

CLARIFLOW® Pharmaceutical Grade

Low Protein-Binding PES Membrane for Sterilizing Pharmaceutical Solutions



Clariflow® Pharmaceutical Grade cartridges are designed to produce end-product sterility during pharmaceutical final filtration. They deliver unsurpassed performance and reliability due to their materials of construction, comprehensive validation package, complete traceability, and extensive quality assurance program.

These filters achieve superior filtration characteristics because of a mirrored-anisotropic, hydrophilic polyethersulfone (PES) membrane. This unique membrane morphology provides excellent flow rates, extended on-stream life, and low protein-binding characteristics. And it eliminates the need for wetting agents or surface treatments that could leach out during processing and adulterate the end product.

Clariflow cartridges are manufactured in a certified class 10,000 cleanroom, and each is flushed with non-pyrogenic deionized water and integrity tested before shipment to assure consistent performance and quality.

BENEFITS

- High flow rates reduce processing time
- Quantitative bacterial retention provides sterile effluent
- Non-pyrogenic for use in critical applications
- Long service life minimizes change-out frequency
- Biologically inert and low protein-binding nature maximizes product yields

STERILIZING APPLICATIONS

- Therapeutic Agents
- Bacterial Growth Media
- Water for Injection (WFI)
- Immunological Preparations
- Sera and Plasma Fractions

DETAILS

LIQUID FLOW RATES*

10 inch (25 cm) cartridges:

0.1 µm	1.0 gpm/psid (0.06 lpm/mbar)
0.2 µm	1.4 gpm/psid (0.08 lpm/mbar)

5 inch (13 cm) cartridges:

0.2 µm	0.6 gpm/psid (0.03 lpm/mbar)
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(*for fluids with viscosity of 1 cp)

MATERIALS OF CONSTRUCTION

Membrane:	Polyethersulfone (0.1 µm - single layer; 0.2 µm - double layer)
Support Layers:	Polypropylene
Structure:	Polypropylene

All components meet USP-XXIV Class VI-121°C criteria and are Thermally Bonded to assure integrity and reduce extractables.

MAXIMUM DIFFERENTIAL PRESSURE

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

Reverse:	50 psid (3.4 bar) @ 75°F (24°C)
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STEAM STERILIZABLE AND SANITIZABLE

Cartridges may be Steamed or Autoclaved up to 20 times @ 275°F (135°C). Cartridges may also be chemically sanitized in place using common sanitizing agents.

BACTERIA RETENTION

Cartridges have been validated for **complete** retention of greater than 10⁷ organisms/cm² of filtration area per HIMA methodology (ASTM F838-83) using *Acholeplasma laidlawii* (0.1 µm) or *Brevundimonas diminuta* (0.2 µm). A representative sample from each manufacturing lot is challenged **prior to release for shipment** in order to assure that these filters will meet this criteria.

INTEGRITY TEST VALUES

FILTER RATING	BUBBLE POINT		DIFFUSIONAL FLOW		
	µm	psig	bar	cc/min	TEST PRESSURE
				psig	bar
0.1	≥45*	3.1*	≤25	55	3.8
0.2 (5 inch)	≥55	3.8	≤10	45	3.1
0.2 (10 inch)	≥55	3.8	≤20	45	3.1

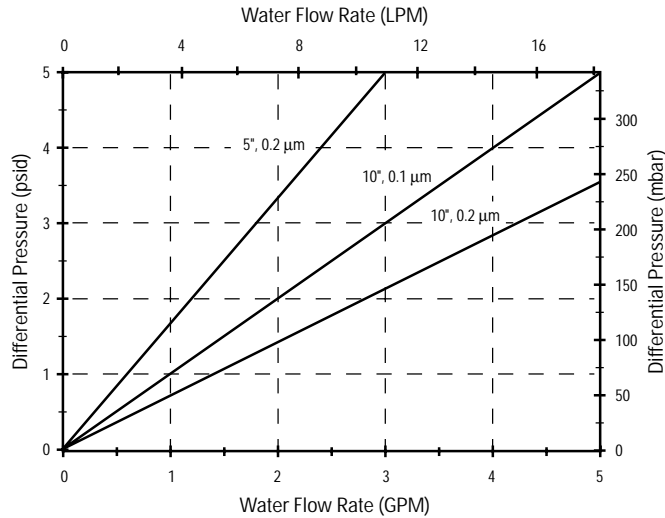
*In 60% IPA/40% DI Water.

All cartridges are tested at PTI using the diffusive flow test in water.

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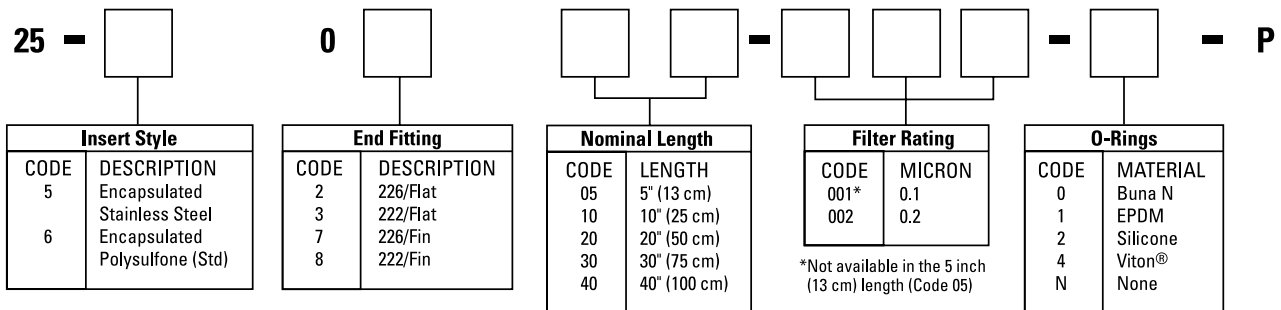
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PERFORMANCE ATTRIBUTES



ORDERING INFORMATION

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



Specifications are nominal and are subject to change without notice. Detailed technical information and selection assistance are available from the company.

TECHNICAL SUPPORT and PRODUCT ORDERING

PTI Advanced Filtration provides unsurpassed product consistency and cost-efficiency for our customers. Our experienced professionals can help you select the right solution for your application. For more information or to place an order, contact your local distributor. Information on product specifications, applications and chemical compatibility can be found on our web site at www.pti-afi.com or through your nearest PTI Advanced Filtration office.

PTI designs and manufactures an extensive line of innovative solutions for specific applications in Biopharmaceutical, Microelectronics, Food & Beverage, Industrial and Chemical industries.

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