

Clariflow® Pharmaceutical Grade

Low Protein-Binding PES Membrane for
Sterilizing Pharmaceutical Solutions

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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 onstream 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 cleanroom environment, and each is flushed with non-pyrogenic deionized water and integrity tested before shipment to assure consistent performance and quality.



Parker Hannifin Corporation provides our customers with unsurpassed product consistency and cost-efficiency. 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.

Parker Hannifin Corporation designs and manufactures an extensive line of innovative solutions for specific applications in the Microelectronics, Biopharmaceutical, Food and Beverage, Industrial and Chemical industries.

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

Applications

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

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Liquid Flow Rates*

10 inch (250 mm) cartridges:

0.1 µm 1.0 gpm/psid (5.49 lpm/100 mbar)

0.2 µm 1.4 gpm/psid (7.69 lpm/100 mbar)

5 inch (130 mm) cartridges:

0.2 µm 0.6 gpm/psid (3.29 lpm/100 mbar)

*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

Biological Safety

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

Maximum Operating

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)

Drug Master File

No. 11825, registered with the USFDA

Steam Sterilizable and Sanitizable

Cartridges may be Steamed or Auto-claved 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.

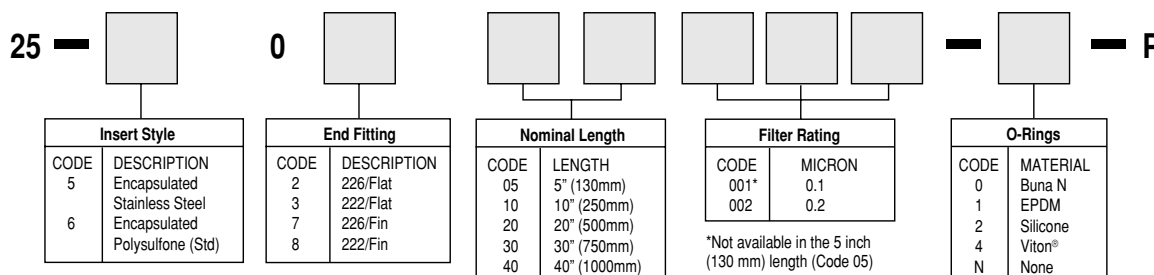
Integrity Test Values

Filter Rating	Bubble Point*		Diffusional Flow		
	µm	psig	bar	cc/min	psig
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 a 60% IPA/40% DIWater.

Ordering Information

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



TECHNICAL SUPPORT and PRODUCT ORDERING

Parker Process 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.parker.com or through your nearest Parker Process Advanced Filtration office. Parker Process Advanced Filtration designs and manufactures an extensive line of innovative solutions for specific applications in Biopharmaceutical, Microelectronics, Food & Beverage, Industrial and Chemical industries.

