

# Pharmsteri™ II GHC PES Liquid Capsule Filter

*Delivers superior throughput for broad challenging feed streams while minimize product loss in sterile filtration*

As biological manufacturing rapidly increases in capacity, end users are challenged to purify a diverse array of new biologics such as monoclonals, antibody-drug conjugates, and new modalities in gene therapies in a risk-free and economical environment. Entegris is a leading expert in controlling particles and impurities and we are leveraging our extensive knowledge in purity manufacturing for strict semiconductor applications into the life sciences market.

Pharmsteri™ II GHC (gamma, high capacity) PES capsule filters are made of 0.45+0.22 µm or 0.65+0.22 µm dual-layer hydrophilic polyethersulfone (PES) membranes with highly asymmetric morphology, and special designed core and shell with high-grade, gamma-stable polypropylene (PP) to minimize upstream hold up volume.

Single use capsule sizes from disc to 10" provide end users flexibility from lab scale to commercial manufacturing. Different connector types facilitate assembly at either point of use or pre-assembled in sterile tube sets.

## 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 high fouling fluids



*Gamma irradiation stable up to 45 kGy*

## 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>Gamma stable and autoclavable</b>	Autoclave claims allow users the advantage of choosing to integrate buffer filters in situ to meet their own specific templates and needs  Gamma capability ensures that integrators can connect these filters into any customer-specific, single-use assembly and provide it as a sterile final assembled product
<b>Broad chemical compatibility</b>	pH 1~14, allows use in a range of chemistries 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

		50mm Disc	3"/5"/10" In-Line Capsules
<b>Materials</b>	Media	Polyethersulfone	Polyethersulfone
	Support	Polypropylene	Polypropylene
	Core, cage, end caps	Polypropylene	Polypropylene
	O-ring	Silicone	Silicone
<b>Sealing technology</b>		Mechanical sealing with O-ring	Thermal bonding without adhesives
<b>Pore size</b>		0.45+0.22 µm 0.65+0.22 µm	0.45+0.22 µm 0.65+0.22 µm
<b>Filtration area</b>		17.3 cm <sup>2</sup>	3" 0.16 m <sup>2</sup>
			5" 0.30 m <sup>2</sup>
			10" 0.60m <sup>2</sup>
<b>Integrity</b>	Bubble point	≥3.65 bar (53 psi) air with water	
	Water Diffusion	3"	≤ 6.8 mL/min @ 40psi @ 25°C (77°F)
		5"	≤ 11.5 mL/min @ 40psi @ 25°C (77°F)
10"		≤ 21.5 mL/min @ 40psi @ 25°C (77°F)	
<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)	40 psi (2.8 bar) @ 60°C (140°F)
	Maximum differential pressure	Forward 60 psi (4.1 bar) @ 25°C (77°F)	Forward 60 psi (4.1 bar) @ 25°C (77°F)
		Forward 30 psi (2.1 bar) @ 60°C (140°F)	Forward 30 psi (2.1 bar) @ 60°C (140°F)
<b>Bacteria Retention</b>	Sterilizing grade membrane		>10 <sup>7</sup> CFU/cm <sup>2</sup> B. diminuta per the ASTM F838.
	<b>Multiple sterilization Cycles</b>	2 cycles of autoclave, 30 min at 130°C (266°F)	
<b>Gamma stability</b>	Gamma irradiation stable up to 45 kGy		
<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 gamma and after a water flush, meeting the requirements of USP <643>		
<b>Conductivity*</b>	≤1.3 µS/cm post gamma and after water flush, meeting the requirements of USP <645>		
<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		

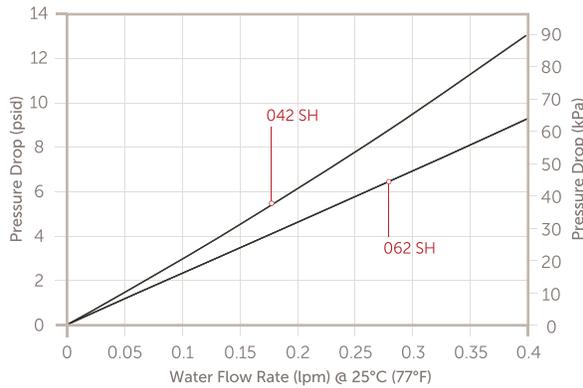
## SPECIFICATIONS

<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

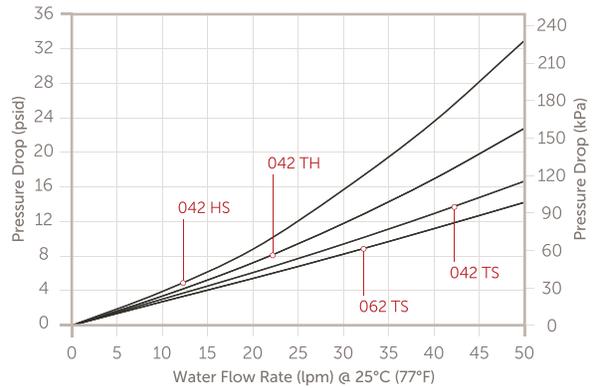
\*Test post-gamma irradiation. Refer to our validation guide for details.

## PERFORMANCE DATA

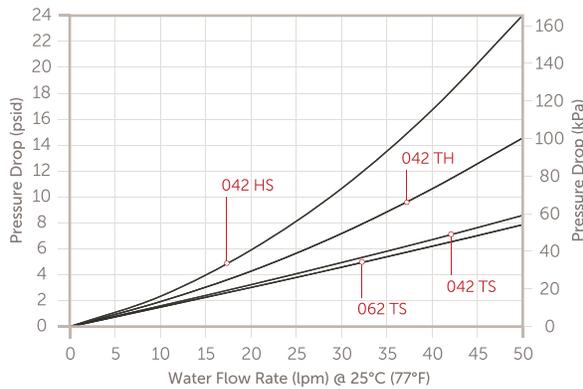
50 mm Disc



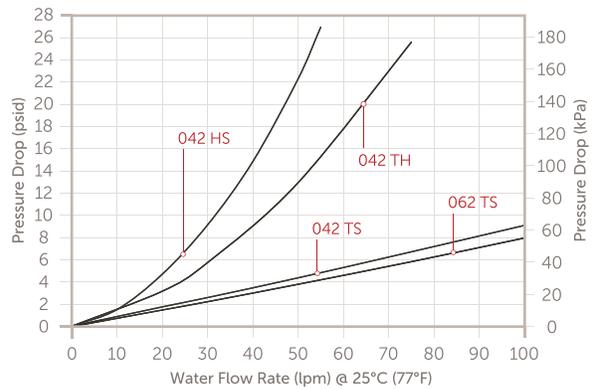
3-inch Capsules



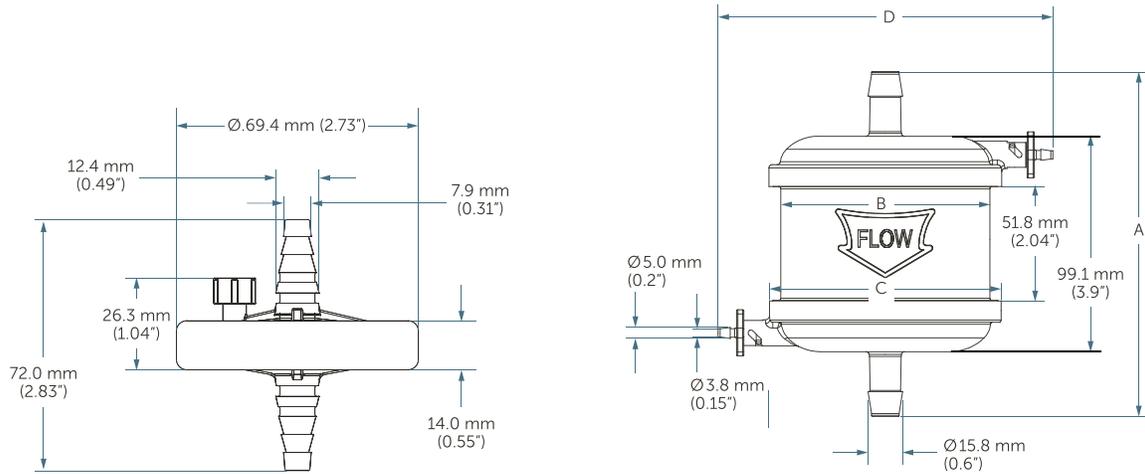
5-inch Capsules



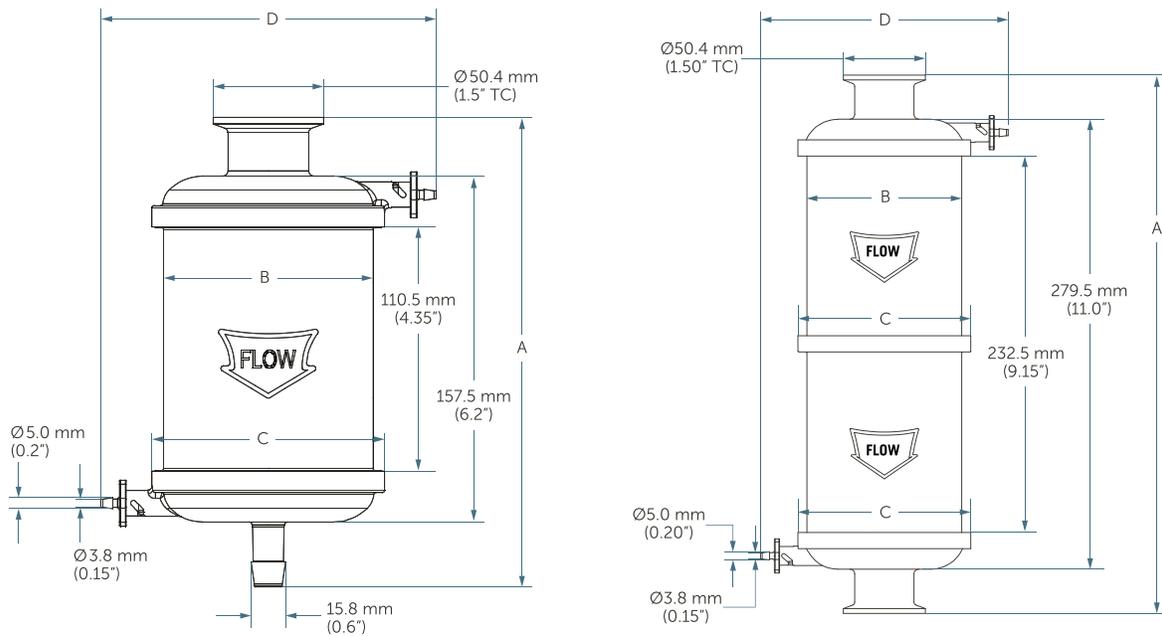
10-inch Capsules



## 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")



Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
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")

## DIMENSIONS

5-inch HB-HB	219.5 mm (8.96")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
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")

## ORDERING INFORMATION

Pharmsteri II GHC PES capsule filter: part number

PST	SD	-			
				<b>Retention rating</b>	
				042 = 0.45 + 0.22 $\mu$ m	
				062 = 0.65 + 0.22 $\mu$ m	
				<b>Membrane</b>	
				SD = PES dual layer	
				<b>Code and O-ring</b>	
				TS = 1.5" TC inlet/outlet, silicone O-ring	
				HS = 1/2" HB inlet/outlet, silicone O-ring	
				TH = 1.5" TC inlet, 1/2" HB outlet	
				FS = 3/4" TC inlet/outlet, silicone O-ring	
				BS = 1/4" HB inlet/outlet, silicone O-ring	
				FB = 3/4" TC inlet, 1/4" HB outlet	
				SH = 1/4" HB inlet/outlet, disc only	
				<b>Size</b>	
				00 = 50 mm disc	
				0M = mini	
				01 = 1"	
				03 = 3"	
				05 = 5"	
				10 = 10"	
				<b>Pack</b>	
					1 = 1 ea/box
					2 = 2 ea/box
					3 = 3 ea/box
					4 = 4 ea/box
				<b>Capsule type</b>	
				SU = single use	
				GS = gamma sterilized	

Notes:

1. TS/HS/TH code for 3"/5"/10", FS/BS/FB code for mini/1", SH code for 50mm disc
2. 5"/10" as 1 ea/box, 3" as 2 ea/box, mini/1" as 4 ea/box, 50mm disc as 3 ea/box
3. Mini/1" under development, sample available for evaluation

## FOR MORE INFORMATION

Please call your Regional Customer Service Center today to learn what Entegris can do for you. Visit [entegris.com](https://www.entegris.com) and select the [Contact Us](#) link to find the customer service center nearest you.

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