

Sartopore® 2 XLI 0.2 µm

Sterilizing Grade MidiCaps®, MaxiCaps® and Capsules



sartorius stedim

biotech

Membrane Filter Cartridges



Description

Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules are self contained filter units that are especially designed for sterilizing grade filtration of pharmaceutical solutions with a homogenous particle spectrum. The unique heterogeneous double layer PES membrane combination of Sartopore® 2 XLI filters is specifically developed to provide exceptional high total throughputs and outstanding flow rates for totally chemically defined process fluids and other process fluids of biotech manufacturing processes with small particle spectrum.

Applications

Typical applications of Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules include sterilizing grade filtration of:

- Ophthalmic solutions
- Chemically defined cell culture media
- High viscous large volume parenterals
- Any fully chemically defined media

Economy

The combination of the built-in 0.35 µm pre-filter in front of a 0.2 µm final filter together with the 30% enlarged effective filtration area per XLI filter element provide an outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Compatibility

The PES membrane of Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules provide broad chemical compatibility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple autoclaving cycles up to 134°C.

Scalability

Sartopore® 2 XLI filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

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 XLI MidiCaps®, MaxiCaps® and Capsules are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control

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

Documentation

Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Specifications

Materials

| | |
|----------------------|------------------------------|
| Pre-filter Membrane: | Polyethersulfone, asymmetric |
| Endfilter Membrane: | Polyethersulfone, asymmetric |
| Support Fleece: | Polypropylene |
| Core: | Polypropylene |
| End Caps: | Polypropylene |
| Capsule Housing: | Polypropylene |
| O-Rings: | Silicone |
| Filling Bell: | Polycarbonate |

Pore Size

0.35 µm + 0.2 µm

Available Sizes | Filtration Area

Capsules

Size 4 0.021 m² | 0.22 ft²

MidiCaps

Size 7 0.065 m² | 0.7 ft²

Size 8 0.13 m² | 1.4 ft²

Size 9 0.26 m² | 2.8 ft²

Size 0 0.52 m² | 5.6 ft²

MaxiCaps

Size 1 0.8 m² | 8.6 ft²

Size 2 1.6 m² | 17.2 ft²

Size 3 2.4 m² | 25.8 ft²

Available Connectors Capsules

SS, SO, OO

Available Connectors MidiCaps®

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

Available Connectors MaxiCaps®

SS, SO, OO, FF, BB

S: 1½" Tri-Clamp (Sanitary)

O: ½" Single stepped hose barb

F: ¾" Tri-Clamp (Sanitary)

H: ¼" Multiple stepped hose barb (with filling bell at the outlet)

B: ¾" - 1" Multiple stepped hose barb

S: ½" Tri-Clamp (only Capsule Size 4)

O: Multiple stepped hose barb (only Capsule Size 4)

Operating Parameters

| | |
|------------------------|------------------------|
| Max. Allowable | 5 bar 72.5 psi |
| Differential Pressure: | at 20°C (MidiCaps®) |
| | 4 bar 58 psi at 20°C |
| | (MaxiCaps® & Capsule) |
| | 2 bar 29 psi at 80°C |

Max. Allowable Back Pressure: 2 bar | 29 psi at 20°C

По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,
Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

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Specifications

Extractables

Sartopore® 2 XLI 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

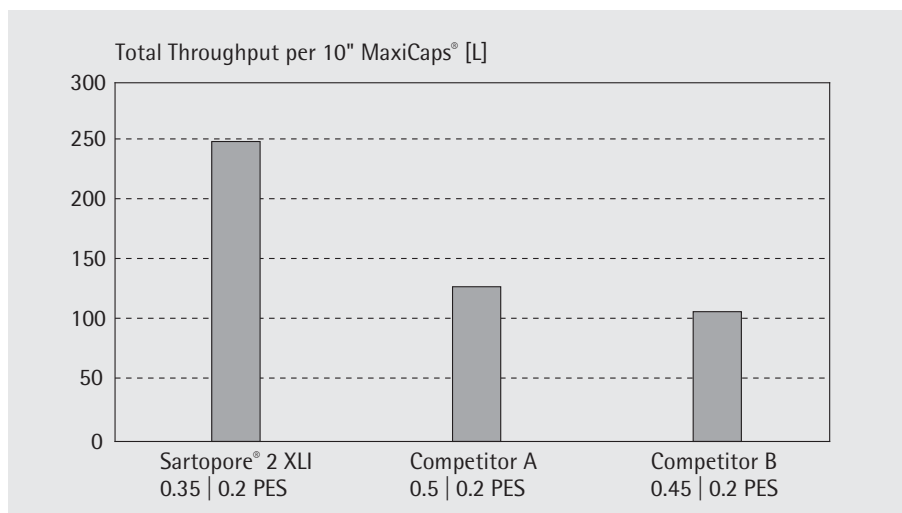
Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Chemically Defined Cell Culture Media



Sterilization

Autoclaving:

134°C, 2 bar, 30 min

Sterilization Cycles (MaxiCaps® & MidiCaps®)

Autoclaving: Min. 25

No In-Line Steam Sterilization

Technical References

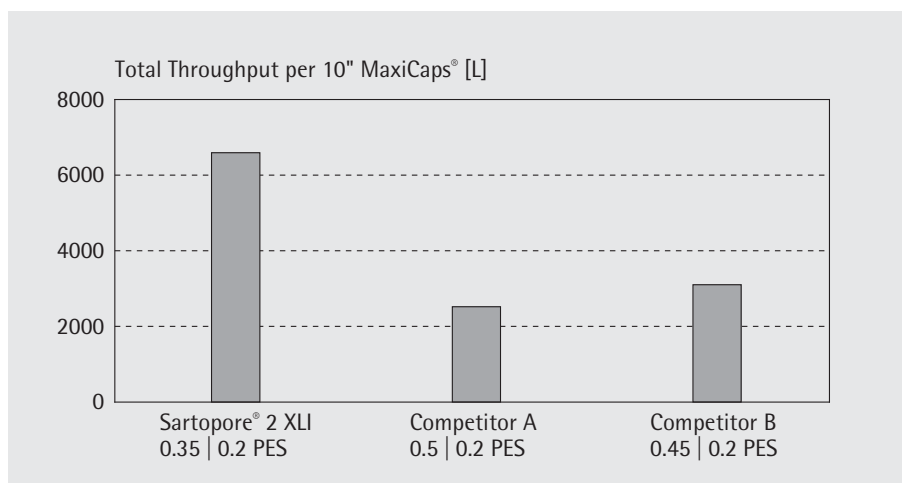
Validation Guide:

SPK5768-e

Extractables Guide:

SPK5776-e

Ophthalmic Solution



Order Codes

| | Pore Size [µm] | Pack size [pieces] | Test Pressure [bar psi] | Max. Diffusion [ml/min] | Min. Bubble Point [bar psi] |
|----------------------------|----------------|--------------------|---------------------------|-------------------------|-------------------------------|
| XLI MidiCaps®: | | | | | |
| 544530717--**--A | 0.35 + 0.2 | 4 | 2.5 36 | 5 | 3.2 46 |
| 544530718--**--A | 0.35 + 0.2 | 4 | 2.5 36 | 6 | 3.2 46 |
| 544530719--**--A | 0.35 + 0.2 | 4 | 2.5 36 | 9 | 3.2 46 |
| 544530710--**--V | 0.35 + 0.2 | 2 | 2.5 36 | 18 | 3.2 46 |
| XLI MaxiCaps®: | | | | | |
| 544130711--** | 0.35 + 0.2 | 1 | 2.5 36 | 23 | 3.2 46 |
| 544130712--** | 0.35 + 0.2 | 1 | 2.5 36 | 46 | 3.2 46 |
| 544130713--** | 0.35 + 0.2 | 1 | 2.5 36 | 69 | 3.2 46 |
| XLI Capsules Size 4 | | | | | |
| 544130714--**--B | 0.35 + 0.2 | 5 | 2.5 36 | 1.1 | 3.2 46 |

** : Connector Style

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