

Pharmsteri™ PES Disposable Filter

Cost-effective, safe, sterile filtration for single-use pharmaceutical applications

Pharmsteri™ PES disposable filters are designed for providing smart, safe filtration for single-use pharmaceutical applications. Constructed of autoclavable polypropylene (PP) components and a hydrophilic polyethersulfone (PES) membrane, these single-use filters can help eliminate cleaning problems and extra validation costs.

Single-layer and dual-layer configurations available to provide you the flexibility of choices for multiple applications. Filters with single-layer 0.45 µm PES membrane are typically utilized for bioburden reduction to protect downstream filters or columns while single-layer 0.22 µm filters are normally utilized for sterile filtration with superior flow rate. Dual-layer filters with 0.45/0.22 µm membrane configuration will be good choice for fouling solutions requiring better throughput and high sterility assurance.

APPLICATIONS

- Bioburden reduction or sterile filtration for injections
- Upstream/downstream processing steps
- Buffers
- Culture media
- Intermediates

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
Meet USP <88> Class VI Plastic Test and USP<87> Biological Reactivity Test	Provides biocompatibility insurance and global regulatory compliance



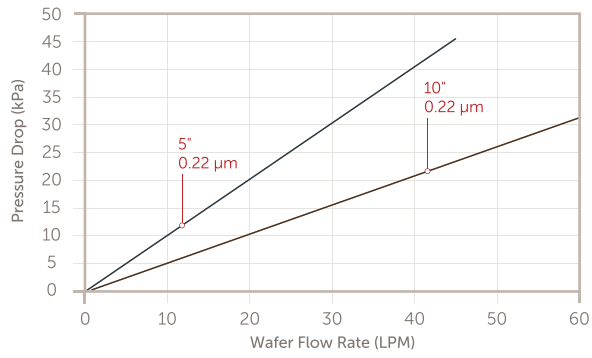
Allows high flow and low hold-up volume of liquids.

SPECIFICATIONS

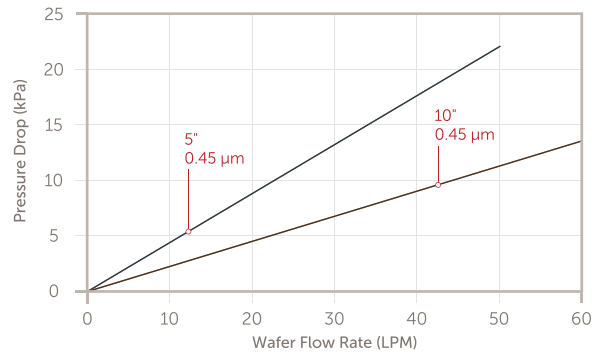
Retention rating	Single-layer	0.22, 0.45 µm
	Dual-layer	0.45 / 0.22 µm
Materials	Membrane	Polyethersulfone (PES)
	Housing, support	Polypropylene
	Sleeve, core, top, end caps	Polypropylene
	O-ring	Silicone
Sealing technology	Thermal bonding without adhesives	
Filtration area	10" Single-layer	0.6 m ²
	10" Dual-layer	0.53 m ²
	5" Single-layer	0.3 m ²
	5" Dual-layer	0.25 m ²
Integrity test (0.22 µm)	Minimum bubble point at 25°C (77°F)	≥50.7 psi (3500 mbar)
	Maximum diffusion flow at 40.6 psi (2800 mbar) @ 25°C (77°F)	5": ≤15 mL/min
		10": ≤30 mL/min
Maximum operating conditions	Maximum forward differential pressure	70.5 psi (5.0 bar) @ 25° ±2°C (77°F), 43.5 psi (3.0 bar) @ 60° ±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)	
Extractables	Tested according to USP<665>. Report is available upon request.	
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	Filters with the claim passed the bacterial challenge testing using <i>Brevundimonas diminuta</i> (ATCC 19146) at a minimum challenge concentration 1x10 ⁷ CFU/cm ² (0.22 µm) per ASTM F838 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

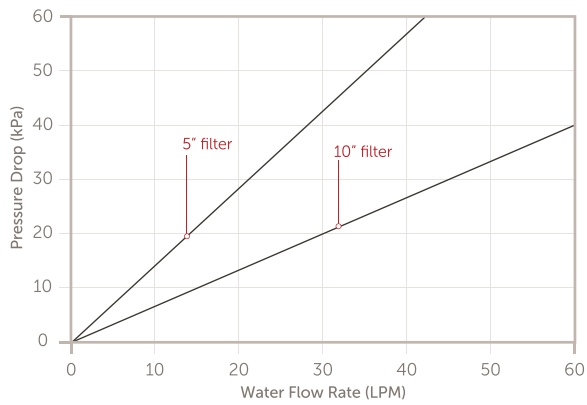
Flow Rate for 0.22 μm



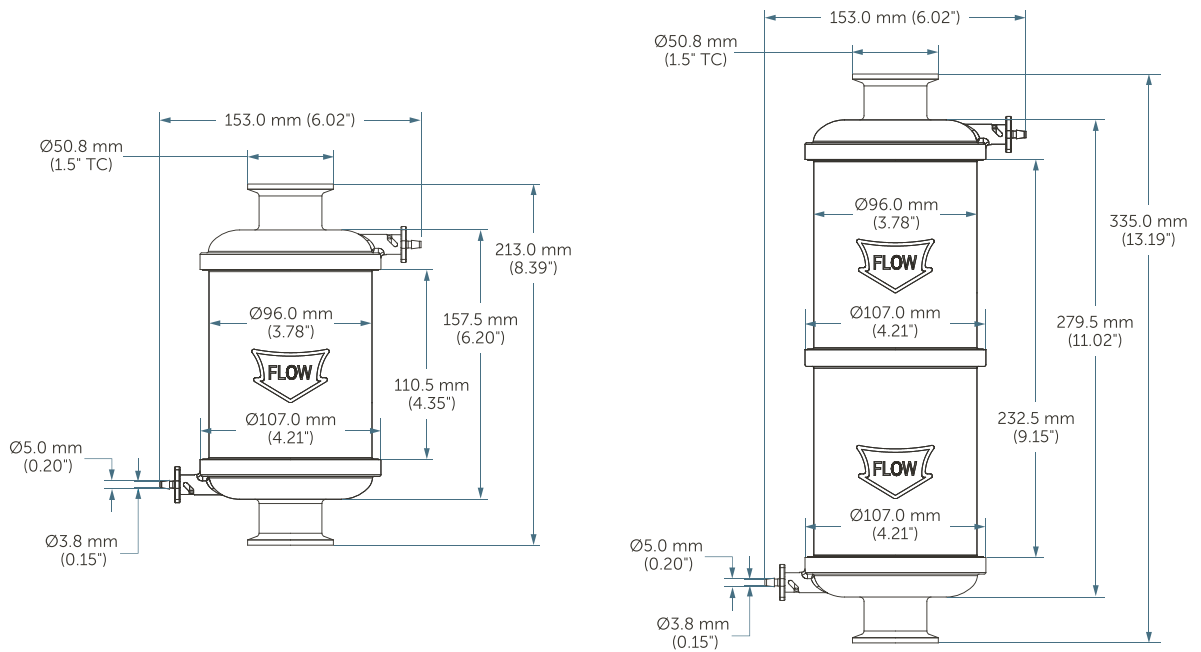
Flow Rate for 0.45 μm



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

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