

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.

Key features

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

Applications

- Antibodies
- Protein Solutions
- Buffers
- Vaccine concentrates
- Small Volume Parenterals

Microbially Validated as per ASTM F 838-05

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

Meets and Exceeds USFDA 21 CFR 177.1520



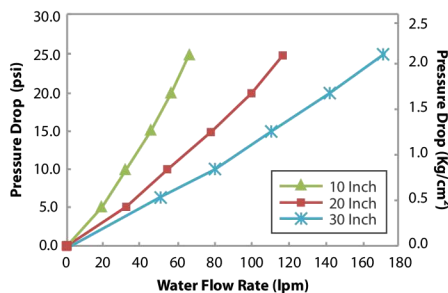
Specifications

Pore Size
0.2 µm

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Typical Water Flow Rates, 0.2 µm



Microbial Retention

LRV >7 for *B. diminuta* (ATCC 19146) per cm²

Sterilization

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

Maximum Operating Temperature

80 °C @ ≤ 30 psi (2 Kg/cm²)

Maximum Differential Pressure

50 psi (3.5 Kg/cm²) @ 25 °C

Bubble Point

≥ 50psi (3.51Kg/cm²) with Water

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

Passes test as per USP <1231>

Ordering Information

Type	Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size		
	Code	Length and EFA	Code	Code	Code	Code	Code	Code	Code	Code	Code		
AseptiSure WS (0.45 µm upstream)	CWHX	5" (3000 cm ²)	53	0.2 µm	01	7P	A0	Silicone	SS	Non-Sterile	1	1	01
		10" (6000 cm ²)	54			7P without fin	A1	EPDM	SE				
		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

CWHX	56	01	A0	SS	1	01
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