COFILTERS

PTFE Air Capsule Filter

Delivers superior airflow at low pressure drop with lower blockage risk in moist air sterile filtration

Sterile venting and gas filtration are critical for various process steps in pharmaceutical and biopharmaceutical manufacturing, to maintain a sterile barrier or ensure process gases or wastes are properly filtered. Cofilters is a leading expert in controlling particles and impurities and we are leveraging our expertise and experience in material science and filter manufacturing for strict semiconductor applications into the life sciences market.

The capsule filters are validated with liquid bacterial challenge test ensuring retention even in humid process conditions. PTFE membrane provides high hydrophobicity which contributes to reduced blockage risk under moist air and less airflow drop at longer service time.

APPLICATIONS

- Single use bioreactor vessels or bags
- Mixer vessels or bags
- Storage or holding vessels or bags
- Filling tube sets or bag assemblies
- Carboys or Bottles assemblies
- Filtration or transfer assemblies
- Integrity test manifolds
- Single use cell therapy devices or assemblies



Provides high air flow at lower pressure drop

FEATURES & BENEFITS

Best-in-class air flowrate	Optimized membrane structure provides high air flow at lower pressure drop while maintaining high retention level
High hydrophobicity	Low blockage risk under humid process conditions and long lifespan
Sterilizing grade meets Bacterial Challenge Test (ASTM F838)	Challenged in liquid, ensures that microorganisms, such as bacteria, are removed from the fluid stream while not adversely affecting product
Gamma irradiation compatible	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
PFAS Alternative	No Per and Polyfluoroalkyl Substances (PFAS) used in the material of construction
Comprehensive validation	Product has been rigorously validated to product specification and industry standards with comprehensive documentation to support compliance

SPECIFICATIONS

		50mm Disc	1"/3"/5"/10" In-line Capsule	
Materials	Media	Hydrophilic PTFE	Hydrophilic PTFE	
	Support	Polyethylene	Polyethylene	
	Core, cage, end caps	Polypropylene	Polypropylene	
	O-ring	NA	Silicone	
Sealing technology		Thermal and ultrasonic bonding	Thermal bonding without adhesives	
Pore size		0.22 µm	0.22 µm	
Filtration area		<0.06 cm_2	1"	0.06 cm2
			3"	0.10 m_2
			5"	0.2 m_2
			10"	0.4 m_2
Integrity	Bubble point	≥1.45 bar (21 psi) 60% IPA with water	≥1.45 bar (21 psi) 60% IPA with water	
	Diffusion flow	NA	1"	≤1.35 mL/min @1.10 bar, 60% IPA with water
			3"/5"/10"	NA
	Water intrusion	NA	1"	NA
			3"	≤0.25 mL/min @2.62 bar
			5"	≤0.43 mL/min @2.62 bar
			10"	≤0.55 mL/min @2.62 bar
Maximum operating conditions	Maximum operating temperature	60°C (140°F)	60°C (140°F)	
	Maximum operating pressure	30 psi (2.1 bar) @ 25°C (77°F)	1"	80 psi (5.5 bar) @ 25°C (77°F)
			3"/5"/10"	60 psi (4.1 bar) @ 25°C (77°F)
		20 psi (1.4 bar) @ 60°C (140°F)	30 psi (2.1 bar) @ 60°C (140°F)	
	Maximum forward differential pressure	30 psi (2.1 bar) @ 25°C (77°F)	1"	30 psi (2.1 bar) @ 25°C (77°F)
			3"/5"/10"	60 psi (4.1 bar) @ 25°C (77°F)
	Maximum reverse differential pressure	15 psi (1.0 bar) @ 25°C (77°F)	1"	15 psi (1.0 bar) @ 25°C (77°F)
			3"/5"/10"	30 psi (2.1 bar) @ 25°C (77°F)
Bacteria Retention*	>10^7 CFU/cm^2 B. diminuta per the ASTM F838.			
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>			

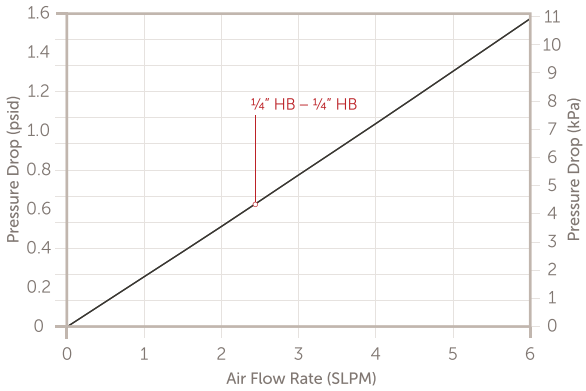
SPECIFICATIONS

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)
Material toxicity*	All components meet the requirements of the USP <87>, Biological Reactivity Test
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*	Non-Volatile Residue (NVR) tested at two successive 24-hour extractions in 50% ethanol with vibration per USP <665>&<1665>
Quality	100% integrity tested, manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system

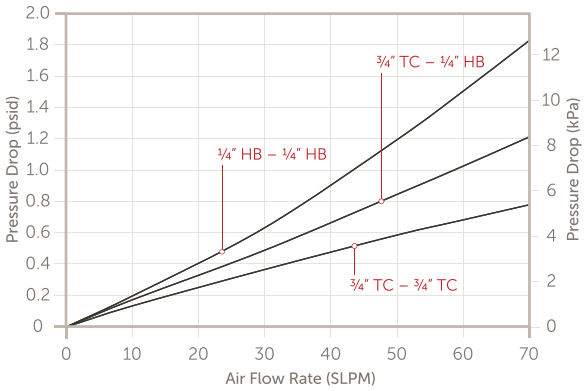
*Test post-gamma irradiation. Refer to our validation guide for details.

PERFORMANCE DATA

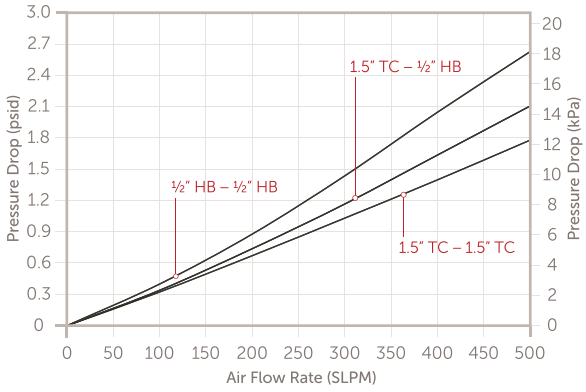
50 mm Disc



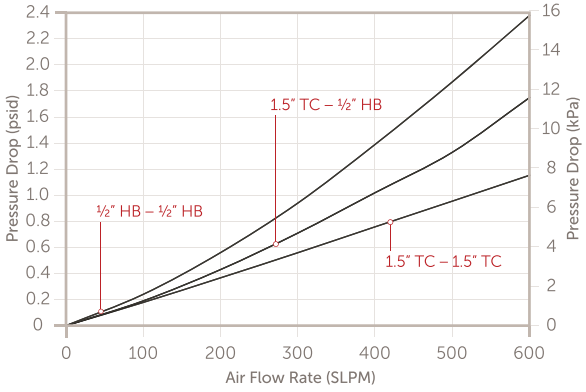
1-inch Capsules



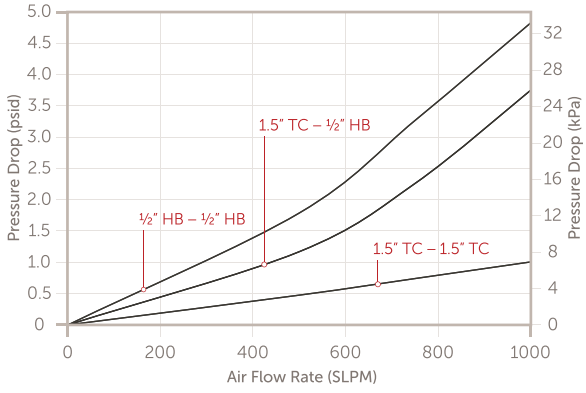
3-inch Capsules



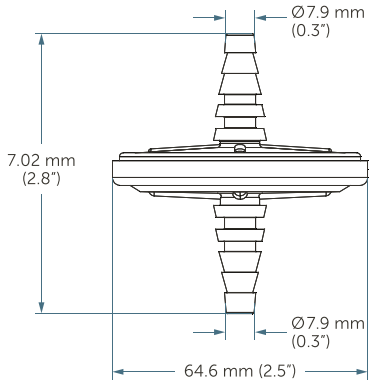
5-inch Capsules

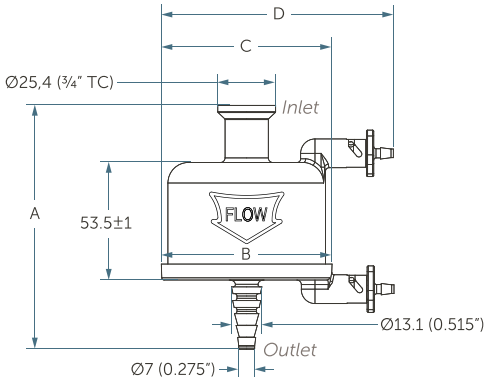


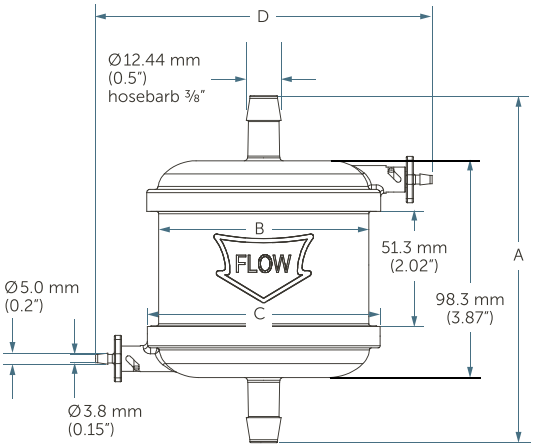
10-inch Capsules

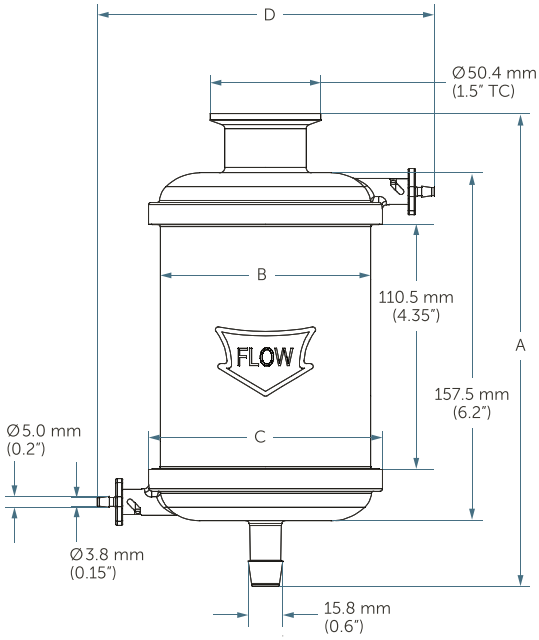


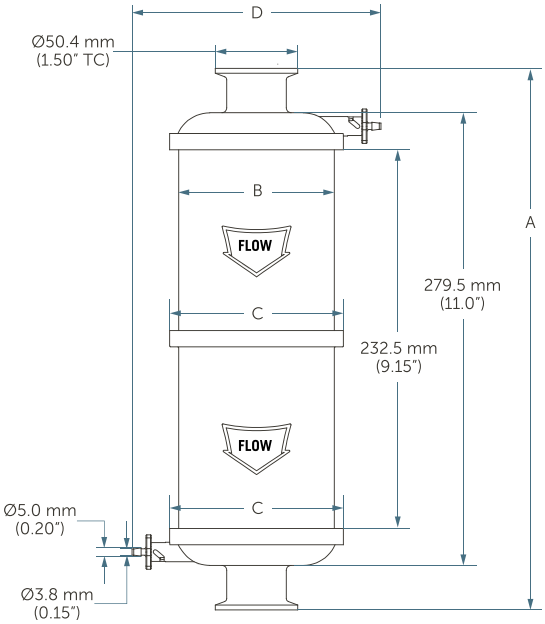
DIMENSIONS











COFILTERS

Corporate Headquarters

#401-13, #6 Building
Pharmaceutical Port
Qiantang District,
Hangzhou City, China