

0.1µm AseptiCap WS-y Hydrophilic PVDF Membrane Capsule Filters

mdi 0.1 µm AseptiCap WS-y 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 larger pore size upstream membrane to protect the downstream membrane for enhanced throughput.

0.1 μm AseptiCap WS-y 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



Specifications

Materials of Construction

Membrane	Hydrophilic PVDF
Plastic Components	Polypropylene

Microbial Retention

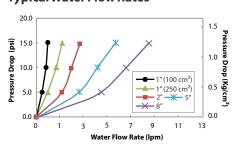
LRV >7 for Acholeplasma laidlawii (ATCC 23206) per cm²

Bubble Point with 50% IPA/Water >31psi

Maximum Operating Temperature 80° C @ \leq 30 psi (2 Kg/cm²)

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

Typical Water Flow Rates



Sterilization

By Irradiation: Gamma irradiatiable up to 50 kGy

By Autoclave: Autoclavable at 125°C for 30 minutes, 1 cycle after gamma irradiaton. 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 a 3 liter flush

Extractables with WFI

Passes NVR test as per USP <661>

Oxidizable Substances

- 1" and 2" capsule filters as inlet and outlet

Passes test as per USP <1231>

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

Ordering Information

Туре		Size		Pore Size Inlet/Outl		Inlet/Outlet	Radiation Sterilizable		Х	Sterility		Pack Size		
	Code	Length and EFA	Code		Code		Code		Code			Code		Code
AseptiCap WS	DWSX	1" (100 cm ²)	31	0.1µm	36	1/4" SHB	Α	Yes	R		Non-Sterile	1	1	01
(with 0.45µm Upstream)		1" (250 cm ²)	51			½" Hose Barb	D	No****	Х		Gamma Sterile	3		
AseptiCap WS	DWS1	2" (500 cm ²)	52			1½" Sanitary Flange	E						'	
(with 0.2μm Upstream)		5" (1000 cm ²)	53			¾" Sanitary Flange	S	* Single sten 1/3"	hose harh ar	nd 3/8" h	ose barb end con	nections	are no	t availahle
		8" (2000 cm²)	57			Quick Connector	J	in 1" Capsule filte		14 5/0 11	iose barb ena con	ricctions	raic no	t a vallable
					Single Step ½" Hose Barb*	Q	**Male luer slip end connection is available as outlet only in 1" capsule filters							
						Female Luer Lock	U	***3/16" hose ba	irb end conn	ection is	s available in:			

Female Luer Lock

FFA Fffti Filturation Am	_	Male Luer Slip^^	VV	- 5" as outlet only						
EFA : Effective Filtration Are	ea ea	3/16" Hose Barb***	N	****Gamma sterile capsule filters cannot be gamma irradiated again						
Example	3/8" Hose Barb*	1								
DWSX	53	36	3/8" Hose Barb* QQ		R	Х	1	01		

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For Non-Sterile: DWSX5336OORX101

For Gamma Sterile: DWSX533600XX301