



Standard Operating Procedure

Biopharmaceutical Development Program

Title: Operation of the SMA-CA200 Pressurized Air Sampler

SOP Number: 22307

Revision Number: 03

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Approval/Date: _____

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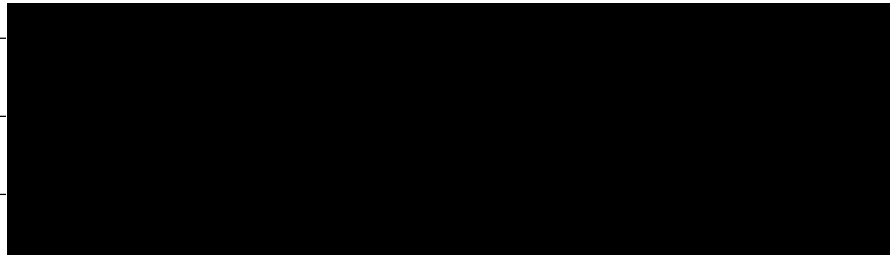


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1.0 Purpose

This procedure describes the operation of the SMA-CA200 Pressurized Air Sampler for measuring viable particles in pressurized process gases, air, and gas cylinders.

2.0 Scope

This procedure will be performed by Process Analytics/Quality Control (PA/QA) personnel when sampling compressed gases and air in use at the Biopharmaceutical Development Program (BDP).

3.0 Authority and Responsibility

- 3.1 The Director, Process Analytics/Quality Control (PA/QA) has the authority to define this procedure.
- 3.2 The Director, and PA/QA are responsible for training personnel in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).

- 3.3 PA/QA personnel are responsible for the implementation of this procedure.
- 3.4 BQA is responsible for quality oversight of this operation.

4.0 Materials

- 4.1 SMA-CA 200 Pressurized Air Sampler.
- 4.2 TSA Plates, BDP PN 10006 or BDP approved equivalent.
- 4.3 Fittings to connect gas to air sampler.

5.0 Procedure

- 5.1 Turn the power on by pushing the power switch up.
- 5.2 The low battery light will illuminate if the battery is low.
 - 5.2.1 Plug the battery charger into the wall and make sure that the brown in-line rocker switch is in the '**Off**' position.
 - 5.2.2 Plug the charger into the SMA "**Recharge**" port on the front of the instrument.
 - 5.2.3 Turn the in-line rocker switch to the '**On**' position.
 - 5.2.4 The charger's green or yellow light should illuminate.
 - 5.2.5 The yellow light indicates that the battery is charging and the green light indicates that the battery is fully charged.
- 5.3 Program the timer to the desired sampling duration.
 - 5.3.1 The standard sampling duration should be set to **12.36** minutes. This is based on sampling 0.35m³ at the 1CFM (60CFH) flowrate as described in step 5.11, which is then converted to 1m³ in the results by multiplying colony counts by a factor of 2.86. Other sampling intervals and conversions may be used with BQAE approval and should be noted in the comments of Form 22307-01.
 - 5.3.2 The black **Timer Reset** button must be depressed and held during the entire programming process.
 - 5.3.3 Press the red **P2** button on the timer face. The time will be displayed on the LCD screen.
 - 5.3.4 Press the button directly beneath the digit that is to be changed. The numbers will scroll from 0 to 9 and back to 0. When the desired digit is reached, release the button.
 - 5.3.5 After all the numbers are changed, press the "**E**" button to save the value in the memory.
 - NOTE:** The timer display is shown at a decimal value of 1/100 of a minute. (Ex. A time value of 15 minutes is programmed as 15.00.) The intervals of one minute as decimal values are **_.25** for 15 seconds, **_.50** for 30 seconds, and **_.75** for 45 seconds. (Ex. A time value of 15 minutes and 45 seconds would be programmed as 15.75.)
- 5.4 Connect the gas line to the sample port to be tested through a regulator.
- 5.5 Remove the sampling head by turning the handles counter clockwise to loosen the top from the instrument.
- 5.6 Place a TSA agar plate on the four risers that are attached to the base. Remove the lid.

- 5.7 Replace the top of the sampler making sure that the rubber O-ring is in its groove. Tighten the clamps by turning in a clockwise direction.
- 5.8 Connect the other end of the gas line to the quick-connect fitting located on the top of the instrument.
- 5.9 Turn the gas on making sure that the output pressure does not exceed 100 PSI.
- 5.10 Start the sampling cycle by pushing the **Start/Reset** switch on the front panel.
- 5.11 Turn the rotameter knob counter/clockwise until the float reaches 60 CFH (60CFH = 1 CFM).
- 5.12 The green LED sampling light will flash during the sampling period. When sampling is completed, the red "**Complete**" LED light will illuminate and the green "**Sampling**" LED light will stop flashing.
- 5.13 If activated, the alarm will sound when sampling is complete. Press the alarm **Reset** button to silence the alarm.
- 5.14 Turn off the supply valve on the source of the tested air.
- 5.15 There is a LED light on the top of the instrument that is illuminated when the cap is under pressure. Hold the pressure release button on the front panel until the pressure LED light goes off.
- 5.16 Remove the top of the sampler by unscrewing the clamps. Remove the agar plate and replace the lid.
- 5.17 Turn the power off to conserve the battery. If the instrument is not used for 10 minutes, it will turn off automatically.

6.0 Incubation of TSA Plates

Incubate TSA plates in the inverted position at 20-25°C for 120 – 168 hours and at 30-35°C for 60-76 hours. After the required incubation period, count the number of colonies and record the data on Form 22307-01, SMA-CA200 Pressurized Air Sampler Report.

7.0 Documentation

- 7.1 Document results on Form 22307-01, SMA-CA200 Pressurized Air Sampler Report.
- 7.2 Document maintenance, cleaning, calibration, and usage in the logbook.

8.0 Attachments

- 8.1 **Attachment 1** Form 22307-01, SMA-CA200 Pressurized Air Sampler Report
- 8.2 **Attachment 2** SMA-CA200 Pressurized Air Sampler Diagram

**Attachment 1
Form 22307-01, SMA-CA200 Pressurized Air Sampler Diagram**

NCI-Frederick
Form No.: 22307-02
SOP No.: 22307
Revision 03: OCT 13 2015

SMA-CA200 Pressurized Air Sampler Report

Date: _____

TSA Plate Lot Number/Expiration Date: _____

Equipment	MEF #	Calibration Due Date
SMA-CA200 Air Sampler		
Incubator, 20-25°C		
Incubator, 30-35°C		

20-25°C		30-35°C	
Time/Date In	Time/Date Out	Time/Date In	Time/Date Out

Sample ID	Sample Description	# of Colonies	X 2.86	CFU/m ³
	Negative Control			

Comments: _____

Assay Performed By/Date: _____

Assay Read By/Date: _____

PA Review By/Date: _____

QC# _____

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Initials/Date _____

Attachment 2 SMA-CA200 Pressurized Air Sampler Diagram

