

CLARIFLOW® II-B CAPSULES

Low Protein-Binding Encapsulated PES Membrane Filters for Superior Flow Rates



Clariflow II-Biological Grade capsules deliver high-purity fluids for small volume 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.

Clariflow II-Biological Grade 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

- Faster processing of batches
- Qualitative bacterial retention reduces initial bioburden
- Non-pyrogenic for use in critical applications
- Long service life minimizes change-out frequency
- Maximizes product yields

APPLICATIONS

- Sera and Vaccines
- Bacterial Growth Media
- Protein-Containing Preparations
- Parenteral Solutions
- Buffers & Reagents

SPECIFICATIONS

FILTER RATING AND FLOW RATES

DOUBLE SIZE µm	TYPICAL WATER FLOW RATE	
	gpm/psid	lpm/100 mbar
0.1	0.7	2.7
0.2	1.4	5.5
0.45	3.1	12.3

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

The Clariflow II-Biological Grade filters' typical titre reduction values as shown have been established using a challenge methodology based on ASTM F838-83.

CLEANING AND STERILIZATION

Clariflow II-Biological Grade capsules can be repeatedly in-situ steam sterilized or autoclaved at up to 266°F (130°C). 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

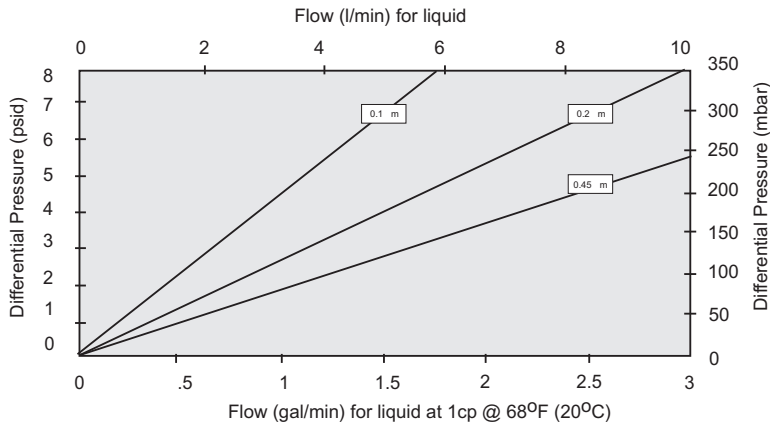
FILTER RATING µm	BUBBLE POINT		DIFFUSIONAL FLOW	
	psig	bar	TEST PRESSURE psig	FLOW ml/min
0.1	49.0	3.38	40.6	6.1
0.2	36.0	2.48	24.7	6.1
0.45	19.3	1.33	14.5	6.1

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PERFORMANCE ATTRIBUTES

Clean Water flow Characteristics for Standard Size Clariflow II-B PES Capsules



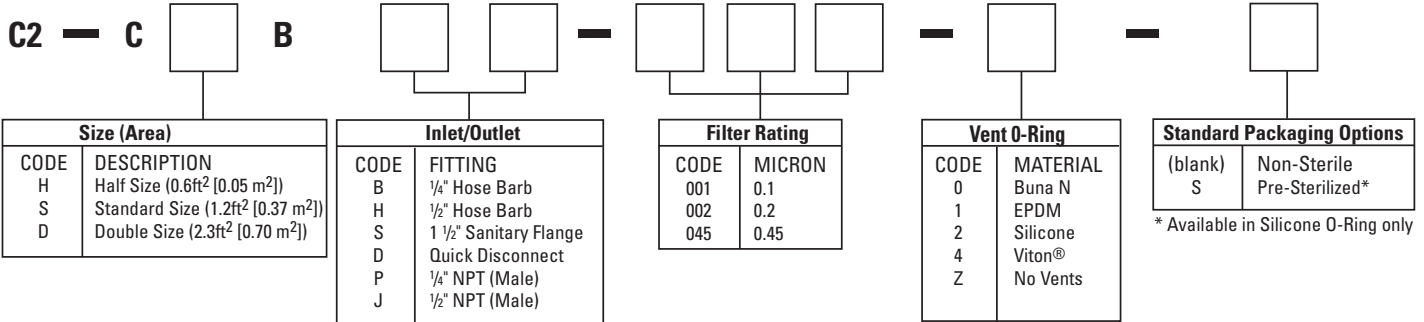
BACTERIAL TITRE REDUCTION

Based on ASTM F838-83 methodology

Test Organism	Approx. Cell Size (µm)	Micron Rating			
		0.10	0.20	0.45	0.65
Acholeplasma laidlawii	0.08	>106	104	-	-
Brevundimonas diminuta	0.30	>1010	104	102	-
Serratia marcescens	0.5	>1012	1010	104	104
Leuconostoc oenos	0.5	>1012	1012	108	105

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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