

Pharmsteri™ II GHF PES Liquid Capsule Filter

Delivers superior flow rates in a broad range of chemical conditions to deliver significant economic advantages

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 GHF PES liquid capsule filters are made of a high-grade, gamma-stable polypropylene (PP) shell and a hydrophilic, polyethersulfone (PES) membrane with nominal pore rating at 0.22 µm.

Single-use capsules provide end users unparalleled flexibility and adaptability in a smaller footprint than traditional cartridges in a stainless steel housing. This flexibility allows end users to scale their templates up and out, improves process economics, enables multiuse facilities, and reduces the risk of contamination entering the manufacturing process.

APPLICATIONS

- Buffers
- Chemical solutions
- Small molecule preparations
- Chemical drugs formulations
- Cleaning and sanitization solutions



Fully validated for gamma compatibility up to 45 kGy

FEATURES & BENEFITS

Gamma stable and autoclavable materials of construction	Enable sterilization using caustics or autoclaving, or for optimal bioprocessing, integrate into single-use assemblies for gamma irradiation
Sterilizing grade meets Bacterial Challenge Test (ASTM F838)	Ensures that microorganisms, such as bacteria, are removed from the fluid stream while not adversely affecting product
On site or integrator compatible	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
Broad chemical compatibility	pH 1~14, allows use in a range of chemicals including acids and bases
Best-in-class flow rates	Meets or exceeds other commercially available filters allowing increased volumes to be processed in a limited time

SPECIFICATIONS

		50mm Disc	3"/5"/10" In-line Capsules	
Materials	Media	Polyethersulfone (PES)	Polyethersulfone (PES)	
	Support	Polyester	Polyester	
	Film edge		Polypropylene/polyethylene copolymer	
	Core, cage, end caps	Polypropylene	Polypropylene	
	O-ring	Silicone	Silicone	
Sealing technology		Mechanical fsealing with O-ring	Thermal bonding without adhesives	
Pore size		0.22 μm	0.22 μm	
Filtration area		17.3 cm ²	3"	0.19 m ²
			5"	0.36 m ²
			10"	0.72 m ²
Integrity	Bubble point	-	≥3.65 bar (53 psi) air with water	
	Water Diffusion	-	3"	≤6.5 mL/min @ 40 psi at 25°C (77°F)
			5"	≤13.0 mL/min @ 40 psi at 25°C (77°F)
			10"	≤25.0 mL/min @ 40 psi at 25°C (77°F)
Maximum operating conditions	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)	
		Reverse 10 psi (0.7 bar) @25°C (77°F)	Reverse 10 psi (0.7 bar) @ 25°C (77°F)	
Bacteria Retention		Sterilizing grade membrane	>10 ⁷ CFU/cm ² B. diminuta per the ASTM F838.	
Multiple sterilization cycles	2 cycles of autoclave, 30 min at 130°C (266°F)			
Gamma stability	Gamma irradiation stable up to 45 kGy			
Endotoxin releasing*	<0.25 EU/mL as determined by the LAL test, meeting the requirements of USP <85>			
Particulates*	Particulate matter release meets the requirement of USP <788>			
Non-fiber releasing	Manufactured with non-fiber release materials and tested according to 21 CFR 210.3 (b) (6)			
TOC*	<0.5 mg/L post gamma and after a water flush, meeting the requirements of USP <643>			
Conductivity*	≤1.3 μS/cm post gamma and after water flush, meeting the requirements of USP <645>			

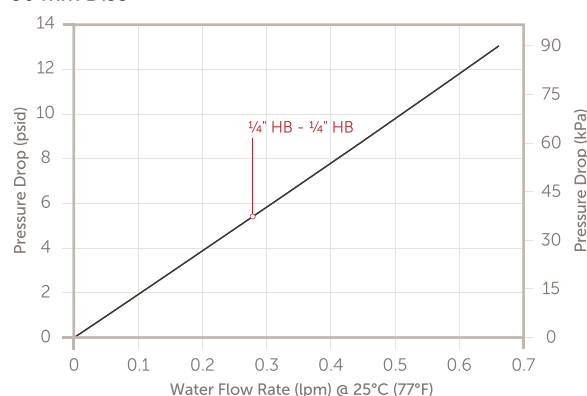
SPECIFICATIONS

Material toxicity*	All components meet the requirements of the USP <87>, Biological Reactivity Test and the USP <88> Reactivity Test for Class VI Plastics
Animal Free	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
Extractables*	Tested according to BioPhorum Operations Group (BPOG) guideline. Report is available upon request.
Quality	100% integrity tested, manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system

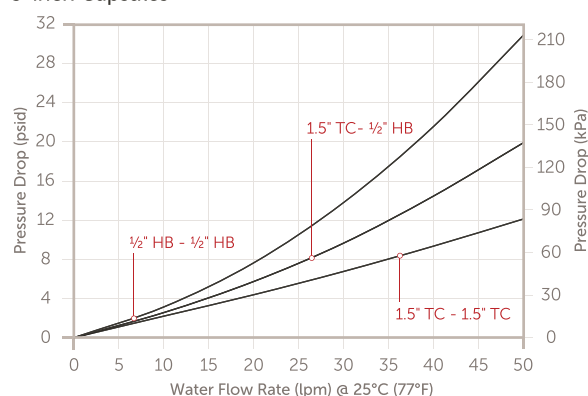
*Test post-gamma irradiation. Refer to our validation guide for details.

PERFORMANCE DATA

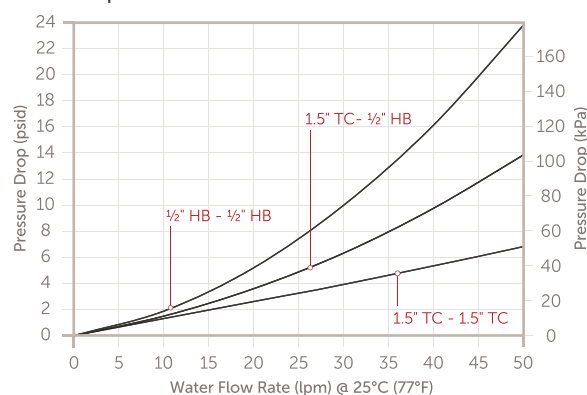
50 mm Disc



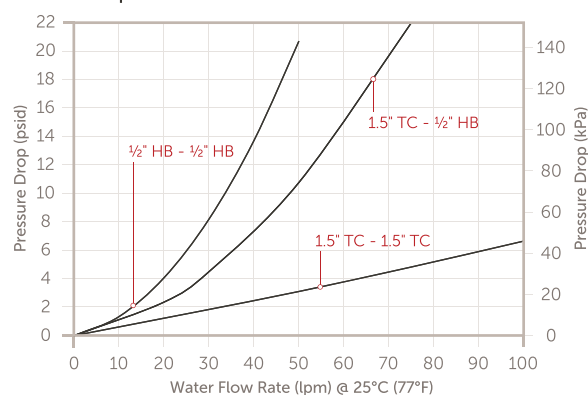
3-inch Capsules



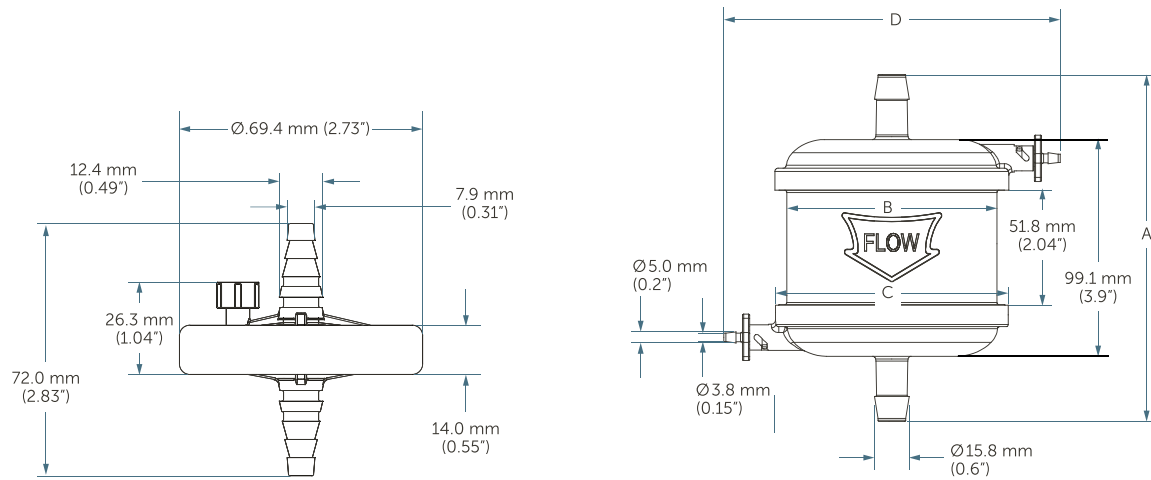
5-inch Capsules



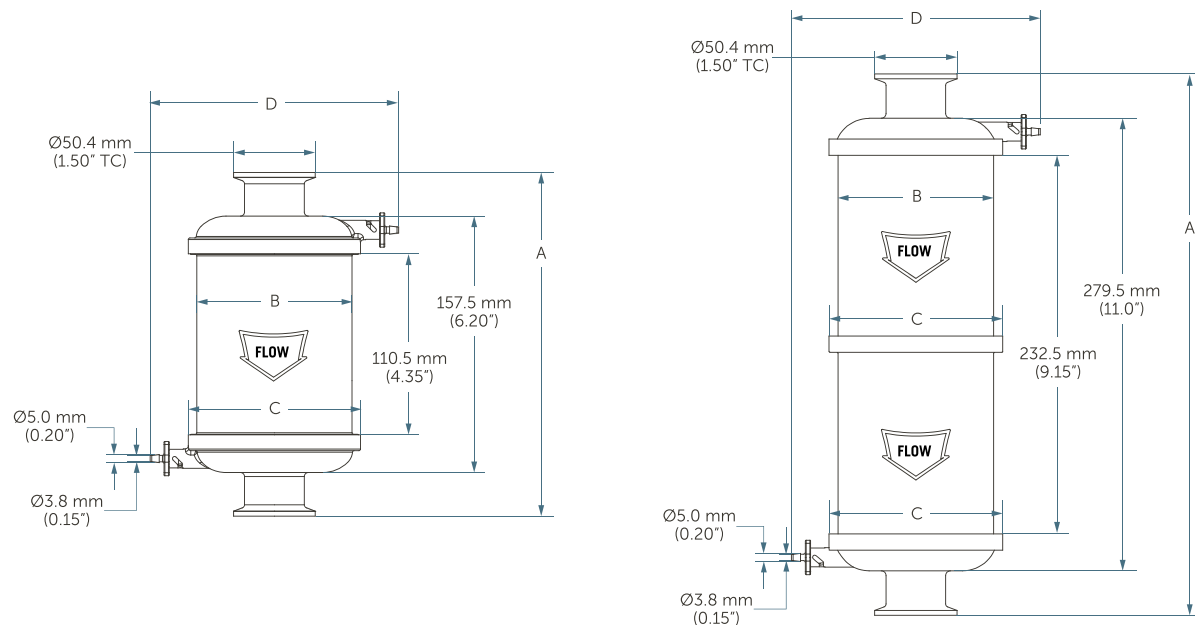
10-inch Capsules



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")



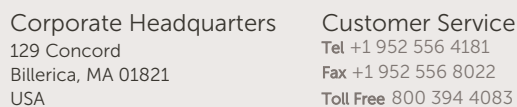
Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
5-inch TC-TC	213.2 mm (8.39")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch TC-HB	216.5 mm (8.52")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")

[illegible]

1. TS/HS/TH code for 3"/5"/10", SH code for 50mm disc
2. 5"/10" as 1 ea/box, 3" as 2 ea/box, 50mm disc as 3 ea/box

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