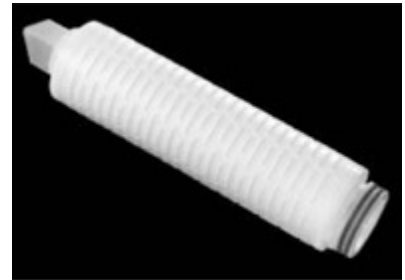


Emflon® PFR Sterile Air Membrane Cartridges



Description

Pall Emflon® PFR sterile air filter cartridges feature Pall's advanced 0.2 µm polytetrafluoroethylene (PTFE) double layer membranes. They are designed to completely remove bacteria, viruses and particles from air and gas streams, even in the presence of humidity and moisture. Pleated with very high area into sanitary single open ended (SOE) AB style cartridges, Emflon PFR filters are built to withstand adverse in situ steaming conditions in either the forward or reverse direction. Suitable applications are fermenter inlet air and exhaust venting, sterile process air, and sterile venting of tanks, lyophilizers and autoclaves.

- Pall PTFE membranes
- Inherently hydrophobic
- Double layer for added assurance
- High flow/low pressure drop
- 100% bacteria retentive in liquids
- 100% virus retentive in gases
- Melt-sealed construction
- Enhanced steaming resistance
- 100% Forward Flow tested
- Water intrusion testable
- Individually serialized
- Manufactured for use in conformance with cGMP
- ISO 9000 Certified Quality System
- Pharmaceutical "P" optimized
- Certificate of Test provided
- Validation Guide available

Specifications

Materials

- FDA-listed materials per 21-CFR
 - Membranes: double layer PTFE
 - Support/Drainage: Polypropylene, oxidation resistant
 - Core/Cage/End Caps/Adapters: Polypropylene, oxidation resistant
 - Code 7/2 adapters with encapsulated stainless steel reinforcing ring

- O-rings: silicone ¹

Removal Ratings

Air/Gases: <0.003 µm, particulate

²
Liquids: 0.2 µm, sterilizing ³

Configurations (AB Code 7)

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- Single open ended
 - Double 226 O-ring adapter
 - Finned end, bayonet lock.

Dimensions (nominal)

- Lengths: 5 in. (127 mm), 10 in. (254 mm), 20 in. (508 mm), 30 in. (762 mm),
40 in. (1016 mm)
 - Diameter: 2.75 in. (70 mm)

Filter Area (nominal)

- 8.6 ft² (0.8 m²) per 10 in. (254 mm) element
- 4.1 ft² (0.4 m²) per 5 in. (127 mm) element

Operating Conditions

Max. Differential Pressure/Temp:

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- 77 psid (5.3 bar) at 68°F (20°C)
 - 60 psid (4.1 bar) to 176°F (80°C)

Typical Continuous Air Service Life:⁶

- 12 months to 166°F (60°C)

Typical Vent Service Life:

- 6 months to 176°F (80°C)

Autoclave/Steaming

- Cumulative Steaming Time:⁷ 165 hrs (1hr cycles) to 289°F (140°C)
 - Max. Forward Steaming Conditions:
 - 14.5 psid (1.0 bard) at 257°F (125°C)
 - 4.4 psid (0.3 bard) at 289°F (142°C)
 - Max. Reverse Steaming Conditions:
 - 7.3 psid (0.5 bard) at 257°F (125°C)
 - 3.0 psid (0.2 bard) at 289°F (142°C)

Aqueous Extractables (20°C)

- <5 mg per 10 in. (254 mm) element after 1 hour steam at 257°F (125°C)

Quality/Bio–Safety

Biological Tests:

- Meets USP Biological Reactivity, *In Vivo*, for Class VI–121°C plastics.

Effluent Quality Tests:

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- Meets Cleanliness per USP Particulates in Injectables.
- Non–Fiber–Releasing per 21CFR
- Non–Pyrogenic per USP Bacterial Endotoxins (<0.25 EU/ml).
- Meets Oxidizables and pH per USP packaged waters.

Steam Resistance: Lot samples multicycle autoclave challenged.

Integrity Test Values

Per 10 in. (254 mm) Cartridge:⁹

- Forward Flow (air test gas):
60:40 IPA:Water wet (v:v) \leq 15 cc/min at 15 psi (1035 mbar)
 - Water Intrusion: \leq 0.33 cc/min at 36 psi (2485 mbar)

¹ Other polymers available.

² By NaCl CNC particle analysis. Also retains 100% of

Brevundimonas diminuta bacteria, bacteriophage and virus aerosols.

³ Lot samples of assemblies retain $>10^7$ cfu/cm² of *Brevundimonas diminuta* in liquid per mod. ASTM F838–83 and FDA guidelines.

⁴ AB05 style is Code 2 flat end. Other adapter codes available.

⁵ In air/N₂ service or other compatible gases.

⁶ For continuous air flow above 60°C, Emflon CFR filters are recommended. Emflon PFR can be operated at higher temperatures for shorter time periods.

⁷ Lab tests to establish multi-cycle resistance. Filters should be qualified in actual use.

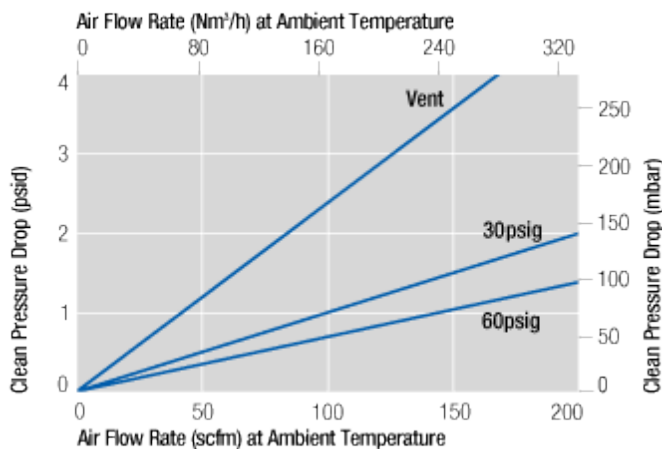
Contact Pall for recommended procedures.

⁸ Per lot sample soak or rinse-up flush aliquots.

⁹ Contact Pall for multi-element values. AB05PFR value is 7.8 cc/min.

Performance

Pressure Drop vs. Air Flow Rates¹⁰



¹⁰ Typical initial clean medium ΔP per 10 in. (254 mm) element, air at 68

°F (20°C). For multi-element cartridges, divide pressure drop by number of 10 in. (254 mm) elements. Non-linear cartridge turbulence factors are incorporated into housing pressure drop values. For complete assembly pressure drop, add filter cartridge medium value to housing value at specified flow rate. For gases other than air or nitrogen, contact your local Pall distributor.

Note

: Curve labels denote inlet pressures.

Ordering Information

Part Numbers / Ordering Information

Part Number ¹¹	Nominal Length	AB Style Code ¹²
AB05PFR2PVH4	5 in. (127 mm)	2

AB1PFR7PVH4	10 in. (254 mm)	7
AB2PFR7PVH4	20 in. (508 mm)	7
AB3PFR7PVH4	30 in. (762 mm)	7
AB4PFR7PVH4	40 in. (1016 mm)	7

¹¹ P at end of part number indicates optimized and qualified for Pharmaceutical use including encapsulated stainless steel reinforcing adapter ring for steaming

in situ, 100% integrity testing and Certificate of Test provided. V indicates optimized for vent/air/gas service. H4 suffix=Silicone O-rings (standard). See Appendix for available alternate O-ring polymers and codes.

¹² AB05 standard with Code 2 flat cap, other lengths Code 7 with finned cap. Both with double 226 O-rings. See Appendix for adapter dimensions and alternate codes.

Note

: For sizing filters or other information, please contact your local Pall distributor.

Specifications and Availability

: The information provided is a guide to the part number structure and possible options. Product availability may be subject to change without notice. All specifications are nominal. This literature was reviewed for accuracy at the time of publication. For current information on the products and test methodologies, consult your local Pall distributor.