MICROCONTAMINATION CONTROL

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.

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

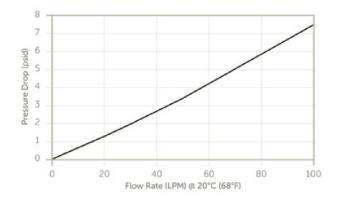
Gamma stable and autoclavable materials of construction	Enable sterilization with caustic or autoclave, or use with gamma irradiated assemblies to eliminate bio contamination	
Sterilizing grade meets Bacterial Challenge Test (ASTM F838)	Ensures that no bacteria are present after filtering buffers	
On 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 pH1- 14	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

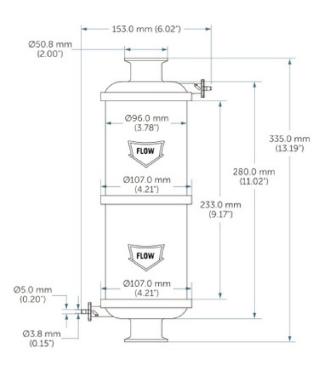
Pore size	0.22 µm			
Materials	Media	Polyethersulfone (PES)		
	Support	Polyester		
	Film edge Polypropylene/polyethylene cop			
	Core, cage, end caps	Polypropylene		
	O-ring	Silicone		
Sealing technology	Thermal bonding without adhesives			
Filtration area	≥0.72 m²/10" device			
Maximum operating conditions	Maximum forward differential pressure	4.0 bar (60 psi) @ 25°C (77°F)		
		2.5 bar (40 psi) @ 60°C (140°F)		
	Maximum reverse pressure	1.7 bar (25 psi) @ 25°C (77°F)		
Multiple sterilization cycles	2 cycles of autoclave, 30 min at 127°C (261°F)			
Gamma stable	Gamma irradiation stable up to 45 kGy			
Endotoxin releasing	<0.25 EU/mL as determined by the LAL test			
TOC	<0.5 mg/L after a water flush of 10 L/10" device			
Conductivity	≤1.3 µS/cm after water flush of 10 L/10" device			
Material toxicity	All components meet the requirements of the USP <87>, Biological Reactivity Test for Class VI Plastics			
Quality	Manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system			

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 <u>Argenpore.com</u> and select the <u>Contact Us</u> link to find the customer service center nearest you.

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