



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Air born Particle Counter

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 cleaning, calibration and operation of Air born particle counter.

2.0 SCOPE:

This SOP is applicable for all the air born particle counters, Model - Laser - II used in manufacturing.

3.0 RESPONSIBILITY:

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE:

4.1 Operation

4.1.1 Connect the plug of the instrument the power supply and switch 'ON' the mains.

4.1.2 Switch 'ON' the instrument by pressing the ON/OFF switch, provided at the front and charge.

4.1.3 After charging, place the instrument in the area to be sampled and switch ON.

4.1.4 Mount zero count filter on the instrument and start instrument by pressing start button.

4.1.5 Ensure that all ZERO value is observed for all sized selected. If not then repeat the procedure until ZERO COUNT is observed.

4.1.6 Remove zero count filter and connect the adapter onto the free end of the tubing & fit the sample probe over the adapter inlet.

4.1.7 If needed connect the T/RH sensor.

4.1.7.1 To connect the T /RH sensor, do not twist the sensor.

4.1.7.2 Position the sensor above the base so that the red dots are aligned.

4.1.7.3 Carefully push the sensor straight down into the connector. You shall hear a slight click sound as it locks into place.



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4.1.8 When disconnecting the T/RH sensor, you must lift up gently on the cylindrical sleeve (near the base of the sensor) to release the clips that hold the sensor in place.

4.1.9 Do not twist or pull up on the sensor in your attempt to remove it.

4.1.9.1 To disconnect the T/RH sensor, grasp the cylindrical sleeve at the base of the sensor and pull up.

4.1.9.2 The sleeve will move upward as the clip tabs release from the base.

4.1.9.3 Continue to lift up on the sensor sleeve. The sensor will disengage from the base of the unit.

4.1.10 Enter into sampling setup screen by pressing the sample setup key.

4.1.11 The location field allow operator to include the location name.

4.1.12 Select the sampling mode i.e. either for a designated time or a designated volume.

4.1.13 If required give delay time to run the pump before actual sampling.

4.1.14 Also feed inter sample delay, number of replicates to be sampled and units for sampling.

4.1.15 If desired enable auto printing to print the report after each sampling.

4.1.16 Exit the setup screen by pressing the topmost key to return to main menu screen.

4.1.17 To collect the sample data press green start button on the control panel. After initial delay countdown sampling will start.

4.1.18 Operator can stop the sampling by pressing red stop key on the control panel.

4.1.19 At the end of sampling pump would automatically turn itself OFF and results would be displayed on the screen.

4.1.20 If auto print is activated then the report would be printed automatically. If not then the print the report by pressing the print soft key on the control panel.

4.1.21 In case of in error in the sampling it will be indicated on the report by printing INVALID in the report.

4.1.22 Error free sampling is indicated by printing VALID in the report.

4.2 Calibration

4.2.1 Calibrate the air born particle counter once in a year.

4.2.2 Get the instrument calibrated by the authorized distributor of particle measuring system.



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4.3 Cleaning

- 4.3.1 Ensure that the power supply to the air particle counter is switched off and main cord is removed from the supply.
- 4.3.2 Clean the air particle counter with a clean dry soft cloth everyday.
- 4.3.3 A cloth wetted in disinfectant solution may be used occasionally.

5.0 SAFETY & PRECAUTIONS:

Always use zero count filter before routine use.

6.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date
00	First Issue	-----

7.0 REFERENCES:

Not applicable.

8.0 ABBREVIATIONS:

- SOP : Standard Operating Procedure
- T : Temperature
- RH : Relative Humidity

9.0 ANNEXURES:

Not applicable