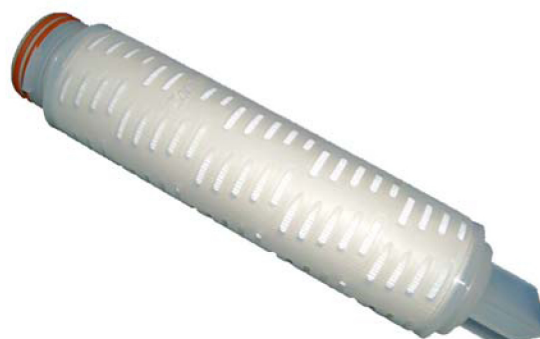


PureFlo® Pharmaceutical Grade Cartridges

The PureFlo® Pharmaceutical Grade Cartridges are designed for product sterility. The all-polypropylene construction provides excellent chemical compatibility and superior flow per unit area as compared to other membrane cartridges. PureFlo® Pharmaceutical Grade Cartridges have been designed for final filtration in biopharmaceutical applications. The hydrophilic PES membrane does not require pre-wetting agents, thereby eliminating a potential source of contamination. Also, the PES membrane has low protein-binding characteristics to maximize yields.

No adhesives, binders, or surfactants are used in the manufacturing process. All cartridges are rinsed with pyrogen-free water to reduce extractables and downtime. All filter cartridges are 100% integrity tested to ensure filter performance and quality. PureFlo® Pharmaceutical Grade Cartridges are well-suited for critical applications where superior flow and bacterial retention is required.



SPECIFICATIONS

Bacterial Retention

Complete retention of $\geq 10^7$ organisms/cm² of *Brevundimonas diminuta* in accordance with the current HIMA challenge methodology (ASTM F838-05). Validation guide available upon request.

Water Bubble Point Specification

0.1 μ m : 23 psi (0.16 MPA) in IPA

0.2 μ m : 50 psi (0.35 MPA)

Bio-Safety

Filter effluent is non-pyrogenic per USP bacterial endotoxin (<0.25 EU/ml)

Sterilization & Autoclaving

The filters can be sterilized by autoclaving for up to 50 cycles at 125 °C (257 °F) for 30 minutes. The filters can also be sterilized by steam-in-place procedure up to 30 cycles at 135 °C (275 °F) for 30 minutes at less than 0.3 bar differential pressure. The filters can also be sanitized by hot water or common chemicals that are compatible with filter components.

Applications

| | |
|----------------|--------------------------------|
| Culture media | Fermentation Broths |
| Serums | LVP (Large Volume Parenterals) |
| Vaccines | Pharmaceuticals |
| Fine Chemicals | Biologics |
| Antibiotics | Beverages |
| Water | Scale-Up Processes |

Regulatory Compliance

Manufactured from materials that conform to the requirements of 21 CFR Part 177 of the U.S. Code of Federal Regulations and USP Class VI Biological Test for Plastics.

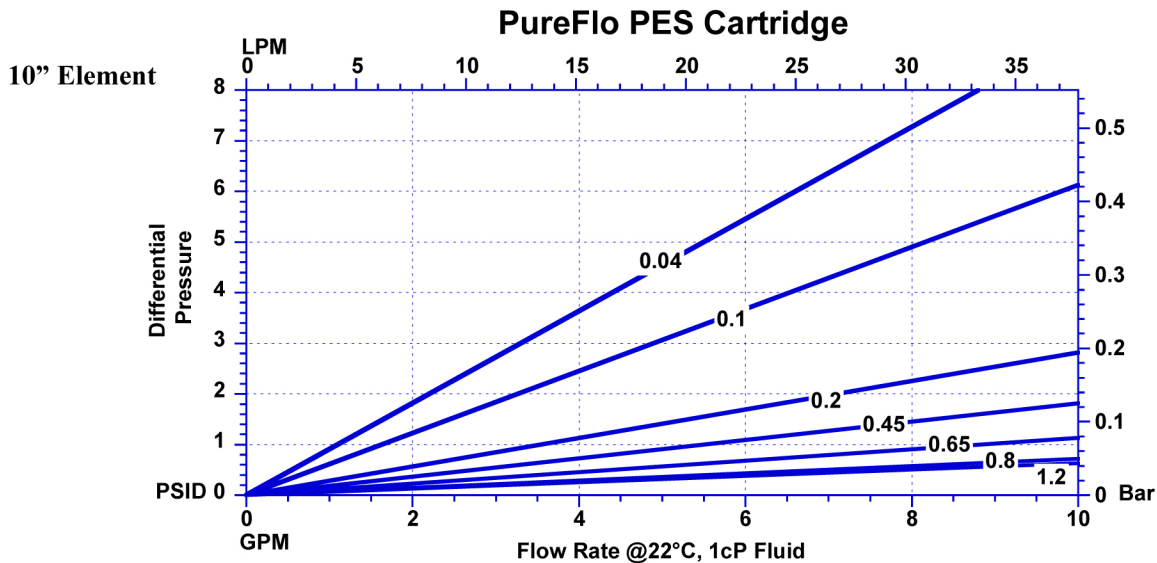
Features

Benefits

| | |
|---|--|
| <ul style="list-style-type: none"> ■ Hydrophilic PES Membrane (Absolute Rated) | <ul style="list-style-type: none"> ■ Inherently hydrophilic ■ High flow rate reduces processing time ■ Low protein-binding membrane maximizes yields ■ Biologically inert membrane ■ Bacterially retentive to produce sterile solutions |
| <ul style="list-style-type: none"> ■ Wide Chemical & Thermal Compatibility | <ul style="list-style-type: none"> ■ Provides excellent compatibility with a wide-range of chemicals |
| <ul style="list-style-type: none"> ■ Low Levels of Filter Extractables | <ul style="list-style-type: none"> ■ No adhesives, binders, or surfactants are used during manufacturing resulting in superior downstream cleanliness ■ All cartridges are rinsed with pyrogen-free water |



PureFlo[®] Pharmaceutical Grade Cartridges



Materials of Construction

Membrane: Hydrophilic Polyethersulfone (PES)
Membrane Supports: Polypropylene
Cage, Core, End Caps: Polypropylene
Gasket / O-Rings: EPDM, Buna N, Silicone,
Viton, TES, and TEV

Dimensions (nominal)

Lengths: 5 in. (13 cm), 10 in. (25 cm),
20 in. (51 cm), 30 in. (76 cm),
40 in. (102 cm)
Diameter: 2.75 in. (70 mm)

Effective Filtration Area

0.65 m² (7 ft²) per 10" cartridge element

Operating Conditions

Maximum Forward Differential Pressure:
5.0 bar (72.5 psid) at 22°C
2.0 bar (29 psid) at 80°C
Maximum Reverse Differential Pressure:
3.0 bar (43.5 psid) at 22°C
1.0 bar (14.5 psid) at 80°C
Maximum Operating Temperature: 80°C

PureFlo PES Pharmaceutical Grade Cartridge Ordering Guide

| PureFlo PES Filter Cartridges | Removal Rating | End Modifications | Length | O-Ring / Gasket Materials | Package Qty | Options | Options |
|---|------------------|---------------------------------|-----------|----------------------------|---------------|-------------------------------------|--|
| MCS = PES with PP construction Pharma grade | 04 = 0.04 micron | 0 = 222 O-Ring Flat | 1 = 10" | E = EPDM | 1 = 1pc/ pack | - 5 = SS Insert - RI = RFID Chip | -PH = Pharma Grade -ETO = ETO Sterilization -G(pore Size)= Glass Fiber PreFilter -P(pore Size)= Poly Pro Media PreFilter -S(pore Size) = PES PreFilter |
| | 10 = 0.10 micron | 3 = 222 O-Ring w/tabs Spear | 2 = 20" | N = Buna N | | | |
| | 20 = 0.20 micron | 5 = 222 O-Ring Spear | 3 = 30" | P = Peroxide Cured EPDM | | | |
| | 50 = 0.45 micron | 6 = 226 O-Ring Flat | 4 = 40" | Q = Platinum Cured Silicon | | | |
| | 65 = 0.65 micron | 7 = 226 O-Ring Spear | 5 = 5" | S = Silicone | | | |
| | 80 = 0.80 micron | 8 = 223 O-Ring Flat | 9 = 9.75" | T = TEV or FEP Gasket | | | |
| | 1X = 1.20 micron | F = DOE Flat Gasket | | U = TES* | | | |
| | | S = SOE Flat Gasket | | V = Fluoroelastomer | | | |
| | | Z = SOE Internal O-ring Flat ** | | | | | |

Example - Pharmaceutical grade, 10", 0.2 micron cartridge, with 2-222 Silicone o-ring, Flat end cap, and no inse

* - not available in Code Z

** - only available in 5", 9.75", 10" and 20", retrofit for DOE housings

