

Sartopore 2 0.1 µm

Sterilizing Grade and Mycoplasma Retentive Filter Cartridges



Description

Sartopore 2 0.1 µm rated filter cartridges are especially developed for validated sterile filtration and reliable mycoplasma removal from any media likely to contain it such as those originating from animal sources. In addition these elements are ideally suited for removal of unusually small microorganisms that have been shown to pass through a 0.2 µm rated sterilizing grade filter.

Applications

Typical applications include sterilizing grade filtration and Mycoplasma removal from:

- Animal Sera
- Cell Culture Media
- Media Components
- Bioprocessed Pharmaceuticals
- Biological Fluids

Any other application requiring sub 0.2 µm filtration for enhanced sterility assurance.

Compatibility

Featuring a unique hydrophilic polyether-sulfone membrane, Sartopore 2 0.1 µm cartridges are compatible from pH 1 to pH 14 and to numerous steam sterilization cycles. Therefore they are also ideally suited for filtration of solutions with high | low pH and for multiple SIP | CIP cycles.

Performance

Sartopore 2 0.1 µm cartridges provide exceptionally high flow rates, resulting in economical sizing of filtration systems. Due to the "built-in prefiltration" by a 0.2 µm membrane, Sartopore 2 0.1 µm rated cartridges achieve outstanding total throughputs.

Wettability

Sartopore 2 cartridges can be easily wetted out for integrity testing even after drying at 80 °C for 12 hours

Microbiological Retention

Sartopore 2 0.1 µm rated filter cartridges are validated as sterilizing grade filters according to ASTM F 838-83 standard and for Mycoplasma removal with a Log Reduction Value (LRV) of 7 for *Acholeplasma laidlawii*.

Quality Control

Each individual element is tested for integrity by diffusion test prior to be released assuring absolute reliability.

Documentation

Sartopore 2 0.1 µm rated cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Specifications

Materials

Prefilter Membrane:	Polyethersulfone, asymmetric
Endfilter Membrane:	Polyethersulfone, asymmetric
Support Fleece:	Polypropylene
Core:	Polypropylene
End Caps:	Polypropylene
O-Rings:	Silicone (optional EPDM or Viton)

Pore Size

0.2 µm + 0.1 µm

Available Sizes | Filtration Area

Size 1	10"	0.6 m ² 6 ft ²
Size 2	20"	1.2 m ² 12 ft ²
Size 3	30"	1.8 m ² 18 ft ²

Available Adapters

21, 25, 27, 28

Operating Parameters

Max. Allowable Differential Pressure:	5 bar 75 psi at 20 °C
	2 bar 29 psi at 80 °C
Max. Allowable Back Pressure:	2 bar 29 psi at 20 °C

Membrane Filter Cartridges

Specifications

Extractables

Sartopore 2 0.1 µm rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test and Mycoplasma removal.

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization:

134 °C, 20 min. at max differential pressure of 0.5 bar | 7.25 psi

Autoclaving:

134 °C, 2 bar | 29 psi, 30 min

Sterilization Cycles

In-Line Sterilization: Min. 25
Autoclaving: Min. 25

Technical References

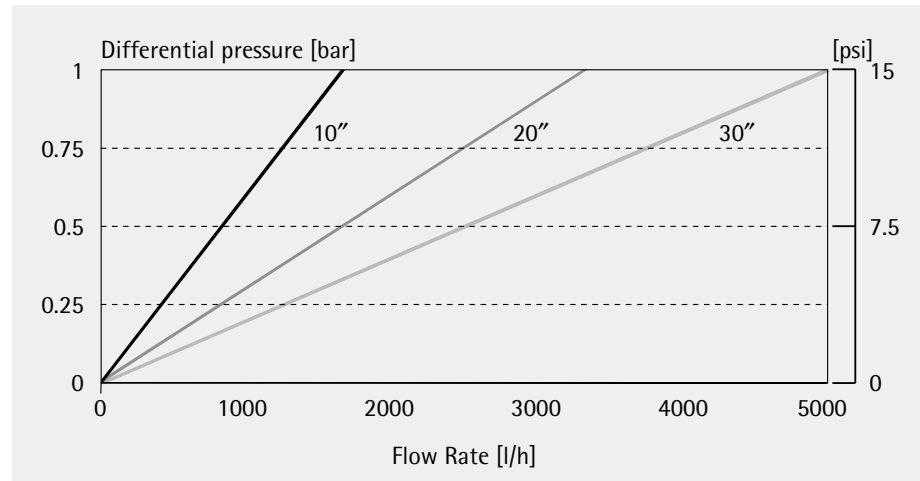
Validation Guide:

SPK5735-e

Extractables Guide:

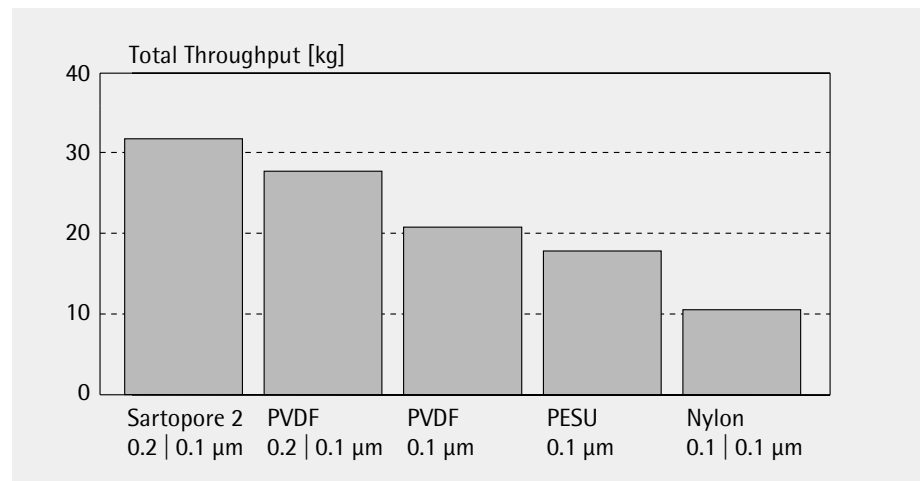
SPK5731-e

Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20 °C

Total Throughput Comparison



10" Cartridge format

Ordering Information

Order Code.	Pore size [µm]
544**58K1	0.1
544**58K2	0.1
544**58K3	0.1

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