

AseptiCap WS-y Hydrophilic PVDF Membrane **Capsule Filters**

mdi AseptiCap WS-y 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 \triangleright
- 100% integrity tested
- Low protein binding \triangleright
- Low extractables
- \triangleright Very low hold up volume in filters

Applications

Sterile Filtration of

- Antibodies \triangleright
- Protein Solutions
- **Buffers**
- Vaccine concentrates \triangleright
- 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

Ordering Information



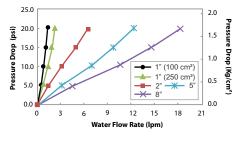
Specifications

Pore Size 0.2 µm

Materials of Construction

Membrane	Hydrophilic PVDF
Plastic Components	Polypropylene

Typical Water Flow Rates, 0.2µm



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 °C @ < 30 psi (2 Kg/cm²)

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

Bubble Point (with water)

0.2 \mum: \geq 50psi (3.51Kg/cm²) **0.45 \mum:** > 30 psi (2.11 Kg/cm²)

Sterilization

By Irradiation: Gamma irradiatiable 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

DST DWSX01R1610C

Extractables with WFI

Passes NVR test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Туре		Size		Pore Size		Inlet /Outlet		Radiation Sterilizable		X Sterility		y Pack Size			
	Code	Length and EFA	Code		Code		Code		Code			Code		Code	
		1" (100 cm ²)	31	0.2µm	01	1⁄4″ SHB	A	Yes	R	1	Non-Sterile	1	1	01	
	DWSX	1" (250 cm ²)	51	0.45µm	02	1/2" Hose Barb	D	No*****	Х	1	Gamma Sterile	3			
Upstream)	DWS5	2" (500 cm ²)	52			1½"Triclover	E	*0.8 µm upstream is available with 0.45µm capsule filters only							
AseptiCap WS (with 0.8μm Upstream)*		5" (1000 cm ²)	53			34" Sanitary Flange	S	**Single step ½" hose barb and 3/8" Hose Barb end connections are not ava in 1" capsule filter						ot availak	
		8" (2000 cm ²)	57			Quick Connector	J								
Single Step ½" Hose Barb**							Q	***Male luer slip end connection is available as outlet only in 1" capsule filters ****3/16" hose barb end connection is available in:							
Female Luer Lock EFA: Effective Filtration Area Male Luer Slip***						U	- 1" and 2" capsule filters as inlet and outlet - 5" as outlet only								
						W									
					3/16" Hose Barb****	N	*****Gamma sterile capsule filters cannot be gamma irradiated again								
Example 3/8" Hose Barb**							1	-							
DWSX		53		01		QQ		R		Х	1		0	1	
For Non-Steri	le: DWS	X5301OORX101		For Ga	mma Ste	erile: DWSX5301OOXX301					•				

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