Pharmsteri[™] PES Disposable Filter

Cost-effective, safe, sterile filtration for pharmaceutical applications

PharmsteriTM PES disposable filters are designed for provide smart, disposable, safe filtration for pharmaceutical applications. Constructed of polypropylene (PP) components and a hydrophilic polyethersulfone (PES) membrane, these disposable filters can help eliminate cleaning problems and extra validation costs.

Our portfolio of Pharmsteri PES filters is 100% tested during manufacturing to ensure high quality performance, providing sterility assurance. The T-style configuration is ideal for quicker and easier installation.



Allows high flow and low hold-up volume of liquids.

APPLICATIONS

- Bioburden reduction or sterile filtration for injections
- Bulk chemicals
- Buffers

FEATURES & BENEFITS

Polypropylene and PES construction	Allows use in a broad range of applications
1.5" Tri-Clamp connector	Allows easier, user-friendly installation
Optimized form factor	Allows high flow and low pressure drop, lowering cost of ownership
All components meet USP <88> Class VI Plastics Test	Provides biosafety insurance and global regulatory compliance

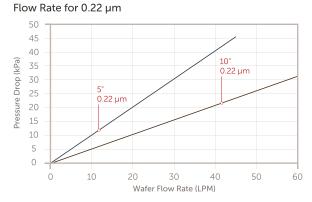


SPECIFICATIONS

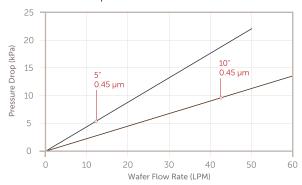
Retention rating	Single-layer	0.22, 0.45 μm	
	Dual-layer	0.45 + 0.22 μm	
Materials	Membrane	Polyethersulfone (PES)	
	Housing, support	Polypropylene	
	Sleeve, core, top, end caps	Polypropylene	
	O-ring	Silicone	
Sealing technology	Thermal bonding without adhesives		
Filtration area	10" Single-layer	≥0.6 m²	
	10" Dual-layer	≥0.53 m²	
	5" Single-layer	≥0.3 m²	
	5" Dual-layer	≥0.25 m²	
Integrity test (0.22 µm)	Minimum bubble point at 25°C (77°F)	≥3500 mbar	
	Maximum diffusion flow at 2800 mbar @ 25°C (77°F)	5": <u>≤</u> 15 mL/min	
		10": ≤30 mL/min	
Maximum operating conditions	Maximum forward differential pressure	5.0 bar @ 25° \pm 2°C (77°F), 3.0 bar @ 60° \pm 2°C (140°F)	
Sterilization cycles	Maximum 5 cycles of autoclave @ 127°C (261°F), 30 min		
Endotoxin releasing	<0.25 EU/mL according to the USP test methodology		
TOC	<0.5 mg/L after a water flush of 11 L/10" filter		
Conductivity	≤1.3 µS/cm after water flush of 11 L/10" filter		
Particle release	Meets the requirements of WFI set by USP		
Non-fiber releasing	Meets the criteria for a non-fiber releasing filter defined in 21 CFR 210.3(b)(6)		
NVR	After autoclaving and 24-hours in 50% ethanol water with vibration (contact Entegris for details)		
Material toxicity	All components meet the requirements of the USP <88> Reactivity Test for Class VI Plastics		
	Filters meet the requirements of USP <87> Biological Reactivity Tests In Vitro Cytotoxicity		
Bacterial challenge test	Passed the bacterial challenge test using \textit{Brevundimonas diminuta} (ATCC 19146) at a minimum challenge concentration $1x10^7$ CFU/cm ² (0.22 μ m) per ASTM methodology		
Indirect food additive	Meets the FDA Indirect Food Additive requirements cited in 21 CFR 177-182		
Food contact material	(EU) No. 1935/2004, (EU) No. 10/2011		
Quality	Manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system		

PERFORMANCE DATA

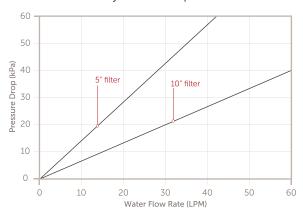
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Flow Rate for 0.45 µm

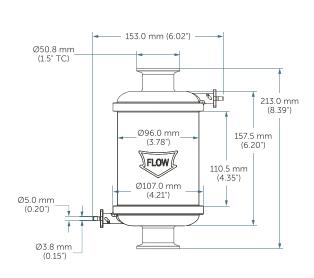


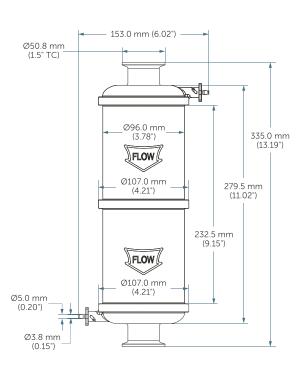
Flow Rate for Dual-layer 0.45+0.22 µm



DIMENSIONS







ORDERING INFORMATION

PART NUMBER	RETENTION RATING	LENGTH
PSTSUS022FS10-A2	0.22 μm	10"
PSTSUS022FS5-A2	0.22 μm	5"
PSTSUS045FS10-A2	0.45 μm	10"
PSTSUS045FS5-A2	0.45 μm	5"
PSTSUSD42FS10-A2	0.45 + 0.22 μm	10"
PSTSUSD42FS5-A2	0.45 + 0.22 μm	5"

FOR MORE INFORMATION

Please call your Regional Customer Service Center today to learn what Entegris can do for you. Visit entegris.com and select the Contact Us link to find the customer service center nearest you.

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