AseptiSure® TK Hydrophilic/Hydrophobic Membrane Cartridge Filters

Membrane Technologies

DATA SHEET

mdi *AseptiSure® TK* cartridge filters incorporate a specially designed combination of validated sterilizing grade hydrophobic PTFE as well as hydrophilic Polyethersulfone (PES) membrane to facilitate and provide unique performance advantages in post steam-in-place (SIP), pre-use integrity testing of aseptic filtration systems.

AseptiSure® TK cartridge filters help carry out critical functions such as steam penetration, condensate removal, filter drying, filter wetting and integrity testing while maintaining sterility of the aseptic filtration system (SIP or autoclaved).

Advantages

- Allows unlimited water for injection (WFI) flushing of sterilizing grade product filter for easy wetting for post SIP, pre-use integrity testing
- Allows fast drying of the filtration system necessary for processes involving oily solutions
- Acts as a sterile barrier against inadvertent ingress of environmental air

Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR Part 210.3(b)(6)
Meets and Exceeds USFDA 21 CFR Part 177.1520

Key features

- Absolute retention
- 100% integrity tested
- High heat stability
- Total Traceability: Unique marking on each filter
- Individual COQ for each filter

Specifications

Pore Size
0.2 µm

Membrane
Hydrophobic PTFE and Hydrophilic PES

Microbial Retention
LRV >7 for *B. diminuta* (ATCC 19146) per cm^2

Maximum Operating Temperature
80 °C @ ≤ 30 psi (2 Kg/cm^2)

Maximum Differential Pressure
50 psi (3.51 Kg/cm^2) @ 30 °C

Bubble Point
≥ 16psi (1.12 Kg/cm^2) with 70% IPA

Sterilization
Autoclavable/ In-line steam sterilizable at 135°C for 30 minutes, 4 cycles.

Toxicity
Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics.

Typical Water Flow Rates
18 lpm @ 1.4 kg/cm^2 at 27°C

Typical Air Flow Rates
(After passage of steam condensate)
6 Nm^3/h at ΔP=1.5psi

Cytotoxicity
Passes the Biological Reactivity Tests, In Vitro for Cytotoxicity as described in USP<87>

Bacterial Endotoxin
Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Fiber Release
Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release

Particle Release:
The filtrate complies with USP <788> test for particulate matter in injections

TOC and Conductivity
Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a specified minimal flush

Oxidizable Substances
Passes test as per USP <1231>

Bioburden
Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1:1995

Ordering Information

Type		Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure® TK	CPTK	5″	53	0.2µm	01	7P	A0	Silicone	SS	Non-Sterile	1	1	01
		10″	54			Seal-M	J0						
						Seal-O	F0						

Example

CPTK	53	01	F0	SS	1	01

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