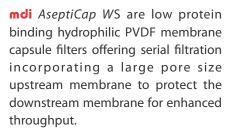


AseptiCap WS Hydrophilic PVDF Membrane Large Capsule Filters



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 USFDA 21 CFR 177.1520



Specifications

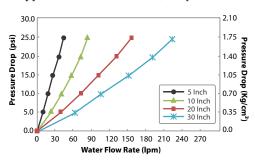
Pore Size

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 μm: LRV >7 for *B. diminuta* (ATCC

19146) per cm²

0.45μm: LRV >7 for Serratia marcescens

(ATCC 14756) per cm²

Maximum Operating Temperature $80 \,^{\circ}\text{C} \,@\,\leq\, 30 \,\text{psi} \,(2 \,\text{Kg/cm}^2)$

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

Bubble Point

0.2 μm: ≥ 50psi (3.51Kg/cm²) with Water **0.45 μm:** ≥ 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

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		Γ
	Code	Length and EFA	Code		Code		Code	Г
AseptiCap WS	LWSX	5" (3000 cm ²)	53	0.2 μm	01	1½" Sanitary Flange	E	1
(0.45 µm upstream)	LWSA	10" (6000 cm ²)	54	0.45 μm	02	Single Step ½" Hose Barb	Q]
AseptiCap WS	LWS5	20" (12000 cm ²)	55			3/4" Sanitary Flange****	Е	1
(0.8 μm upstream)*	LWSS	30" (18000 cm ²)	56]		¾" Hose Barb	- 1	
				•		1" Hose Barb***	Z	1

EFA: Effective Filtration Area

Х	Inline/T-Line		Sterility	Pack Size		
		Code		Code		Code
	Inline	Х	Non-Sterile	1	1	01
	T-Line**	Т	EO Sterile	2		
					•	

*0.8µm upstream is available with 0.2µm capsule filters only
**T-line Capsule Filter are available with 1½″Sanitary Flange I/O only
***1″Hose Barb connection is not available in 5″ capsule filters

***1"Hose Barb connection is not available in 5" capsule filters

****3/4" Sanitary Flange is available only in 5" and 10" capsule filters

Note: Size 5" is available in Inline Capsule filters only

Example								
LWSX	56	01	QQ	X	X	1	01	