COFILTERS

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. Cofilters 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.

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

Best-in-class throughput or capacity	Dual layer and highly asymmetric membrane minimize pressure build-up while processing large volume fluids
Low hold-up volume	Structure design helps minimize dead zone which can cause loss of high value products
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
Gamma stable and autoclavable	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 chemistries including acids and bases
Comprehensive validation	Product has been rigorously validated to product specification and industry standards with comprehensive documentation to support compliance

SPECIFICATIONS

		50mm Disc	Mini/1"/3"/5"/10" In-Line Capsules	
Materials	Media	Polyethersulfone	Polyethersulfone	
	Support	Polypropylene	Polypropylene	
	Core, cage, end caps	Polypropylene	Polypropylene	
	O-ring	NA	Silicone	
Sealing technology		Mechanical sealing with O-ring	Thermal bonding without adhesives	
Pore size		0.45+0.22 µm	0.45+0.22 µm	
		0.65+0.22 µm	0.65+0.22 µm	
Filtration area		17.3 cm^2	Mini	260 cm^2
			1"	560 cm^2
			3"	0.16 m^2
			5"	0.30 m^2
			10"	0.60m^2
Integrity	Bubble point	NA	≥3.65 bar (53 psi) air with water	
	Water Diffusion @ 40 psi@ 25°C (77°F)	NA	Mini	≤ 1.8 mL/min
			1"	≤ 3.8 mL/min
			3"	≤ 6.8 mL/min
			5"	≤ 11.5 mL/min
			10"	≤ 21.5 mL/min
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 relesing*	<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	<0.5 mg/L post gamma and after a water flush, meeting the requirements of USP <643>			
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			

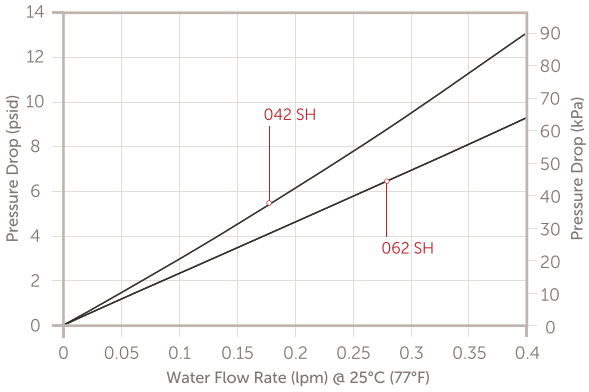
SPECIFICATIONS

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

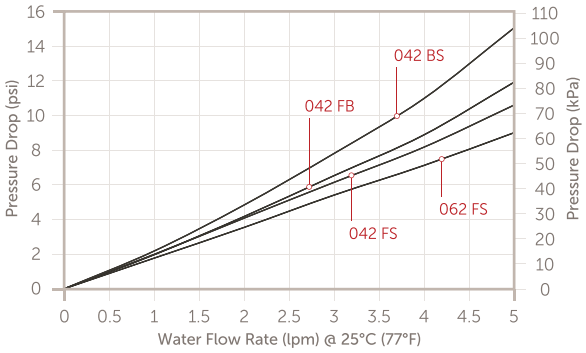
*Test post-gamma irradiation. Refer to our validation guide for details.

PERFORMANCE DATA

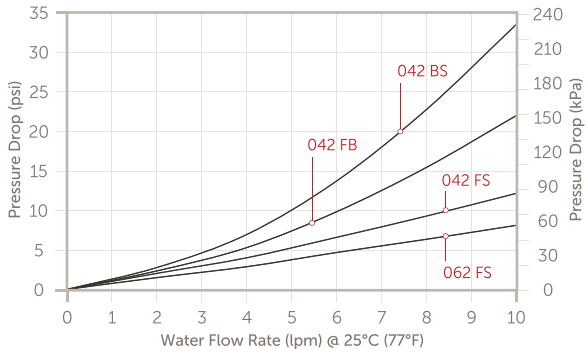
50 mm Disc



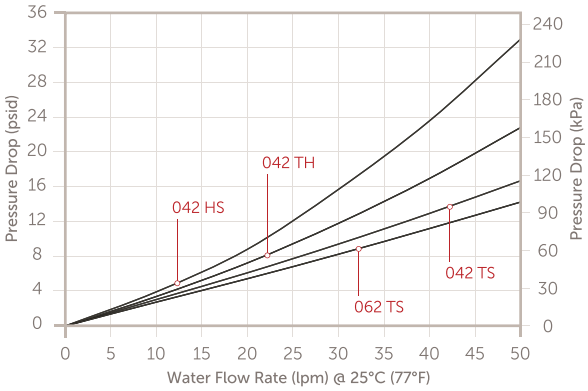
Mini Capsules



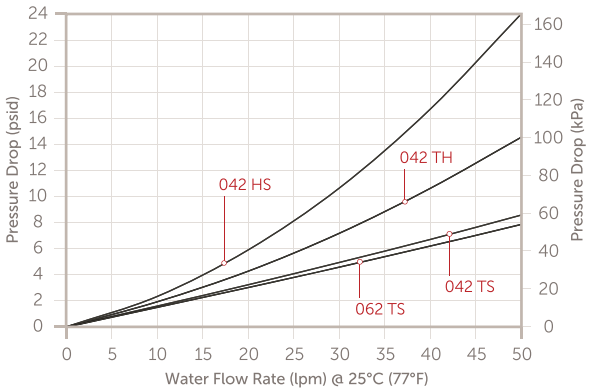
1-inch Capsules



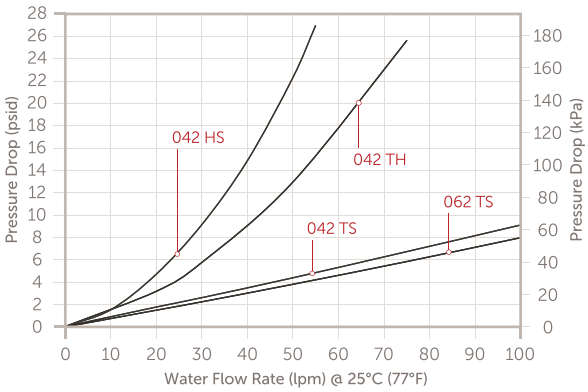
3-inch Capsules



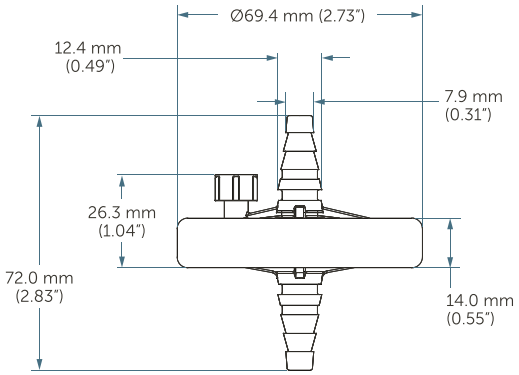
5-inch Capsules

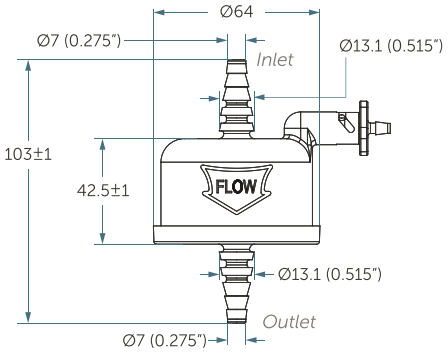


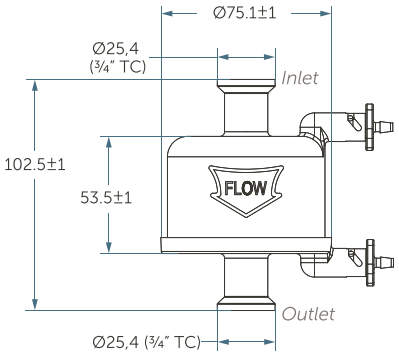
10-inch Capsules

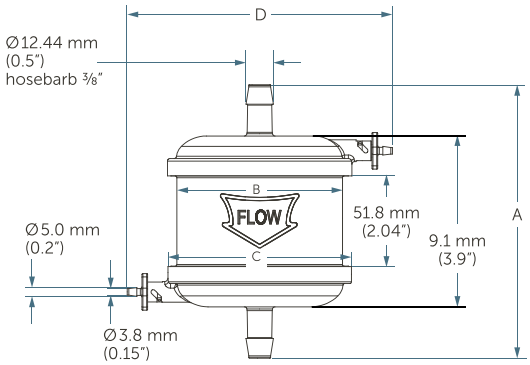


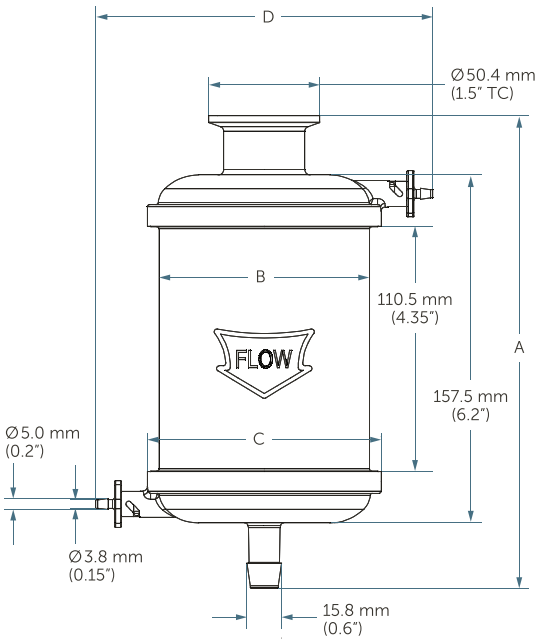
DIMENSIONS

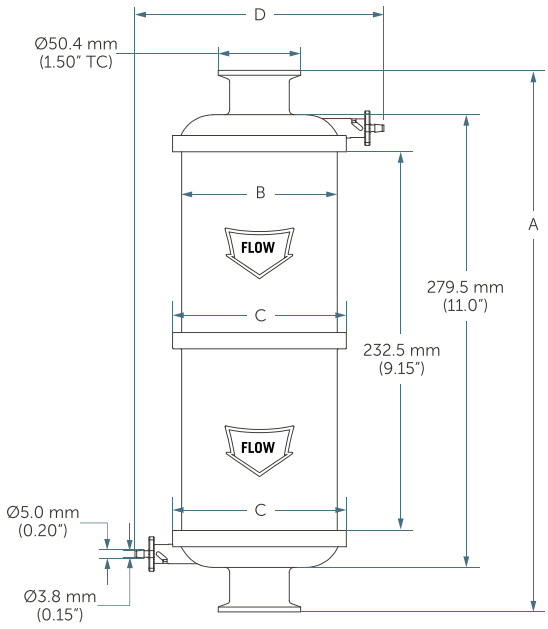












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