mdi Membrane Technologies

0.2µm *AseptiCap WS* Hydrophilic PVDF Membrane Inline Capsule Filters

mdi *AseptiCap WS* are low protein binding hydrophilic PVDF membrane inline capsule filters, designed for sterile filtration of very small fluid volumes in formulation and process development labs.

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.

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

Applications

Sterile Filtration of

- Antibodies
- Protein Solutions
- Buffers
- Heat labile additives
- Vaccine concentrates
- Small Volume Parenterals

Key features

- Absolute retention
- 100% integrity tested
- Low protein binding
- Low extractables
- Very low hold up volume

Specifications

Construction			
Pore Size		0.2µm	
Membrane		Hydrophilic PVDF	
Plastic Components		Polypropylene	
Size			
Size		25 mm	50 mm
Effective Filtration Area (Nominal)		5 cm^2	20 cm^2
Integrity Testing/Retention			
Bubble Point		≥ 50psi (3.52 Kg/cm^2) with Water	
Microbial Retention		LRV>7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2	
Operational			
Max. Operating Temperature		55 °C	60 °C
Max. Differential Pressure		75 psi (5 Kg/cm^2 @25°C)	42 psi (3 Kg/cm^2) @ 30 °C
Sterilization	By Gas	Sterilization by Ethylene Oxide	
	By Autoclave	Autoclavable at 125°C for 30 minutes, 2 cycles. Cannot be in-line steam sterilized	
Assurance			
Bacterial Endotoxin		Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>	
Toxicity		Passes Biological reactivity Test, *In Vivo*, as per USP <88> for Class VI plastics	

DATA SHEET

Assurance	
Cytotoxicity	Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity
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

25 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code		Code				Code		Code
AseptiCap WS (0.45µm Upstream)	IWSX	25mm	06	0.2 µm	01	⅛" Hose Barb	H	⅛" Hose Barb	H			Non Sterile	1	100	04
						¼" Hose Barb	B	¼" Hose Barb	B			EO Sterile	2		
						Female Luer Lock	M	Male Luer Slip	N						
								Male Luer Lock	L						

Example:

IWSX	06	01	M	N	X	X	1	04

50 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code		Code				Code		Code
AseptiCap WS (0.45 µm Upstream)	IWSX	50 mm	10	0.2 µm	01	¼" SHB	B	¼" SHB	B			Non Sterile	1	10	02
Vented *AseptiCap WS* (0.45 µm Upstream)	VWSX					¾" Sanitary Flange	S	¾" Sanitary Flange*	S			EO Sterile	2	100	04

* In vented *AseptiCap WS* ¾" Sanitary Flange is available as outlet only

Example:

IWSX	10	01	S	S	X	X	1	04

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