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1.0 Purpose

This procedure describes testing for the presence of oil in compressed gas distribution systems servicing the Biopharmaceutical Development Program (BDP) for current Good Manufacturing Practices (CGMP) use. The gases to test include air which is used for Compressed Air (CA) and Pharmaceutical Air (PA), nitrogen, and carbon dioxide.

2.0 Scope

This SOP applies to BDP personnel who perform this testing, as well as those who review the results from this testing. This SOP applies to operation of the Aerotest Sampler (single-tube). The testing performed is part of the testing plan of **SOP 22314 – Monitoring of BDP GMP Compressed Gases**.

3.0 Authority and Responsibility

- 3.1 The Director, Process Analytics/Quality Control (PA/QC) has the authority to define this procedure.
- 3.2 Biopharmaceutical Development Program (BDP) Production personnel and PA/QC personnel are responsible for performing this procedure.
- 3.3 PA/QC is responsible for training personnel on this procedure and documenting this training to Biopharmaceutical Quality Assurance (BQA).
- 3.4 PA/QC is 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 and Equipment

- Aerotest Sampler, BDP MEF #76920 or equivalent.

- Dräger tubes for oil detection, BDP PN 21573.
- Calibrated timer.
- Plastic tubing, two (2) inch section.
- Dräger tube tip opener.
- Pressure regulator assembly for Aerotest Sampler.

5.0 Setup for Aerotest Sampler

- 5.1 Attach the blue gas inlet connection on the Aerotest unit to the compressed gas source. A pressure regulator may be used between the source and the Aerotest unit although it is not required if the pressures are within the allowable range and the hardware used to connect the Aerotest unit to the source can withstand the expected pressures.
- 5.2 Slowly open the compressed gas supply. The supply pressure should be between 30-150 psig per the manufacturer although no points in the ATRF should be above 110 psig.
- 5.3 Turn the attenuator/flow control knob counterclockwise until the 2.0 L/min marking on the gauge is in the middle of the silver ball.
- 5.4 Flush the gas system through the Aerotest unit for at least three (3) minutes.
- 5.5 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.
- 5.6 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).
- 5.7 Allow gas to flow through the tube for three (3) minutes and forty-five (45) seconds using a calibrated timer.

6.0 Sample Analysis

- 6.1 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.

- 6.2 Allow the reagent to flow into the outer indication layer to ~ 10 mm (1 cm).
- 6.3 Wait at least one (1) minute ten (10) seconds before evaluation.
- 6.4 If no color change occurs, the oil content of the compressed gas is < 1.0 mg/m³.
- 6.5 If the media changes to light beige or yellow, oil has been detected. Perform another sample to confirm the presence of oil starting at step 5.2. If the second sample does not show signs of oil, perform a third test. Two consecutive negative retests are required for the sample point to be considered free of oil. If the second or third sample confirms oil presence, notify the appropriate parties per **SOP 22313 - Environmental and Utility Monitoring - Excursions Event Initiation and Investigation**.



7.0 Documentation

- 7.1 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 **SOP 21531 - Equipment Logs**.
- 7.2 Record all calibration and maintenance activities in the Aerotest Sampler equipment logbook.
- 7.3 Record all results on Form 22927-01 or Form 22314-01 and attach to the QC Test Request Form (22002-01). Form 22314-01 is the preferred form when sampling is associated with the compressed gas monitoring program. Submit this form according to **SOP 22002 - Request for Quality Control Testing**.
- 7.4 Corrective actions on a compressed gas system as a result of the detection of oil shall be documented in the corresponding compressed gas system equipment log per **SOP 21531**.

8.0 Maintenance

- 8.1 Ensure calibration of the flow device is up to date prior to use.
- 8.2 Inspect the testing apparatus to ensure integrity of fittings and the flow device prior to use. Correct any deficiencies prior to use.

9.0 References and Related Documents

SOP 21531 *Equipment Logs*

SOP 22002 *Request for Quality Control Testing*

SOP 22313 *Environmental and Utility Monitoring - Excursions Event Initiation and Investigation*

SOP 22314 *Monitoring of BDP GMP Compressed Gases*

Form 22927-01 Dräger Tube Test Report

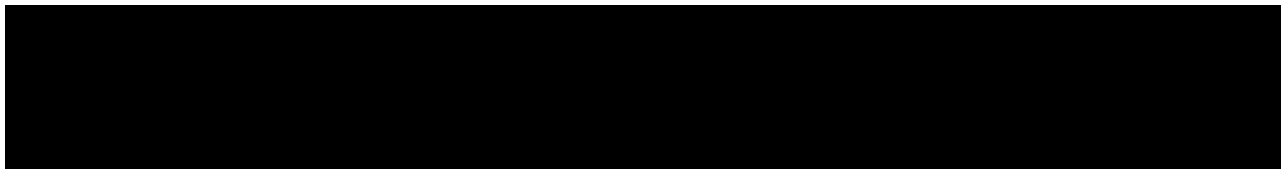
Aerotest instruction sheets.

Dräger tube (Oil) instruction sheet.

10.0 Attachments

- 10.1 Attachment 1 Setup Diagram for Aerotest Sampler

11.0 Change Summary



Attachment 1

Setup Diagram for Aerotest Sampler

