

# SAFETECT® FILTERS

## PES FILTERS

Safetect® Filters are available in hydrophilic polyethersulfone (PES) media constructions to meet the needs of bioburden reduction, pre-filtration, and steam-in-place requirements, for a wide range of critical processing requirements.

### MEDIA INFORMATION

TYPE	MEDIA	FEATURES	TYPICAL APPLICATIONS
PME	Double-layer PES - Symmetric Inner and outer layer	<ul style="list-style-type: none"> <li>• Bioburden reduction</li> <li>• Pre-filtration</li> <li>• Low extractables</li> </ul>	<ul style="list-style-type: none"> <li>• Pre-filtration of cell culture medium</li> <li>• Buffer filtration</li> </ul>

### BIOLOGICAL SAFETY

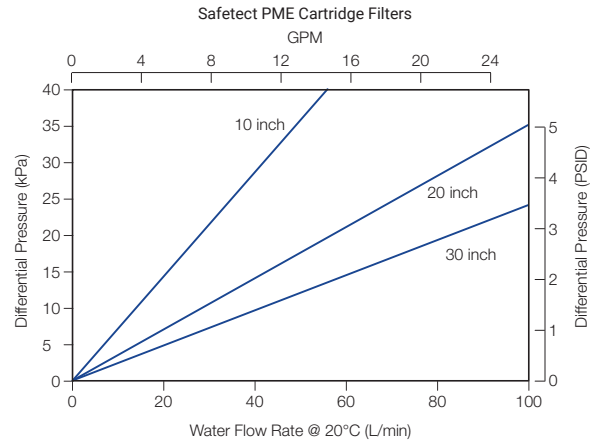
<b>Sterilization</b>	Steam-in-Place: Can be steam sterilized 50 cycles for 30 minutes at 135°C (<0.3 bar, 5 psi). Autoclave: Can be autoclaved 50 cycles for 30 minutes at 130°C.
<b>Particle Shedding</b>	Autoclaved filter effluent meets the requirements in USP <788> for large volume parenterals.
<b>Non-fiber Releasing</b>	Component materials meet the criteria for a "Non-fiber-releasing filter" as defined in 21 CFR 210.3(b) (6).
<b>USP &lt;87&gt; Cytotoxicity</b>	Meets the criteria of the USP <87> In-Vitro Biological Reactivity Test.
<b>USP &lt;88&gt; Biological Reactivity</b>	Meets the criteria of the USP <88> Biological Reactivity Test for Class V1-121 °C plastics.
<b>Indirect Food Additive</b>	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.
<b>Quality Assurance</b>	These products are manufactured in a facility which adheres to ISO® 9001 Practices.



## SAFETECT SPECIFICATIONS

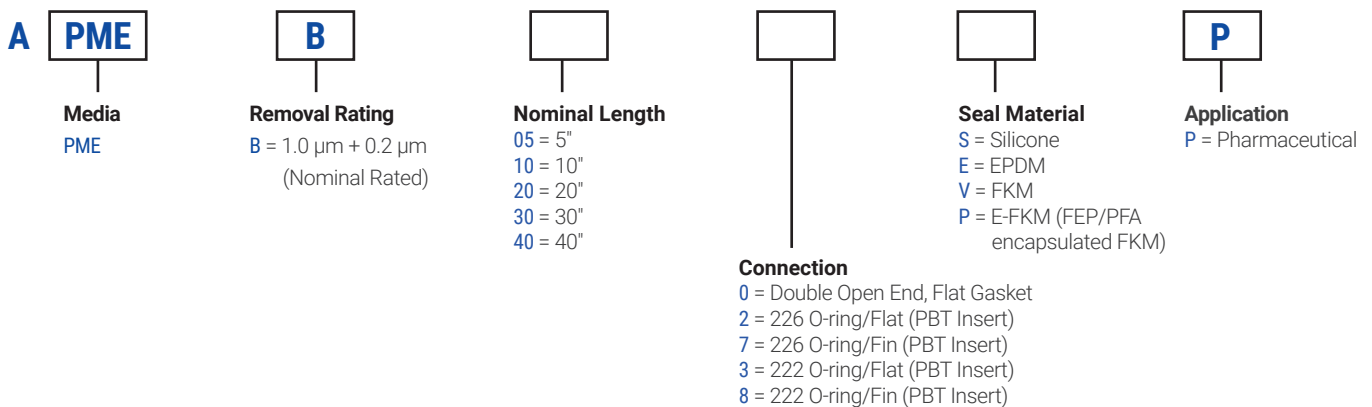
<b>Filter media</b>	Dual Layer Hydrophilic Polyethersulfone (PES)
<b>Core/Cage/End Cap</b>	Polypropylene
<b>Capsule Shell</b>	Polypropylene
<b>O-ring</b>	Silicone/EPDM/FKM/E-FKM
<b>O-ring insert</b>	PBT
<b>Max. Operating temperature</b>	0.69 MPa (6.9 bar, 100 psi) at 25°C 0.40 MPa (4.0 bar, 58 psi) at 60°C 0.24 MPa (2.4 bar, 35 psi) at 80°C
<b>Max. Differential pressure</b>	Forward: 0.69 MPa (6.9 bar, 100 psi) at 25°C 0.40 MPa (4.0 bar, 58 psi) at 60°C 0.24 MPa (2.4 bar, 35 psi) at 80°C Reverse: 0.30 MPa (3.0 bar, 44 psi) at 25°C 0.10 MPa (1.0 bar, 15 psi) at 80°C
<b>Water Bubble Point at 20°C</b>	≥0.27 MPa (2.7 bar, 39 psi), air
<b>Sterilization</b>	Steam-in-Place: Can be steam sterilized 50 cycles for 30 minutes at 135°C (<30.3 bar, 5 psi) Autoclave: Can be autoclaved for 50 cycles of 30 min. at 130°C.
<b>TOC/Conductivity at 25°C</b>	Autoclaved filter effluent meets the USP <643> for Total Organic Carbon and USP <645> for Water Conductivity per WFI requirements after a UPW flush of 20L.

## FLOW RATES



## CARTRIDGE ORDERING INFORMATION

EXAMPLE: **APMEB107E1P** dual-layer PME, 1.0 µm + 0.2 µm, 10", 226 o-ring/fin, EPDM o-ring



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