

mdi AseptiCap WS-γ are low protein binding hydrophilic PVDF gamma sterilizable membrane capsule filters offering serial filtration incorporating a larger 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

Sterile Filtration of

- 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

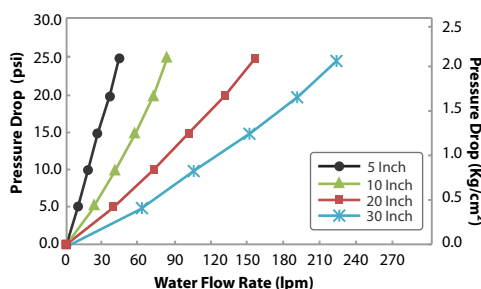
Pore Size

0.2 μm and 0.45 μm

Materials of Construction

Membrane	Hydrophilic PVDF
Plastic Components	Polypropylene

Typical Water Flow Rates, 0.2μm Filters



Microbial Retention

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

0.45μm: LRV >7 for *Serratia marcescens* (ATCC 14756) per cm²

Maximum Operating Temperature

80 °C @ ≤30 psi (2 Kg/cm²)

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 Irradiation: Gamma irradiatable up to 50 kGy

By Autoclave: Autoclavable at 125°C for 30 minutes, 1 cycle after gamma irradiation. Cannot be in-line steam sterilized

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		Inlet /Outlet		Radiation Sterilizable		Inline/T-Line		Sterility		Pack Size		
	Code	Length and EFA	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code		
AseptiCap WS (0.45 μm upstream)	LWSX	5" (3000 cm ²)	53	0.2μm	01	1½"Triclover	E	Yes	R	Inline	X	Non-Sterile	1	1	01
		10" (6000 cm ²)	54	0.45μm	02	Single Step ½" Hose Barb	Q	No**	X	T-Line***	T	Gamma Sterile	3		
		20" (12000 cm ²)	55			3/8" Hose Barb	I								
AseptiCap WS (0.8 μm upstream)*	LWS5	30" (18000 cm ²)	56			1" Hose Barb	Z								
		EFA: Effective Filtration Area													

**0.45 μm capsule filters are available with 0.8 μm upstream only
**Gamma sterile capsule filters cannot be gamma irradiated again
***T-line Capsule Filters are available with 1½" Sanitary Flange I/O Connections only
Size 5" is available in Inline Capsule filters only

Example

LWSX	56	01	QQ	R	X	1	01
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For Non-Sterile: LWSX5601QQRX101

For Gamma Sterile: LWSX5601QQXX301

DST LWSXRX1600B