0.1µm *AseptiSure WS* Hydrophilic PVDF Membrane Cartridge Filters

mdi *AseptiSure WS* are low protein binding hydrophilic PVDF membrane cartridge filters offering serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

These cartridge filters are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as absolute retention efficiency, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

Complies with USFDA 21 CFR 210.3(b)(6)

Meets and Exceeds USFDA 21 CFR 177.1520

Key features

- Absolute retention
- 100% integrity tested
- Low protein binding
- Low extractables

Applications

- Cell culture media
- Growth regulators
- Small Volume Parenterals

Specifications

Pore Size
0.1 µm

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Microbial Retention
LRV >7 for *A. laidlawii* (ATCC 23206) per cm^2

Sterilization
Autoclavable/ Inline steam sterilizable at 135°C for 3 cycles of 30 minutes each

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

Maximum Differential Pressure
50 psi (3.5 Kg/cm^2) @ 25 °C

Bubble Point
≥ 31psi (2.18Kg/cm^2) with 50% IPA/ Water Solution

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

Cytotoxicity
Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity

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 flushing with a specified volume of WFI

Extractables with WFI
Passes test as per USP <661>

Oxidizable Substances
Within limits as specified in USP <1231>

Ordering Information

Type		Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code		Code		Code		Code
AseptiSure WS (0.2 µm upstream)	CWH1	5" (3000 cm^2)	53	0.1 µm	36	7P	A0	Silicone	SS	Non-Sterile	1	1	01
		10" (6000 cm^2)	54			7P without fin	A1	EPDM	SE				
AseptiSure WS (0.2 µm upstream)	CWHX	20" (12000 cm^2)	55			'O'	D0	Viton	SV				
		30" (18000 cm^2)	56					FEP Encapsulated Viton	FV*				

*FV is available in Code A0(7P) and A1 (7P without fin) only
Size 5" is available in Code A0(7P) and A1 (7P without fin) only

EFA: Effective Filtration Area

Example

CWH1	56	36	A0	SS	1	01

DATA SHEET

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