0.1µm *AseptiCap WS-γ* Hydrophilic PVDF Membrane Large Capsule Filters

mdi 0.1µm *AseptiCap WS-γ* are low protein binding hydrophilic PVDF membrane capsule filters, validated to retain mycoplasma, a critical requirement for sterilization of mammalian cell culture media.

These capsules offer serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

0.1µm *AseptiCap WS-γ* 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
- Very low hold up volume in filters

Applications

Sterile Filtration of

- Cell culture media
- Growth regulators
- Small Volume Parenterals

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 210.3(b)(6)

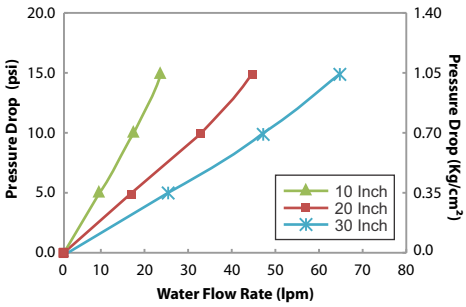
Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Typical Water Flow Rates



Microbial Retention

LRV >7 for *Acholeplasma 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 with 50% IPA

≥ 31psi

Sterilization

By Irradiation: Gamma irradiatiable up to 50 kGy

By Autoclave: Autoclavable at 125°C for 30 minutes, 1 cycle after gamma irradiation. Can not 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 NVR test as per USP <661>

Oxidizable Substances

Passes test as per 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
AseptiCap WS (0.2µm upstream)	LWS1	5" (3000 cm^2)	53	0.1µm	36	1½" Sanitary Flange	E	Yes	R	Inline	X	Non-Sterile	1	1	01
		10" (6000 cm^2)	54			Single Step ½" Hose Barb	Q	No**	X	T-Line***	T	Gamma Sterile	3		
AseptiCap WS (0.45µm upstream)	LWSX	20" (12000 cm^2)	55			¾" Sanitary Flange****	S								
		30" (18000 cm^2)	56			3/8" Hose Barb	I								
						1" Hose Barb*	Z								

*1" Hose Barb is not available in 5" capsule filters
**Gamma sterile capsule filters cannot be gamma irradiated again
***T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections only
****3/4" Sanitary Flange is available only in 5" and 10" capsule filters
Note: Size 5" is available in Inline Capsule filters only

EFA: Effective Filtration Area

Example

LWS1	54	36	QQ	R	X	1	01

For Non-Sterile: LWS15436QQRX101 **For Gamma Sterile: LWS15436QQXX301**

DATA SHEET

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