mdi
Membrane Technologies

0.1 µm *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

- Cell culture media
- Growth regulators
- Small volume parenterals

Complies with USFDA 21 CFR 210.3(b)(6)
Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

Pore Size
0.1 µm

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Microbial Retention
LRV >7 for *A. laidlawii* (ATCC 23206) per cm^2

Maximum Operating Temperature
80 °C @ ≤ 30 psi (2 Kg/cm^2)

Maximum Differential Pressure
60 psi (4 Kg/cm^2) @ 30 °C

Bubble Point
≥31psi (2.18 Kg/cm^2) with 50% IPA/ water solution

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

Type		Size		Pore Size		Inlet /Outlet		X	Inline/T-Line		Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code			Code		Code		Code
AseptiCap WS (0.2 µm upstream)	LWS1	5" (3000 cm^2)	53	0.1 µm	36	1½" Sanitary Flange	E		Inline	X	Non-Sterile	1	1	01
		10" (6000 cm^2)	54			Single Step ½" Hose Barb	Q		T-Line*	T	EO Sterile	2		
AseptiCap WS (0.45 µm upstream)	LWSX	20" (12000 cm^2)	55			3/8" Hose Barb	I							
		30" (18000 cm^2)	56			1" Hose Barb	Z							

EFA: Effective Filtration Area

*T-line Capsule Filter are available with 1½"Sanitary Flange I/O Connections only
Size 5" is available in Inline Capsule filters only

Example

LWS1	56	36	QQ	X	X	1	01

DATA SHEET

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