

# Sartopore 2 0.45 µm

## Bioburden & Particle Reductive Filter Capsules & MaxiCaps



### Description

Sartopore 2 0.45 µm membrane filter capsules are self contained, ready to use filter units for bioburden reduction and particle removal from a broad range of pharmaceutical products. Membrane prefiltration of aqueous solutions and highly viscous difficult to filter pharmaceutical products can be accomplished due to the outstanding total throughput and flow rate performance of Sartopore 2 0.45 µm filter capsules.

### Applications

Typical applications include bioburden reduction and particle removal from:

- Therapeutics
- Injectables
- Buffers
- Biological Fluids
- Tissue Culture Media
- Acidic and basic solutions

### Compatibility

The polyethersulfone membrane is compatible with a pH range from pH 1 to pH 14 making Sartopore 2 capsules ideal for filtration of solutions with high | low pH.

### Easy to use

Sartopore 2 capsules are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

### Flexibility

Sartopore 2 0.45 µm capsules and MaxiCaps are available with various filtration areas from 300 cm<sup>2</sup> | 0.3 ft<sup>2</sup> up to 1.8 m<sup>2</sup> | 18 ft<sup>2</sup> for easy use in any filtration process independent of the batch size.

### Cost Saving

The use of the capsule design concept avoids investment in stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

### Microbiological Retention

Sartopore 2 0.45 µm rated filter capsules are fully validated with a Log Reduction Value (LRV) of 7 for *Serratia marcescens* 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 capsules and MaxiCaps 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
Capsule Housing:	Polypropylene

#### Pore Size

0.8 µm + 0.45 µm

#### Available Sizes | Filtration Area

##### Capsules

Size 5	0.03 m <sup>2</sup>   0.3 ft <sup>2</sup>
Size 7	0.05 m <sup>2</sup>   0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup>   2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup>   5 ft <sup>2</sup>

##### MaxiCaps

Size 1	0.6 m <sup>2</sup>   6 ft <sup>2</sup>
Size 2	1.2 m <sup>2</sup>   12 ft <sup>2</sup>
Size 3	1.8 m <sup>2</sup>   18 ft <sup>2</sup>

#### Available Connectors

SS, SO, OO

#### Operating Parameters

Max. Allowable Differential Pressure:	4 bar   58 psi at 20 °C
	3 bar   43.5 psi at 50 °C (MaxiCaps)
	2 bar   29 psi at 80 °C

Max. Allowable Back Pressure:	2 bar   29 psi at 20 °C
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#### Integrity Test Limits

Maximum Allowable Diffusion at 1.7 bar / 22 psi & 20 °C

Capsule Size	Maximum Diffusion	Minimum Bubble Point
Size 1	12 ml/min	2.2 bar/32 psi
Size 2	24 ml/min	2.2 bar/32 psi
Size 3	36 ml/min	2.2 bar/32 psi
Size 5	2 ml/min	2.2 bar/32 psi
Size 7	3 ml/min	2.2 bar/32 psi
Size 8	4 ml/min	2.2 bar/32 psi
Size 9	6 ml/min	2.2 bar/32 psi
Size 0	12 ml/min	2.2 bar/32 psi

# Membrane Filter Capsules & MaxiCaps

## Specifications

### Extractables

Sartopore 2 0.45 µm rated filter capsules and MaxiCaps 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

### Autoclaving:

134 °C, 2 bar | 29 psi, 30 min

No In-Line Steam Sterilization

### Sterilization Cycles

Autoclaving: Min. 25

## Technical References

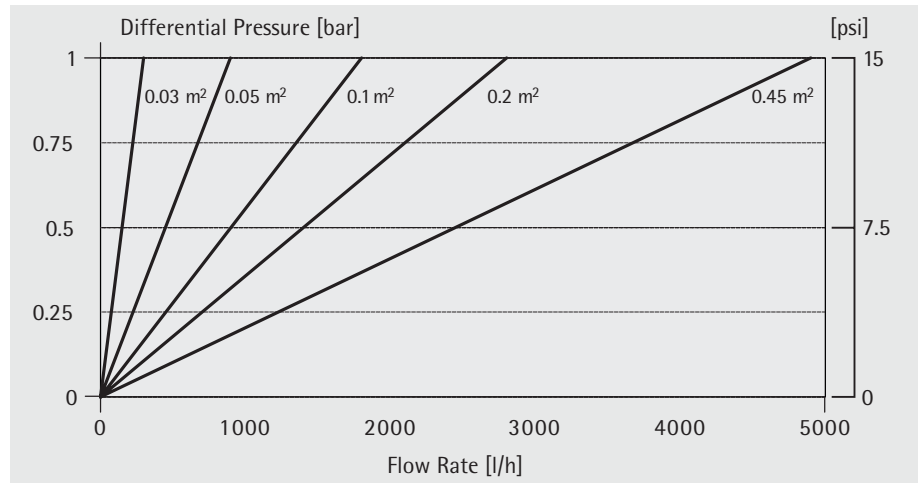
### Validation Guide:

SPK5732-e

### Extractables Guide:

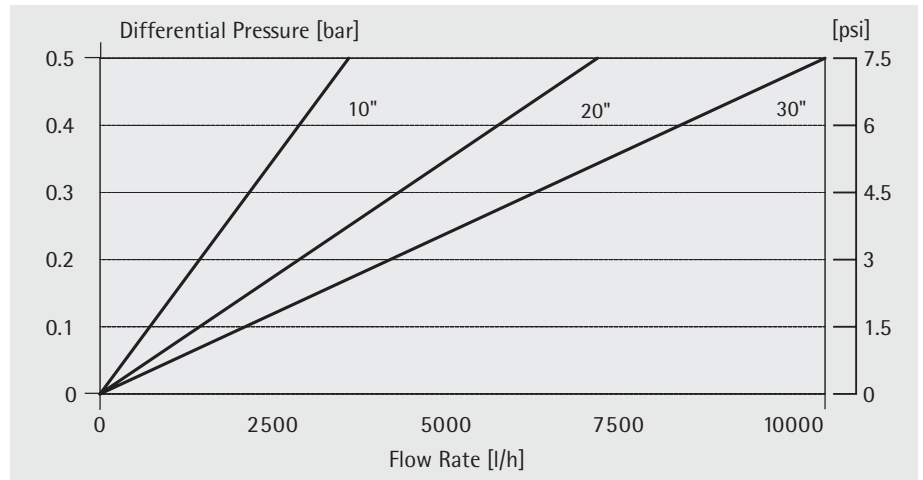
SPK5731-e

Water Flow Rates for Sartopore 2 0.45 µm Capsules



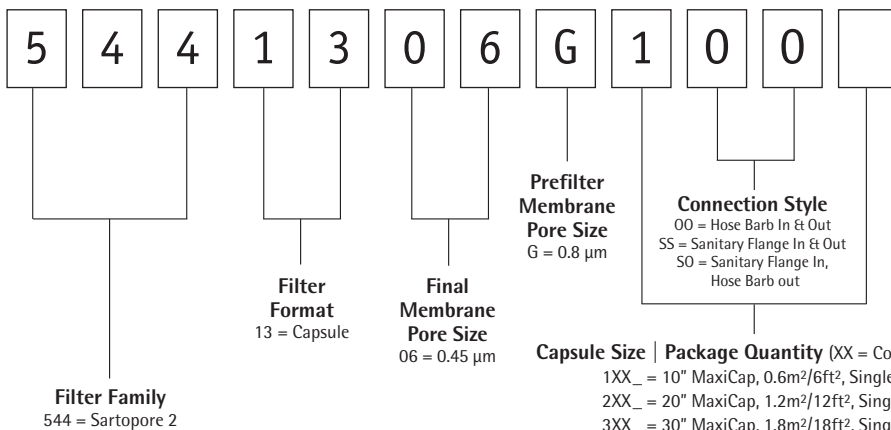
Standardized at 20 °C

Water Flow Rates for Sartopore 2 MaxiCaps



Standardized at 20 °C

## Ordering Guide:



### Capsule Size | Package Quantity (XX = Connection Style)

- 1XX\_ = 10" MaxiCap, 0.6m²/6ft², Single Unit
- 2XX\_ = 20" MaxiCap, 1.2m²/12ft², Single Unit
- 3XX\_ = 30" MaxiCap, 1.8m²/18ft², Single Unit
- 5XXB = 300 cm² / .3 ft² Capsule, Pack of 5
- 7XXB = 500 cm² / .5 ft² Capsule, Pack of 5
- 8XXB = 0.1 m² / 1 ft² Capsule, Pack of 5
- 9XXA = 0.2 m² / 2 ft² Capsule, Pack of 4
- 0XX\_ = 0.45 m² / 5 ft² Capsule, Single Unit

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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Publication No.: SPK2044-e04041  
Order No.: 85030-515-63