PureTain®
PUPSIT ASSEMBLIES

Parker's PUPSIT (pre-use post sterilization integrity test) assemblies ensure sterility in final fill applications in accordance with PUPSIT requirements.

PUPSIT Assemblies are designed for single-use bioprocessing applications where the product cannot be terminally sterilized and requires sterile filtration in the final downstream process steps.

They combine the benefits of both filtration and single-use tube sets to provide a pre-assembled, fully enclosed and sterile plug-and-play PUPSIT solution - where the sterile filters can be fully integrity tested without risking any contamination of the fluid flow path in the final downstream process.

As per the latest EU GMP Annex 1, PUPSIT is now a default requirement for manufacturers who cannot terminally sterilize their product in its final container, and therefore, need to employ sterile filtration.

Designed with compliance to these revised regulations, Parker's PUPSIT single-use assemblies can be customized to fit process needs with a range of options around tubing, filtration, sampling and connectability to meet the specific needs of your process.

PUPSIT Assemblies, PureTain®

Features and Benefits

- Pre-sterilized and ready to use
- Fully enclosed fluid pathway
- Customizable to suit process requirements
- Available as a standalone assembly, or as part of an automated solution

Qualtiy and Compliance

Quality assurance is built into all Parker products through a rigorous product design process, careful selection of suppliers and materials, and manufacture within a highly controlled environment using validated production technologies in adherence to cGMP. With regstrations and certifications to ISO9001 (Quality Management Systems) and ISO14001 (Environmental Management Standard) across our sites globally, all of our transfer lines are manufactured within an ISO Class 7 cleanroom and can be supplied in one of the three formats below:

- Non-irradiated / ready to sterilize (RTS)
- Gamma-irradiated (low bioburden)
- Gamma-irradiated (validated sterile according to ISO 11137-2 to conform with Annex 1)

All assemblies are supplied certified and comply with the following regulations:

- USP 85 (Endotoxin)
- USP 88 Class VI (Biological Reactivity)
- USP 788 (Particulates)
- USP 661 (Enclosures)
- EMA/410/01 (TSE/BSE)
- Other compliance statements are available upon request (e.g. extractables and leachables)

Applications

- Downstream sterile filtration
- Final fill solutions
- Drug stubstance / drug product formulation
- Vaccine production

Support and Design

PUPSiT requires a high degree of planning prior to implementation to ensure the system design and operation is safe, repeatable, reliable, does not compromise product safety, and is not a burden to manufacturing operations.

Implementation of PUPSIT will mean risk-re-assessing the final sterilizing process step to determine what new risks require mitigation.

The following steps can be considered when implementing your PUPSIT system:

- Filter selection
- Filter integrity test method selection
- Wetting method
- System design
- System location
- System operation

Parker's global single-use team can assist in the design, validation, qualification and implemenation of your single-use solution, calling upon our expertise in filtration, single-use systems, sensing and automation.

Ordering Information

Authorized Distributor

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