

# Omni-Clear™ SM Series

Validated Pleated Cartridges Utilizing Polyethersulfone Membrane



## Description

Purolator's Omni-Clear™ SM series filter cartridges are manufactured to conform with the stringent quality standards required by filters that come in contact with biologicals, pharmaceuticals, and other critical processes. The filter cartridges are non-toxic per ISO 10993-5 Elution Test, meet the requirements of USP 29 Biological Test for Plastics, Class VI, 121 °C, and are manufactured using components that are FDA listed as appropriate for food contact. To ensure the purity of the assembled filter components, all cartridges are assembled in a Class 10,000 Clean Room and are constructed and sealed using an advanced thermal bonding process with no bonding agents, resins, or glues. Omni-Clear SM Series filter cartridges are supported by a validation guide prepared specifically for manufacturers requiring product documentation as part of their qualification process.

Omni-Clear pleated cartridges are manufactured with advanced hydrophilic polyethersulfone (PES) membranes and polypropylene components. The low protein binding nature of the filter membrane ensures suitability in many critical applications. The PES membrane provides absolute particle retention and is compatible with a broad range of chemicals and pH extremes. The cartridges are autoclave and steam sterilizable and can withstand repeated sterilization cycles.

All pharmaceutical, biological, and microbial grade filters are non-destructively integrity tested and flushed with purified water before release. The pharmaceutical grade cartridges are laboratory tested to certify that the filtrate has an endotoxin level below 0.125 EU/mL. To ensure full traceability, each Omni-Clear filter segment is marked with a lot number and individual serial number in addition to product model number.

## Features and Benefits

- High surface area filter cartridges, constructed of pleated polyethersulfone membranes, provide absolute particle retention and long on-stream life cycles.
- Quantitative retention of  $10^7$  CFU/cm<sup>2</sup> *Brevundimonas diminuta* ATCC 19146 per ASTM F838-05.
- Cartridges are sealed using an advanced thermal bonding process and flushed with ultrapure water to ensure the lowest level of extractables.
- Each cartridge is stamped with product and lot number for identification and 100% traceability.
- All cartridges are constructed and assembled in a Class 10,000 Clean Room environment to ensure minimal particle contamination.
- All materials of construction are FDA listed for food and beverage contact according to CFR Title 21, meet the requirements under USP Class VI, and are non-toxic per ISO 10993-5 Elution Test.
- Absolute removal ratings available from 0.1 to 1.2 µm.

## Applications

- Pharmaceuticals / Biologicals
- High Purity Chemicals
- Large and Small Volume Parenterals
- Acids, Bases and Oxidants
- High Purity Water
- Fragrances
- Ophthalmic Solutions
- Inks and Dyes
- Wines
- Bottled Water

## Materials of Construction

|                       |                             |
|-----------------------|-----------------------------|
| Filter Media          | Asymmetric Polyethersulfone |
| Support Media         | Polypropylene               |
| Cage, Core, Endcaps   | Polypropylene               |
| O-Rings/Gaskets       | EPR, Silicone, PTFE*        |
| Internal Support Ring | Stainless Steel             |

\*Other materials available

## Nominal Dimensions

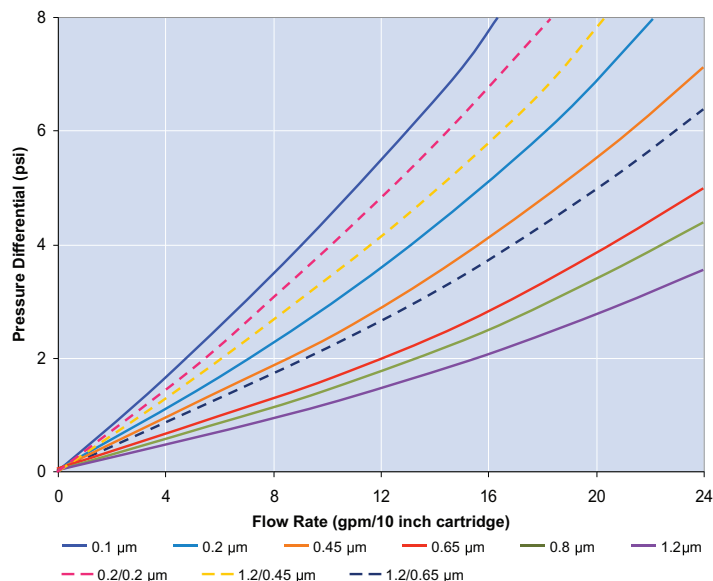
| Length Designation |                    | A   | B    | C    | D    |
|--------------------|--------------------|-----|------|------|------|
| Diameter           | (in)               | 2.7 | 2.7  | 2.7  | 2.7  |
|                    | (cm)               | 6.9 | 6.9  | 6.9  | 6.9  |
| Length             | (in)               | 10  | 20   | 30   | 40   |
|                    | (cm)               | 25  | 51   | 76   | 102  |
| Filtration Area*   | (ft <sup>2</sup> ) | 7.5 | 15.0 | 22.5 | 30.0 |
|                    | (m <sup>2</sup> )  | 0.7 | 1.4  | 2.1  | 2.8  |

\*Double layer cartridges have 5.8 ft<sup>2</sup> of effective filtration area per 10 inch segment

## Flow Rate and Integrity

| Part Number           | Flow at 1 psid (gpm) | Integrity Values              |                            |                            |
|-----------------------|----------------------|-------------------------------|----------------------------|----------------------------|
|                       |                      | Diffusive Flow Pressure (psi) | Diffusive Flow Volume (mL) | Minimum Bubble Point (psi) |
| <b>10 inch Length</b> |                      |                               |                            |                            |
| SM001                 | 0.6                  | 50                            | 20                         | 60                         |
| SM002                 | 2.4                  | 36                            | 20                         | 45                         |
| SM004                 | 4.2                  | 20                            | 20                         | 24                         |
| SM006                 | 7.3                  | 14                            | 20                         | 16                         |
| SM008                 | 7.5                  | 12                            | 20                         | 14                         |
| SM009                 | 8.3                  | 10                            | 20                         | 12                         |
| SM022                 | 1.0                  | 40                            | 10                         | 45                         |
| SM094                 | 2.0                  | 22                            | 10                         | 24                         |
| SM096                 | 5.5                  | 14                            | 10                         | 16                         |

## Water Flow Rate



## Operating Conditions

| Maximum Differential Pressure | Maximum Operating Temperature |
|-------------------------------|-------------------------------|
| 60 psid (4 bar)               | 68 °F (20 °C)                 |
| 30 psid (2 bar)               | 140 °F (60 °C)                |

## Sterilization

|               |            |                 |
|---------------|------------|-----------------|
| Autoclave     | 30 minutes | 259 °F (126 °C) |
| In-line Steam | 30 minutes | 275 °F (135 °C) |

## Cartridge Selection Guide

| Cartridge Media Type           | Grade  | Series  | Layer                    | Nominal Length (inches)              | Cartridge Style   | Gasket or O-Ring   | Utilization  |
|--------------------------------|--|---|--------------------------|--------------------------------------|---|--|--|
| SM                             | 002  | P   | 1                        | A                                    | 3   | 03   | S  |
| SM = Polyethersulfone Membrane | 001 = 0.1 µm<br>002 = 0.2 µm<br>004 = 0.45 µm<br>006 = 0.65 µm<br>008 = 0.8 µm<br>009 = 1.2 µm<br>022 = 0.2/0.2 µm<br>094 = 1.2/0.45 µm<br>096 = 1.2/0.65 µm | M = Microbial<br>B = Biological<br>E = Electronic<br>P = Pharmaceutical | 1 = Single<br>2 = Double | A = 10<br>B = 20<br>C = 30<br>D = 40 | 2 = DOE<br>3 = 222/Flat<br>6 = DOE/Internal 120 O-Ring<br>7 = 226/Fin<br>7A = 226/Flat<br>8 = 222/Fin | 01 = EPR<br>03 = Silicone<br>04 = Nitrile<br>08 = Viton<br>09 = PTFE Gasket<br>10 = PTFE/Viton | N = Non-Steam Sterilizable<br>S = Steam Sterilizable |

### Purolator Liquid Process

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