



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Operation of the SMA P200-03 MicroPortable Air Sampler
SOP Number: 22312
Revision: 03

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1. 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 continuous environmental monitoring of aseptic operation.

2. SCOPE

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

3. RESPONSIBILITIES

3.1 Director / Process Analytics/Quality Control (PA/QC)

- Defines procedure

3.2 PA/QC

- Assigns procedure
- Trains personnel
- Reviews data

3.3 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight

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4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
10006	TSA Plates	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
20315	Sterile wipes	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
30129	Septihol 70% Isopropanol solution	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Various	Sterile gloves	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

5. EQUIPMENT

- VAI SMA P-200-03 Air Sampler with sampling head

6. 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 6.1 to 6.7 (see **Attachment 1**). The pre-set value of 999999 allows the unit to run in a continuous sampling mode.

- 6.1 Turn the power on by pushing the red button upward to the on position.
- 6.2 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.
- 6.3 Push the PST key on the face plate so that the display screen reads RST: PST 1.
- 6.4 Press the arrow button on the counter. The first display number will be blinking to activate the volume change mode.
- 6.5 Press the arrow key to get to the desired numeric position, and use the + and - keys to adjust the numbers accordingly.
- 6.6 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.
- 6.7 Repeat steps 6.2 - 6.7 changing "PST 1" to "PST 2" to program PST 2 (see **Attachment 1**).

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7. PROCEDURE

- 7.1 Technicians performing this assay must wear gloves and use proper aseptic technique to avoid contamination of the TSA plates or the air sampler.
 - 7.2 The sampling head with metal tube may be fitted with a length of silicone tubing up to 18 inches secured on the tube and should be autoclaved in advance of the process. Autoclaved components do not require further sanitization.
 - 7.3 Spray gloved hands and non-sensitive parts of the instrument with 70% Isopropanol, wipe other areas with a sterile wipe moistened with 70% Isopropanol and allow the instrument to dry.
 - 7.4 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.
 - 7.5 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.
- 7.6 Turn the power on by pushing the red button upward.
 - 7.7 Place sampler in a suitable location for monitoring of airborne viables.
 - 7.8 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.
 - 7.9 Lift the SMA sampling head slightly off the sampler and place a labeled, TSA plate into the unit.
 - 7.10 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.

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- 7.11 Aseptically remove the SMA sampling head, retrieve the media plate and replace the lid on the plate.
- 7.12 If additional sampling is needed, place a new media plate into the sampler and repeat steps 7.6 to 7.12 as needed for each sample point.
- 7.13 When all samples are collected, clean the SMA lid with Septihol, BDP PN 30129, and sampling head with Septihol.
- 7.14 Submit the sample plates to the PA/QC microbiology lab for incubation. TSA plates are incubated per **SOP 22315 Environmental Monitoring in BDP GMP Areas** [REDACTED].
- 7.15 Count the colonies on each plate and record the information on appropriate forms.
- 7.16 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**, for documenting and reviewing results.

8. PREVENTATIVE MAINTENANCE

- 8.1 When finished using the instrument, attach the power adapter to the instrument and plug it into an outlet to charge the battery. The power adapter will indicate when the battery is charged.
- 8.2 Maintenance and calibration of the unit are to be performed yearly, as scheduled by Facility Management.

9. DOCUMENTATION AND RECORDS

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

10. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22315	Environmental Monitoring in BDP GMP Areas [REDACTED]
N/A	SMA MicroPortable Operators Manual



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11. ATTACHMENTS

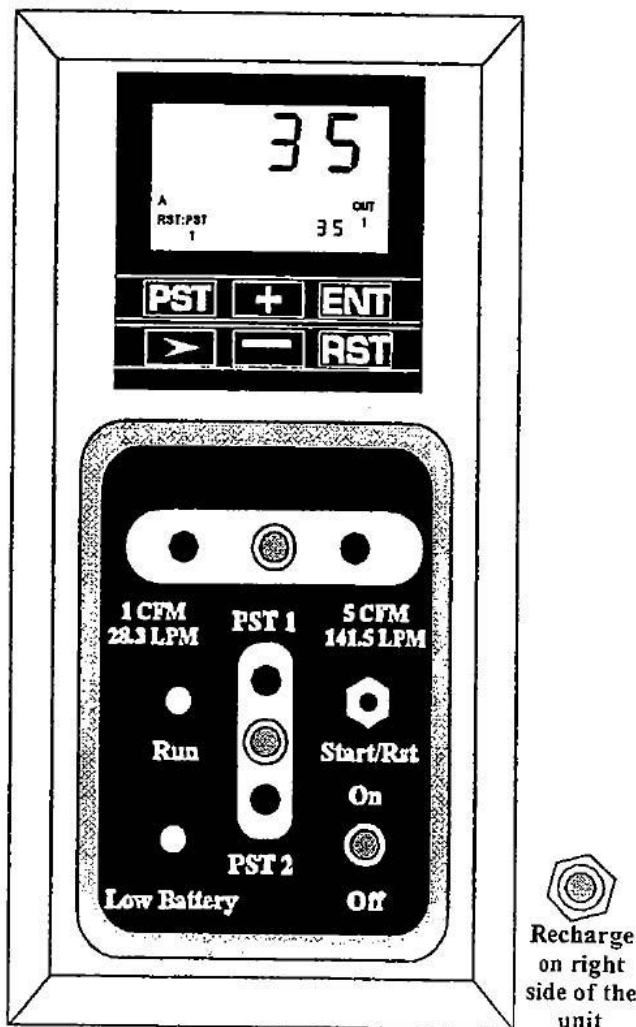
Attachment 1 Drawing of Unit Showing the Control Panel

Attachment 2 Picture of SMA 200-03 Instrument

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Attachment 1 Drawing of Unit Showing the Control Panel

SMA-P200-03



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Attachment 2 Picture of SMA 200-03 Instrument

