

Pharmsteri™ II PES 0.22 Buffer 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 PES 0.22 buffer 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

- Pharmaceutical
- Monoclonal antibodies
- Antibody-drug conjugate (ADC)
- Gene therapies and modalities
- Bioburden reduction in buffers
- Sterile filtration of fluids used in biomanufacturing
- Intermediates and raw material filtration



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

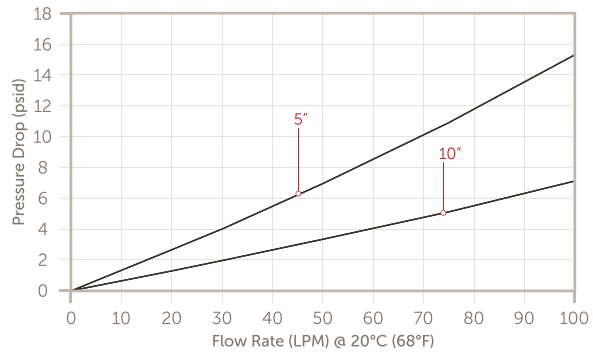
SPECIFICATIONS

		50mm Disc	5-inch Capsule	10-inch Capsule
Materials	Media	Polyethersulfone (PES)	Polyethersulfone (PES)	Polyethersulfone (PES)
	Support	Polyester	Polyester	Polyester
	Film edge		Polypropylene/polyethylene copolymer	Polypropylene/polyethylene copolymer
	Core, cage, end caps	Polypropylene	Polypropylene	Polypropylene
	O-ring	Silicone	Silicone	Silicone
Sealing technology		Mechanical force by over-molding	Thermal bonding without adhesives	Thermal bonding without adhesives
Pore size		0.22 μm		
Filtration area		17.3 cm^2	0.36 m^2	0.72 m^2
Integrity	Bubble point	≥ 3 bar (43.5 psi) air with water	-	-
	Water Diffusion	-	≤ 13.0 mL/min @ 40 psi at 25°C (77°F)	≤ 25.0 mL/min @ 40 psi at 25°C (77°F)
Maximum operating conditions	Maximum operating pressure	60 psi (4.1 bar) @ 25°C (77°F)	80 psi (5.5 bar) @ 25°C (77°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)	
		Reverse 10 psi (0.7 bar) @ 25°C (77°F)		
Bacteria Retention		-	$>10^7$ 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>			
TOC*	<0.5 mg/L post gamma and after a water flush, meeting the requirements of USP <643>			
Conductivity*	≤ 1.3 $\mu\text{S}/\text{cm}$ 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			
Extractables*	Tested according to BioPhorum Operations Group (BPOG) guideline. Report is available upon request.			
Quality	Manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system			

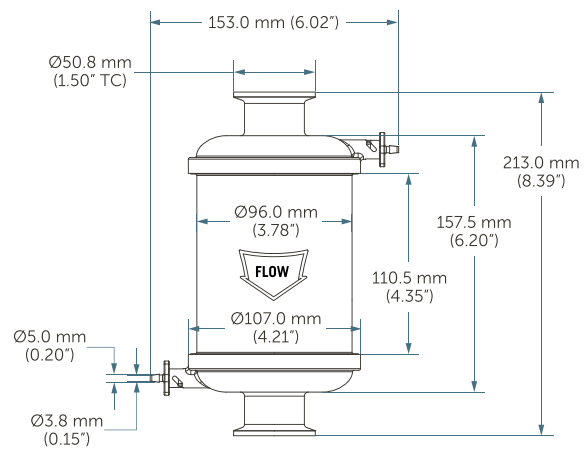
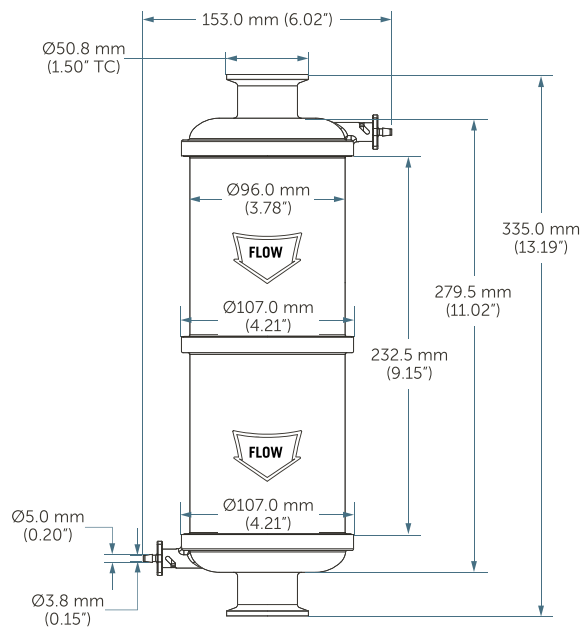
*Test post-gamma irradiation. Refer to our validation guide for details.

PERFORMANCE DATA

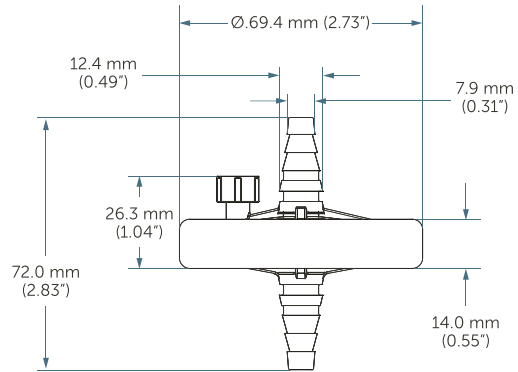
Pressure vs. Flow



DIMENSIONS



DIMENSIONS



ORDERING INFORMATION

PART NUMBER	INLET AND OUTLET CONNECTION	VENT AND DRAIN CONNECTION	SIZE	PACKAGING CONFIGURATION
PSTSUSA022SH003	1/4" stepped hose barb	Luer male with cap	50 mm disc	Three per box
PSTSUSA022TS051	1.5" sanitary Tri-Clamp®	1/8" hose barb	5" capsule	One per box
PSTSUSA022TS101	1.5" sanitary Tri-Clamp®	1/8" hose barb	10" capsule	One per box

FOR MORE INFORMATION

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