

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

- Cell culture media
- Growth regulators
- Small Volume Parenterals



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

Meets and Exceeds USFDA 21 CFR 177.1520

### 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<sup>2</sup>

#### 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<sup>2</sup>)

#### Maximum Differential Pressure

50 psi (3.5 Kg/cm<sup>2</sup>) @ 25°C

#### Bubble Point

≥ 31psi (2.18Kg/cm<sup>2</sup>) 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	Code	Code	Code				
AseptiSure WS (0.2 µm upstream)	CWH1	5" (3000 cm <sup>2</sup> )	53	0.1 µm	36	7P	A0	Silicone	SS	Non-Sterile	1	1	01		
		10" (6000 cm <sup>2</sup> )	54			7P without fin	A1	EPDM	SE						
AseptiSure WS (0.2 µm upstream)	CWHX	20" (12000 cm <sup>2</sup> )	55			'O'	D0	Viton	SV					FEP Encapsulated Viton	FV*
		30" (18000 cm <sup>2</sup> )	56												

\*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
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