

Data Sheet

Charged Durapore® Hydrophilic 0.22 µm Cartridge Filters

Cationically charged cartridge filters for sterile filtration, endotoxins removal, low preservative adsorption

Charged Durapore® 0.22 µm hydrophilic cartridges are sterilizing-grade cartridge filters manufactured from polyvinylidene fluoride (PVDF) membrane modified to give it a net positive charge.

Endotoxins will easily pass through a 0.22 µm sterilizinggrade membrane filter where size exclusion is the only retention mechanism. Because endotoxins are negatively charged, a positively charged membrane can aid in the removal of endotoxins that are far smaller than the rated pore size of the filter. Charged Durapore® 0.22 µm hydrophilic cartridges are designed for the removal of endotoxins from pharmaceutical-grade water systems.



Benefits

- Low protein binding membrane yields high protein recovery with minimal loss of valuable product.
- Superior membrane for filtration processes requiring high flow rates and throughputs.
- Ideal for designing scalable solutions from bench top to full-scale manufacturing.



Endotoxin Removal

Charged Durapore® 0.22 μ m hydrophilic cartridges are designed for the removal of endotoxins from pharmaceutical-grade water systems. The filters are certified for an LRV >5 when challenged with 10 6 pg/mL of purified *E. coli* (Type 055:B5 LPS) endotoxin in water.

Low Preservative Binding

Adsorptive loss of quaternary amines and other positively charged preservatives can be minimized by using cationically charged Durapore® membrane.

Robust Design

The filters may be steam sterilized 10x for 30 minutes at 135 °C. They will withstand a forward differential pressure of 80 psid at 25 °C and intermittent back pressure of 50 psi at 25 °C.

High Performance

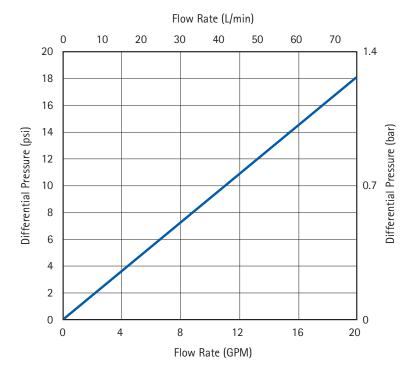
Charged Durapore® membrane is based on the same membrane used in standard Durapore® and offers high flow rates, high throughput, low extractables and reliable bacterial retention.

Regulatory Compliance

No surfactants or adhesives are used in cartridge construction. All cartridges are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO® 9001 and ISO® 14001 Quality Systems Standard. Each cartridge is shipped with a Certificate of Quality, integrity tested during manufacturing and is supported with a comprehensive Validation Guide for compliance with regulatory requirements.

Figure 1.

Typical water flow rate at 23 °C



Specifications

1.9 ft² (0.2 m²) per 4-inch (10.2 cm) Optiseal® cartridge 7.4 ft² (0.7 m²) per 10-inch (25.4 cm) cartridge 14.8 ft² (1.4 m²) per 20-inch (50.8 cm) cartridge 22.2 ft² (2.1 m²) per 30-inch (76.2) cartridge
Modified polyvinylidene fluoride (PVDF) membrane with a net positive charge. Non-woven polypropylene pleat supports upstream and downstream. Rigid polypropylene outer sleeve, core, end caps and adapter. Silicone O-rings.
Charged Durapore® membrane samples exhibit LRV >5 when challenged with 10 ⁶ pg/mL of purified <i>Escherichia coli</i> (Type 055:B5 LPS) endotoxins
Each cartridge must pass our integrity test, which is correlated to the <i>B. diminuta</i> ASTM® bacterial challenge test.
Cartridges are quantitatively retentive of <i>Brevundimonas diminuta</i> ATCC® 19146 at a minimum challenge level of 10 ⁷ CFU (colony forming units) per cm ² of filtration area using ASTM® F-838-83 methodology.
≥2760 mbar (40.0 psig)
Aqueous extraction contains <0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test
135 °C, 30 minutes, up to 10 times, Steam-in-Place
80 psid (5.5 bar) at 25 °C in the forward direction 50 psid (3.4 bar) at 25 °C in the reverse direction
Component materials meet the criteria of the USP <88> Reactivity Test for Class VI Plastics.
Autoclaved (126 °C, 30 minutes) 4-inch (10.2 cm) Optiseal® cartridges will meet the current USP WFI Oxidizable Substance requirements after a 0.5-liter water flush. Autoclaved (126 °C, 30 minutes) 10-inch (25.4 cm) cartridges will meet the current USP WFI Oxidizable Substance requirements after a 1.0-liter water flush per 10-inch (25.4 cm) cartridge.
Autoclaved (126 °C, 60 minutes) cartridges are non-toxic per USP <88> Safety Test.
Charged Durapore® CCGL and LCGL cartridge filters are manufactured with a PVDF membrane which meets the criteria for a non-fiber releasing filter as defined in the Code of Federal Regulations 21 CFR 210.3 (b) (6).
Autoclaved at 126 °C for 30 minutes, 4-inch (10.2 cm) Optiseal® cartridge has ≤10 milligrams extractables in water after 24-hour static soak at room temperature. Autoclaved at 126 °C for 30 minutes, 10-inch (25.4 cm) cartridge has ≤ 20 milligrams extractables in water after 24-hour static soak at room temperature.
≤ 4.0 cc/min at 30 psid (2.07 bar) in the forward direction per 4-inch (10.2 cm) Optiseal® cartridge. ≤ 10.0 cc/min at 30 psid (2.07 bar) in the forward direction per 10-inch (25.4 cm) cartridge.
≤ 8 psid (0.55 bar) at 2 gpm (7.6 Lpm) per 4-inch (10.2 cm) Optiseal® cartridge at 23 °C. ≤ 3 psid (0.21 bar) at 2 gpm (7.6 Lpm) per 10-inch (25.4 cm) cartridge at 23 °C.

Ordering Information*

Nominal	length	
Inches	cm	Catalogue No.
10	25.4	CCGL01TP1
20	50.8	CCGL02TP1
30	76.2	CCGL03TP1
10	25.4	CCGL51TP1
20	50.8	CCGL52TP1
30	76.2	CCGL53TP1
10	25.4	CCGL71TP1
20	50.8	CCGL72TP1
30	76.2	CCGL73TP1
10	25.4	CCGL81TP1
20	50.8	CCGL82TP1
30	76.2	CCGL83TP1
4	10.2	LCGL04TP6
	10 20 30 10 20 30 10 20 30 10 20 30	10 25.4 20 50.8 30 76.2 10 25.4 20 50.8 30 76.2 10 25.4 20 50.8 30 76.2 10 25.4 20 50.8 30 76.2

^{*} For capsules or cut disks ordering information, speak with your local sales representative.

To Place an Order or Receive Technical Assistance

In Europe, please call Customer Service:

France: 0825 045 645 Germany: 01805 045 645 Italy: 848 845 645

Spain: 901 516 645 Option 1 Switzerland: 0848 645 645 United Kingdom: 0870 900 4645 For other countries across Europe, please call: +44 (0) 115 943 0840

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^{**} Silicone O-rings are standard