



Sartobran® P 0.45 µm

Bioburden and Particle Retentive MaxiCaps® and MidiCaps®



Description

Sartobran® P 0.45 µm rated MaxiCaps® and MidiCaps® are ideally suited for bioburden and defined particle reduction from biopharmaceutical solutions. They can be used for protection of sterilizing grade membrane filters or subsequent downstream processing equipment in biotech production processes.

Applications

Featuring extremely low adsorptive cellulose acetate membranes, Sartobran® P filter elements are ideally suited for filtration of highly valuable protein solutions or solutions containing preservatives. They assure highest protein yield and rapid preservative recovery.

Typical applications include:

- Coagulation Factors, Albumin, IgG
- Bacterial & Viral Vaccines
- MAB
- Bio-processed Pharmaceuticals
- Diagnostics
- Purified Protein Solutions
- Biological Fluids
- Fluids containing preservatives

Easy to use

Sartobran® P MaxiCaps® and MidiCaps® are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

Flexibility

Sartobran® P 0.45 µm MaxiCaps® and MidiCaps® are available with various filtration areas from 500 cm² | 0.54 ft² up to 1.8 m² | 19.4 ft² for easy adoption to any filtration process independent from the batch size.

Scalability

Consistent and predictable scale-up and down trials can reliably be performed as all Sartobran® P MaxiCaps® and MidiCaps® are produced with the same type of membrane and identical materials of construction.

Cost Saving

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

Quality Control

Each individual element is tested for integrity by Bubble Point and Diffusion test prior to be released assuring absolute reliability.

Documentation

Sartobran® P MaxiCaps® and MidiCaps® are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Specifications

Materials

Pre-filter Membrane	Cellulose Acetate
Endfilter Membrane	Cellulose Acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

Pore Size Combination

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

MidiCaps®

Size 7	0.05 m ² 0.54 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 MaxiCaps®, MidiCaps®

S:	Tri-Clamp 50 mm (1½")
O:	½" single stepped hose barb
F:	Tri-Clamp 25 mm (¾")

Operating Parameters

Max. Allowable Differential Pressure	5 bar 72.5 psi at 20°C (MidiCaps®)
	2 bar 29 psi at 80°C (MidiCaps®)
	4 bar 58 psi at 20°C (MaxiCaps®)
	3 bar 43.5 psi at 50°C (MaxiCaps®)
Max. Allowable Back Pressure	2 bar 29 psi at 20°C

Specifications

Extractables

Sartobran® P 0.45 µm rated filter MaxiCaps® and MidiCaps® meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

Individually integrity tested

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

pH Compatibility

Sartobran® P filters have a limited pH compatibility in the range of pH 4–8.

This range covers most of the relevant bio-pharmaceutical applications.

Sterilization

Autoclaving:

134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles

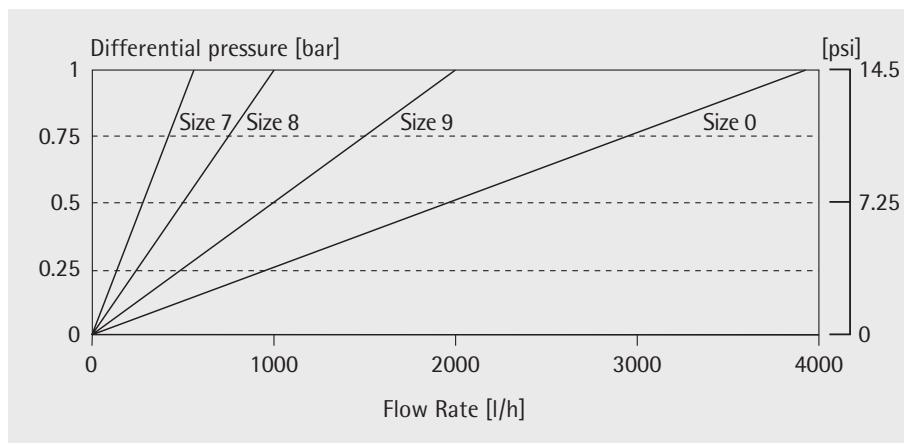
Autoclaving: Min. 25

Technical References

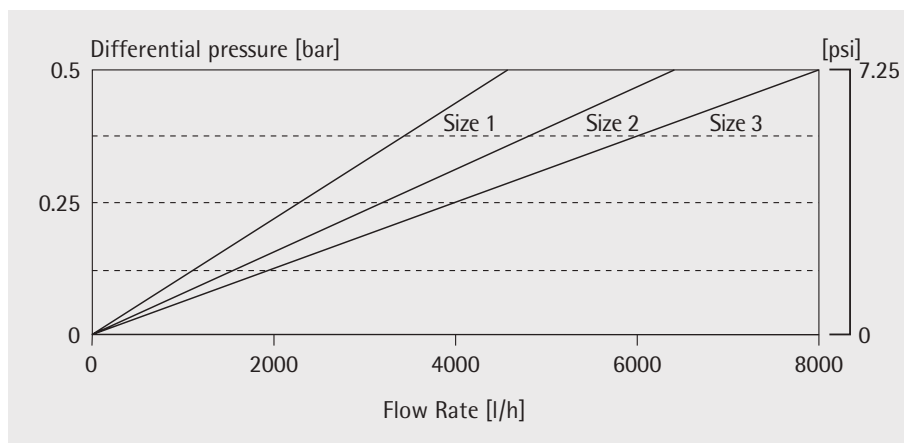
Validation Guide:

SPK5726-e

Water Flow Rates for MidiCaps® with SS adapter



Water Flow Rates for MaxiCaps®



Standardized at 20°C

Ordering Information

Order Code	Pore size [µm]	Pack size [Pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
MaxiCaps®:					
5231306D1--**	0.45	1	1.5 22	15	2.0 29
5231306D2--**	0.45	1	1.5 22	30	2.0 29
5231306D3--**	0.45	1	1.5 22	45	2.0 29
MidiCaps®:					
5235306D7--**--A	0.45	4	1.5 22	3	2.0 29
5235306D8--**--A	0.45	4	1.5 22	4	2.0 29
5235306D9--**--A	0.45	4	1.5 22	5	2.0 29
5235306D0--**--V	0.45	2	1.5 22	10	2.0 29

** : Connector Styles (first code letter represents the inlet, the second the outlet)

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

Phone +49.551.308.0
Fax +49.551.308.3289

www.sartorius-stedim.com

USA Toll-Free +1.800.368.7178
UK +44.1372.737159
France +33.442.845600
Italy +39.055.63.40.41
Spain +34.90.2110935
Russian Federation +7.812.327.5.327
Japan +81.3.4331.4300

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