Rieckermann
Machinery & Industrial Solutions

Glatt®

PRE-USE POST-STERILIZATION INTEGRITY TEST (PUPSIT)

ENSURING A SAFE & EFFICIENT IMPLEMENTATION OF PUPSIT
IN COMPLIANCE WITH ANNEX 1 REQUIREMENTS

Under Annex 1, stricter requirements for sterile filtration and integrity testing have been introduced:
The integrity of the sterilized filter must be verified before use (PUPSIT – Pre-Use Post-Sterilization Integrity Test) to ensure no damage or loss of integrity has occurred.

Key requirements
- A sterilizing-grade filter should undergo a non-destructive integrity test after use.
- The test process must be validated and correlate with microbial retention capability.
- Common test methods: Bubble Point, Diffusive Flow, Water Intrusion, Pressure Hold Test.

PUPSIT (Pre-Use Post-Sterilization Integrity Testing) is generally a regulatory requirement for all processes involving sterile filtration of products that cannot be terminally sterilized in their final container.

It ensures that:
- The filter is intact before use (**Pre-Use**),
- The test is performed after sterilization (**Post-Sterilization**), and
- The filter integrity is verified (**Integrity Testing**).

Only in exceptional cases - where PUPSIT is not technically feasible due to specific process limitations - can alternative approaches be considered, provided that a detailed risk assessment is conducted and appropriate mitigation strategies are implemented. Together with our trusted partner **Glatt**, we offer expert guidance to help you implement the right solution tailored to your production environment.

WHAT TO CONSIDER WHEN ADAPTING TO PUPSIT?

According to Annex 1, sterility and compliance must be ensured in integrity testing.
In order to achieve an optimal result, some challenges and risks must be taken into account.

Challenges

- The sterilized filter must be tested while maintaining system sterility.
- The filter must not be removed for visual inspection or integrity testing.

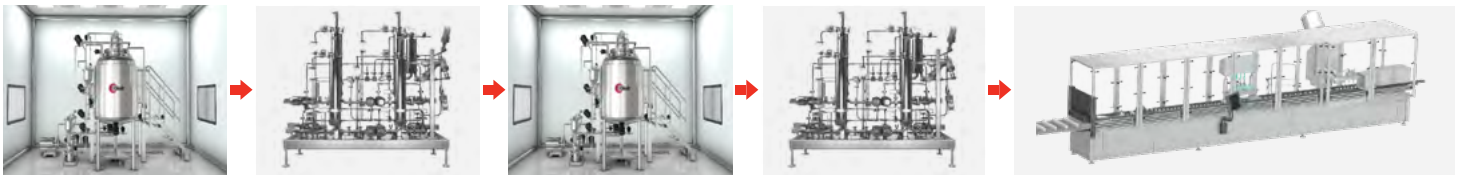
Risks

- Additional operator steps = higher risk of human error
- More components & connections = increased risk of leakage
- Manual PUPSIT execution = potential process weakness

WHICH PROCESS STEPS REQUIRE PUPSIT?

In the case of an already existing filtration (Version A), a second filtration needs to be integrated before the filling machine to ensure compliance with requirements. In production facilities without filtration, a filtration step must be added after the compounding vessel to ensure sterility.

Version A – Solution line



Compounding Vessel | Filtration | Holding Vessel | Filtration | Filling machine

Version B – Suspension line

STERILE AP1

Compounding Vessel | Filtration | Holding Vessel | Filling machine

WE SUPPORT YOU WITH AN INNOVATIVE, RELIABLE AND STERILE PROCESS

- Maintains sterility with no manual intervention required
- Enables product charging and recovery while testing medium

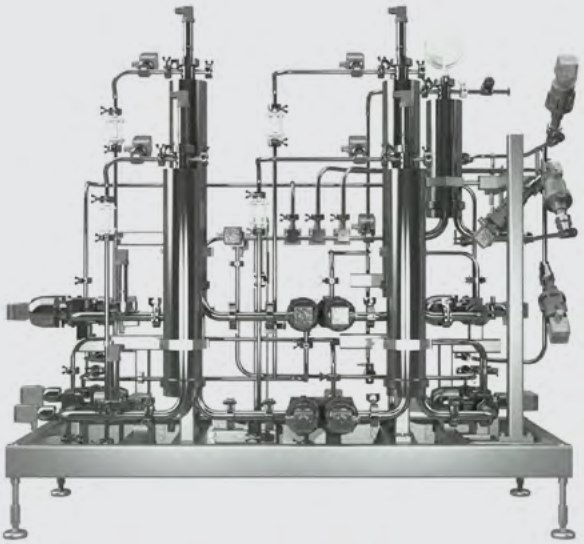
A fully automated system ensures seamless and reliable operation across all batches, providing consistent compliance with PUPSIT requirements.

PUPSIT - YOUR BENEFITS

Implementing PUPSIT ensures early detection of filter defects, significantly reducing the risk of downstream contamination.

By identifying potential issues before filtration begins, you can:

- Enhance product safety
- Maintain regulatory compliance
- Minimize costly batch failures



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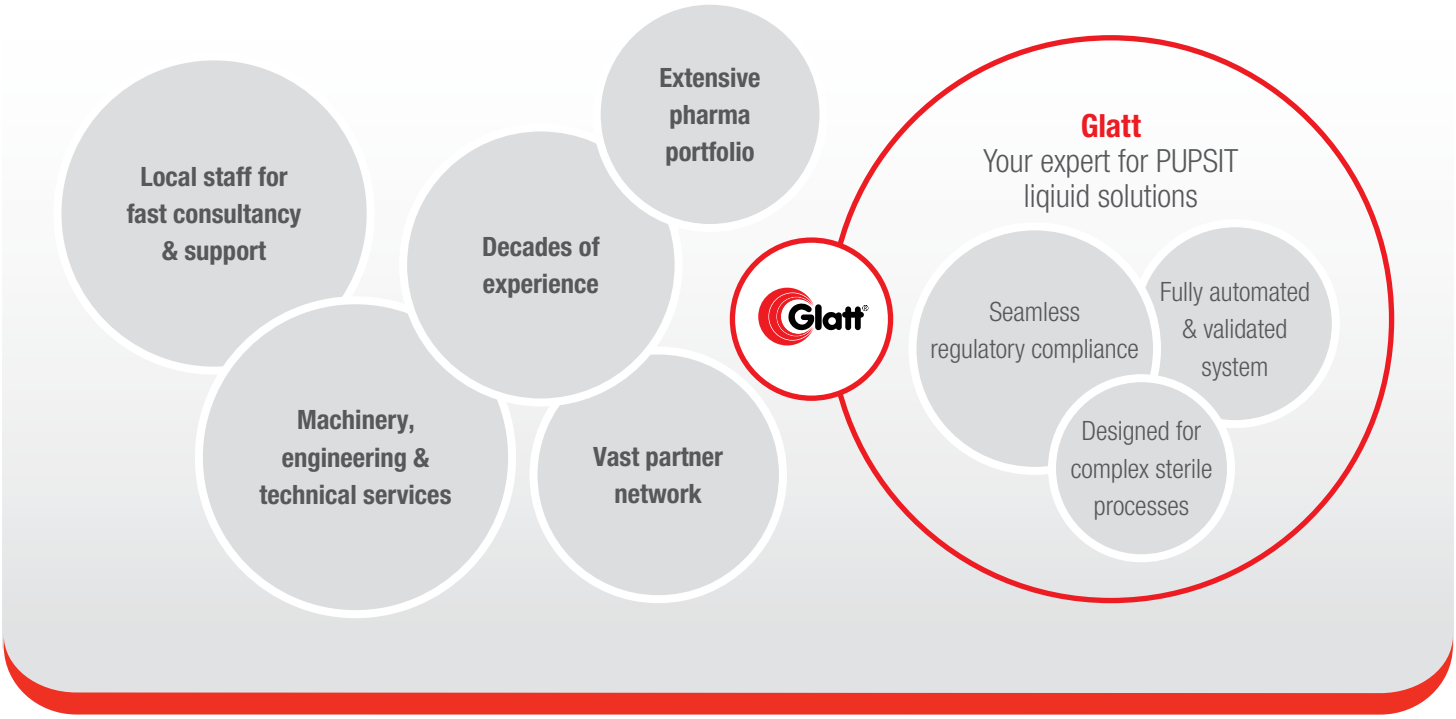

ACT NOW!

It is a choice between business opportunities & sales ban.

Stay ahead of regulatory requirements & secure your production with a trusted PUPSIT implementation.

ENGINEERING | MACHINERY | SERVICES

360° customized industrial solutions

For the pharmaceutical industry, Rieckermann supplies solutions and services for the processing, production, and packaging of all types of pharmaceuticals in liquid, solid, or semi-solid form. Furthermore, we serve customers who produce active pharmaceutical ingredients, medical devices, and cosmetics.

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