0.1 µm *AseptiCap WS* Hydrophilic PVDF Membrane Capsule Filters

DATA SHEET

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
- Very low hold up volume in filters

Applications

Sterile Filtration of

- Cell culture media
- Growth Regularors
- 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 (2.18Kg/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 a 3 liter flush

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		X	X	Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code				Code		Code
AseptiCap WS (0.2 µm Upstream)	DWS1	1" (250 cm^2)	51	0.1 µm	36	¼" SHB	A			Non-Sterile	1	1	01
		2" (500 cm^2)	52			½" Hose Barb	D			EO Sterile	2		
AseptiCap WS (0.45 µm Upstream)	DWSX	5" (1000 cm^2)	53			1½" Sanitary Flange	E						
		8" (2000 cm^2)	57			¾" Sanitary Flange	S						
						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

EFA: Effective Filtration Area

Example

DWSX	53	36	EE	X	X	1	01

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