

Sartopore 2 0.2 µm

Sterilizing Grade Filter Cartridges and Mini Cartridges



Description

Sartopore 2 0.2 µm rated sterilizing grade filter cartridges are designed for filtration of a broad range of pharmaceutical products where compliance with cGMP requirements has to be fulfilled. Sartopore 2 cartridges feature a unique hydrophilic heterogeneous double layer Polyethersulfone membrane with broad chemical compatibility, high thermal resistance and higher throughput and flow-rate than any other sterilizing grade filter cartridge.

Applications

Typical applications include sterilizing grade filtration of:

- Therapeutics
- Biological Fluids
- Ophthalmics
- SVPs, LVPs
- Antibiotics
- WFI
- Chemicals
- Cleaning and sanitizing agents
- Bulk pharmaceutical products

Compatibility

The polyethersulfone membrane is compatible with a pH range from pH 1 to pH 14 and unaffected by steam sterilization cycles making Sartopore 2 cartridges ideal for filtration of solutions with high | low pH and for SIP | CIP-cycles.

Performance

Sartopore 2 cartridges provide an exceptionally high total throughput by fractionated filtration due to the "built-in prefiltration" of the 0.45 µm membrane. The asymmetric pore structure of the polyethersulfone membrane provides high flow rates at low pressure drops.

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 filter cartridges are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-83 guidelines.

Quality Control

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation

Sartopore 2 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 of Construction

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

0.45 µm + 0.2 µm

Available Sizes | Filtration Area

Standard Cartridges

Size 0	5"	0.3 m ² 3 ft ²
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

Mini Cartridges

Size 7	0.05 m ² .5 ft ²
Size 8	0.1 m ² 1 ft ²
Size 9	0.2 m ² 2 ft ²

Available Adapters | Connectors

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	

Integrity Test Limits

Maximum Allowable Diffusion at 2.5 bar / 36 psi @ 20 °C

Cartridge Size	Maximum Diffusion	Minimum Bubble Point
Size 0	10 ml / min	3.2 bar 46 psi
Size 1	18 ml / min	3.2 bar 46 psi
Size 2	36 ml / min	3.2 bar 46 psi
Size 3	54 ml / min	3.2 bar 46 psi
Size 7	4 ml / min	3.2 bar 46 psi
Size 8	5 ml / min	3.2 bar 46 psi
Size 9	7 ml / min	3.2 bar 46 psi

Membrane Filter Cartridges

Specifications

Extractables

Sartopore 2 0.2 µm rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics 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

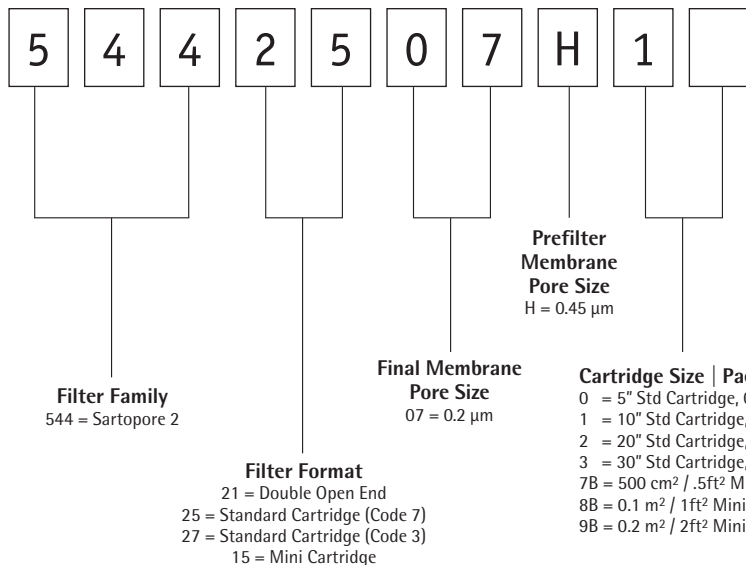
Validation Guide:

SPK 5732-e

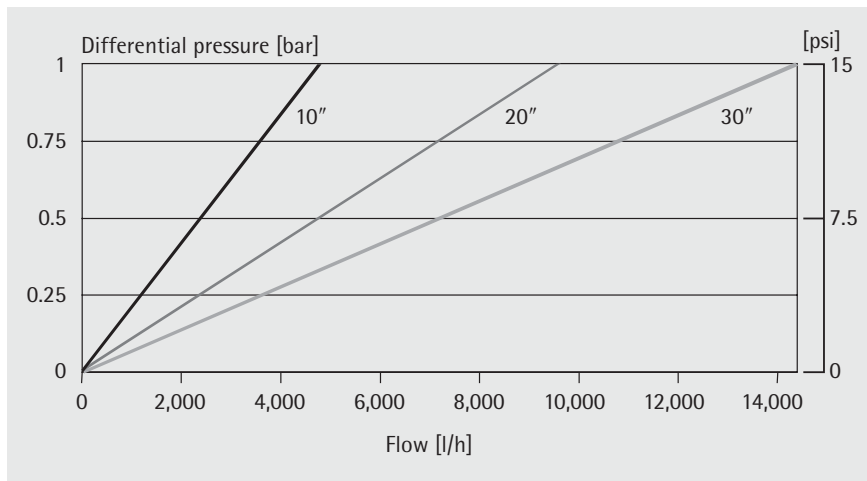
Extractables Guide:

SPK 5731-e

Ordering Guide:

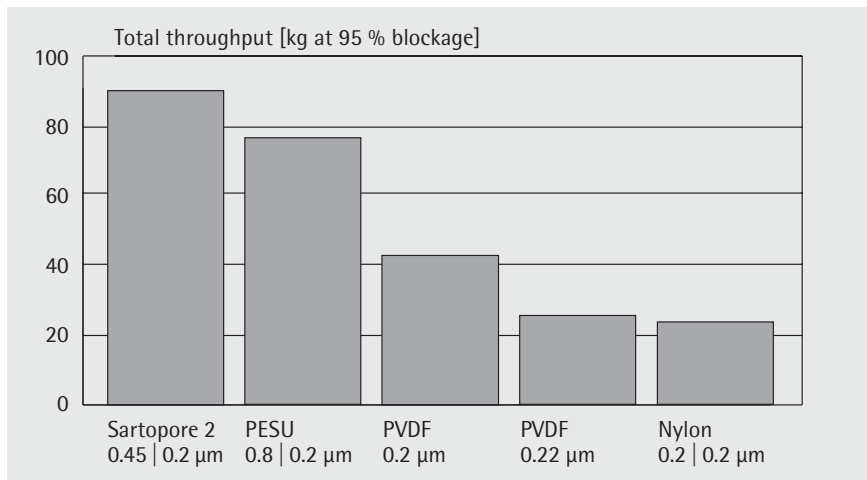


Water Flow Rates for 10 , 20 and 30 Cartridges



Standardized at 20 °C

Total Throughput Comparison



Sartorius AG
Weender Landstrasse 94-108
37075 Goettingen, Germany
Phone +49.551.308.0
Fax +49.551.308.3289
www.sartorius.com

USA +1.631.2544249
UK +44.1372.737100
France +33.1.69192100
Italy +39.055.634041
Spain +34.91.3586100
Japan +81.3.33293366

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