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

mdi 0.1 µm *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 larger pore size upstream membrane to protect the downstream membrane for enhanced throughput.

0.1 µm *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

Specifications

Materials of Construction

Membrane	Hydrophilic PVDF
Plastic Components	Polypropylene

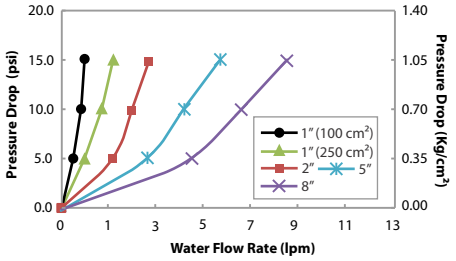
Microbial Retention
LRV >7 for *Acholeplasma laidlawii* (ATCC 23206) per cm^2

Bubble Point with 50% IPA/Water
≥ 31 psi

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

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

Typical Water Flow Rates



Sterilization By Gamma Irradiation
Gamma irradiatiable up to 50 kGy. Gamma sterilized capsule filters must not be autoclaved or 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
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

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code		Code			Code		Code
AseptiCap WS (with 0.45µm Upstream)	DWSX	1" (100 cm^2)	31	0.1µm	36	¼" SHB	A	Yes	R		Non-Sterile	1	1	01
		1" (250 cm^2)	51			½" Hose Barb	D	No****	X		Gamma Sterile	3		
AseptiCap WS (with 0.2µm Upstream)	DWS1	2" (500 cm^2)	52			1½" Sanitary Flange	E							
		5" (1000 cm^2)	53			¾" Sanitary Flange	S							
		8" (2000 cm^2)	57			Quick Connector	J							
						Single Step ½" Hose Barb*	Q							
						Female Luer Lock	U							
						Male Luer Slip**	W							
						3/16" Hose Barb***	N							
						3/8" Hose Barb*	I							

* Single step ½" hose barb and 3/8" hose barb end connections are not available in 1" Capsule filter
**Male luer slip end connection is available as outlet only in 1" capsule filters
***3/16" hose barb end connection is available in:
- 1" and 2" capsule filters as inlet and outlet
- 5" as outlet only

****Gamma sterile capsule filters cannot be gamma irradiated again

EFA: Effective Filtration Area

Example							
DWSX	53	36	QQ	R	X	1	01

For Non-Sterile: DWSX5336QQRX101 **For Gamma Sterile: DWSX5336QQXX301**

DATA SHEET

Advanced Microdevices Pvt. Ltd., 20-21, Industrial Area, Ambala Cantt - 133006, INDIA
Tel: +91-171-2699290, 2699471 Email: info@mdimembrane.com Website: www.mdimembrane.com