



Sartopore® 2 0.1 µm

Sterilizing Grade and Mycoplasma Retentive Filter Cartridges



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

Cartridges

Size 0	5"	0.3 m ²	3.2 ft ²
Size 1	10"	0.6 m ²	6.5 ft ²
Size 2	20"	1.2 m ²	12.9 ft ²
Size 3	30"	1.8 m ²	19.4 ft ²

Mini Cartridges

Size 7	0.05 m ²	0.5 ft ²
Size 8	0.1 m ²	1.1 ft ²
Size 9	0.2 m ²	2.2 ft ²

Available Adapters Cartridges

21, 25, 27, 28

Available Adapters Mini Cartridges

15, 18

Operating Parameters

Max. Allowable Differential Pressure:	5 bar 72.5 psi at 20°C
	2 bar 29 psi at 80°C
Max. Allowable Back Pressure:	2 bar 29 psi at 20°C

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 polyethersulfone 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.

По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,
Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

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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:

SPK5732-e

Extractables Guide:

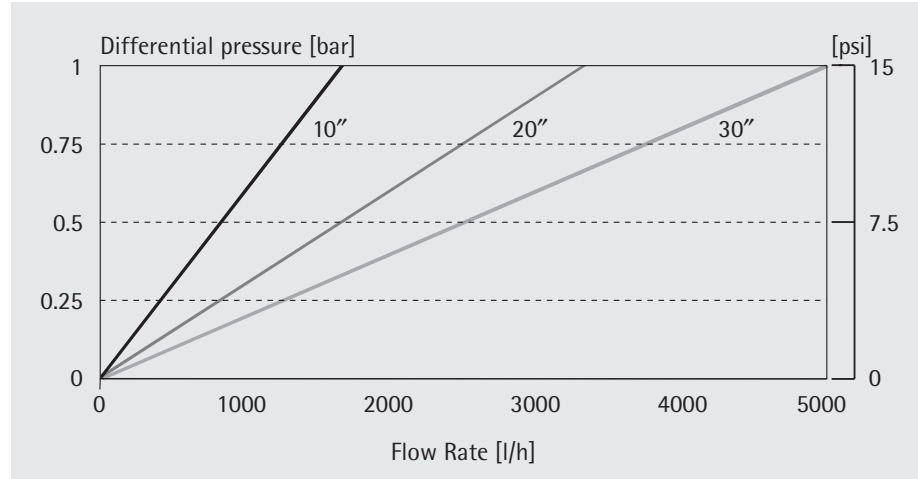
SPK5731-e

Ordering Information

Order Code	Pore size [µm]	Pack size [Pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]
Standard Cartridges				
544**58K0	0.1	1	4.0 58	
544**58K1	0.1	1	4.0 58	24
544**58K2	0.1	1	4.0 58	48
544**58K3	0.1	1	4.0 58	72
Mini Cartridges				
544**58K7-----B	0.1	5	4.0 58	4
544**58K8-----B	0.1	5	4.0 58	6
544**58K9-----B	0.1	5	4.0 58	9

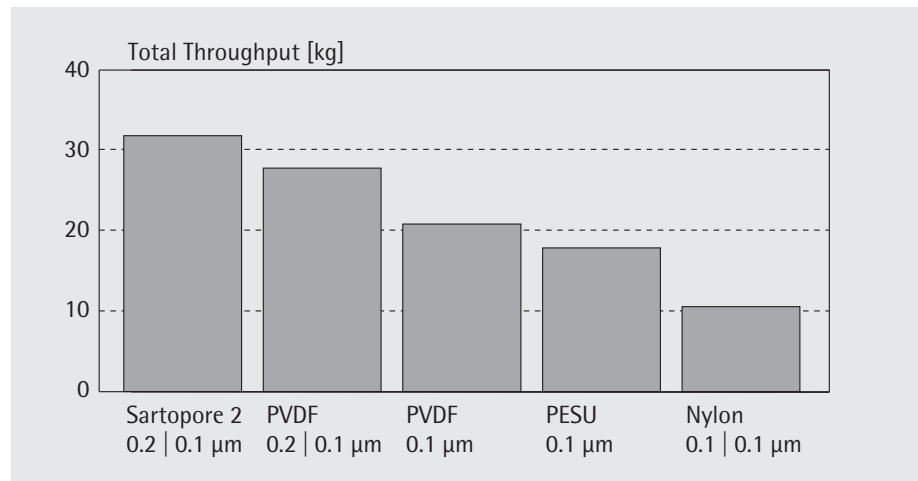
** : Adapter Type

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



Standardized at 20 °C

Total Throughput Comparison



10" Cartridge format



Sartopore® 2 0.2 µm

Sterilizing Grade Filter 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

Cartridges

Size 0	5"	0.3 m ²	3.2 ft ²
Size 1	10"	0.6 m ²	6.5 ft ²
Size 2	20"	1.2 m ²	12.9 ft ²
Size 3	30"	1.8 m ²	19.4 ft ²

Mini Cartridges

Size 7	0.05 m ²	0.5 ft ²
Size 8	0.1 m ²	1.1 ft ²
Size 9	0.2 m ²	2.2 ft ²

Available Adapters Cartridges

21, 25, 27, 28

Available Adapters Mini Cartridges

15, 18

Operating Parameters

Max. Allowable Differential Pressure:	5 bar 72.5 psi at 20°C
	2 bar 29 psi at 80°C
Max. Allowable Back Pressure:	2 bar 29 psi at 20°C

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

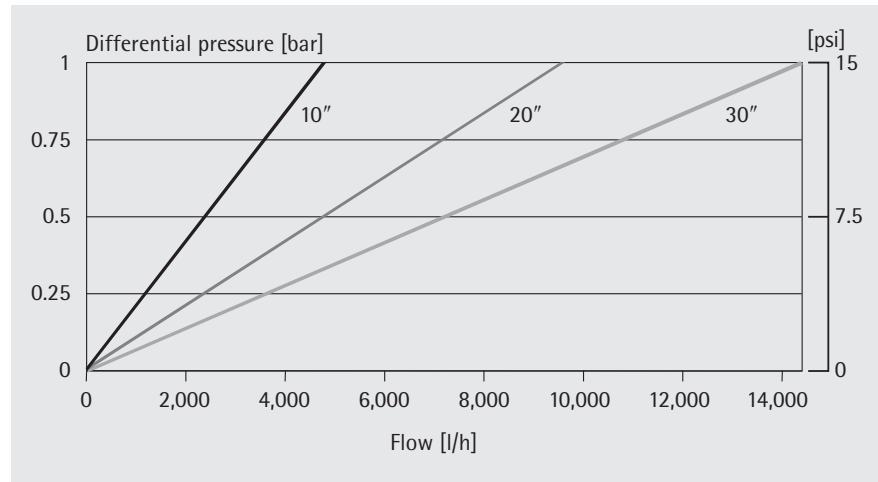
Validation Guide:

SPK 5732-e

Extractables Guide:

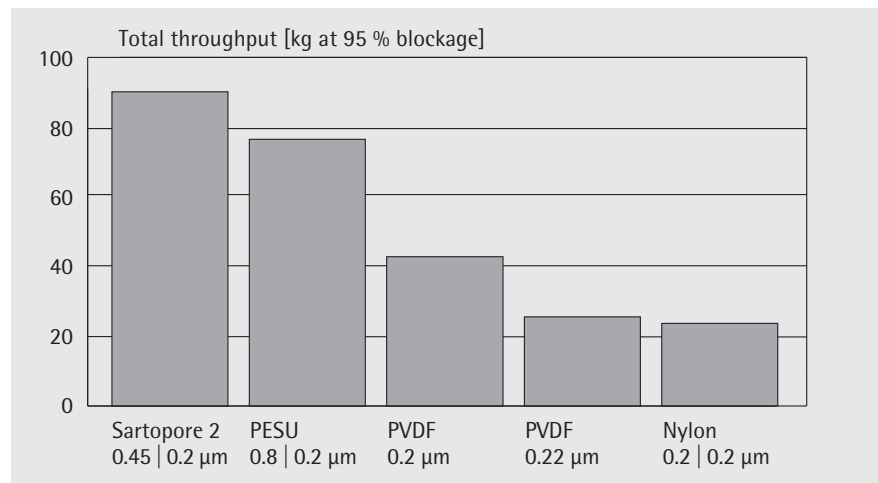
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Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20 °C

Total Throughput Comparison



10" Cartridge format

Ordering Information

Order Code	Pore size [µm]	Pack size [Pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
Standard Cartridges					
544**07H0	0.2	1	2.5 36	10	3.2 46
544**07H1	0.2	1	2.5 36	18	3.2 46
544**07H2	0.2	1	2.5 36	36	3.2 46
544**07H3	0.2	1	2.5 36	54	3.2 46
Mini Cartridges					
544**07H7-----B	0.2	5	2.5 36	4	3.2 46
544**07H8-----B	0.2	5	2.5 36	5	3.2 46
544**07H9-----B	0.2	5	2.5 36	7	3.2 46

** : Adapter Type



Sartopore® 2 0.45 µm

Bioburden & Particle Reductive Filter Cartridges



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

0.8 µm + 0.45 µm

Available sizes | Filtration Area

Cartridges

Size 0	5"	0.3 m ²	3.2 ft ²
Size 1	10"	0.6 m ²	6.5 ft ²
Size 2	20"	1.2 m ²	12.9 ft ²
Size 3	30"	1.8 m ²	19.4 ft ²

Mini Cartridges

Size 7	0.05 m ²	0.5 ft ²
Size 8	0.1 m ²	1.1 ft ²
Size 9	0.2 m ²	2.2 ft ²

Available Adapters Cartridges

21, 25, 27, 28

Available Adapters Mini Cartridges

15, 18

Operating Parameters

Max. Allowable Differential Pressure:	5 bar 72.5 psi at 20°C
	2 bar 29 psi at 80°C
Max. Allowable Back Pressure:	2 bar 29 psi at 20°C

Description

Sartopore® 2 0.45 µm rated filter cartridges are designed for bioburden reduction and particle removal from a broad range of pharmaceutical products. They offer extremely high flow rates and total throughputs and are therefore ideally suited for membrane prefiltration of aqueous solutions and highly viscous, difficult to filter pharmaceutical products.

Applications

Typical applications include bioburden reduction and particle removal from:

- Buffers
- Biological Fluids
- Ophthalmics
- LVP
- Antibiotics
- Bulk pharmaceutical products

Compatibility

Featuring a unique hydrophilic polyethersulfone membrane, Sartopore® 2 0.45 µm cartridges are compatible with solutions from pH 1 to pH 14 and are unaffected by numerous steam sterilization cycles. They are ideally suited for filtration of solutions with high | low pH and for multiple SIP | CIP cycles.

Performance

Sartopore® 2 0.45 µm cartridges provide exceptional high flow rates, resulting in economical sizing of filtration systems. Due to the "built-in prefiltration" by a 0.8 µm membrane, Sartopore® 2 0.45 µm rated cartridges offer 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 0.45 µm rated filter cartridges are validated for removal of *Serratia marcescens* with a Log Reduction Value (LRV) of 7 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

Extractables

Sartopore® 2 0.45 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 using *Serratia marcescens*

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

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:

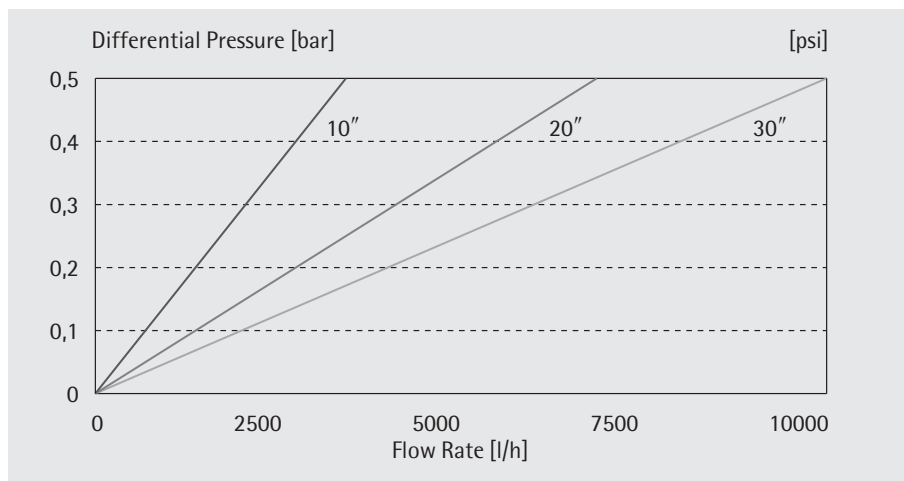
SPK5731-e

Ordering Information

Order Code	Pore size [µm]	Pack size [Pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
Standard Cartridges					
544**06G0	0.45	1	1.7 25		
544**06G1	0.45	1	1.7 25	12	2.2 32
544**06G2	0.45	1	1.7 25	24	2.2 32
544**06G3	0.45	1	1.7 25	36	2.2 32
Mini Cartridges					
544**06G7-----B	0.45	5	1.7 25	3	2.2 32
544**06G8-----B	0.45	5	1.7 25	4	2.2 32
544**06G9-----B	0.45	5	1.7 25	6	2.2 32

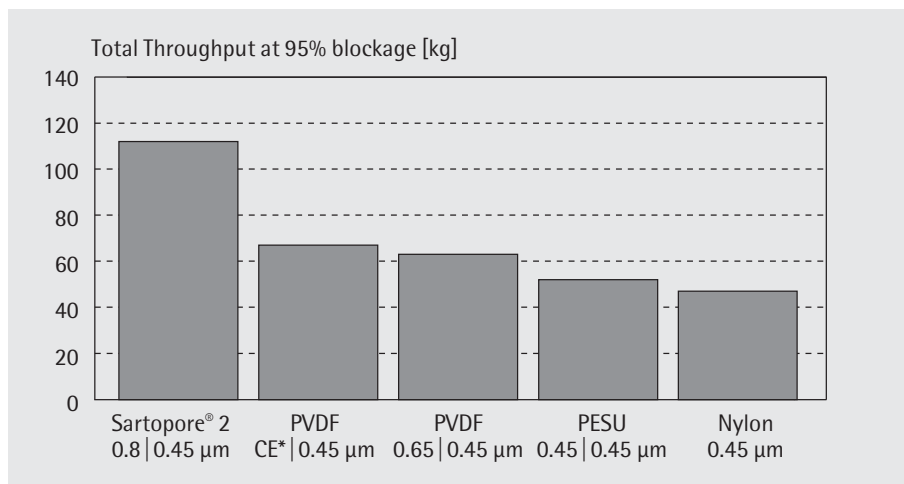
** : Adapter Type

Water Flow Rates for Standard Cartridges



Standardized at 20 °C

Total Throughput Comparison



10" Cartridges

* Cellulose Ester prefilter

По вопросам продаж и поддержки обращайтесь:

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Нижегород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

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