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MANUFACTURER TECHNICAL STATEMENT

AP Series LN_2 Foggers for Pharmaceutical Airflow Visualization

Manufacturer position regarding neutral-buoyancy tracer suitability, self-pressurized control, passive dewar systems, and proper smoke-study use

Prepared by Applied Physics

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Applies to	AP Series liquid-nitrogen foggers, including active self-pressurized and passive dewar configurations.
Manufacturer position	Properly operated AP Series LN_2 foggers are scientifically suitable for pharmaceutical airflow visualization as passive/functionally neutrally buoyant water-fog tracers.
Scientific basis	Established steam/LN_2 cleanroom fog patent history, independent ~3 µm neutrally-buoyant commercial precedent, first-principles aerosol dynamics, and published micron-water-droplet tracer literature.
Important boundary	This statement supports the tracer technology; the client remains responsible for adequate dynamic smoke-study execution and site-specific qualification/documentation.

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Manufacturer Position

Applied Physics has reviewed the relevant FDA airflow-visualization expectations, EU GMP Annex 1, ISO 14644-3, the historical cleanroom-fog patent record, independent steam/LN_2 fogger specifications, aerosol-tracer literature, and cryogenic pressure-control literature.

Based on that evidence, Applied Physics concludes that the AP Series liquid-nitrogen fogging method is scientifically suitable for pharmaceutical airflow visualization when the unit is properly operated and the study configuration is controlled so that tracer behavior faithfully represents the local airflow.

The steam/LN_2 generation principle has been used for cleanroom airflow visualization for decades. U.S. Patent 4,771,608 (1988) and U.S. Patent 4,875,340 (1989) describe steam passed over liquid nitrogen / cryogenic material to form a high-density, non-contaminating fog and explicitly describe the fog as neutrally buoyant. TSI/MSP independently specifies a steam + LN_2 cleanroom fogger producing approximately 3 µm droplets and neutrally-buoyant fog for airflow tracking. [6-8]

AP Series Technology Families

Architecture	Representative AP Series models	Technical distinction
Active self-pressurized LN_2	AP30, AP50, AP100, AP200	Uses self-generated/stored cryogenic pressure with controlled delivery to provide greater flow-control authority, repeatability, and opportunity for efficient LN_2 use.
Passive dewar LN_2	AP35, AP95, AP175	Relies primarily on natural LN_2 boil-off/passive dewar behavior; simpler architecture with longstanding historical precedent for cleanroom airflow visualization.

Both architectures use the same fundamental fog-generation principle: heated high-purity water vapor is rapidly cooled/condensed by liquid nitrogen / cold nitrogen vapor into a dense population of micron-scale water droplets. The tank architecture changes how the cryogen is supplied and controlled; it does not change the fundamental tracer physics.

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Neutral-Buoyancy / Passive-Tracer Basis

Applied Physics documentation identifies a nominal AP Series LN_2 droplet range of approximately 2-3 µm. At this size, calculated gravitational settling is approximately 0.13-0.29 mm/s in still air. At a representative 0.45 m/s airflow, that is approximately 0.03-0.06% of the airflow speed. Published quantitative gas-flow studies successfully use larger ~4-6 µm water droplets as passive PIV tracers. [9-11]

Accordingly, the aerodynamic behavior of the nominal 2-3 µm AP Series water fog has a strong basis for faithful airflow following. As with any fogger, thermal bias and source momentum must also be appropriately controlled during use.

Why Self-Pressurization and Control Valves Matter

- Self-pressurization provides a more controlled pressure differential for cryogen/nitrogen delivery than reliance on instantaneous natural boil-off alone.
- Control valves meter cryogen delivery, helping stabilize fog density and the thermal balance between warm water vapor and cold nitrogen.
- Metering allows the operator to avoid unnecessary over-feed, which can waste LN_2 and can over-cool the plume.
- Fog volume and velocity control help minimize source-induced airflow disturbance and avoid over-fogging/visibility problems.
- These controls improve repeatability and can improve practical LN_2 efficiency, but the valves themselves are not the source of neutral buoyancy; they help maintain the conditions under which the micron-scale fog behaves as a faithful tracer.

Recommended Regulatory Use

This statement may be provided as manufacturer technical support in an airflow-visualization qualification, inspection response, CAPA, or scientific justification. It should be used together with the facility-specific executed smoke study, approved SOP/protocol, and applicable site records.

Controlled conclusion: Applied Physics considers properly operated AP Series LN_2 foggers - including both self-pressurized and passive dewar configurations - scientifically suitable for pharmaceutical airflow visualization. The steam/LN_2 fog-generation method has direct historical and independent industry precedent as a neutrally buoyant, non-contaminating cleanroom airflow tracer. The self-pressurized architecture adds control authority over cryogen delivery to improve repeatability, thermal balance, and efficient use of LN_2; passive dewar systems remain valid because the underlying tracer-generation mechanism is the same.

This technical statement does not represent FDA approval, certification, or endorsement and does not

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replace the facility's responsibility to demonstrate adequate airflow visualization under actual operating conditions.

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Authorization

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