



Biopharmaceutical Development Program

Standard Operating Procedure

Title: **Operation of the SMA P200-03 MicroPortable Air Sampler**

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1.0 Purpose

This SOP provides instruction for the aseptic operation of the SMA 200-03 portable air sampling instrument. This equipment is used for detection of viable particles during environmental monitoring of aseptic operation.

2.0 Scope

Biopharmaceutical Development Program (BOP) personnel will perform this procedure.

3.0 Authority and Responsibility

- 3.1 The Director, Process Analytics/Quality Control (PA/QC) has the authority to define this procedure.
- 3.2 PA/QC is responsible for assignment of this procedure, training of personnel and for documenting this training to Biopharmaceutical Quality Assurance (BOA).
- 3.3 PA/QC is responsible for reviewing the data and documentation of the results of this procedure.

4.0 Materials

- 4.1 VAI SMA P-200-03 Air Sampler with sampling head.
- 4.2 TSA Plates, BDP PN 10006.
- 4.3 Sterile gloves.
- 4.4 Sterile wipes, BDP PN 20315.
- 4.5 Septihol, BDP PN 30129 or BDP approved equivalent.

5.0 Setting of Preset (PST) Volumes

NOTE: The volume of air to be sampled is pre-programmed into the SMA P-200-03. Two volumes (PST 1 = 999999, and PST 2 is open for future use) can be preset. To program (or change) the PST values, follow steps 5.1 to 5.7 (see Attachment 1). The pre-set value of 999999 allows the unit to run in a continuous sampling mode.

- 5.1 Turn the power on by pushing the red button upward to the on position.
- 5.2 To program the first PST 1, push the toggle switch up to the PST 1 position. Push the PST key on the face plate so that the display screen reads RST: PST 1.
- 5.3 Push the PST key on the face plate so that the display screen reads RST: PST 1.
- 5.4 Press the arrow button on the counter. The first display number will be blinking to activate the volume change mode.
- 5.5 Press the arrow key to get to the desired numeric position, and use the + and - keys to adjust the numbers accordingly.
- 5.6 When the correct value is reached, press the ENT key on the face plate and the volume is set and stored in the PST 1 memory.
- 5.7 Repeat steps 5.2 - 5.7 changing "PST 1" to "PST 2" to program PST 2 (see Attachment1).

6.0 Procedure

- 6.1 Technicians performing this assay must wear gloves and use proper aseptic technique to avoid contamination of the TSA plates or the air sampler.
- 6.2 Spray gloved hands and the instrument with 70% ethanol or suitable decontamination agent. Clean instrument with a sterile wipe moistened with 70% ethanol and allow the instrument to dry.
- 6.3 There are 2 toggle switches on the SMA P-200-03 Air Sampler. One is used to set the air flow rate, the other to select the air volume to be sampled. For routine operation, set the flow rate to 1 CFM (i.e., move the toggle switch for the sample rate to the left - see Attachment 1). To select a flow rate of 5 CFM, move the toggle button to the right. This sets the rate that the unit draws air over the plate.
- 6.4 Move the other toggle switch up to select PST 1 or down to select PST 2 preset volume values (see Attachment 1).

NOTE: Both toggle switches need to be set on values and not in the middle or the instrument will not turn on.
- 6.5 Turn the power on by pushing the red button upward.
- 6.6 Place sampler in a suitable location for monitoring of airborne viables.
- 6.7 Verify that the SMA sampling head with metal tube has been autoclaved prior to use.

- 6.8 Unwrap SMA sampling head from the blue autoclave wrapping and place onto the unit. Verify that the sampling head fits correctly into the groove around the unit's top surface.
- 6.9 Lift the SMA sampling head slightly off the sampler and place a properly-labeled, TSA plate into the unit.
- 6.10 Check that the flow rate and volume switches are set appropriately and press the start/run button. A green light indicates the sample is running. After the collection cycle, the sample is finished and the green light will turn off. For continuous monitoring it will be necessary for the operator to manually turn off the sampler prior to removing the TSA plate.

NOTE: TSA plates should not be exposed for more than 3 hours before replacing with a fresh plate to avoid drying out the agar.

- 6.11 Aseptically remove the SMA sampling head, retrieve the media plate and replace the lid on the plate.
- 6.12 If additional sampling is needed, place a new media plate into the sampler and repeat steps 6.6 to 6.12 as needed for each sample point.
- 6.13 When all samples are collected, clean the SMA lid with Septihol, BDP PN 30129, and sampling head with Septihol.
- 6.14 Submit the sample plates to the PA/QC microbiology lab for incubation. TSA plates are inverted and incubated at 20° – 25°C for 120 – 168 hours and then incubated at 30°-35°C for 60-76 hours.
- 6.15 Count the colonies on each plate and record the information on appropriate forms.
- 6.16 After incubation, retain TSA plates that show growth of organisms in the PA/QC laboratory at 2° - 8°C for 3 months in case colony speciation is requested. . Reference **SOP 22315 - Environmental Monitoring in BDP GMP Areas at the ATRF**, for documenting and reviewing results.

7.0 Preventative Maintenance

- 7.1 When finished using the instrument, attach the power adapter to the instrument and plug it into an outlet in order to charge the battery. The power adapter will indicate when the battery is charged.
- 7.2 Maintenance and calibration of the unit are to be performed yearly, as scheduled by BQA Engineering.

8.0 Documentation

- 8.1 Record use, calibration, autoclave information (load # and date) for the sampling head and preventative maintenance in the equipment logbook.

9.0 References and Related Documents

- 9.1 **SOP 22315** *Environmental Monitoring in BDP GMP Areas at the ATRF*
- 9.2 SMA MicroPortable Operators Manual

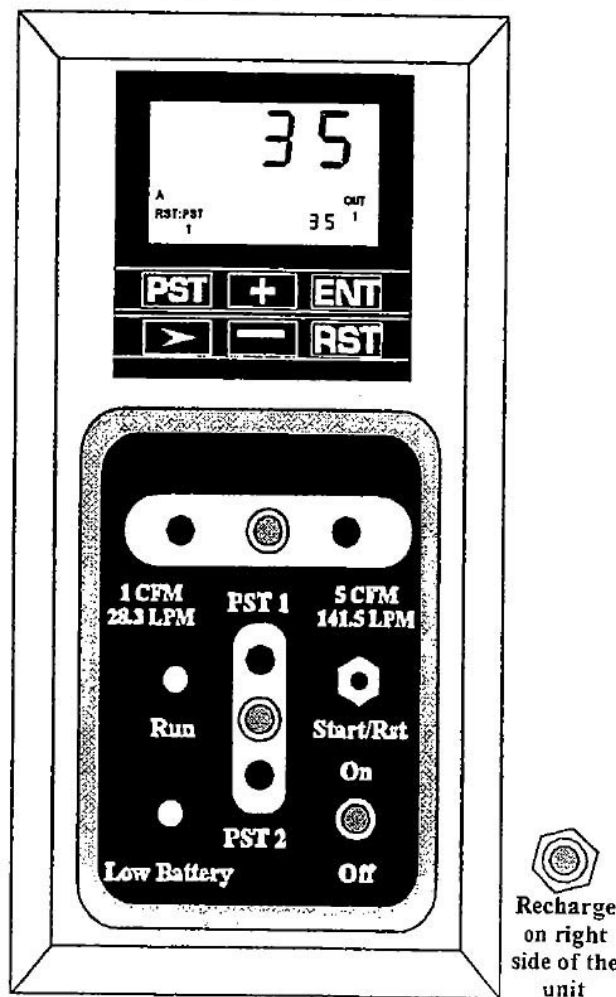
10.0 Attachments

- 10.1 **Attachment 1** Drawing of Unit Showing the Control Panel
- 10.2 **Attachment 2** Picture of SMA 200-03 Instrument

Attachment 1

Picture of SMA 200-03 Instrument

SMA-P200-03



Attachment 2
Picture of SMA 200-03 Instrument

