

biotech

Sartobran® P 150 & 300 0.2 µm

Sterilizing Grade Filter Capsules



Description

The Sartobran® 150 & 300 are disposable, sterile ready-to-use membrane filter capsules. They are designed for use in small-scale production of high value pharmaceutical and biotech products, due to the ultra low binding of their cellulose acetate membrane for proteins and preservatives. The Sartobran® 150 and 300 feature the same materials and type of construction as any other Sartobran® P filter element, for easy scale-down and scale-up, making them perfect for R&D Labs in pharmaceutical development.

Applications

Typical applications include sterilizing grade filtration of any solution sensitive to adsorption like:

- Therapeutics
- Bioprocessed Pharmaceuticals
- Serum
- Injectables
- Media
- Buffers

Performance

The unique pleated filter construction and the "built-in-prefiltration" offers excellent flow rates and superior total throughput performance, especially in comparison to conventional stacked disc filter systems.

High Product Yield

The highest product yields are realized by the combination of extremely low residual volume in the capsule housing and ultra low unspecific adsorption of the cellulose acetate membrane.

Automatic venting

A hydrophobic PTFE vent filter membrane positioned at the highest point upstream allows easy venting of the capsule and prevents product loss during the venting process.

Scalability

Featuring the same materials and type of construction as any other Sartobran® P filter element, Sartobran® P 150 & 300 are ideally suited for R&D Labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high value products .

Microbiological Retention

Sartobran® P 0.2 μm rated 150 & 300 capsules are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-83 quidelines.

Quality Control

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation

Sartobran® P 150 & 300 capsules 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		
Housing:	Polypropylene		

Pore Size

 $0.45 \mu m + 0.2 \mu m$

Available Sizes | Filtration Area

Size 4 0.015 m² | 0.16 ft² Size 5 0.03 m² | 0.32 ft²

Available Connectors

SS, SO, OO (Type 150) OO (Type 300)

Operating Parameters

Max. Allowable Differential Pressure:	4 bar 58 psi at 20 °C 2 bar 29 psi at 80 °C
Max. Allowable Back Pressure:	2 bar 29 psi at 20°C

По вопросам продаж и поддержки обращайтесь:

Extractables

Sartobran® P 0.2 μm rated 150 & 300 filter capsules 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 (Type 300) Max. 3 (Type 150)

Technical References

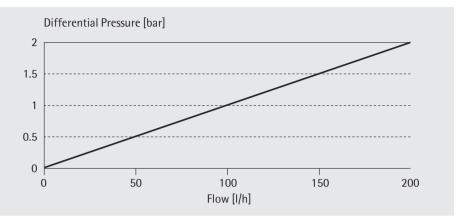
Validation Guide:

SPK5726-e

Extractables Guide:

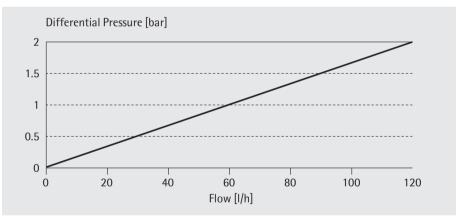
SPK5720-e

Water Flow Rate Sartobran® 300



Standardized at 20 °C

Water Flow Rate Sartobran® 150



Standardized at 20 °C

Ordering Information

Order Code	Pore size [µm]
Sartobran® 150	
5231307H400B	0.2
5231307H4SOB	0.2
5231307H4SSB	0.2
Sartobran® 300 5231307H500B	0.2



Sartobran® 0.1 µm

Sterilizing Grade MaxiCaps® and Capsules



Description

Sartobran® P 0.1 µm rated, high-flow filter elements are designed to give enhanced sterility assurance for applications with microorganisms present that can pass through 0.2 µm rated sterilizing grade filters. The Sartobran® P's cellulose acetate membrane offers ultra low binding properties for proteins and preservatives, making Sartobran® P filters the ideal choice for filtration of high value bio-pharmaceutical products.

Applications

All applications which require sterilizing grade filtration with retention finer than conventional 0.2 µm sterilizing grade filters for removal of unusually small microorganisms. This typically includes:

- Bio-processed pharmaceuticals
- Long term filling operations
- Filtration in pharmaceutical water systems

Any other application requiring sub 0.2 μ m filtration for enhanced sterility assurance.

Flow Rates

Higher flow rates than other 0.1 μ m rated filters provide short filtration time and gentle product treatment, even if replacement of conventional 0.2 μ m rated filters is necessary.

Total Throughput

Due to the "built-in prefiltration" by a $0.45~\mu m$ membrane, Sartobran® P 0.1 μm filters provide higher total throughputs than any other 0.1 μm rated filter for economical process design.

Highest Product Yield

The ultra low adsorption characteristic of the Sartobran® P's cellulose acetate membrane provides the highest product yield – especially important for high value proteins.

Flexibility

Sartobran P 0.1 μ m MaxiCaps & Capsules are available with various filtration areas from 500 cm² to 1.8 m² for simple linear scale up and process flexibility.

Quality Control

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation

Sartobran® P MaxiCaps® & Capsules 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
O-Rings:	Silicone (optional EPDM or Viton)

Pore Size

 $0.45 \mu m + 0.1 \mu m$

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 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

Available Connectors MaxiCaps®

SS, SO, OO, FF, FO

Capsules

SS, SO, 00

Operating Parameters

Max. Allowable Differential Pressure:	4 bar 58 psi at 20°C 2 bar 29 psi at 80°C
Max. Allowable Back	2 bar 29 psi at 20°C
Pressure:	

Connector Sizes

O Hose barb

S 11/2" Tri-Clamp (Sanitary)

F 3/4" Tri-Clamp (Sanitary) (Only MaxiCaps®)

Extractables

Sartobran® P 0.1 µm rated MaxiCaps® & Capsules meet or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

100% Individually integrity tested

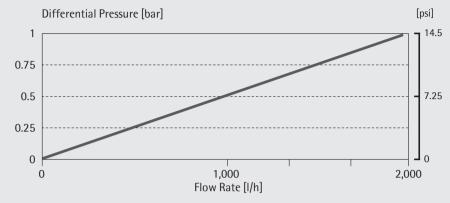
Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test.

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Water Flow Rates for MaxiCaps® Size 1



Standardized at 20 °C

Sterilization

Autoclaving:

134°C, 2 bar | 29 psi, 30 min

No In-Line Steam Sterilization

Sterilization Cycles

Autoclaving:

Min. 25

Technical References

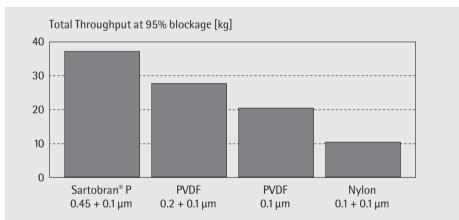
Validation Guide:

SPK5726-e

Extractables Guide:

SPK5720-e

Total Throughput Comparison



MaxiCaps® size 1

Order Information

Order Code	Pore size [µm]		Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
MaxiCaps [®]					
5231358H1**	0.1	1	3.0 44	15	3.8 55
5231358H2**	0.1	1	3.0 44	30	3.8 55
5231358H3**	0.1	1	3.0 44	45	3.8 55
Capsules					
5231358H7**B	0.1	5	3.0 44	3	3.8 55
5231358H8**B	0.1	5	3.0 44	4	3.8 55
5231358H9**A	0.1	4	3.0 44	5	3.8 55

**: Connector Style



Sartobran® P 0.2 μm

Sterilizing Grade MidiCaps®, MaxiCaps® and Capsules



Description

Sartobran® P MidiCaps®, MaxiCaps® and Capsules are self contained, ready to use, sterile filter units for sterilizing grade filtration in the pharma | biotech industry. The extremely low unspecific adsorption of their cellulose acetate membranes assures highest protein yields and rapid preservative recovery.

Applications

Sartobran® P filter elements have proven throughout the years to be the first choice for all applications in the biopharmaceutical industry requiring low adsorption capabilities. They are typically used for sterilizing grade filtration of:

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

Easy to use

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

Flexibility

Sartobran® P 0.2 μm MidiCaps®, MaxiCaps® and Capsules are available with various filtration areas from 150 cm² | 0.15 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 MidiCaps®, MaxiCaps® and Capsules 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.

Microbiological Retention

Sartobran® P MidiCaps®, MaxiCaps® and Capsules 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 guidelines.

Quality Control

Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

Documentation

Sartobran® P MidiCaps®, MaxiCaps® and Capsules 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

Prefilter 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

 $0.45 \mu m + 0.2 \mu m$

Available Sizes | Filtration Area

Capsules

 $0.015 \text{ m}^2 \, | \, 0.16 \text{ ft}^2$ Size 4 0.03 m² | 0.32 ft² Size 5

MidiCaps[®]

Size 7 0.05 m² | 0.54 ft² $0.1 \text{ m}^2 | 1.1 \text{ ft}^2$ Size 8 0.2 m² 2.2 ft² Size 9 Size 0 0.45 m² 4.8 ft²

MaxiCaps[®]

 $0.6 \text{ m}^2 | 6.5 \text{ ft}^2$ Size 1 1.2 m² 12.9 ft² Size 2 1.8 m² 19.4 ft² Size 3

Available Connectors Capsules SS, SO, 00 (Size 4), 00 (Size 5)

Available Connectors MidiCaps® SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps® SS, SO, OO, FF, BB

S: 11/2" Tri-Clamp (Sanitary) 0: 1/2" Single stepped hose barb F: 3/4" Tri-Clamp (Sanitary) H: 1/4" Multiple stepped hose barb (with filling bell at the outlet) 3/4" – 1" Multiple stepped hose barb

Operating Parameters

Max. Allowable	5 bar 72.5 psi at
Differential Pressure:	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

Max. Allowable Back

2 bar | 29 psi at 20°C

20°C (MaxiCaps)

Pressure:

Extractables

Sartobran® P 0.2 μm rated MidiCaps®, MaxiCaps® and Capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving:

134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles

Autoclaving:

Min. 25

Technical References

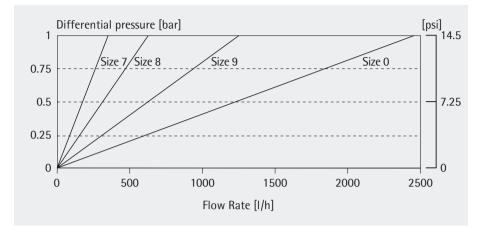
Validation Guide:

SPK5726-e

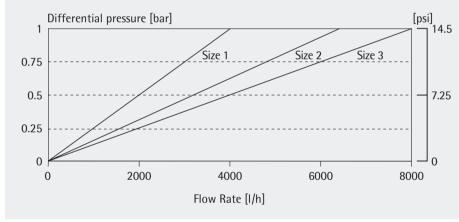
Extractables Guide:

SPK5720-e

Water Flow Rates for MidiCaps® with SS inlet and outlet



Water Flow Rates for MaxiCaps®



Standardized at 20 °C

Order Information

Order Code	Pore size [µm]	Pack size [Pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
Capsules:					
5231307H4**B	0.2	5	2.5 36	1	3.2 46
5231307H500B	0.2	5	2.5 36	2	3.2 46
MidiCaps®:					
5235307H7**A	0.2	4	2.5 36	3	3.2 46
5235307H8**A	0.2	4	2.5 36	4	3.2 46
5235307H9**A	0.2	4	2.5 36	5	3.2 46
5235307H0**V	0.2	2	2.5 36	10	3.2 46
MaxiCaps®:					
5231307H1**	0.2	1	2.5 36	15	3.2 46
5231307H2**	0.2	1	2.5 36	30	3.2 46
5231307H3**	0.2	1	2.5 36	45	3.2 46

^{**:} Connector Styles



Sartobran® P 0.45 µm

Bioburden and Particle Retentive MidiCaps® and MaxiCaps®



Description

Sartobran® P 0.45 μm rated MidiCaps® and MaxiCaps® 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

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



Flexibility

Sartobran® P 0.45 µm MidiCaps® and MaxiCaps® 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 MidiCaps® and MaxiCaps® 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 B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

Documentation

Sartobran® P MidiCaps® and MaxiCaps® 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

Prefilter 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

 $0.65 \mu m + 0.45 \mu m$

Available Sizes | Filtration Area

MidiCaps®

Size 7	0.05 m ² 0.54 ft
Size 8	0.1 m ² 1.1 ft ²
Size 9	0.2 m ² 2.2 ft ²
Size 0	$0.45 \text{ m}^2 4.9 \text{ ft}^2$

MaxiCaps®

Size 1	0.6 m^2	6.5 ft ²
Size 2	1.2 m ²	12.9 ft ²
Size 3	1 8 m ²	19 4 ft2

Available Connectors MidiCaps®

SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps® SS, SO, OO, FF, BB

S:	11/2" Tri-Clamp (Sanitary)
0:	1/2" Single stepped hose barb
F:	3/4" Tri-Clamp (Sanitary)
H:	1/4" Multiple stepped hose barb
	(with filling bell at the outlet)
B:	³ / ₄ " – 1" Multiple stepped hose barb

Operating Parameters

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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 20°C (MaxiCaps®)

Max. Allowable Back Pressure:

2 bar 29 psi at 20°C

Extractables

Sartobran® P 0.45 µm rated filter MidiCaps® and MaxiCaps® 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

Sterilization

Autoclaving:

134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles

Autoclaving: Min. 25

Technical References

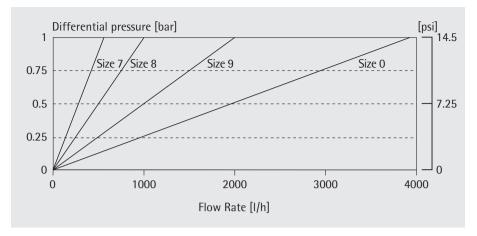
Validation Guide:

SPK5726-e (MaxiCaps®)

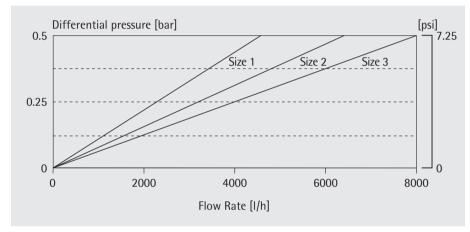
Extractables Guide:

SPK5731-e

Water Flow Rates for MidiCaps® with SS inlet and outlet



Water Flow Rates for MaxiCaps®



Standardized at 20°C

Order Information

Order Code	Pore size [μm]	Pack size [Pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
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
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

^{**:} Connector Styles

По вопросам продаж и поддержки обращайтесь: