

CLARIFLOW® II-P CAPSULES

Higher performing encapsulated PES Membrane Filters For Sterile Filtration



The higher performing Clariflow II-Pharmaceutical Grade Capsules are designed to deliver sterilizing grade performance in critical biopharmaceutical applications.

The polyethersulfone membrane is inherently hydrophilic and therefore does not require the addition of wetting agents. This results in lowering extractables as well as compatibility with a wide range of chemicals across the pH range - including many organic solvents. The PES membrane also exhibits: low protein-binding characteristics; is biologically inert; and bacterial retentive.

The capsules are available in a variety of sizes and end-fitting combinations.

The encapsulated design maximizes efficiency by providing faster, easier change-out without laborious cleaning procedures.

BENEFITS

- High flow rates reduce processing time
- Quantitative bacterial retention produces sterile solutions
- Biologically inert, low protein-binding membrane maximizes product yields
- Inherently hydrophilic for cleaner filtrates

APPLICATIONS

- Sera and Vaccines
- Bacterial Growth Media
- Protein-Containing Preparations
- Parenteral Solutions
- Buffers and Reagents
- End Product Sterilization

SPECIFICATIONS

FITRER RATING AND FLOW RATES

| DOUBLE SIZE µm | TYPICAL WATER FLOW RATE | |
|-------------------|-------------------------|--------------|
| | gpm/psid | lpm/100 mbar |
| 0.1 | 0.10 | 2.0 |
| 0.2 | 0.20 | 3.5 |
| 0.45 | 0.45 | 5.5 |

MATERIALS OF CONSTRUCTION

| | |
|-----------------------|------------------|
| Filtration Membrane | Polyethersulfone |
| Upstream Support | Polyester |
| Downstream Support | Polyester |
| Inner Support Core | Polypropylene |
| Outer Protection Cage | Polypropylene |
| Capsule Body | Nylon |
| End Caps | Nylon |

Materials conform to the relevant requirements of 21CFR Part 177 and current USP Plastics Class VI-121°C and ISO10933 equivalents.

RECOMMENDED OPERATING CONDITIONS

Capsules may be operated up to a temperature of 104°F (40°C) at line pressures up to 72 psig (5.0 bar) for liquids and 58 psi (4.0 bar) in air/gas.

RETENTION CHARACTERISTICS

Clariflow II-Pharmaceutical Grade capsules are validated by bacterial challenge testing to methods specified in ASTM F838-83 with typical in-house challenge levels being $>10^7$ /cm².

AUTOCLAVABLE AND SANITIZABLE

Capsules may be autoclaved up to 10 times (30 minutes) at 266°F (130°C), or chemically sanitized in place using common sanitizing agents. The capsules can also be sanitized with hot water at up to 194°F (90°C) and are compatible with a wide range of chemicals.

STANDARD PACKAGING OPTIONS

- Non-Sterile
- Pre-Sterilized

INTEGRITY TEST VALUES

All filters are flushed with pharmaceutical grade purified water prior to shipping. They are integrity testable to the following limits:

Double Size Capsule

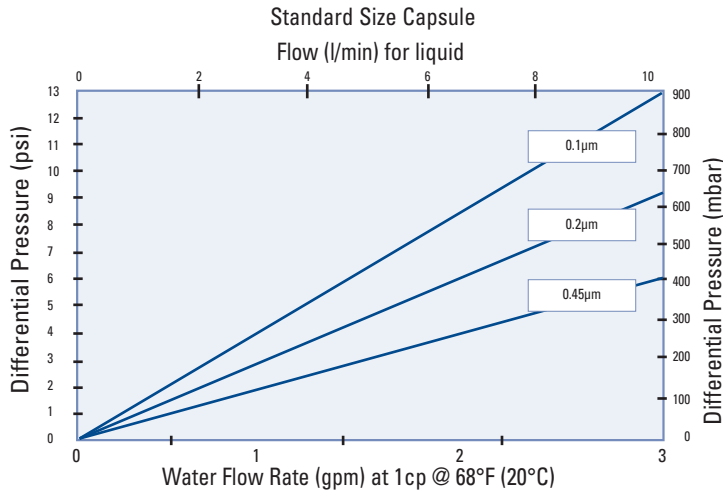
| FILTER RATING | BUBBLE POINT | | DIFFUSIONAL FLOW | |
|---------------|--------------|------|------------------|--------------------|
| | µm | psig | bar | TEST PRESSURE psig |
| 0.1 | 34.2* | 2.36 | 70 | 10.3 |
| 0.2 | 49.0 | 3.38 | 41 | 6.1 |
| 0.45 | 36.0 | 2.48 | 25 | 6.1 |

*In a 60/40 solution of IPA/Water

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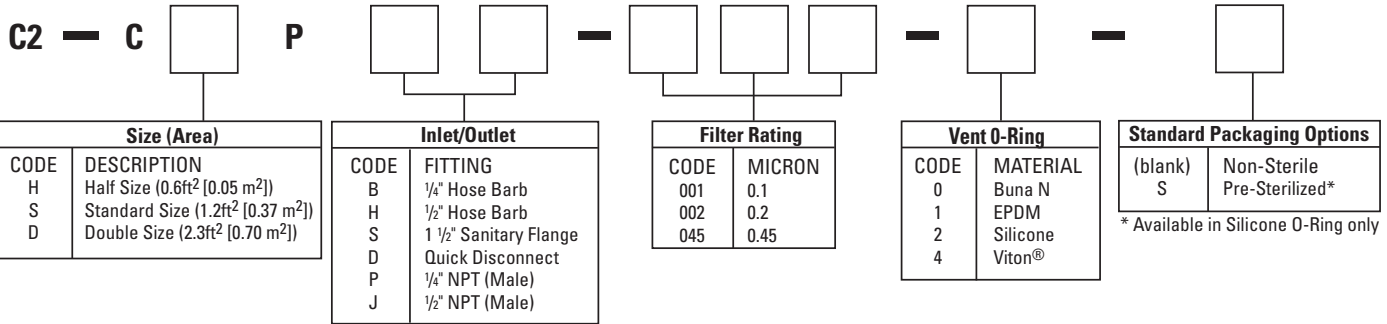
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PERFORMANCE ATTRIBUTES



ORDERING INFORMATION

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



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 Advanced Filtration 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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