

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
Broad chemical compatibility	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
Best-in-class flow rates	pH 1~14, allows use in a range of chemicals including acids and bases
	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>			
Material toxicity*	All components meet the requirements of the USP <87>, Biological Reactivity Test and the USP <88> Reactivity Test for Class VI Plastics			

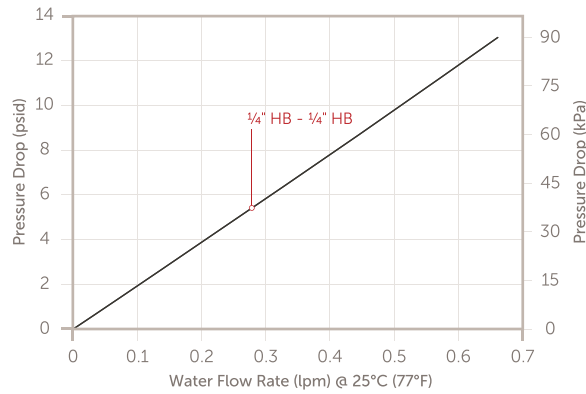
SPECIFICATIONS

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

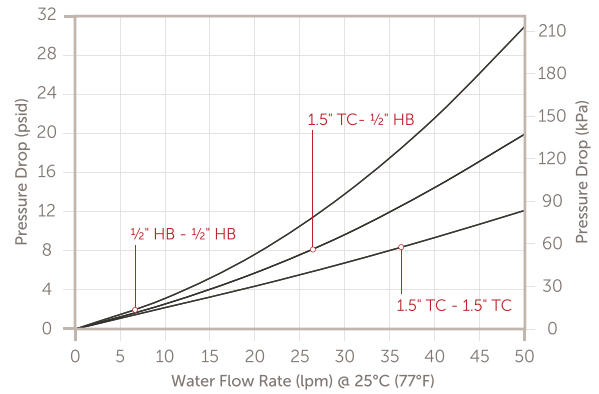
*Test post-gamma irradiation. Refer to our validation guide for details.

PERFORMANCE DATA

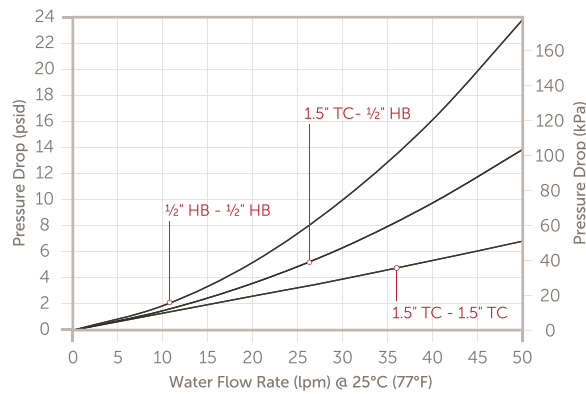
50 mm Disc



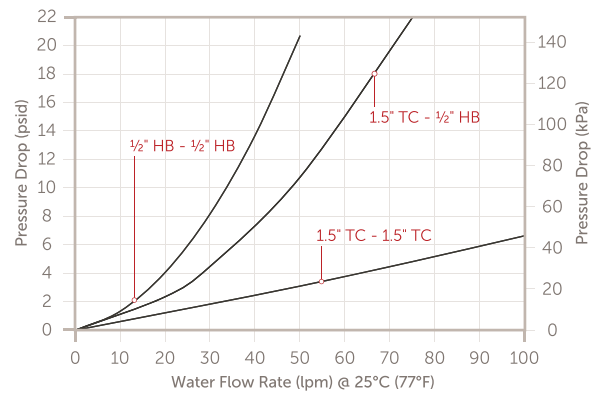
3-inch Capsules



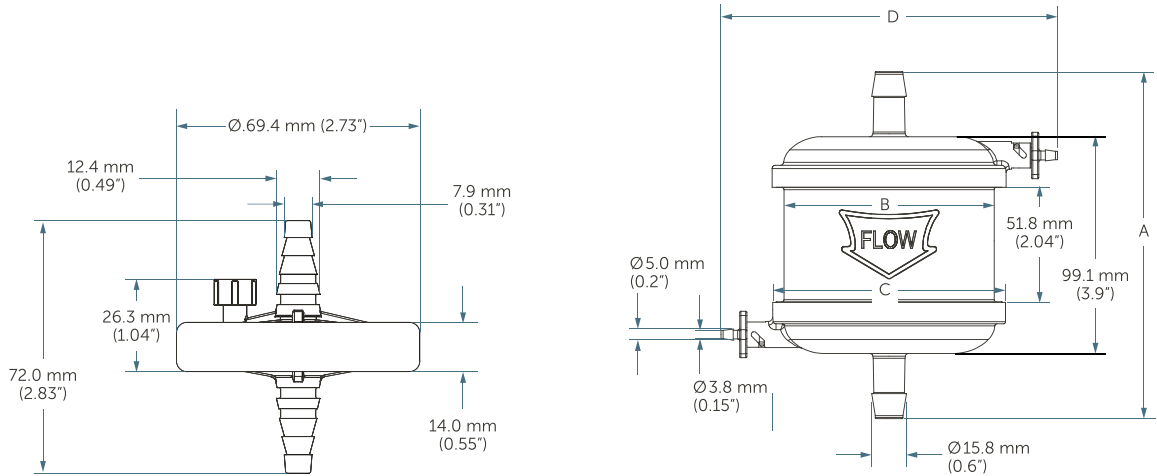
5-inch Capsules



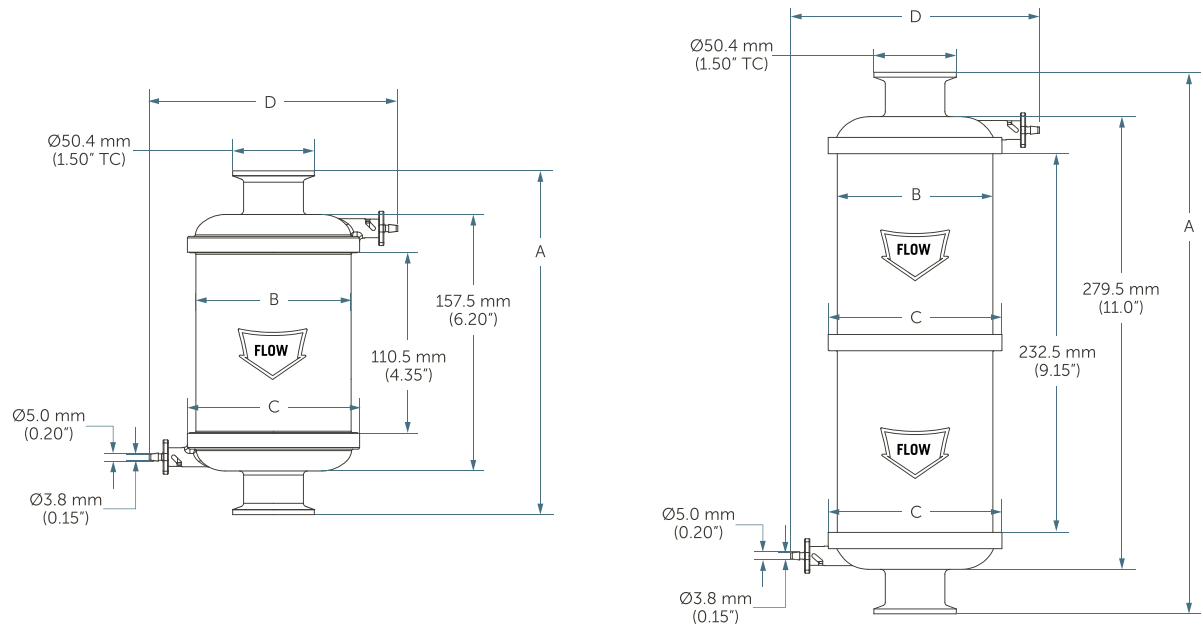
10-inch Capsules



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")
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")

DIMENSIONS

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 GHF PES: part number

PST SA 022 -

PST	SA	022	-			
					Pack	1 = 1 ea/box
					Size	2 = 2 ea/box
					Code and O-ring	3 = 3 ea/box
					TS = 1.5" TC inlet/outlet, silcone O-ring	
					HS = ½" HB inlet/outlet, silcone O-ring	
					TH = 1.5" TC inlet, ½" HB outlet	
					SH = ¼" HB inlet/outlet, disc only	
					Pore rating	
					022 = 0.22 µm	
					Membrane	
					SA = PES single-layer	
					Single use	
					SU = gamma compatible	
					GS = gamma sterilized	

Notes:

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

FOR MORE INFORMATION

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

TERMS AND CONDITIONS OF SALE

All purchases are subject to Entegris' Terms and Conditions of Sale. To view and print this information, visit entegris.com and select the [Terms & Conditions](#) link in the footer.



Corporate Headquarters
129 Concord
Billerica, MA 01821
USA

Customer Service
Tel +1 952 556 4181
Fax +1 952 556 8022
Toll Free 800 394 4083

Entegris®, the Entegris Rings Design®, and other product names are trademarks of Entegris, Inc. as listed on entegris.com/trademarks. All third-party product names, logos, and company names are trademarks or registered trademarks of their respective owners. Use of them does not imply any affiliation, sponsorship, or endorsement by the trademark owner.

©2023 Entegris, Inc. | All rights reserved. | Printed in the USA | 9000-12184DSA-0325

www.entegris.com