



Membrane Technologies

# 0.2µm, Polyethersulfone Membrane Capsule Filters Type MDKL

MDKL capsule filter are specially designed for use in formulation/process development labs and compounding pharmacies.

These provide a large area filtration device for small volumes of difficult to filter solutions and are available with special end connections to allow use with syringe or peristaltic pump.

## 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
- Cell culture media containing serum
- Media additives
- pH adjusters
- Final product concentrates
- Small volume parenterals



<b>Microbially Validated as per ASTM F 838-05</b>
<b>Complies with USFDA 21 CFR 210.3(b)(6)</b>
<b>Meets and Exceeds USFDA 21 CFR 177.1520</b>

## Specifications

### Pore Size

0.2 µm

### Membrane

Hydrophilic Polyethersulfone

### Microbial Retention

LRV >7 for *B. diminuta* (ATCC 19146) per cm<sup>2</sup>

### Maximum Operating Temperature

80 °C @ ≤30 psi (2 Kg/cm<sup>2</sup>)

### Maximum Differential Pressure

60 psi (4 Kg/cm<sup>2</sup>) @ 25 °C

### Bubble Point

≥50psi (3.51Kg/cm<sup>2</sup>) with Water

## Sterilization

**By Autoclave:** Autoclavable at 125°C for 30 minutes. 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 specified minimal flush

## Extractables with WFI

Passes NVR test as per USP <661>

## Oxidizable Substances

Passes test as per USP <1231>

## Ordering Information

Type		Size (EFA)		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
MDKL	MDKL	1"	51	0.2µm	01	¼" SHB	A			Non Sterile	1	1	01
		2"	52			¼" MNPT	B			EO Sterile	2		
		5"	53										
		8"	57										

Example:

MDKL	52	36	BA	X	X	1	01
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Example for Non Sterile: MDKL5201BAXX101

Example for EO Sterile: MDKL5201BAXX101

DATA SHEET

DST MDKL01X1518G