

Lifecube™ SAP PUPSIT Semi-Automatic System

In pharmaceutical production, it is crucial to ensure the quality and safety. Therefore, regulatory agencies in various countries have established strict regulations and guidelines for sterile pharmaceutical production.

PUPSIT (Pre-Use/Post-Sterilization Integrity Testing) is one of the key regulations and practices. It refers to the integrity test of the sterile filter after sterilization and before production to ensure that the sterile filter maintains its integrity and filtration capacity throughout the production process, thus ensuring the sterility of final drug product.

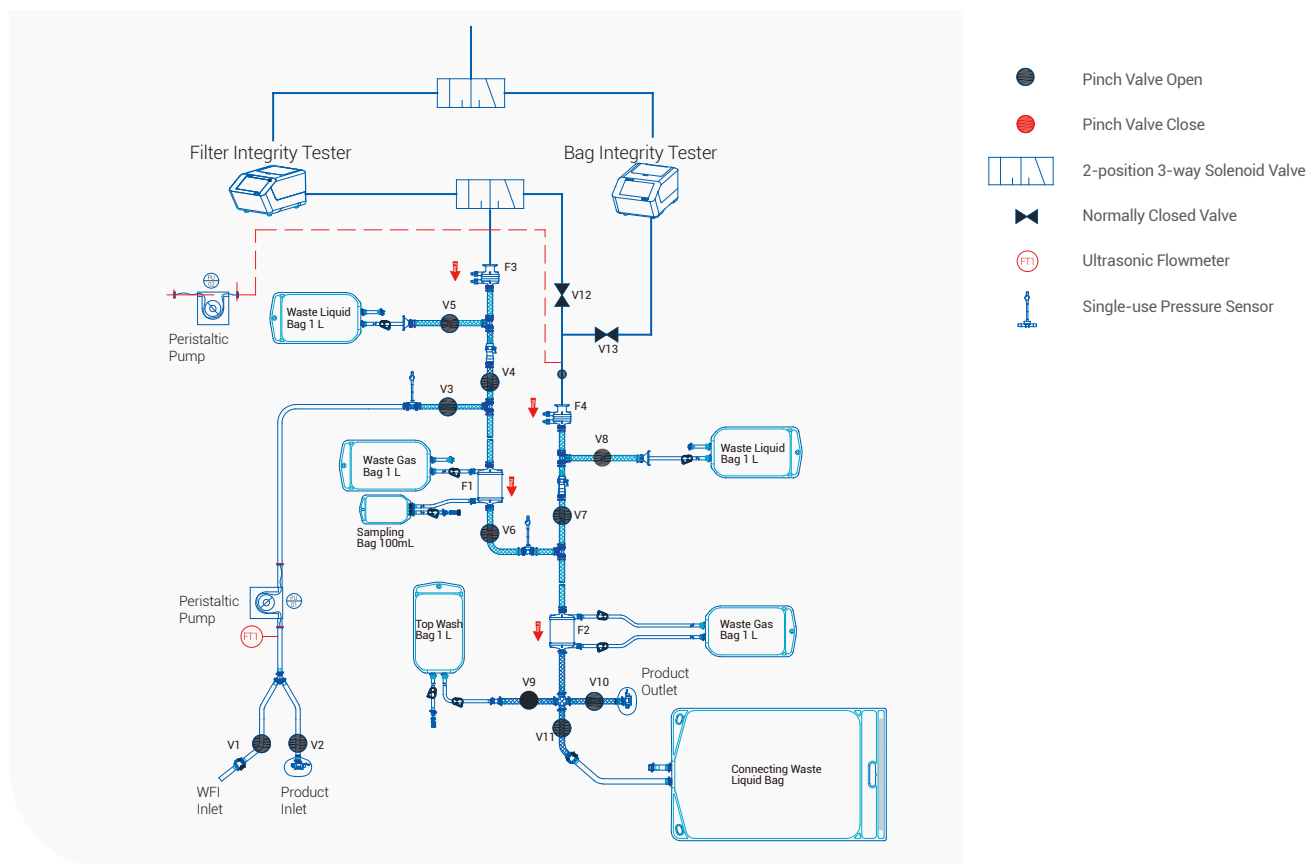
Cobetter's designed PUPSIT Semi-Automatic System is based on relevant engineering requirements and practical experience. The system enables pre-use/ post-sterilization integrity testing of sterile filters to be carried out efficiently and simply.



Advantages

- Set the operation parameters and methods in advance to reduce manual operation steps
- Equipped with Cobetter self-produced Certitest 20 Filter Integrity Tester and Bag Integrity Tester, flexible customization of integrity test schemes
- Customised programme design based on actual customer process requirements
- Pumps and weighing modules can be customized according to different liquid properties or production levels
- Real-time monitoring and alarm to reduce the probability of risk occurrence
- Data integrity records and management, and audit trail is allowed
- Self-produced single-use consumables to ensure a stable supply chain
- PUPSIT assemblies are manufactured in the ISO 4.8 clean area to strictly control the cleanliness of the single-use consumables.

Figure 1. PUPSIT Scheme example



Function

Functional Module	Test Step
Leak test	Leaking test of the tubing assembly
Bag integrity test	Pre-filtration integrity test of top wash bags and waste liquid bags
Sterile filter wetting	Wetting the sterile filters in preparation for pre-filtration integrity testing (diffusion flow)
Sterile filter integrity test before filtration	Diffusion flow testing for sterile filter integrity
Gas filter integrity test	Pre-filtration gas filter integrity test (water intrusion)
Liquid top washing	Cleaning the tubing and draining WFI
Liquid filtration	Sterility filtration the product solution
Final integrity test	Perform integrity test after final sterile filtration

Software Function Module

Manual mode	All components can be operated individually, and a single process step can be operated manually
Single module formula	All process modules can be run individually, each process module can set parameters individually
Semi-automatic formula	The formulas runs in sequence, with parameters and steps that can be set according to actual needs
Authority management	Custom permissions, user management, password management, audit trail, electronic signature
Other functions	Flow calibration, weight calibration, data backup, data recovery
Regulatory compliance	Complies with FDA 21 CFR part11

Product List

Lifecube® SAP Single-use PUPSIT Assembly

Item	Specifications
Gas filter	Cobetter Bricap C01, C02, C03 capsule filter
Sterile filter	Cobetter Bricap L02 - L10 capsule filter
Single-use 2D bag	Cobetter Lifecube Single-use 2D Storage Bag (100 mL-50 L)
Single-use pressure sensor	Cobetter Lifemeta SPC single-use pressure sensor Body material PSF Pressure range 0~30 PSI Accuracy 0-6 psi ±2% 6-30 psi ±3%
Reinforced silicone tubing	Cobetter Lifemeta ST9B reinforced silicone tubing, with max. pressure 5 bar
Silicone tubing	Lifemeta STT platinum-cured silicone tubing, with max. pressure 2 bar
Tube fitting	Straight tube fitting, Cross fitting, Tee Fitting, Y-Fitting

Hardware Configuration List

Item	Specifications
Main pump	Speed range: 0-650 rpm; Accuracy: ± 0.1% Flow range: ≤13 L/min; Accuracy: < 3% FS Suitable for 73# and 82# tubing
Auxiliary pump	Speed range: 0-600 rpm; Accuracy: ± 0.1% Flow range: ≤13 L/min; Accuracy: < 5% FS Suitable for 73# and 82# tubing
Electrically controlled pinch valves	Suitable for reinforced silicone tubing, with maximum pressure 5 bar
Weighing module	Max. weighing: 60 kg; Accuracy: ≤ 5 g Max. weighing: 11 kg; Accuracy: ≤ 1 g
Filter integrity tester	Cobetter Certitest 20 Plus Filter Integrity Tester Pressure range: 100-8000 mbar; diffusion accuracy: 4% or 2 mL/min whichever is greater
Bag integrity tester	Cobetter Certitest Bag Integrity Tester Pressure range: 0-300 mbar; Accuracy: Max±0.3 mbar
Control cabinet	Siemens PLC control system
HMI	Siemens SIMATIC IPC477E 15" touchscreen Windows 10 IoT Enterprise 2019 LTSC, 64-bit



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Specifications subject to change without notice. CBPLSUSPA245b E