

ADDRESSING PUPSIT CHALLENGES: Air Management and Integrity with PureFlo® PE G50A



Abstract

Pre-Use Post-Sterilization Integrity Testing (PUPSIT) is widely used to support sterility in biopharmaceutical manufacturing, yet it presents significant operational and technical challenges that can compromise process efficiency. This application note evaluates PureFlo® PE G50A, a cutting-edge gas filter designed to overcome some of these hurdles by optimizing air exchange efficiency, preventing microbial contamination, and enhancing system robustness during PUPSIT. Testing demonstrates that the inclusion of these filters does not compromise integrity test result accuracy, supporting EU GMP Annex 1 compliance while improving process reliability.

Keywords & Phrases

- PUPSIT (Pre-Use Post-Sterilization Integrity Test)
- Sterile Venting
- Integrity Testing
- Single-Use Filtration
- Annex 1 Compliance

Introduction

Pre-Use Post-Sterilization Integrity Testing (PUPSIT) is routinely employed in biopharmaceutical processes to verify the integrity of sterilizing-grade filters prior to use. Despite its value in sterility assurance, PUPSIT introduces several operational and technical challenges – many of which can be mitigated through use of well-designed gas filters such as Saint-Gobain Life Sciences' PureFlo® PE G50A.



PUPSIT Pain Points

Integrity test reliability: A key industry concern is ensuring that added components – like vent filters – do not interfere with the accuracy of liquid filter integrity tests.

Contamination risks: During filling and draining of the single-use system, unfiltered air can introduce microbial contaminants

Pressure-induced leakages: High-pressure integrity testing can stress single-use systems (SUS), potentially causing leaks.

Managing large flush volumes: Large fluid volumes required for wetting and flushing can be logistically challenging in a closed system.

Limited connection options: Filters with few connection types can complicate integration, often requiring adapters that increase system complexity, potential leak points, and overall risk in an already intricate setup.

Inadequate filter wetting: Entrapped air can prevent proper wetting of the filter membrane, leading to false integrity failures and unnecessary process delays.

PureFlo® PE G50A Filter Solution

Minimal restriction to air flow during integrity testing facilitates accurate integrity test results.

Acts as a sterile barrier, reducing the risk of microbial ingress and maintaining aseptic conditions.

Helps manage pressure distribution and support system integrity.

Enables smooth fluid displacement, minimizing air locks and improving process efficiency.

Available in versatile formats with compatible connectors to simplify integration and reduce system complexity.

Facilitates effective air removal during flushing, helping to ensure complete wetting of the filter membrane.

PureFlo® PE G50A Performance Assessment

The following study evaluates the use of Saint-Gobain Life Sciences' PureFlo® PE G50A to facilitate PUPSIT in a single-use system without impacting the reliability of integrity test results.

Sample Selection:

To simulate a challenging PUPSIT scenario, the G50A filter with the most restrictive fitting to gas flow – 1/8" hose barb ("1H") – was used at the gas inlet and outlet of the system.

Table 1. Gas Filter Sample Characteristics

Part Number	G50AUE0201H1H
Product Family	PureFlo® PE
Membrane	0.2 µm Polyethylene
Nominal Filtration Area	15.9 cm ²
Inlet and Outlet Fittings	1/8" Hose Barb
Average Air Flow Performance (vent condition, ambient temperature)	0.76 psid at 5 L/min
Bubble Point (in 60% isopropyl alcohol at 22°C)	≥ 17.4 psi (1.2 bar)

Table 2. Liquid Filter Sample Characteristics

Product Family	PureFlo® Z Series PES
Membrane	0.2 µm Polyethersulfone
Nominal Filtration Area	6400 cm ²
Inlet and Outlet Fittings	1 1/2" Tri-Clamp
Diffusional Flow Rate (in water at 22°C)	≤ 24 mL/min at 40 psi (2.8 bar)
Bubble Point (in water at 22°C)	≥ 50 psi (3.5 bar)

Test Set-Up:

A streamlined test setup was used to simulate key elements of a typical PUPSIT assembly, allowing focused evaluation of gas filter performance under representative conditions. The liquid filter (PureFlo® Z Series PES) was integrity tested with and without the PureFlo® G50A filters installed.

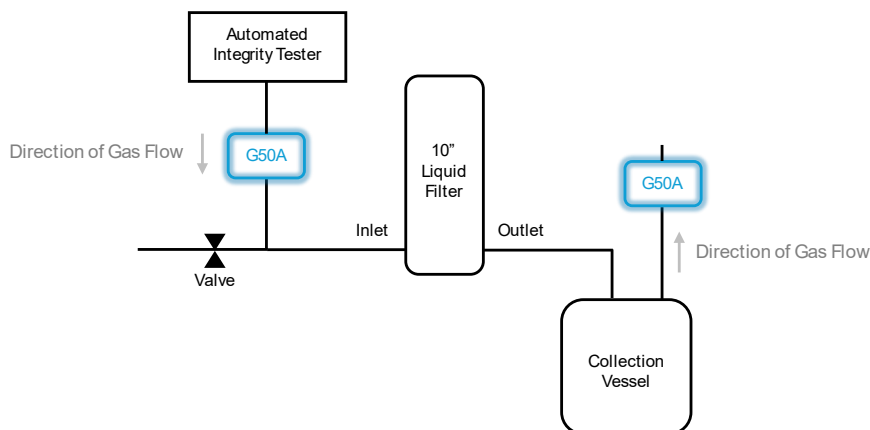


Figure 1. Simulated PUPSIT test stand.

Note: During the study, the system was tested with and without the G50A filters installed to compare the performance.

Test Method:

The integrity of the liquid filter was evaluated using a multi-point diffusion test on an automated integrity tester. This method, unlike standard bubble point or diffusion tests, records diffusive flow at multiple pressures enabling precise comparison between systems with and without gas filters installed.

For both configurations (with and without G50A gas filters), the liquid filter was wetted using clean water at 22°C. Once fully wetted, the system was connected to the integrity tester, and the following parameters were applied:

Test Class:	Standard
Min Pressure:	40.00 psi
Max Pressure:	70.00 psi
Pressure Step:	0.73 psi

Each test was repeated three times using new G50A gas filters to confirm consistency. After testing, the G50A gas filters were also integrity tested to verify they remained integral after exposure to the test conditions.

Results:

All repeated tests yielded consistent outcomes. Figure 3 presents data overlaid from two representative multi-point diffusion tests (with and without G50A gas filters). Throughout the entire duration of the tests — where gas flow eventually exceeded 80 mL/min, no significant differences in flow were detected with the G50A gas filters installed. Additionally, all G50A filter samples passed the post-use integrity test.

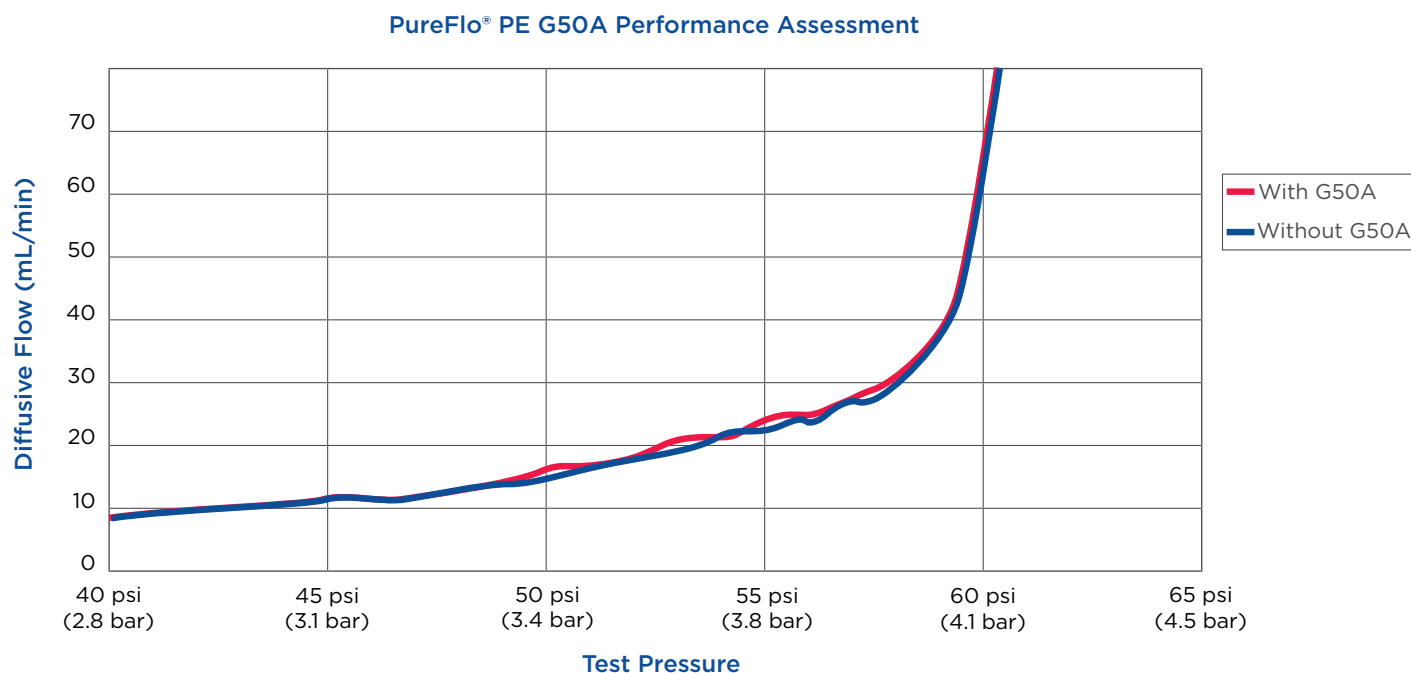


Figure 2. Multi-point diffusional flow and bubble point test results with and without the gas filters installed.

Discussion and Conclusion:

This study demonstrated no significant difference in integrity test results with or without the PureFlo® PE G50A filter samples installed. The PureFlo® PE G50A filters enabled efficient, sterile gas exchange without compromising test accuracy.

This study used the most restrictive G50A configuration (1/8" hose barb), confirming that PureFlo® PE G50A filters, when properly integrated, maintain an adequate system pressure balance and do not interfere with integrity testing of 0.2 µm PES filters in a PUPSIT assembly.

The Future of PUPSIT with PureFlo® PE G50A

The PureFlo® PE G50A gas filter offers a practical and effective solution to several key challenges associated with Pre-Use Post-Sterilization Integrity Testing (PUPSIT). By enabling efficient air removal, maintaining sterility, and supporting pressure stability, the G50A enhances both the reliability and ease of PUPSIT implementation in single-use systems.

Testing confirmed that the inclusion of the G50A does not compromise integrity test accuracy, even in its most restrictive configuration. When properly integrated, it supports compliance with EU GMP Annex 1 while improving process robustness and operational efficiency.

The PureFlo® PE G50A is a valuable tool for biopharmaceutical manufacturers seeking to streamline PUPSIT workflows.

Related Documents

- [PureFlo® PE Disc Capsules G50A Brochure](#)
- [PureFlo® PE Disc Capsules Filter Instructions for Use](#)



Contact us!

Learn more about integrity testing and explore how our tailored solutions support PUPSIT success, enhance bioprocess efficiency, and unlock new performance potential.



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