Table of Contents

1.0 Purpose

This procedure provides instructions for use of the MAS-100/MAS-100 VFAir Samplers. This equipment is used for detection of viable particles during environmental monitoring of building air systems.

2.0 Scope

This SOP applies to trained Biopharmaceutical Development Program (BDP) personnel who use the MAS-100 Air Sampler during environmental monitoring of building air systems.

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 training laboratory personnel and documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 Biopharmaceutical Development Program (BDP) personnel are responsible for the performance of this procedure.

3.4 Trained personnel are responsible for reviewing the data and documentation of the results of this procedure.

3.5 BQA is responsible for quality oversight of this procedure.

4.0 Materials

4.1 MAS-100/MAS-100 VF Air Sampler.

4.2 Tryptic Soy Agar (TSA) Plates, BDP PN 10006, or equivalent.

4.3 Sabouraud Dextrose Agar, BDP PN 10524, or equivalent.

4.4 Gloves.

4.5 Isopropyl Alcohol, BDP PN 30129 or suitable decontaminating agent.

4.6 Sterile wipe, BDP PN 20315, or equivalent.

5.0 MAS-100 Procedure

5.1 Technicians performing this assay must wear gloves and use proper microbiological techniques to avoid contamination of the agar plates.

5.2 Spray gloved hands with isopropyl alcohol.

5.3 Push the “yes” button to activate the MAS-100 Air Sampler.

5.4 Check the dish support jaw settings. Place an agar plate on the dish support. Adjust the 3 jaws with an Allen Key to hold the plate firmly between the jaws to minimize movement.

5.4.1 Open the perforated lid (with dust cover inserted) by smoothly turning to the right.

5.5 Spray the dish support and the perforated lid with isopropyl alcohol or equivalent, and allow to dry.

5.6 To begin sampling, open the perforated lid and place a properly labeled, closed agar plate on top of the dish support and push it between the jaws (readjust the jaws if necessary).

5.7 Remove the agar plate lid and close the perforated lid of the MAS-100 Air Sampler.

5.8 Adjust the position of the sampling head to allow for direct air flow entry.

5.9 The MAS-100 Air Sample volume is set at 350 liters. Press the “Yes” key to accept value.

NOTE: If delayed sampling time or alternative sampling volume is needed refer to the MAS-100 operators’ manual. Should an alternative sample volume be used, record this in the comment section of the appropriate EM form. Return the sample volume to 350 liters.

5.10 Press the “No” key in the “Delay” menu.

5.11 Remove the dust cover and start the collection cycle by pressing the “Yes” key in the “Start” menu.

5.12 After the collection cycle (approximately 3-4 minutes) the red lamp will light up and the total volume of the collection cycle (350 liters) is displayed.

5.13 Spray gloved hands with isopropyl alcohol and open the sampling head. Replace the agar plate lid and remove the plate.

5.14 Press the ”Yes” key and repeat steps 5.5 to 5.12 as needed for all sample points.

5.15 When all samples for a site are complete, clean the perforated lid and dust cover with isopropyl alcohol or equivalent using a sterile wipe.

5.16 Invert the TSA and /or SAB plates, and incubate following **SOP 22315 - *Environmental Monitoring in BDP GMP Areas at the ATRF***.

6.0 MAS-100 VF Procedure

6.1 Technicians performing this assay must wear gloves and use proper microbiological techniques to avoid contamination of the agar plates.

6.2 Spray gloved hands with isopropyl alcohol.

6.3 Press the "►" key for more than two seconds to activate the MAS-100 VF Air Sampler. The unit will show the battery level and the calibration interval/validity.

6.4 Check the dish support jaw settings. Place an agar plate on the dish support. Adjust the 3 jaws with an Allen Key to hold the plate firmly between the jaws to minimize movement.

6.4.1 Open the perforated lid (with dust cover inserted) by smoothly turning to the right.

6.5 Spray the dish support and the perforated lid with isopropyl alcohol or equivalent.

6.6 To begin sampling, open the perforated lid and place a properly labeled, closed agar plate on top of the dish support and push it between the jaws (readjust the jaws if necessary).

6.7 Remove the agar plate lid and close the perforated lid of the MAS-100 VF Air Sampler. If not already, remove the sampler dust cover.

6.8 Adjust the position of the sampling head to allow for direct air flow entry.

6.9 Press the "►" key to enter the sampling volumes menu. Preset 1 is set to 350 liters, press the "►" key again to begin sampling. The unit will beep and a status bar will appear on the screen to show relative progress of the sample.

NOTE: If delayed sampling time or alternative sampling volume is needed refer to the MAS-100 VF operators' manual. Should an alternative sample volume be used, record this in the comment section of the appropriate EM form. Return the sample volume to 350 liters.

6.10 After the collection cycle (approximately 3 ½ minutes) the unit will beep again and the total volume of the collection cycle (350 liters) is displayed.

6.11 Spray gloved hands with isopropyl alcohol and open the sampling head. Replace the agar plate lid and remove the plate.

6.12 Press the "►" key to confirm the cycle and repeat steps 6.5 to 6.10

6.13 When all samples for a site are complete, clean the perforated lid and dust cover with isopropyl alcohol or equivalent using a sterile wipe.

6.14 Invert the TSA and /or SAB plates, and incubate following **SOP 22315 - *Environmental Monitoring in BDP GMP Areas at the ATRF***.

7.0 Documentation

7.1 Record raw data on appropriate environmental monitoring forms and make an entry in the equipment logbook documenting usage.

8.0 References and Related Documents

SOP 22315 *Environmental Monitoring in BDP GMP Areas at the* [redacted]

MAS-100 Operator's Manual.

MAS-100 VF Operator's Manual

9.0 Change Summary

[redacted]