

Sartobran P 0.1 µm

Sterilizing Grade Filter Capsules and MaxiCaps



Description

Sartobran P 0.1 µm rated, high flow filter capsules and MaxiCaps are self contained, ready to use, sterile filter units designed for enhanced sterility assurance in applications with presence of microorganisms that could pass 0.2 µm rated sterilizing grade filters. In addition, the Cellulose Acetate Membrane of the Sartobran P Filter Capsules offers ultra low binding properties for proteins and preservatives making Sartobran P 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 µm filtration for enhanced sterility assurance.

Flow Rates

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

Total Throughput

Due to the "built-in prefiltration" by a 0.45 µm 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.

Microbiological Retention

Sartobran P 0.1 µm rated filter cartridges are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-83 guidelines.

Flexibility

Sartobran P 0.1 µm filters are available in traditional cartridge formats and disposable capsules from 150 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 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 + 0.1 µm

Available Sizes | Filtration Area

Capsules

Size 7	0.05 m ² 0.5 ft ²
Size 8	0.1 m ² 1 ft ²
Size 9	0.2 m ² 2 ft ²
Size 0	0.45 m ² 5 ft ²

MaxiCaps

Size 1	10"	0.6 m ² 6 ft ²
Size 2	20"	1.2 m ² 12 ft ²
Size 3	30"	1.8 m ² 18 ft ²

Available Connectors

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 Pressure:	2 bar 29 psi at 20 °C

Integrity Test Limits

Maximum Allowable Diffusion at 3.0 bar / 44 psi @ 20 °C

Capsule Size	Maximum Diffusion
Size 1	15 ml/min
Size 2	30 ml/min
Size 3	45 ml/min
Size 7	3 ml/min
Size 8	4 ml/min
Size 9	5 ml/min
Size 0	10 ml/min

Membrane Filter Capsules and MaxiCaps

Specifications

Extractables

Sartobran P 0.1 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

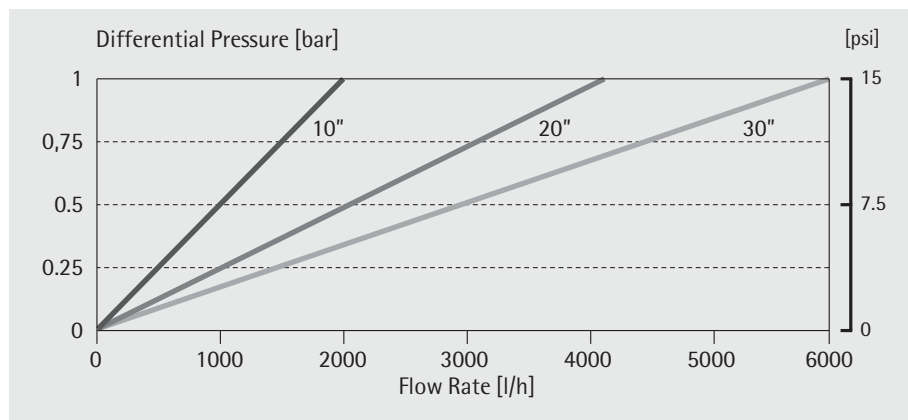
Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test.

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Water Flow Rates for 10", 20" and 30" MaxiCaps



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

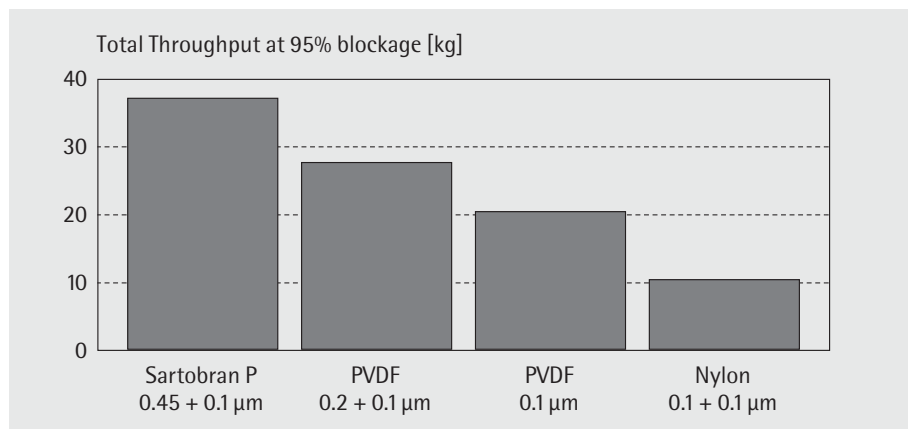
Validation Guide:

SPK5726-e

Extractables Guide:

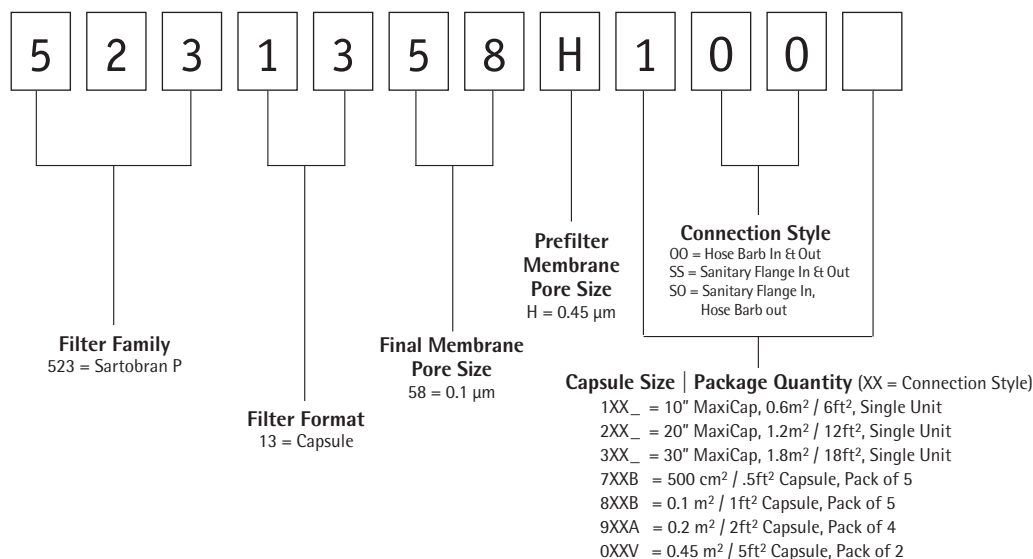
SPK5720-e

Total Throughput Comparison



10" Cartridge format

Ordering Guide:



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