

Pharmsteri™ PES Cartridge Filter

Provides economical filtration for pharmaceutical applications

Pharmsteri PES cartridge filters join our portfolio of filtration solutions that help ensure reliable product processing. Constructed of polypropylene components and hydrophilic polyethersulfone (PES) membrane, Pharmsteri PES cartridge filters are 100% integrity tested during manufacturing to guarantee high quality for bioburden reduction and sterility assurance.

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 standard sterility assurance.

APPLICATIONS

Pharmaceutical

- Bioburden reduction of LVP/SVP
- Sterile filtration for LVP/SVP/API
- Buffers
- Culture medium
- Intermediates

FEATURES & BENEFITS

Various fitting sizes and types available	Fits most stainless-steel housings, providing design flexibility and versatility in a broad range of applications
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 ¹	Provides biocompatibility insurance and global regulatory compliance



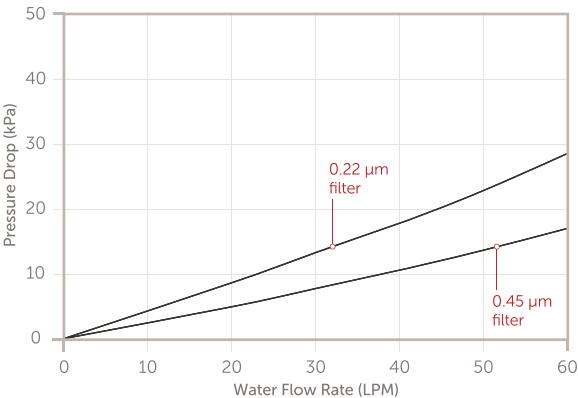
Allows high flow and low pressure drop, lowering cost of ownership.

SPECIFICATIONS

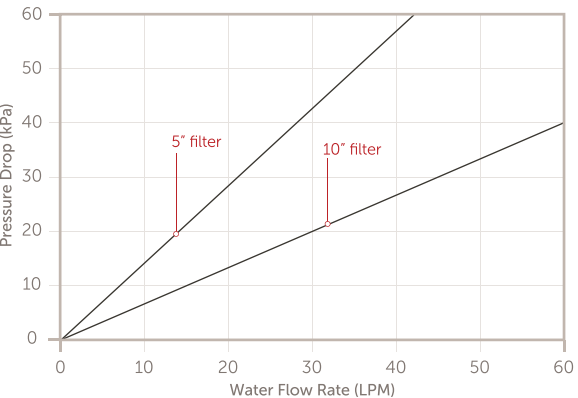
Retention rating	Single-layer	0.22, 0.45 µm
	Dual-layer	0.45/0.22 µm
Materials	Membrane	Polyethersulfone (PES)
	Support	Polypropylene
	Sleeve, core, top, and end caps	Polypropylene
	O-ring	Silicone
Sealing technology	Thermal bonding without adhesives	
Normal effective filtration area	Single-layer	0.6 m ² /10" cartridge
	Dual-layer	0.53 m ² /10" cartridge
Integrity test (0.22µm,0.45/0.22µm)	Minimum bubble point at 25°C (77°F)	≥50.7 psi (3500 mbar)
	Maximum diffusion flow at 40.6 psi(2800 mbar) at 25°C (77°F)	5" cartridge: ≤15 mL/min
		10" cartridge ≤30 mL/min
Maximum operating conditions	Maximum forward differential pressure	60.9 psi (4.2 bar) @ 25°C (77°F), 29.0 psi (2.0 bar) @ 80°C (176°F)
	Maximum operating temperature	80°C (176°F)
Multiple sterilization cycles	20 cycles of steam-in-place (SIP) sterilization or autoclave, 30 min at 127°C (261°F)	
Endotoxin releasing	<0.25 EU/mL as determined by the LAL test	
TOC	<0.5 mg/L after a water flush of 11 L/10" cartridge	
Conductivity	≤1.3 µS/cm after water flush of 11 L/10" cartridge	
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 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

10" Single-layer Cartridge Filter Water Flow

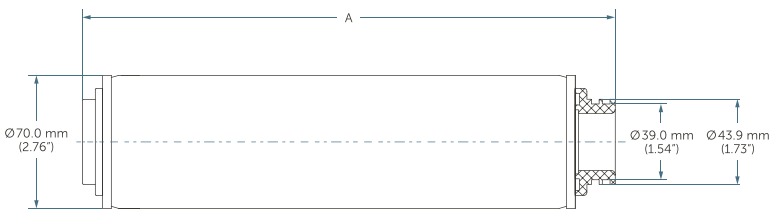


Dual-layer 0.45/0.22µm Cartridge Filter Water Flow



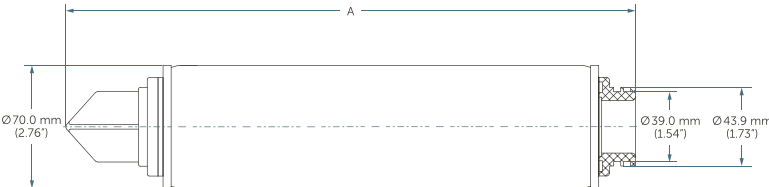
DIMENSIONS

Code 0



Length	Code 0 Dimension A
5"	148.0 mm (5.8")
10"	273.0 mm (10.7")
20"	517.5 mm (20.4")
30"	762.0 mm (30.0")
40"	1006.5 mm (39.6")

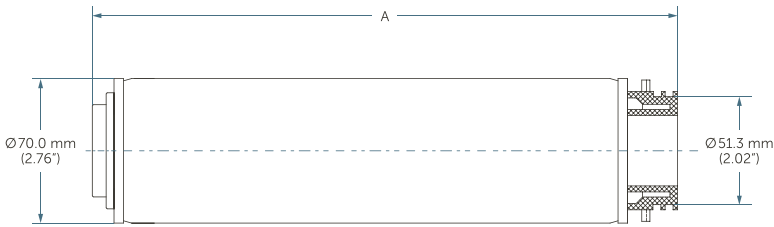
Code 5



Length	Code 5 Dimension A
5"	—
10"	314.0 mm (12.4")
20"	558.5 mm (22.0")
30"	803.0 mm (31.6")
40"	1047.5 mm (41.2")

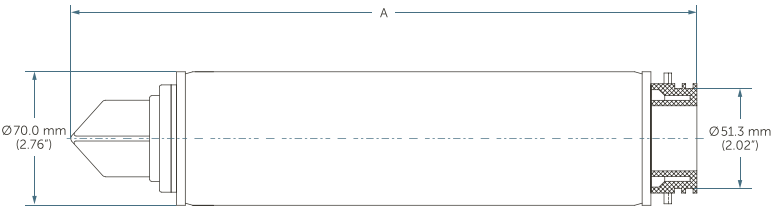
DIMENSIONS

Code 6



Length	Code 6 Dimension A
5"	150.5 mm (5.9")
10"	276.0 mm (10.9")
20"	520.0 mm (20.5")
30"	764.5 mm (30.1")
40"	1009.0 mm (39.7")

Code 7



Length	Code 7 Dimension A
5"	—
10"	316.5 mm (12.5")
20"	561.0 mm (22.1")
30"	805.5 mm (31.7")
40"	1050.0 mm (41.3")

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