



## **Air Flow Visualization Tracer Particles or Test Aerosol**

For Cleanroom & Controlled Environment Air Flow Visualization Studies (AKA Smoke Studies).

The purpose of performing Air Flow Visualization Studies is to accurately visualize the airflow patterns inside a Cleanroom or Controlled Environment. Microrite, Inc. utilizes the Tracer Particle Injection Method as defined in ISO 14644-3:2005. Per this standard, Tracer Particles must be neutrally buoyant (not affected by gravity) and remain visible long enough to allow the visualization of the actual airflow patterns. Tracer Particles that are too large ( $\geq 1.0\mu\text{M}$ ) or disappear rapidly could result in false conclusions related to air flow patterns in cleanrooms. False conclusions regarding air pattern in cleanrooms has led to failed media fills, contaminated products, inspector's observations, warning letters and patient harm.

The Tracer Particles used by Microrite, Inc. are NOT SMOKE PARTICLES. When properly diffused, a neutrally buoyant cloud-like fog containing tracer particles sized between  $0.2\mu\text{M}$  and  $1.0\mu\text{M}$  is released into the cleanroom environment. These sterile particles are comprised of pharmaceutical grade propylene glycol and purified water. This fog is oil-free, non-condensing on cleanroom surfaces and is <sup>1</sup>FDA GRAS approved. For typical Air Flow Visualization Studies, this fog does not <sup>2</sup>condense and pool up on the cleanroom surfaces or cleanroom equipment. This mixture is similar in formulation as that of an E-Cigarette vapor and is non-toxic.

<sup>1</sup>(Generally Regarded as Safe)

<sup>2</sup>Condensation of the vaporized Tracer Particles does occur INSIDE the manifold and tubing and is common to all methods used to perform air flow visualization and must be addressed as part of the smoke study.

The Tracer Particles start as a mixture of pharmaceutical grade propylene glycol and purified water that is vaporized at  $\sim 320^\circ\text{C}$ . The Tracer Particle Generator, transport tubing and Diffuser Manifold cool and condense the vapor to ambient air temperature as the Tracer Particles exit the Diffuser Manifold as a dense fog of <sup>3</sup>neutrally buoyant particles. <sup>3</sup>Neutrally buoyant tracer particles are extremely important as they will accurately follow the air currents and identify <sup>3</sup>dead spaces and eddy currents.

A Diffuser Manifold is required to properly introduce the Tracer Particles into a cleanrooms air flow. Inside the manifold the vapor cools and mixes with air to condense into a fog of Tracer Particles at ambient temperature and pressure while avoiding condensing back into a fluid. This removes the jetting effect of shooting the tracer particles in a single direction (often downward) that may falsely demonstrate unidirectional airflow when dead spaces and eddy currents are present. In addition, excess condensation of the tracer particle on surfaces in the cleanroom is avoided since the fog exits the manifold at the same temperature and pressure as the cleanroom environment.

<sup>3</sup>Water, CO<sub>2</sub> or Nitrogen Based "Cleanroom Fogging Systems" Tracer Particles are NOT Neutrally Buoyant and cannot visualize dead spaces or areas where there is no air flow.

Tracer Particles should remain <sup>4</sup>visible from where they are diffused into the clean air system being tested all the way to the air return. This allows for the visualization of air flow directions and air mixing in both unidirectional and non-unidirectional air flow cleanrooms. More importantly it allows for visualization of Combination-Flow cleanrooms and the interface between unidirectional and non-unidirectional air flows. This is extremely important in aseptic manufacturing where visualizing air flow in conjunction with operator movement at the interface between Grade A and Grade B is critical to the evaluation, qualification and regulatory review of aseptic operations.

<sup>4</sup>Water, CO<sub>2</sub> or Nitrogen Based "Cleanroom Fogging Systems" Tracer Particles dissipate too quickly to evaluate a clean air system accurately.



Just as the biannual Filter Integrity Testing or Filter Leak Testing, Air Flow Visualization studies release a massive number of particles into the cleanroom and clean-air systems by using a test aerosol made up of particles. HEPA filter performance is evaluated by particle leak testing, air velocity and differential pressure across the HEPA filter. Industry experience finds that routine biannual Filter Integrity Testing and Air Flow Visualization Studies have a minimum effect on filter performance. Air velocity and Differential Pressure can be evaluated prior to testing and after to verify that no change has occurred due to the use of the Tracer Particles.

Because Filter Integrity Testing and Air Flow Visualization studies release a massive number of particles into the cleanroom and clean-air systems, cleaning the cleanroom after is required. The very nature of a Smoke Study exceeds the particle concentration limits of the cleanroom. Best cleanroom operational practices require that anytime a cleanroom far exceeds the particle concentration limits for that particular cleanroom class, a complete cleanroom cleaning should occur. Regardless of the material used for the Tracer Particles, any type of Air flow visualization should be undertaken as a major contamination event. Wiping all surfaces with a sterilized 70% Alcohol and 30% purified water solution is recommended at a minimum. For medical product cleanrooms additional sanitization and sterilization is required.

If the cleanroom is used for sterile products, low bioburden products or critical medical product processing, Air Flow Visualization is required by the FDA and other international regulatory bodies. Air Flow Visualization studies are required to be performed in conjunction with the simulation of processing tasks, filling and closing of containers, loading and unloading of freeze dryers, normal and abnormal interventions and aseptic connections. As these simulations mimic actual operations with additional testing personnel, additional equipment (cameras, Tracer Particle Generator, tripods etc.) a deep cleaning inclusive of sanitization, disinfection and sterilization as documented in the customer's validated cleaning program.

Please see the Attached Material Safety Data Sheet for the Smoke Fluid used by Microrite, Inc.

Submitted by:

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