

mdi 0.45µm 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

Bioburden reduction of:

- Intermediate process solutions
- Buffers



Specifications

Pore Size
0.45 µm

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Microbial Retention

LRV >7 for *Serratia marcescens* (ATCC 14756) per cm²

Integrity Testing (Bubble Point)

≥ 30 psi (2.11 Kg/cm²) with water

Sterilization

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

Typical Water Flow Rates (for 10" cartridge filter)

75 lpm @ 15 psi

Maximum Operating Temperature

80 °C @ ≤ 30 psi (2 Kg/cm²)

Maximum Differential Pressure

50 psi (3.5 Kg/cm²) @ 25 °C

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 NVR test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

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

Meets and Exceeds USFDA 21 CFR 177.1520

Ordering Information

Type	Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size		
	Code	Length and EFA	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code	
AseptiSure WS (0.8 µm upstream)	CWH5	5"* (3000 cm ²)	53	0.45 µm	02	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			28 with Fin	C0	FEP Encapsulated Viton	FV**				

EFA: Effective Filtration Area

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

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

Example

CWH5	54	02	A0	SS	1	01
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DST CWH502X1722A