

Large Polyethersulfone Membrane AseptiCap- LKS

Large Polyethersulfone Membrane Capsule Filters

mdi AseptiCap- LKS are extra large disposable Polyethersulfone membrane capsule filters, specially designed for high value biopharma manufacturing processes, providing a unique combination of high throughputs and low hold up volumes. These capsule filters offer serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane and do away with the time and expense associated with assembling, cleaning and validating stainless steel housings.

mdi AseptiCap- LKS capsule filter are offered in various pore size ratings to suit a multitude of applications in life sciences research, biopharmaceuticals and healthcare industries. These products are validated for use in pharmaceutical and biopharmaceutical applications.

Application

- ◆ Scale up of new drug delivery systems
- ◆ Bioburden removal from cell harvest supernatants
- ◆ Sterilization of biopharmaceuticals such as vaccines and therapeutic proteins
- ◆ Sterilization of oncology drugs
- ◆ Sterilization of buffers

Material of Construction

Housing: Polypropylene
Filter Media: Polyethersulfone
Membrane

Support Layer: Polyester

Special Features

- ◆ Absolute retention
- ◆ Low protein binding
- ◆ No elastomeric seals
- ◆ Light weight and self supporting
- ◆ Minimum cleaning and low installation cost
- ◆ Process upscale convenience
- ◆ Large filtration area
- ◆ Low hold up volume
- ◆ Very high flow rates
- ◆ 100% Integrity tested
- ◆ Total traceability

Microbially Validated as per ASTM F 838-83

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520



Specification

Maximum Operating Pressure: 4Kg/cm² @ 30 °C
Maximum Operating Temperature: 80 °C @ < 2Kg/cm²
Retention Efficiency:
0.2 µm: LRV > 7 for Br. diminuta
0.45 µm: LRV > 7 for Serratia marcescens
Sterilization:
25 autoclave cycles of 30 minutes at 121 °C
Biosafety:
Passes the Biological tests for Class VI plastics as per USP
Extractables with Water:
Within limits specified in USP
Fiber Release:
Complies with USFDA CFR Title 21, Part 211.72
Oxidizable Matter:
Passes test as per USP

Integrity Test Data

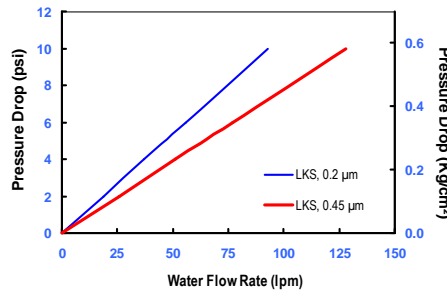
Water Wetted Bubble Point

Pore Size	psi	Kg/cm ²
0.2 µm	≥50	3.52
0.45 µm	≥30	2.10

Air Diffusion Flow (Water Wetted)

Pore Size	Test Pressure	Max. Air Diffusion Flow
0.2 µm	37 psi (2.6 Kg/cm ²)	≤ 30 ml/min
0.45 µm	24 psi (1.68 Kg/cm ²)	≤ 35 ml/min

Water Flow Rate



Type	Code	Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size		Ordering Information
		Length	Code	Code	Code	Code	Code			Code	Qty	Code		
LKS	LKS5	10"	54	0.2 µm	01	1.5" Sanitary Flange		E		Non Sterile	1	1	01	
				0.45 µm	02					ETO Sterile	2			
EXAMPLE LKS5 54 01 EE X X 2 01														