

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



FEATURES & BENEFITS

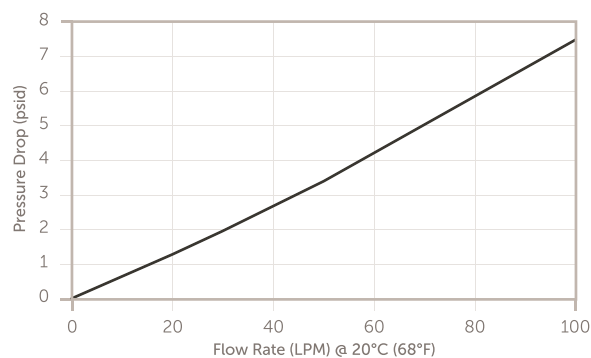
Gamma stable and autoclavable materials of construction	Enable sterilization using caustics or autoclaving, or for optimal bioprocessing, integrate into single-use assemblies for gamma irradiation
Sterilizing grade meets Bacterial Challenge Test (ASTM F838)	Ensures that microorganisms, such as bacteria, 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	Allows use in a range of chemistries 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

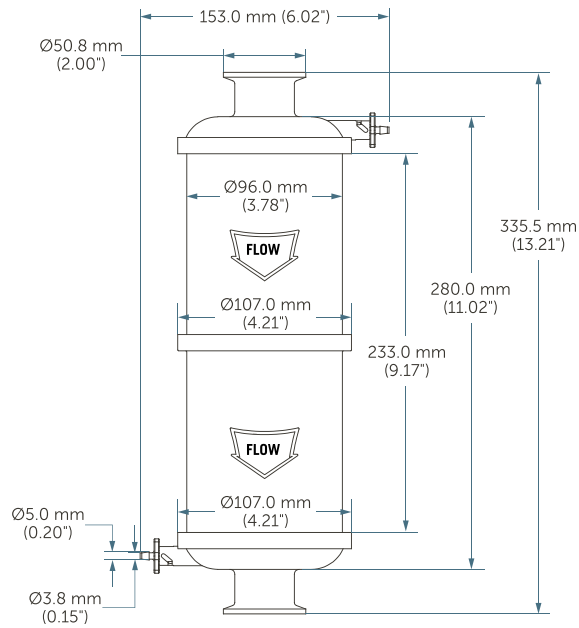
Pore size	0.22 µm	
Materials	Media	Polyethersulfone (PES)
	Support	Polyester
	Film edge	Polypropylene/polyethylene copolymer
	Core, cage, end caps	Polypropylene
	O-ring	Silicone
Sealing technology	Thermal bonding without adhesives	
Filtration area	0.72 m ²	
Maximum operating conditions	Maximum operating pressure	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)
	Reverse	10 psi (0.7 bar) @ 25°C (77°F)
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 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	
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



DIMENSIONS



ORDERING INFORMATION

PART NUMBER	LENGTH	INLET AND OUTLET CONNECTION	VENT AND DRAIN CONNECTION
PSTSUSA022TS101	10"	1.5" sanitary Tri-Clamp®	1/8" hose barb

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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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

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