

Sartopore 2 HF 0.2 µm

Sterilizing Grade Filter Cartridges



Description

Sartopore 2 High Flow sterilizing grade filter cartridges are developed for filtration of water based pharmaceutical formulations. Sartopore 2 HF cartridges feature a unique single layer, hydrophilic polyethersulfone membrane. This membrane is characterized by broadest chemical compatibility, highest thermal resistance, increased mechanical stability and higher flow-rates than any other sterilizing grade filter cartridge offers.

Applications

Typical applications include sterilizing grade filtration of:

- Large Volume Parenterals (LVP)
- Buffers
- WFI
- Cleaning and sanitizing agents
- Bulk pharmaceutical products
- Each application requiring exceptional high flow rates

Compatibility

The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 and to multiple steam sterilization cycles making Sartopore 2 HF cartridges ideal for filtration of solutions with high | low pH and for SIP/CIP-cycles.

Performance

The increased effective filtration area of Sartopore 2 HF filter cartridges allows for highest flow rates and assures thereby most economic design of filtration systems.

Wettability

Sartopore 2 HF cartridges can be easily wetted out for integrity testing even after drying cycles with 80 °C for 12 hours.

Microbiological Retention

Sartopore 2 HF filter cartridges 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 release, assuring absolute reliability.

Documentation

Sartopore 2 HF cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide and an Extractables Guide are available for compliance with regulatory requirements.

Specifications

Materials

Filter Membrane:	Polyethersulfone, asymmetric
Support fleece:	Polypropylene
Core:	Polypropylene
End caps:	Polypropylene
O-Rings:	Silicone

Pore Size

0.2 µm

Available Sizes | Filtration Area

Size 1	10"	0.7 m ²	7ft ²
Size 2	20"	1.4 m ²	14ft ²
Size 3	30"	2.1 m ²	21ft ²

Available Adapters

25

Operating Parameters

Max. allowable Differential pressure:	5 bar	75 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 2.5 bar / 36 psi @ 20 °C

Cartridge Size	Maximum Diffusion	Minimum Bubble Point
Size 1	21 ml/min	3.2 bar/46 psi
Size 2	42 ml/min	3.2 bar/46 psi
Size 3	63 ml/min	3.2 bar/46 psi

Membrane Filter Cartridges

Specifications

Extractables

Sartopore 2 HF 0.2 µm rated filter cartridges 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

In-Line Steam Sterilization

134 °C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Autoclaving:

134 °C, 2 bar, 30 min

Sterilization Cycles

In-Line Sterilization: Min. 25
Autoclaving: Min. 25

Technical References

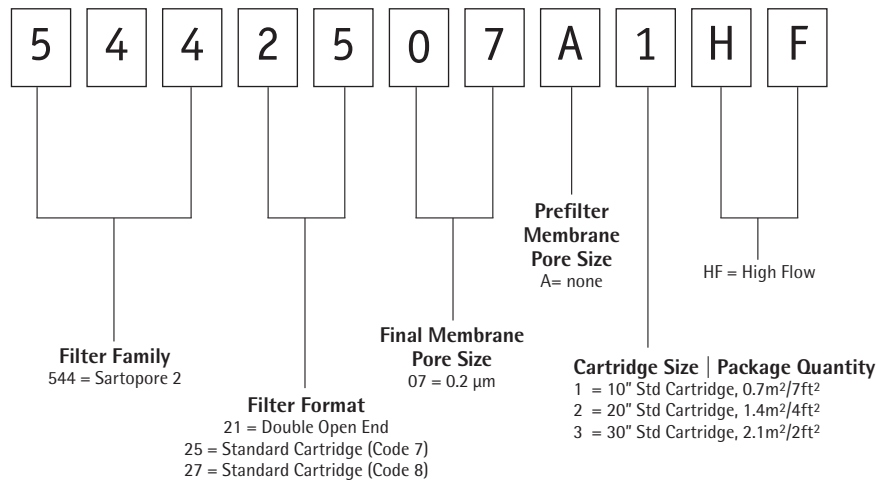
Validation Guide:

SPK 5741-e

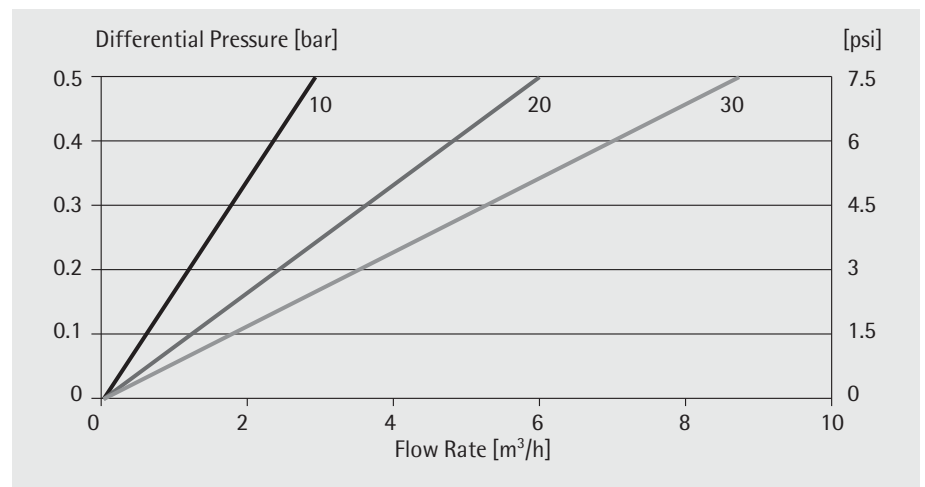
Extractables Guide:

SPK 5742-e

Ordering Guide:

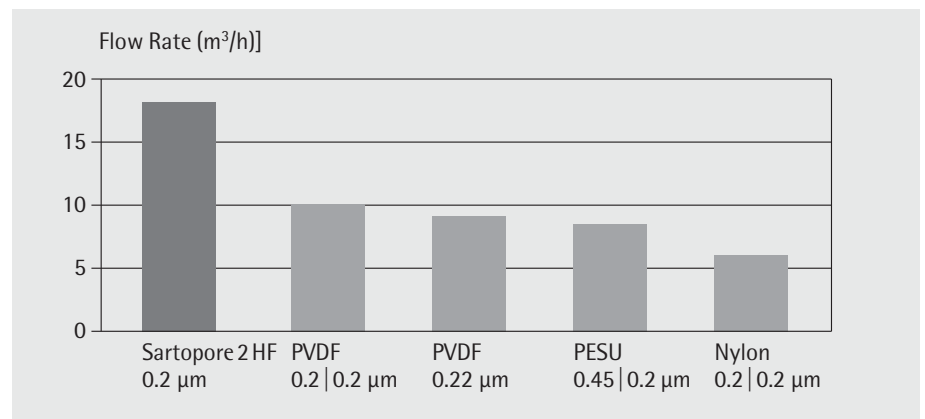


Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20 °C

Flow Rate Comparison



30" Filter cartridges at 1 bar | 14.5 psi differential pressure (20 °C)

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Publication No.: SPK2051-e04041
Order No.: 85030-517-42