cobetter® filtration

Lifecube SAP Single-Use PUPSIT Assembly

Lifecube SAP system products are designed to perform PUPSIT (Pre-Use and Post-Sterilization Integrity Test) for filters in sterile filtration process and can be applied for single or two filters/redundant sterile filtration.

Regulatory Compliance: EU GMP Annex 1

PUPSIT can verify the integrity of a sterilizing grade filter before use and after sterilization.

Full Flexibility of Design, Limited Product Loss

Full line of single-use products including sterilizing-grade filters, storage bags, tubing, aseptic connectors, fittings, pressure gauge, in-line pressure sensors and monitor, etc. Meet almost all need for sterile filtration in final filling.

Delivery Time

Pre and self-produced assemblies, save at least 50% waiting times.

Standardized and Customized Solutions

Configuration-to-Order (CTO): Short delivery time
Engineer-To-Order (ETO) : Flexible design
Meet special single-use assemblies needs

In addition

- The design fully considers the process conditions and facility layout, such as WFI washing, pressure, air/water source etc. We will recommend the bag volume, tube size or combination solutions per the above factors
- Perform PUPSIT for filter with high bubble point
- Flushable components are pre-rinsed, effectively reduce the level of particulate matter and extracts
- Double-layer packaging, pre-irradiated, special needs can be customized three layer packaging, to meet customer needs in different clean areas of unpacking
- Self-produced components to ensure good quality traceability
- Various supporting documents, including validation guide, extractable data, system design guide, user manual, application data, etc

Quality assurance

- 100% Integrity test
- ISO 9001:2015 Quality Management System
- ISO Class 4.8 clean area assemble (equivalent to GMP Class A cleanliness)
- USP<87> Biological Reactivity Test, In Vitro
- USP<88> Class VI plastics Biological Reactivity Test, In Vivo
- Bacterial endotoxin meets WFI requirements (< 0.25 EU/mL)
- Particles matter meet the requirements in CP and USP<788> for large-volume parenterals
- Gamma radiation dose validation according to ISO11137, sterile packaging

Key performance validation

- Leak Test
- Pressure Resistance Test
- Connect strength test

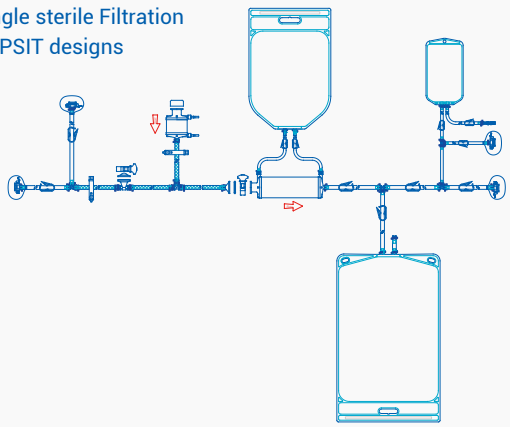
Typical Application

- Terminal Sterilization Filtration (EU GMP requirements)

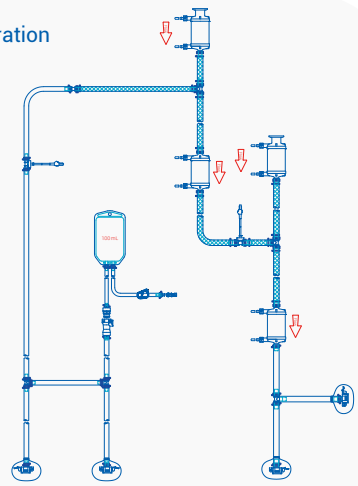
Ordering Information

Customized PUPSIT designs

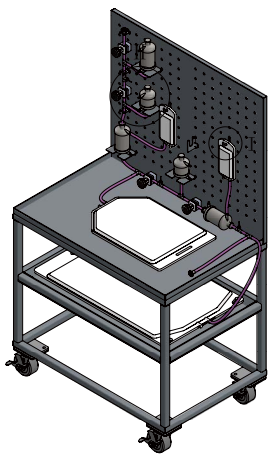
Single sterile Filtration
PUPSIT designs



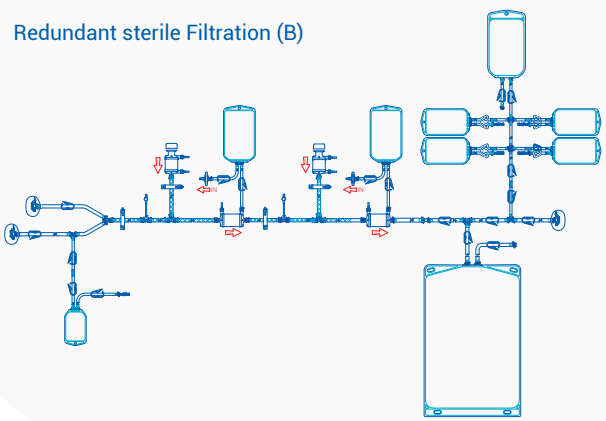
Redundant sterile Filtration
PUPSIT designs (A)



Accessory
Stainless steel Holder



Redundant sterile Filtration (B)



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