

AseptiCap WS Hydrophilic PVDF Membrane Large Capsule Filters

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

These capsule 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
- > Low hold up volume

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 USEDA 21 CEP 177 1520

Meets and Exceeds USFDA 21 CFR 177.152



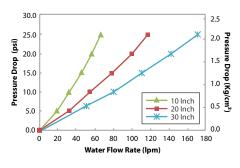
Specifications

Pore Size 0.2 μm and 0.45μm

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Typical Water Flow Rates, 0.2 μm



Microbial Retention

0.2 \mum: LRV >7 for *B. diminuta* (ATCC 19146) per cm²

0.45μm: LRV >7 for *Serratia marcescens* (ATCC 14756) per cm² **Maximum Operating Temperature** $80 \degree C @ \le 30 \text{ psi} (2 \text{ Kg/cm}^2)$

Maximum Differential Pressure 60 psi (4 Kg/cm²) @ 30 °C

Bubble Point

0.2 μ m: \geq 50psi (3.51Kg/cm²) with Water **0.45** μ m: \geq 30 psi (2.11 Kg/cm²) with water

Sterilization

By Autoclave: Autoclavable at 125°C for 30 minutes, 2 cycles. Can not be in-line steam sterilized

By Gas: Sterilization by Ethylene Oxide

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

DST LWSXXXX1611A

Extractables with WFI

Passes test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Ordering Information

Туре		Size		Pore Size		Inlet /Outlet		Х	Inline/T-Line		Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code			Code		Code		Code
AseptiCap WS (0.45 μm upstream)	LWSX	5" (3000 cm ²)	53	0.2 µm	01	1½" Sanitary Flange	E		Inline	Х	Non-Sterile	1	1	01
		10" (6000 cm ²)	54	0.45 μm	02	Single Step ½" Hose Barb	Q		T-Line**	Т	EO Sterile	2		
AseptiCap WS (0.8 μm upstream)*	LWS5	20" (12000 cm ²)	55			³ ⁄ ₄ " Sanitary Flange****	E	***						
		30" (18000 cm ²)	56			¾" Hose Barb	I	*0.8μm upstream is available with 0.2μm capsule filters only **T-line Capsule Filter are available with 1½"Sanitary Flange I/O only						
EFA: Effective Filtration Area						***1"Hose Barb connection is not available in 5" capsule filters								
						****3/4" Sanitary Flange is available only in 5" and 10" capsule filters								
E								Note: S	ize 5″is availa	ble in Inl	line Capsule filters	only		
Example														
LWSX		56		01		QQ		Х	X		1		C)1