Proflow[™] II Pharmaceutical LBR

Pleated PTFE Membrane Cartridge for Pharmaceutical Solvent Sterilization

The Proflow II Pharmaceutical Liquid Bacterial Retentive (LBR) cartridge is designed for those who require sterile pharmaceutical fluids and is validated to provide sterility through the retention of *Brevundimonas diminuta* per HIMA guidelines. Along with its sterilizinggrade performance, this cartridge exhibits high air and fluid flow rates due to the 9.3ft² of expanded PTFE membrane it contains.

Proflow II-LBR cartridges are manufactured in a certified Class 10,000 cleanroom where they are flushed with non-pyrogenic deionized water and 100% integrity tested as well as serialized to provide complete product traceability.

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Contact Information

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Benefits

- Fully validated for sterilizing-grade performance
- Broad chemical compatibility allows use with most pharmaceutical solvents
- Long service life minimizes changeout frequency
- Low differential pressure reduces energy costs
- Integrity tested to ensure quality
- Serialized for immediate traceability

Applications

- Solvent sterilization
- Extraction/crystallization solvents
- Hot WFI filtration
- Aseptic packaging air / sterile air supply
- Fermenter/tank vents

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Liquid Flow Rates*

10 inch (250mm) cartridges Liquid: 1.9gpm/psid (10.43 lpm/100 mbar)

5 inch (130mm) cartridges Liquid: 1.0gpm/psid (5.5 lpm/100 mbar)

Materials of Construction

Membrane: PTFE Support layers: Polypropylene Structure: Polypropylene

All components meet USP XXIII Class VI-121°C criteria and are thermally bonded to assure integrity and minimize extractables.

Effective Filtration Area

10 inch (250mm) cartridges 9.3 ft² (0.86 mm)

5 inch (130mm) cartridges 4.6 ft² (0.43 mm)

Bacteria Retention

Proflow II LBR cartridges will provide a sterile effluent when challenged with greater than 10⁷ CFU of *Brevundimonas diminuta* per cm² of EFA in accordance with the test methodology recommended by HIMA and defined by ASTM method F838-05.

Steam Sterilization

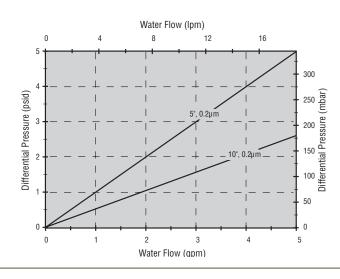
Cartridges may be steamed or autoclaved for over 20 one-hour cycles @ 275°F (145°C). Cartridges may also be chemically sanitized in place using common sanitizing agents.

Maximum Differential Pressure

Forward: 80psid (5.5 bar) @ 75°F (24°C) 40psid (2.8 bar) @ 180°F (82°C)

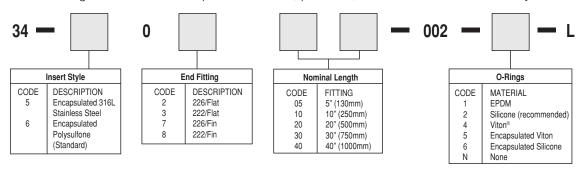
Reverse:

50psid (3.4 bar) @ 75°F (24°C)



Ordering Information

Each cartridge is identified with a product number, pore size, and lot number for traceability.



Proflow is a registered trademark of Parker-Hannifin Corporation. Viton is a registered trademark of E.I. duPont de Nemours & Co. Inc.



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