

Sartobran P 0.45 µm

Bioburden and Particle Reductive Filter Capsules and MaxiCaps



Description

Sartobran P 0.45 µm rated filter capsules and MaxiCaps are self contained, ready to use, sterile filter units, ideally suited for bioburden reduction and particle removal from bio-pharmaceutical solutions for protection of subsequent processes or sterilizing grade filters. 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 prefiltration of high value biological solutions and pharmaceuticals sensitive to adsorption as well as for final filtration of LVP's and Buffers. Typical applications are filtration of:

- Coagulation Factors, Albumine, IgG
- Bacterial and Viral Vaccines
- MAB's
- Bio-processed Pharmaceuticals
- Diagnostics
- Purified Protein Solutions
- LV P
- Buffers

Highest Product Yield

The cellulose acetate membrane of the Sartobran P filters provides the lowest unspecific adsorption of all membrane materials available for highest product recovery rates.

Performance

Due to the "built-in prefiltration" by a 0.65 µm membrane, Sartobran P 0.45 µm filters provide excellent total throughputs and higher flow rates at low differential pressure for gentle product treatment.

Flexibility

Sartobran P 0.45 µm filters are available in disposable capsules and MaxiCaps from 150 cm² to 1.8 m² for simple linear scale up and process flexibility.

Microbiological Retention

Sartobran P 0.45 µm rated filter capsules and MaxiCaps are validated for removal of *Serratia marcescens* with Log Reduction Value (LRV) of 7 according to HIMA and ASTM F-838-83 guidelines.

Quality Control

Each individual element is tested for integrity by diffusion and bubble point test prior to be released assuring absolute reliability.

Documentation

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

Pore Size

0.65 µm + 0.45 µm

Available Sizes | Filtration Area

MaxiCaps

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

Capsules

Size 4	0.025 m ²	0.15 ft ²
Size 5	0.03 m ²	0.3 ft ²
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
Size 0	0.45 m ²	4.8 ft ²

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 1.5 bar / 22 psi & 20°C

Capsule Size	Maximum Diffusion	Minimum Bubble Point
Size 1	15 ml/min	2.0 bar/29 psi
Size 2	30 ml/min	2.0 bar/29 psi
Size 3	45 ml/min	2.0 bar/29 psi
Size 4	1 ml/min	2.0 bar/29 psi
Size 5	2 ml/min	2.0 bar/29 psi
Size 7	3 ml/min	2.0 bar/29 psi
Size 8	4 ml/min	2.0 bar/29 psi
Size 9	5 ml/min	2.0 bar/29 psi
Size 0	10 ml/min	2.0 bar/29 psi

Membrane Filter Capsules and MaxiCaps

Specifications

Extractables

Sartobran P 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

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 Inline Steam Sterilization

Sterilization Cycles

Autoclaving: Min. 25

Technical References

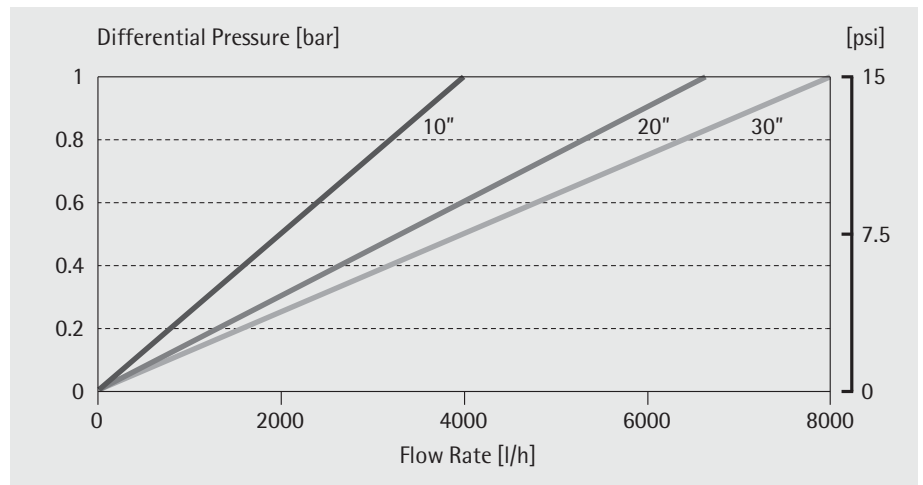
Validation Guide:

SPK 5726-e

Extractables Guide:

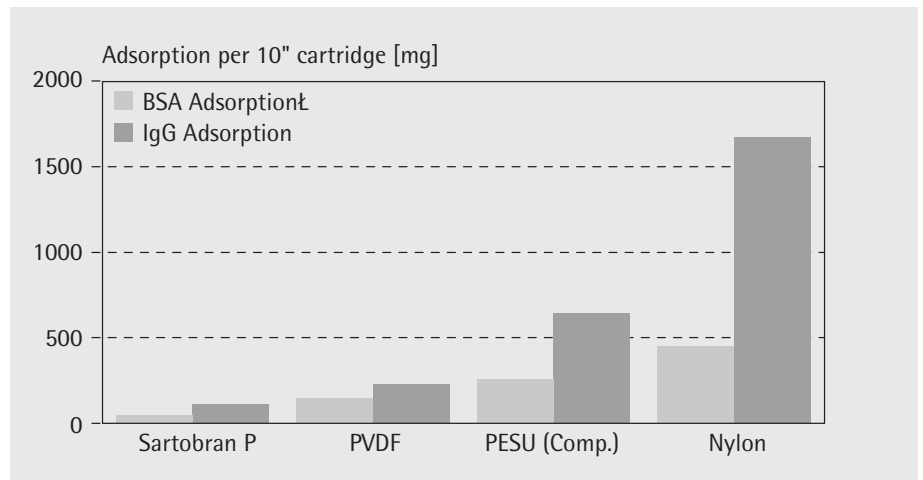
SPK5720-e

Water Flow Rates for MaxiCaps

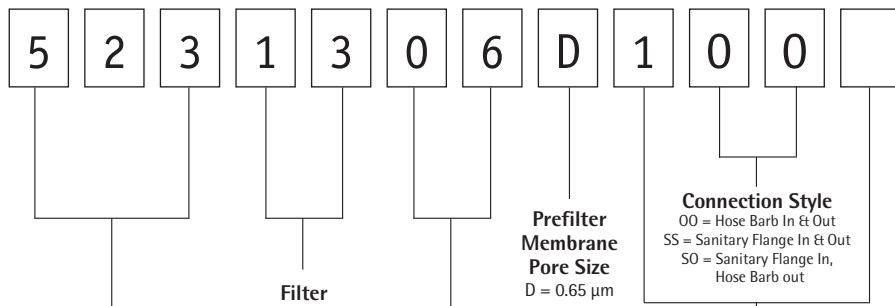


Standardized at 20 °C

Total Throughput Comparison



Ordering Guide:



10" Cartridge format

Filter Family
523 = Sartobran P

Filter Format
13 = Capsule

Final Membrane Pore Size
06 = 0.45 µm

Prefilter Membrane Pore Size
D = 0.65 µm

Connection Style
00 = Hose Barb In & Out
SS = Sanitary Flange In & Out
SO = Sanitary Flange In, Hose Barb out

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
- 4XXB = 150 cm² / .15 ft² Capsule, Pack of 5
- 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
- 0XXV = 0.45 m² / 5 ft² Capsule, Pack of 2

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