



# Sartopore® 2 0.45 µm

Bioburden & Particle Reductive Filter Cartridges



## 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

### 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

Size 1	10"	0.6 m <sup>2</sup>	6.5 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup>	12.9 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup>	19.4 ft <sup>2</sup>

### 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

## 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

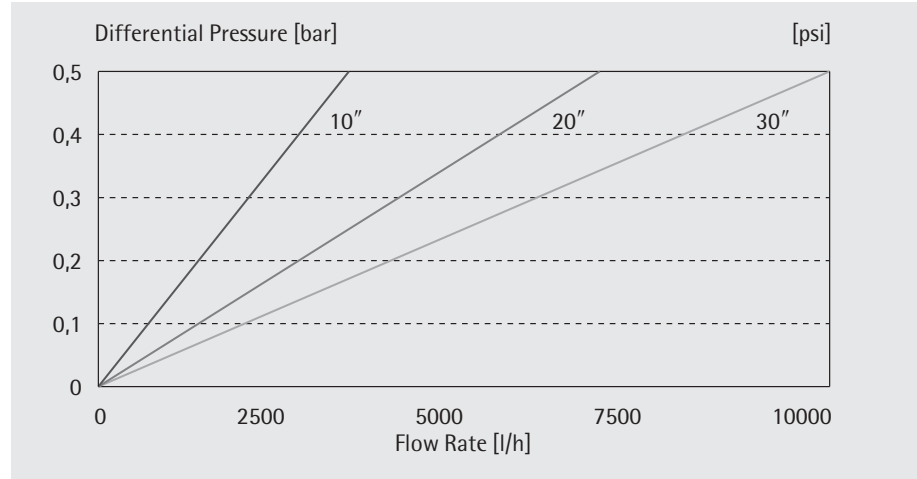
### Validation Guide:

SPK 5732-e

### Extractables Guide:

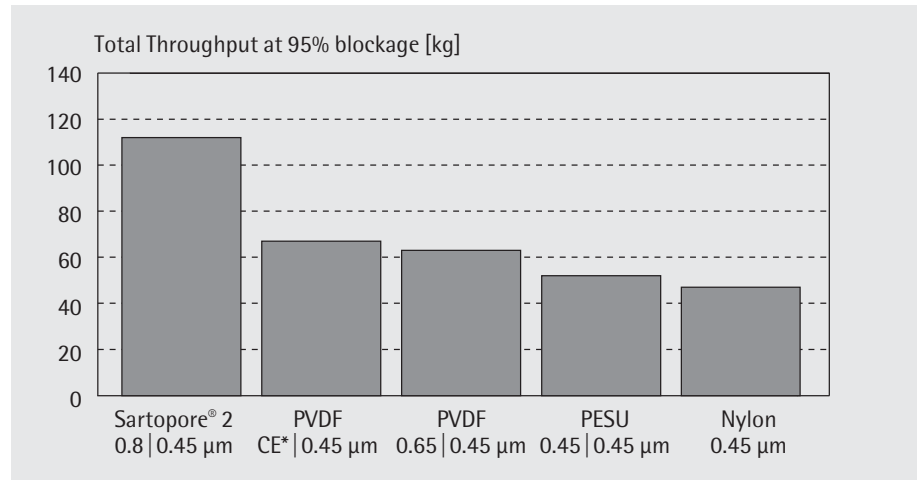
SPK 5731-e

## Water Flow Rates for Standard Cartridges



Standardized at 20 °C

## Total Throughput Comparison



10" Cartridges

\* Cellulose Ester prefilter

## Ordering Information

Order Code.	Pore size [µm]
544**06G1	0.45
544**06G2	0.45
544**06G3	0.45

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