

# Pharmsteri™ AHC PES Liquid Capsule and Cartridge Filter

*Improved throughput and broad chemical compatibility for various challenging fluid streams*

Pharmsteri™ AHC (autoclavable, high capacity) PES capsule and cartridge filters are constructed of highly asymmetric 0.45+0.22 µm or 0.65+0.22 µm dual-layer hydrophilic polyethersulfone (PES) membranes, and high-grade polypropylene (PP) non-woven, core, cage and shell.

Cartridge filters are compatible with existing stainless steel process system, and more economical for large scale manufacturing. Single-use capsule filters provide end users unparalleled flexibility and adaptability in a smaller footprint. Various capsules and cartridge sizes – from disc to 10” capsules and up to 30” cartridges - enables seamless scalability from lab-scale study to pilot and full-scale commercial manufacturing. Multiple connector types and codes are available to ensure easy integration with both single-use and stainless-steel systems.

## APPLICATIONS

- Bioburden or sterile filtration for various process fluids
- Cell culture media and additives
- Process intermediates in mAb, vaccines, etc.
- Column or downstream unit protection
- High concentration buffers
- Bulk drug substances
- Protein solutions or formulations
- Other fouling or non-fouling fluids



## FEATURES & BENEFITS

<b>Best-in-class throughput or capacity</b>	Dual layer and highly asymmetric membrane minimize pressure build-up while processing large volume fluids
<b>Low hold-up volume</b>	Structure design helps minimize dead zone which can cause loss of high value products
<b>Sterilizing grade meets Bacterial Challenge Test (ASTM F838)</b>	Ensures that microorganisms, such as bacteria, are removed from the fluid stream while not adversely affecting product
<b>Broad chemical compatibility</b>	pH 1~14, allows use in a range of chemicals including acids and bases
<b>Comprehensive validation</b>	Product has been rigorously validated to product specification and industry standards with comprehensive documentation to support compliance

## SPECIFICATIONS

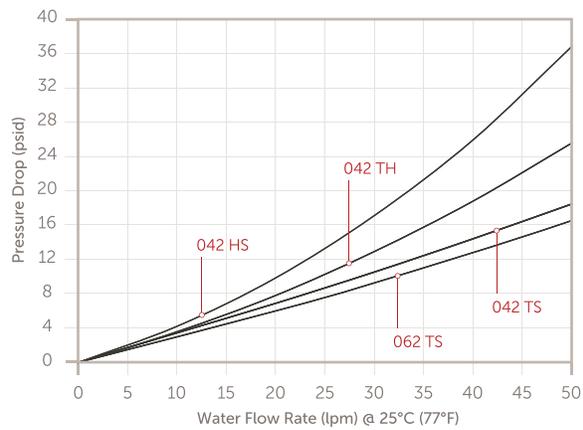
		3"/5"/10" In-line Capsules	5"/10"/20"/30" Cartridges
<b>Materials</b>	Media	Polyethersulfone (PES)	Polyethersulfone (PES)
	Support	Polypropylene	Polypropylene
	Core, cage, end caps	Polypropylene	Polypropylene
	O-ring	Silicone	Silicone
<b>Sealing technology</b>		Thermal bonding without adhesives	Thermal bonding without adhesives
<b>Pore size</b>		0.45+0.22 µm	0.45+0.22 µm
		0.65+0.22 µm	0.65+0.22 µm
<b>Filtration area</b>		3" 0.15 m <sup>2</sup>	5" 0.28 m <sup>2</sup>
		5" 0.28 m <sup>2</sup>	Per 10" 0.55 m <sup>2</sup>
		10" 0.55 m <sup>2</sup>	
<b>Integrity</b>	Bubble point	≥3.65 bar (53 psi) air with water	≥3.65 bar (53 psi) air with water
	Water Diffusion	3" ≤ 6.8 mL/min @ 40 psi at 25°C	5" ≤ 11 mL/min @ 40 psi at 25°C
		5" ≤ 10.5 mL/min @ 40 psi at 25°C	Per 10" ≤ 21 mL/min @ 40 psi at 25°C
<b>Maximum operating conditions</b>	Maximum operating pressure	80 psi (5.5 bar) @ 25°C (77°F)	80 psi (5.5 bar) @ 25°C (77°F)
		40 psi (2.8 bar) @ 60°C (140°F)	29 psi (2.0 bar) @ 80°C (176°F)
	Maximum differential pressure	Forward 60 psi (4.1 bar) @ 25°C (77°F)	Forward 60 psi (4.2 bar) @ 25°C (77°F)
		Forward 30 psi (2.1 bar) @ 60°C (140°F)	Forward 29 psi (2.0 bar) @ 80°C
	Reverse 10 psi (0.7 bar) @ 25°C (77°F)	Reverse 10 psi (0.7 bar) @ 25°C (77°F)	
<b>Bacteria Retention</b>		>10 <sup>7</sup> CFU/cm <sup>2</sup> <i>B. diminuta</i> per the ASTM F838	>10 <sup>7</sup> CFU/cm <sup>2</sup> <i>B. diminuta</i> per the ASTM F838
<b>Multiple sterilization cycles</b>		25 cycles of autoclave, 30 min at 127°C (260.6°F)	25 cycles of autoclave, 30 min at 127°C (260.6°F), or 25 cycles of 30 min steam in place (SIP) at 131°C with differential pressure under 300 mbar
<b>Endotoxin releasing</b>	<0.25 EU/mL as determined by the LAL test, meeting the requirements of USP <85>		
<b>Particulates</b>	Particulate matter release meets the requirement of USP <788>		
<b>Non-fiber releasing</b>	Manufactured with non-fiber release materials and tested according to 21 CFR 210.3 (b) (6)		
<b>TOC</b>	<0.5 mg/L post autoclave and after a water flush, meeting the requirements of USP <643>		
<b>Conductivity</b>	≤1.3 µS/cm post autoclave and after water flush, meeting the requirements of USP <645>		

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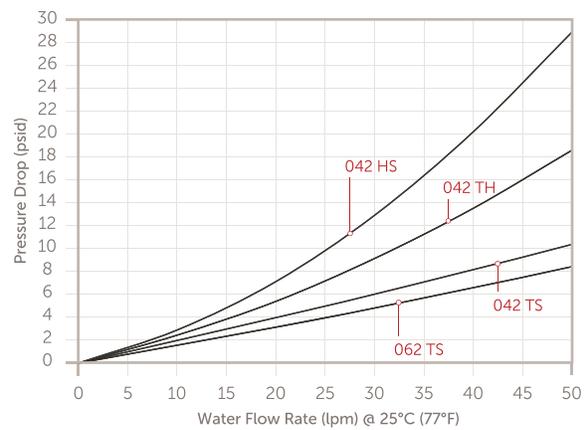
<b>Material toxicity</b>	All components meet the requirements of the USP <87>, Biological Reactivity Test and the USP <88> Reactivity Test for Class VI Plastics
<b>Animal Free</b>	Raw materials used to manufacture this product are not animal derived, meeting the EU directive for animal free CPMP EMA/410/01 and 21 CFR parts 189.5
<b>Extractables</b>	Tested according to BioPhorum Operations Group (BPOG) guideline. Report is available upon request.
<b>Quality</b>	100% integrity tested, manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system

## PERFORMANCE DATA

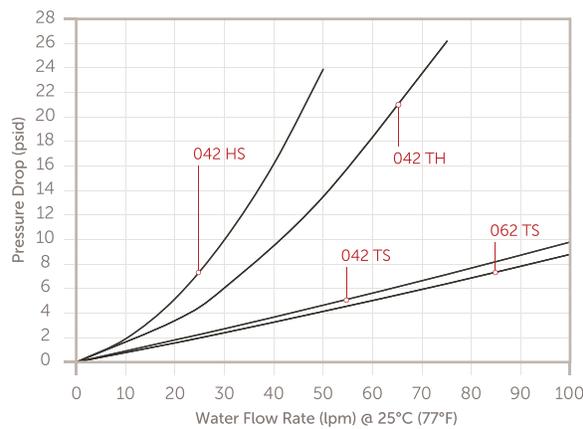
### 3-inch Capsules



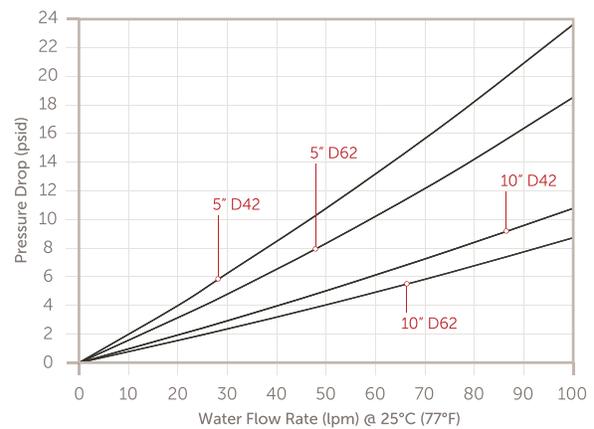
### 5-inch Capsules



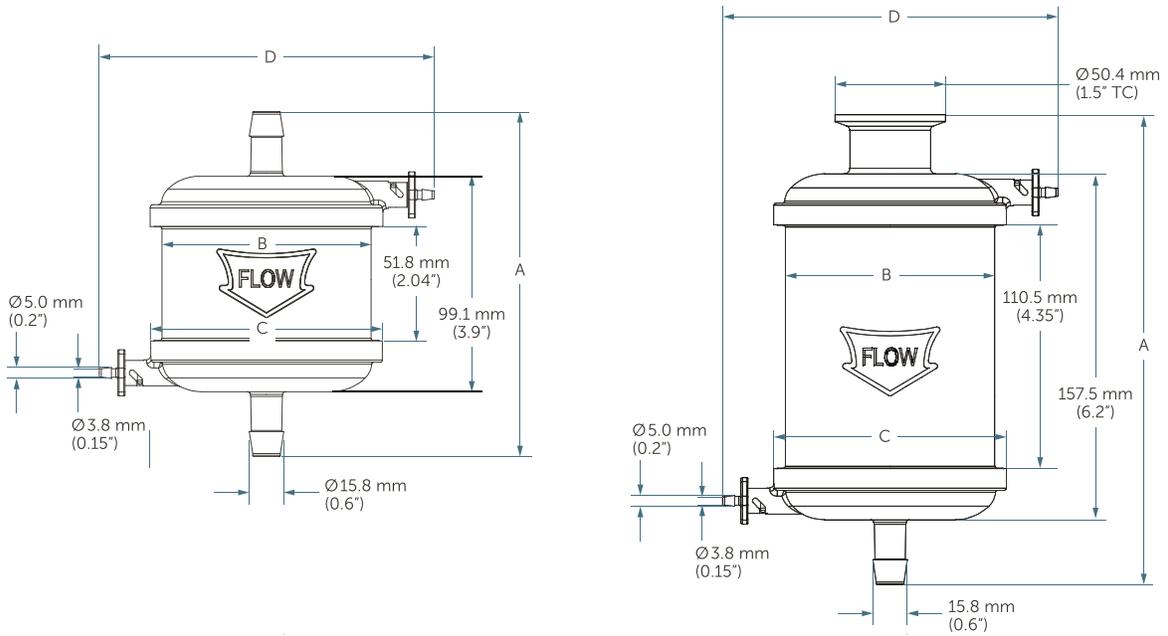
### 10-inch Capsules



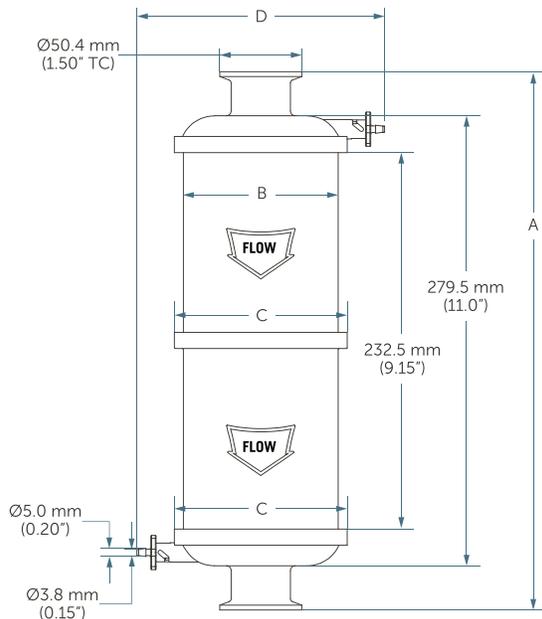
### Cartridge Filters



## DIMENSIONS



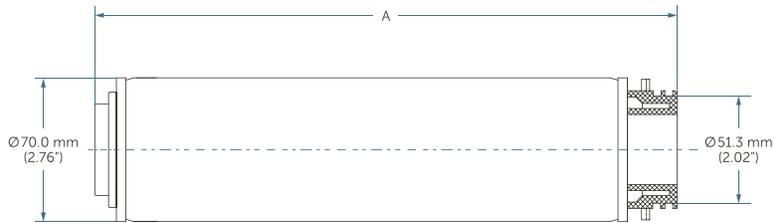
Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
3-inch TC-TC	154.5 mm (6.08")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
3-inch TC-HB	156.7 mm (6.17")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
3-inch HB-HB	159.7 mm (6.29")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch TC-TC	213.2 mm (8.39")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch TC-HB	216.5 mm (8.52")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch HB-HB	219.5 mm (8.96")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")



## DIMENSIONS

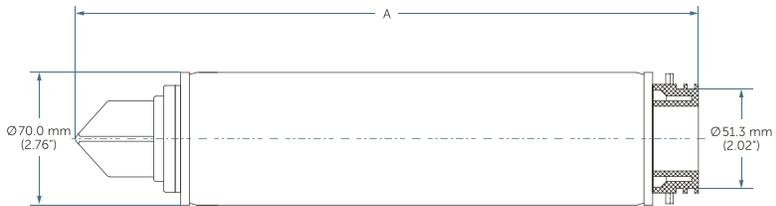
Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
10-inch TC-TC	335.5 mm (13.21")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
10-inch TC-HB	339.0 mm (13.35")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
10-inch HB-HB	342.0 mm (13.46")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")

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")

Code 7

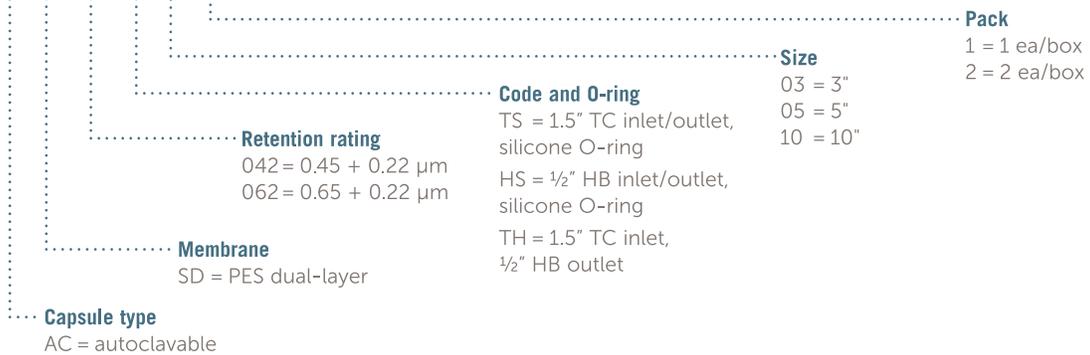


Length	Code 7 Dimension A
5"	199.0 mm (7.8")
10"	316.5 mm (12.5")
20"	561.0 mm (22.1")
30"	805.5 mm (31.7")

## ORDERING INFORMATION

Pharmsteri AHC PES capsule filter: part number

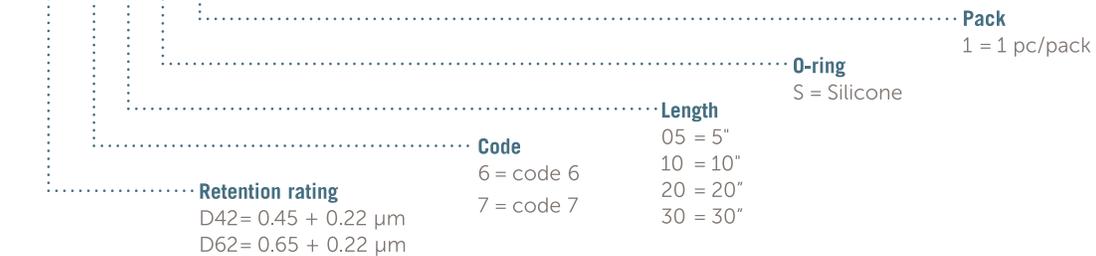
PST AC SD -



Pharmsteri AHC PES cartridge filter: part number

PSTSA

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## FOR MORE INFORMATION

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