	Reason for revision