

National Cancer Institute-Frederick, Frederick, MD  Biopharmaceutical Development Program	STANDARD OPERATING PROCEDURE	Effective Date	Procedure Number
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Title: Testing for the Presence of Oil in Compressed Air Using Dräger Tube Aerotest Samplers

Author/Date: [REDACTED]

Approvals/Date: [REDACTED]

SOP Reference: 22313, 22002

Supersedes: Revision 00 and SOP 22943

Purpose: This procedure describes testing for the presence of oil in compressed air distribution systems servicing the Biopharmaceutical Development Program (BDP) for GMP use.

Scope: This SOP applies to Biopharmaceutical Quality Control (BQC) and other personnel who perform this testing, as well as those who review the results from this testing. This SOP applies to both the Aerotest Sampler (single-tube) and the Aerotest Simultan Alpha Sampler (4-tube). Either of the two units may be used to test for the presence of oil in compressed air systems servicing the BDP.

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1.0 Authority and Responsibility

- 1.1 The Director, Biopharmaceutical Quality Control (BQC) has the authority to define this procedure.
- 1.2 Biopharmaceutical Development Program (BDP) Production personnel and BQC personnel are responsible for performing this procedure.
- 1.3 BQC is responsible for training laboratory personnel and documenting this training to Biopharmaceutical Quality Assurance (BQA).
- 1.4 BQC personnel are responsible for the performance of this procedure.
- 1.5 BQC is responsible for reviewing the data and documentation of the results of this procedure.
- 1.6 BQA is responsible for quality oversight of this procedure.

2.0 Materials and Equipment

- 2.1 Aerotest Sampler, BDP MEF #76920 or equivalent.
- 2.2 Aerotest Simultan Alpha Sampler, BDP MEF #90830 or equivalent.
- 2.3 Dräger tubes for oil detection, BDP PN 21573.
- 2.4 Calibrated timer.
- 2.5 Plastic tubing, 2 inch section.
- 2.6 Dräger tube tip opener.
- 2.7 Pressure regulator assembly for Aerotest Sampler.

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3.0 Setup for Aerotest Sampler (if using Aerotest Simultan Alpha Sampler, proceed to Section 4.0)

- 3.1 Attach the blue tube on the Aerotest unit to one side of the pressure gauge assembly sample port and the compressed air source to the other side.
- 3.2 Slowly open the compressed air supply. The supply pressure should be between 30-150 psig.
- 3.3 Turn the attenuator knob counterclockwise until the 2.0 L/min marking on the gauge is in the middle of the silver ball.
- 3.4 Flush the system for at least 3 minutes.
- 3.5 Cut off both ends of the Dräger tube using the tube opener. Insert the tube as far as it will go into the middle hole of the tube holder and turn once or twice. This will score the glass. Push the scored end into the outer hole. The end breaks off and falls into the container.
- 3.6 Insert the tube into the rubber tube holder on the measuring unit and start the timer. The arrow on the tube indicates the direction of flow (i.e., the arrow must point AWAY from the measuring unit).
- 3.7 Allow air to flow through the tube for 3 minutes and 45 seconds using the calibrated timer.
- 3.8 Proceed to Section 5.0.

4.0 Setup and Sample Collection for the Aerotest Simultan Alpha Sampler

- 4.1 Connect the measuring unit to the compressed air supply.
- 4.2 Slowly open the compressed air supply valve. The supply pressure should be between 40-175 psig.
- 4.3 Flush the system for at least 3 minutes.
- 4.4 Set the timer. For [REDACTED] set the timer to 1 minute and 50 seconds. For [REDACTED] set the timer to 1 minute and 10 seconds.

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NOTE: Building 459 uses SSR H – 1F coolant oil and [REDACTED] uses 30-weight non-detergent oil. The compressed air systems employ filtration systems designed to remove oil and oil vapor.

4.5 Cut off both ends of the Dräger tube using the tube opener. Insert the tube as far as it will go into the middle hold of the tube holder and turn once or twice. This will score the glass. Push the scored end into the outer hole. The end breaks off and falls into the container.

4.6 Insert the tube into the rubber tube holder labeled “OIL” on the measuring unit and start the timer. The arrow on the tube indicates the direction of flow (i.e., the arrow must point AWAY from the measuring unit).

4.7 Allow the air to flow through the tube for the specified time from Section 4.4.

4.8 Proceed to Section 5.0.

5.0 Sample Analysis

5.1 Carefully remove the tube out of the tube holder and bend at the point indicated on the tube (between the two dots) to break the internal reagent-filled ampoule.

CAUTION: The ampoule has concentrated sulfuric acid in it.

5.2 Allow the reagent to flow into the outer indication layer to ~ 10 mm (1 cm).

5.3 Wait at least 1 minute 10 seconds before evaluation.

5.4 If no color change occurs, the oil content of the compressed air is < 1.0 mg/m³.

5.5 If the media changes to light beige or yellow, oil has been detected. Perform another sample to confirm the presence of oil. If the second sample confirms oil presence, notify the appropriate parties per ***SOP 22313 – Environmental and Utility Monitoring - Excursions Event Notification and Evaluation***.

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6.0 Documentation

- 6.1 Record the date and time that the sample was collected, the name of the sample port, and the initials of the person taking the sample in the appropriate Aerotest Sampler equipment logbook.
- 6.2 Record all calibration and maintenance activities in the Aerotest Sampler equipment logbook.
- 6.3 Record all results on Form 22927-01 and attach to the QC Test Request Form (22002-01). Submit this form according to **SOP 22002, Request for QC Testing**.

7.0 Maintenance

- 7.1 Because the Aerotest Simultan Alpha Sampler does not contain a flowmeter, appropriate flow must be verified qualitatively using a bubble test. Perform this test at least annually and document in the equipment logbook.
 - 7.1.1 Connect the measuring unit to the compressed air supply.
 - 7.1.2 Slowly open the compressed air supply valve. The supply pressure should be between 40-175 psig.
 - 7.1.3 Plug the bubble test hose into the Dräger tube "OIL" connection on the unit.
 - 7.1.4 Submerge the other end of the bubble test hose into a water-filled container.
 - 7.1.5 Visually check for bubbles. The volumetric flow rate for the measuring unit is verified as appropriate when the ascending bubbles appear as large blisters that are not countable.

8.0 References

- 8.1 Aerotest and Aerotest Simultan Alpha instruction sheets.
- 8.2 Dräger tube (Oil) instruction sheet.

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ATTACHMENT 1

NCI-Frederick
Form No.: 22927-01
SOP No.: 22927
Revision 01:

Dräger Tube Test Report

Date: _____ Building: _____

Dräger Tube Lot #: _____ Expiration Date: _____

Aerotest Sampler MEF # _____ Calibration Done: _____ Calibration Due: _____

Timer ID # _____ Calibration Done: _____ Calibration Due: _____

Room/Location	Sampled By/Time	Dräger Tube Results	Pass/Fail?	Initials/Date

Comments: _____

QC Reviewed By/Date: _____

QA Reviewed By/Date: _____

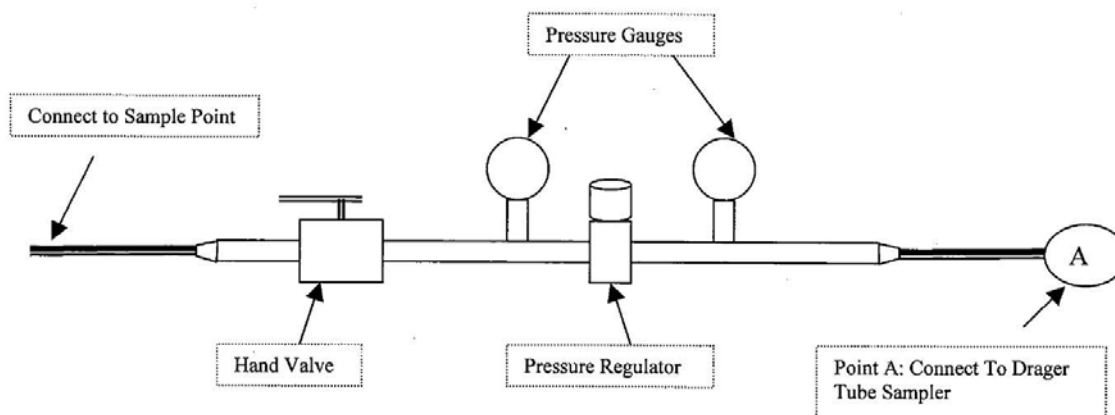
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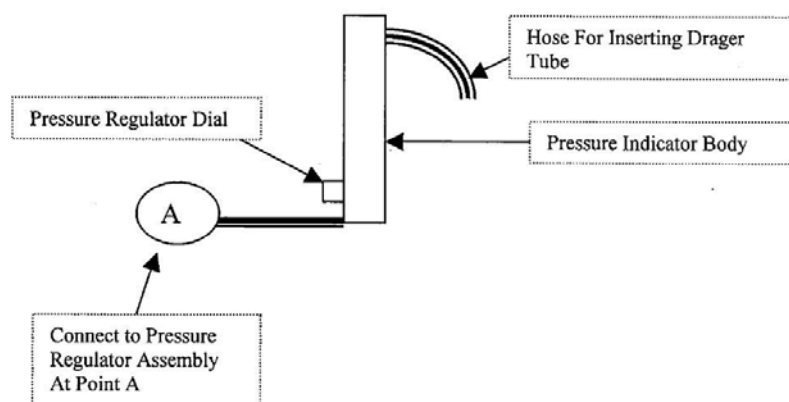
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ATTACHMENT 2 Setup Diagram for Aerotest Sampler

1) Pressure Regulator Assembly



2) Aerotest Dräger Tube Sampler



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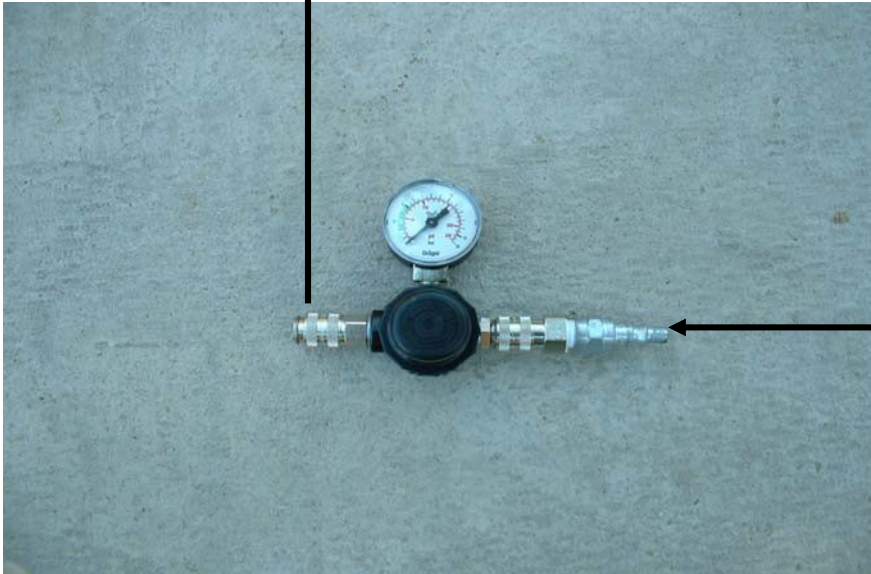
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ATTACHMENT 3
Setup Diagram for Aerotest Simultan Alpha Sampler



Place Drager Tube Here

Connect Regulator to Sampling Body



Connect to Sample Port