

# Sartobran P 0.2 µm

## Sterilizing Grade Filter Capsules and MaxiCaps



### Description

Sartobran P sterilizing grade filter capsules and MaxiCaps are self contained, ready to use, sterile filter units that have proven to be the first choice in the bio-pharmaceutical industry for all applications requiring low adsorption capabilities. The unique low unspecific binding capacity of the cellulose acetate membrane assures the highest protein yield and rapid preservative recovery. Sartobran P filter capsules and MaxiCaps are ideally suited for processing high value biological solutions and pharmaceuticals sensitive to adsorption with low preservative concentrations.

### Applications

Sartobran P filters are ideally suited for all applications that require highest product recovery rates like:

- Coagulation Factors, Albumine, IgG
- Bacterial and Viral Vaccines
- MAB's
- Bio-processed Pharmaceuticals
- Diagnostics
- Purified Protein Solutions
- Biological Fluids
- Solutions containing Preservatives

### Highest Product Yield

The Sartobran P's cellulose acetate membrane provides the lowest unspecific adsorption of any membrane material available, ensuring the highest product recovery rates.

### Performance

Due to the "built-in prefiltration" by a 0.45 µm membrane, Sartobran P 0.2 µm filters provide excellent total throughputs and higher flow rates at low differential pressure for gentle product treatment.

### Flexibility

Sartobran P 0.2 µm filters are available in traditional cartridge formats and disposable capsules from 150 cm<sup>2</sup> to 1.8 m<sup>2</sup> for simple linear scale up and process flexibility.

### Microbiological Retention

Sartobran P 0.2 µm rated filter capsules and MaxiCaps 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

Sartobran P 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:	Cellulose Acetate
Endfilter Membrane:	Cellulose Acetate
Support Fleece:	Polypropylene
Core:	Polypropylene
End Caps:	Polypropylene
Capsule Housing:	Polypropylene

#### Pore Size

0.45 µm + 0.2 µm

#### Available Sizes | Filtration Area

##### Capsules

Size 4	0.015 m <sup>2</sup>   0.15 ft <sup>2</sup>
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	10"	0.6 m <sup>2</sup>   6 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup>   12 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup>   18 ft <sup>2</sup>

#### Available Connectors Capsules | MaxiCaps

SS, SO, 00

#### Operating Parameters

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

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

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

Capsule Size	Maximum Diffusion	Minimum Bubble Point
Size 1	15 ml/min	3.2 bar/46 psi
Size 2	30 ml/min	3.2 bar/46 psi
Size 3	45 ml/min	3.2 bar/46 psi
Size 4	1 ml/min	3.2 bar/46 psi
Size 5	2 ml/min	3.2 bar/46 psi
Size 7	3 ml/min	3.2 bar/46 psi
Size 8	4 ml/min	3.2 bar/46 psi
Size 9	5 ml/min	3.2 bar/46 psi
Size 0	10 ml/min	3.2 bar/46 psi

# Membrane Filter Capsules and MaxiCaps

## Specifications

### Extractables

Sartobran P 0.2 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

### Autoclaving

134 °C, 2 bar | 29 psi, 30 min  
No In-Line Steam Sterilization

### Sterilization Cycles

Autoclaving: Min. 25

### Technical References

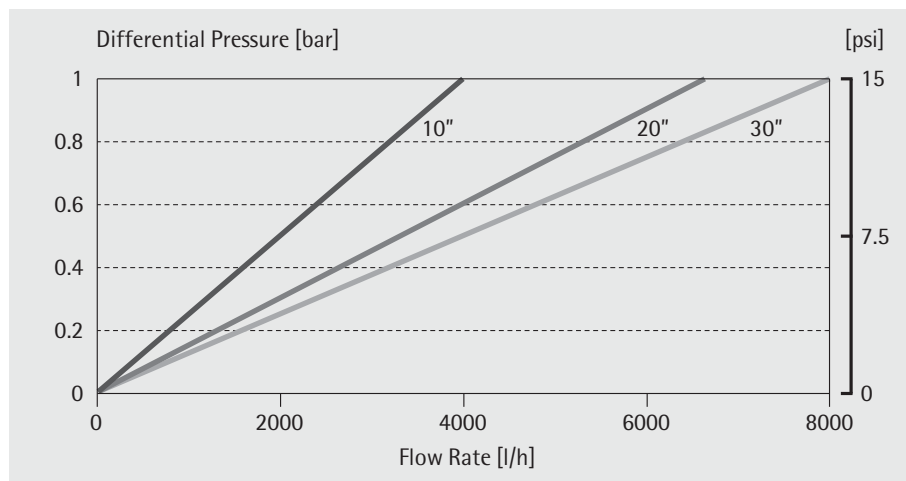
#### Validation Guide:

SPK 5726-e

#### Extractables Guide:

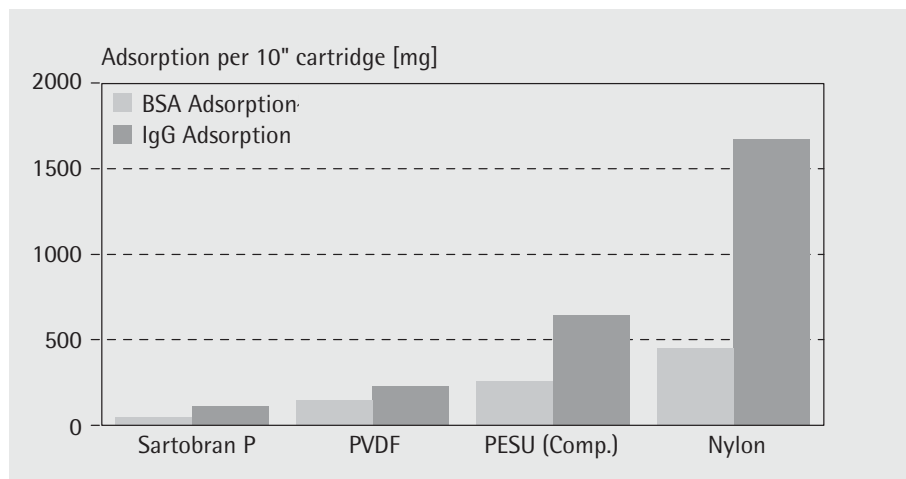
SPK5720-e

## Water Flow Rates for MaxiCaps

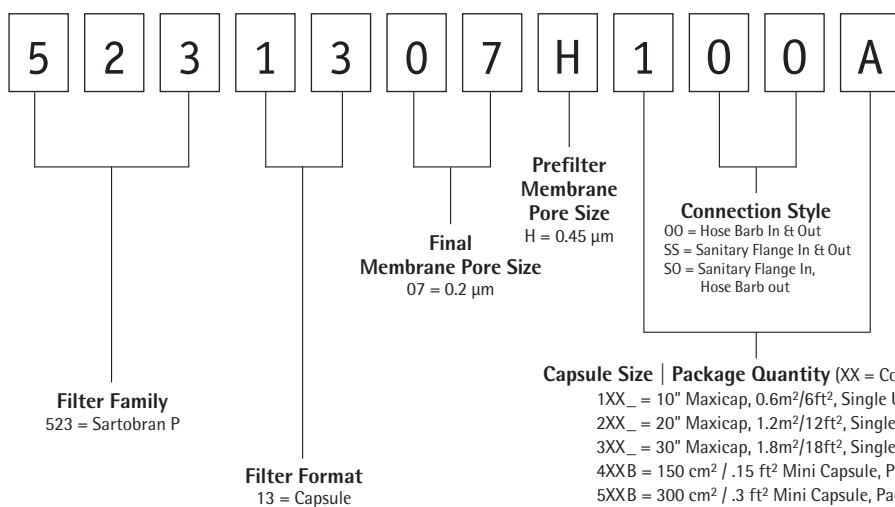


Standardized at 20 °C

## Total Throughput Comparison



## Ordering Guide:



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

- 1XX\_ = 10" Maxicap, 0.6m<sup>2</sup>/6ft<sup>2</sup>, Single Unit
- 2XX\_ = 20" Maxicap, 1.2m<sup>2</sup>/12ft<sup>2</sup>, Single Unit
- 3XX\_ = 30" Maxicap, 1.8m<sup>2</sup>/18ft<sup>2</sup>, Single Unit
- 4XXB = 150 cm<sup>2</sup> / .15 ft<sup>2</sup> Mini Capsule, Pack of 5
- 5XXB = 300 cm<sup>2</sup> / .3 ft<sup>2</sup> Mini Capsule, Pack of 5
- 7XXB = 500 cm<sup>2</sup> / .5 ft<sup>2</sup> Capsule, Pack of 5
- 8XXB = 0.1 m<sup>2</sup> / 1 ft<sup>2</sup> Capsule, Pack of 5
- 9XXA = 0.2 m<sup>2</sup> / 2 ft<sup>2</sup> Capsule, Pack of 4
- 0XXV, = 0.45 m<sup>2</sup> / 5 ft<sup>2</sup> Capsule, Pack of 2

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