

Sartopore 2 0.2 µm

Sterilizing Grade γ-Irradiatable Filter Capsules



Description

Sartopore 2-γ-Capsules are 0.2 µm rated sterilizing grade filter capsules designed for connection to flexible-bag-container-systems prior to sterilization by gamma-irradiation.

Applications

Typical applications include sterilizing grade filtration of:

- Pharmaceuticals
- Biologicals
- Cell Culture Media
- Culture Media Components
- Serum
- Buffers
- Diagnostic Reagents

Compatibility

Sartopore 2-γ-Capsules are designed for sterilization by gamma irradiation ≤ 50 kGy irradiation dosage. The polyethersulfone membrane of the Sartopore 2-γ-Capsules offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited for a broad range of applications in the Pharma | Biotech field.

Performance

Due to the superior construction including a "build-in prefiltration" by a 0.45 µm membrane Sartopore 2-γ-Capsules offer outstanding total throughputs and excellent flow rates.

Flexibility

Sartopore 2-γ-Capsules are available with filtration areas from 0.015 m² | 0.15 ft² up to 0.45 m² | 5 ft² for easy use in any bag-filtration process independent of the batch size.

Microbiological Retention

Sartopore 2-γ-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 integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation

Sartopore 2 Gamma 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:	Polyethersulfone, asymmetric
Endfilter Membrane:	Polyethersulfone, asymmetric
Support Fleece:	Polypropylene
Core:	Polypropylene
End Caps:	Polypropylene
Capsule Housing:	Polypropylene

Pore Size

0.45 µm + 0.2 µm

Available Sizes | Filtration Area

Size 4	0.015 m ² 0.15 ft ²
Size 5	0.03 m ² 0.3 ft ²
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

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

Cartridge Size	Max. Diffusion	Min. Bubble Point
Size 4	1 ml min	3.2 bar 46 psi
Size 5	2 ml min	3.2 bar 46 psi
Size 7	4 ml min	3.2 bar 46 psi
Size 8	5 ml min	3.2 bar 46 psi
Size 9	7 ml min	3.2 bar 46 psi
Size 0	14 ml min	3.2 bar 46 psi

Maximum Allowable Diffusion at 2.5 bar / 36 psi @ 20°C

Membrane Filter Capsules

Specifications

Extractables

Sartopore- γ -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 Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

γ - irradiation \leq 50 kGy irradiation dosage

Autoclaving:

134 °C, 2 bar | 29 psi, 30 min

No In-Line Steam Sterilization

Sterilization Cycles

γ - Irradiation: Max. 1
Autoclaving: Max. 3

Technical References

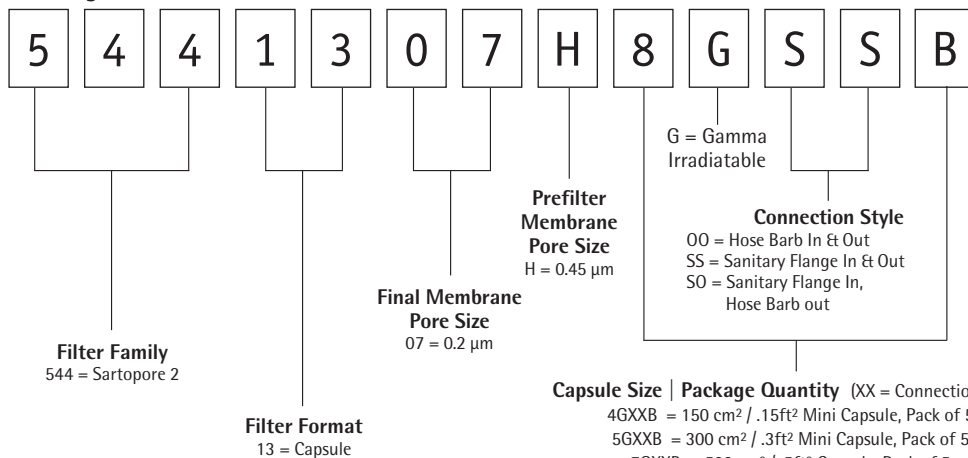
Validation Guide:

SPK5734-e

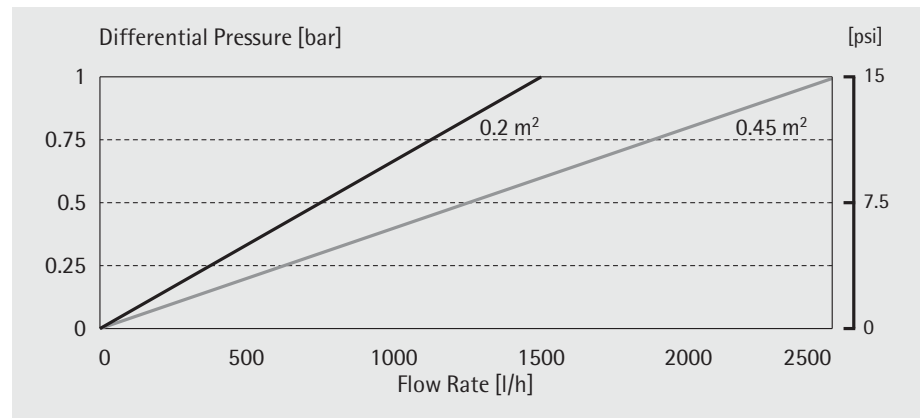
Extractables Guide:

SPK5740-e

Ordering Guide:

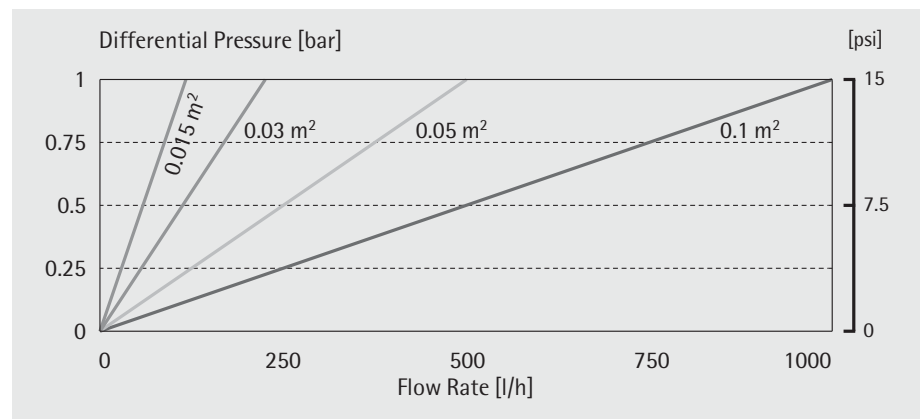


Water Flow Rates for 0.2 m² and 0.45 m² Capsules



Standardized at 20 °C

Water Flow Rates for 0.015 m², 0.03 m², 0.05 m² and 0.1 m² Capsules



Standardized at 20 °C

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