

Pharmsteri™ AHC PES Liquid Capsule and Cartridge Filter

Improved throughput and broad chemical compatibility for various challenging fluid streams

Pharmsteri™ AHC (autoclavable, high capacity) PES capsule and cartridge filters are constructed of highly asymmetric 0.45+0.22 µm or 0.65+0.22 µm dual-layer hydrophilic polyethersulfone (PES) membranes, and high-grade polypropylene (PP) non-woven, core, cage and shell.

Cartridge filters are compatible with existing stainless steel process system, and more economical for large scale manufacturing. Single-use capsule filters provide end users unparalleled flexibility and adaptability in a smaller footprint. Various capsules and cartridge sizes – from disc to 10” capsules and up to 30” cartridges - enables seamless scalability from lab-scale study to pilot and full-scale commercial manufacturing. Multiple connector types and codes are available to ensure easy integration with both single-use and stainless-steel systems.

APPLICATIONS

- Bioburden or sterile filtration for various process fluids
- Cell culture media and additives
- Process intermediates in mAb, vaccines, etc.
- Column or downstream unit protection
- High concentration buffers
- Bulk drug substances
- Protein solutions or formulations
- Other fouling or non-fouling fluids



FEATURES & BENEFITS

| | |
|---|--|
| Best-in-class throughput or capacity | Dual layer and highly asymmetric membrane minimize pressure build-up while processing large volume fluids |
| Low hold-up volume | Structure design helps minimize dead zone which can cause loss of high value products |
| Sterilizing grade meets Bacterial Challenge Test (ASTM F838) | Ensures that microorganisms, such as bacteria, are removed from the fluid stream while not adversely affecting product |
| Broad chemical compatibility | pH 1~14, allows use in a range of chemicals including acids and bases |
| Comprehensive validation | Product has been rigorously validated to product specification and industry standards with comprehensive documentation to support compliance |

SPECIFICATIONS

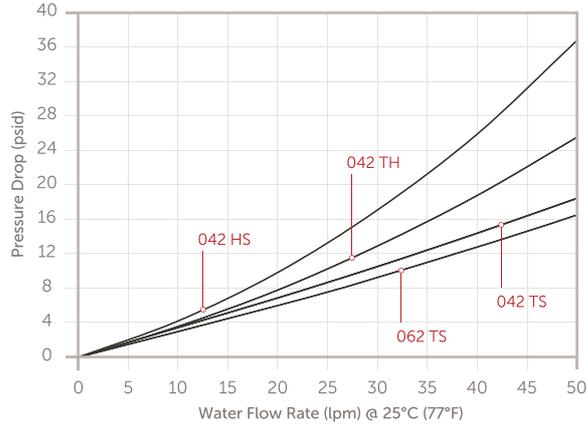
| | | 3"/5"/10" In-line Capsules | | 5"/10"/20"/30" Cartridges | |
|-------------------------------------|---|---|---|---|------------------------------|
| Materials | Media | Polyethersulfone (PES) | | Polyethersulfone (PES) | |
| | Support | Polypropylene | | Polypropylene | |
| | Core, cage, end caps | Polypropylene | | Polypropylene | |
| | O-ring | Silicone | | Silicone | |
| Sealing technology | Thermal bonding without adhesives | | Thermal bonding without adhesives | | |
| Pore size | 0.45+0.22 µm | | 0.45+0.22 µm | | |
| | 0.65+0.22 µm | | 0.65+0.22 µm | | |
| Filtration area | 3" | 0.15 m ² | 5" | 0.28 m ² | |
| | 5" | 0.28 m ² | Per 10" | 0.55 m ² | |
| | 10" | 0.55 m ² | | | |
| Integrity | Bubble point | ≥3.65 bar (53 psi) air with water | | ≥3.65 bar (53 psi) air with water | |
| | Water Diffusion | 3" | ≤ 6.8 mL/min @ 40 psi at 25°C | 5" | ≤ 11 mL/min @ 40 psi at 25°C |
| | | 5" | ≤ 10.5 mL/min @ 40 psi at 25°C | Per 10" | ≤ 21 mL/min @ 40 psi at 25°C |
| | | 10" | ≤ 21 mL/min @ 40 psi at 25°C | | |
| Maximum operating conditions | Maximum operating pressure | 80 psi (5.5 bar) @ 25°C (77°F) | | 80 psi (5.5 bar) @ 25°C (77°F) | |
| | | 40 psi (2.8 bar) @ 60°C (140°F) | | 29 psi (2.0 bar) @ 80°C (176°F) | |
| | Maximum differential pressure | Forward 60 psi (4.1 bar) @ 25°C (77°F) | | Forward 60 psi (4.2 bar) @ 25°C (77°F) | |
| | | Forward 30 psi (2.1 bar) @ 60°C (140°F) | | Forward 29 psi (2.0 bar) @ 80°C | |
| Bacteria Retention | >10 ⁷ CFU/cm ² <i>B. diminuta</i> per the ASTM F838 | | >10 ⁷ CFU/cm ² <i>B. diminuta</i> per the ASTM F838 | | |
| | Multiple sterilization cycles | 25 cycles of autoclave, 30 min at 127°C (260.6°F) | | 25 cycles of autoclave, 30 min at 127°C (260.6°F), or 25 cycles of 30 min steam in place (SIP) at 131°C with differential pressure under 300 mbar | |
| Endotoxin releasing | <0.25 EU/mL as determined by the LAL test, meeting the requirements of USP <85> | | | | |
| Particulates | Particulate matter release meets the requirement of USP <788> | | | | |
| Non-fiber releasing | Manufactured with non-fiber release materials and tested according to 21 CFR 210.3 (b) (6) | | | | |
| TOC | <0.5 mg/L post autoclave and after a water flush, meeting the requirements of USP <643> | | | | |
| Conductivity | ≤1.3 µS/cm post autoclave and after water flush, meeting the requirements of USP <645> | | | | |
| Material toxicity | All components meet the requirements of the USP <87>, Biological Reactivity Test and the USP <88> Reactivity Test for Class VI Plastics | | | | |

SPECIFICATIONS

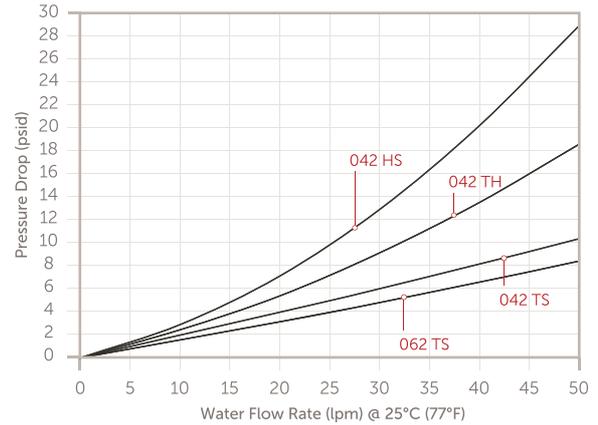
| | |
|---------------------|--|
| Animal Free | Raw materials used to manufacture this product are not animal derived, meeting the EU directive for animal free CPMP EMA/410/01 and 21 CFR parts 189.5 |
| Extractables | Tested according to BioPhorum Operations Group (BPOG) guideline. Report is available upon request. |
| Quality | 100% integrity tested, manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system |

PERFORMANCE DATA

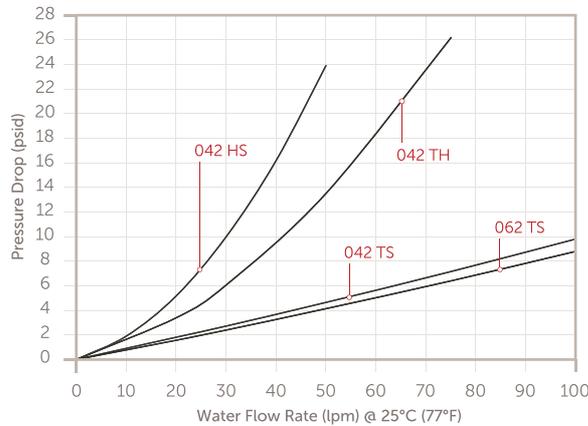
3-inch Capsules



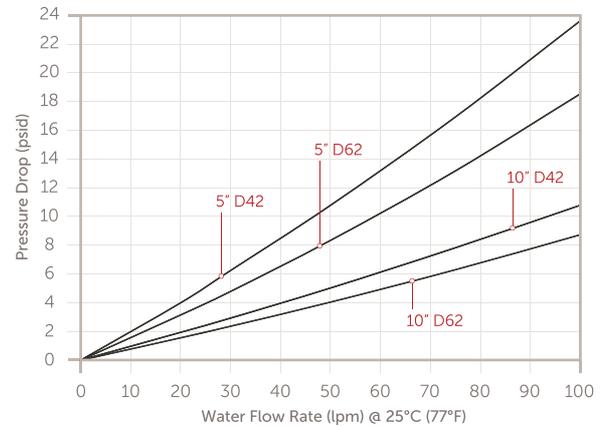
5-inch Capsules



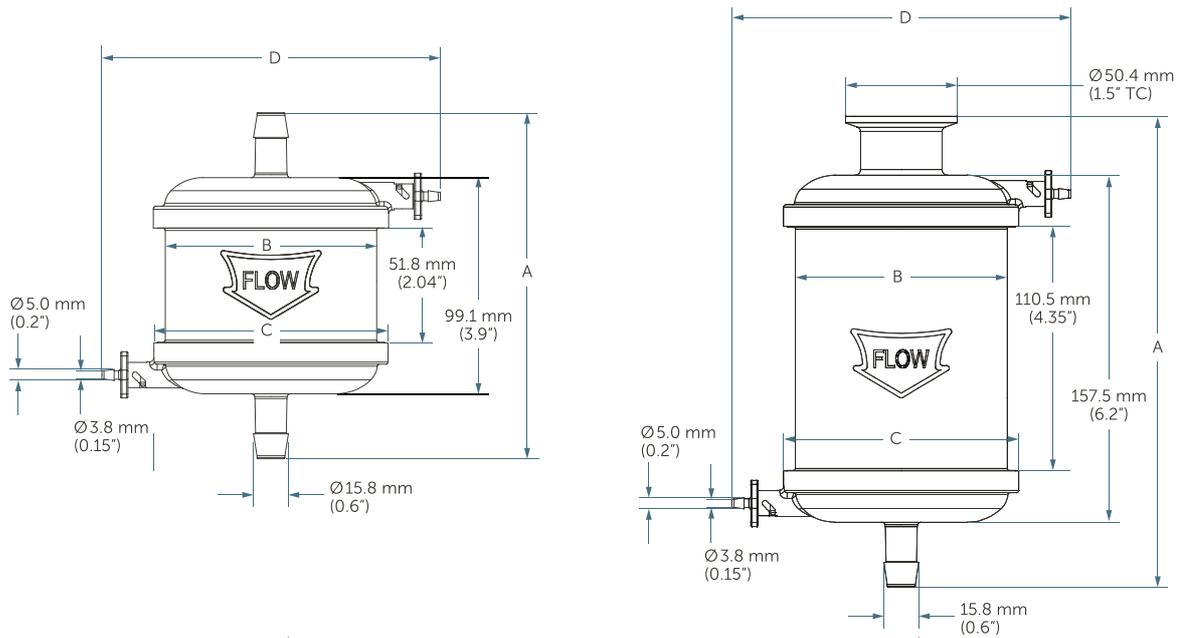
10-inch Capsules



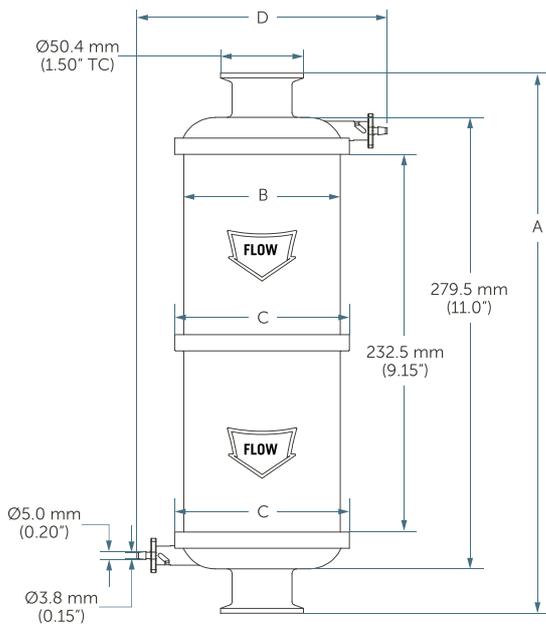
Cartridge Filters



DIMENSIONS



| Size - Connections | Total Length - A | Body Diameter - B | Min Width - C | Max Width - D |
|--------------------|------------------|-------------------|------------------|------------------|
| 3-inch TC-TC | 154.5 mm (6.08") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 3-inch TC-HB | 156.7 mm (6.17") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 3-inch HB-HB | 159.7 mm (6.29") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 5-inch TC-TC | 213.2 mm (8.39") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 5-inch TC-HB | 216.5 mm (8.52") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 5-inch HB-HB | 219.5 mm (8.96") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |



| Size - Connections | Total Length - A | Body Diameter - B | Min Width - C | Max Width - D |
|--------------------|-------------------|-------------------|------------------|------------------|
| 10-inch TC-TC | 335.5 mm (13.21") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 10-inch TC-HB | 339.0 mm (13.35") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |

DIMENSIONS

10-inch HB-HB

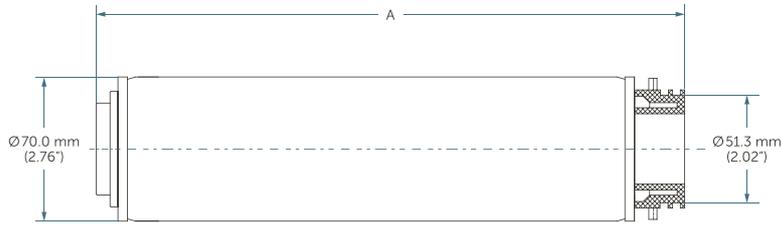
342.0 mm (13.46")

96.0 mm (3.78")

107.0 mm (4.21")

153.0 mm (6.02")

Code 6



Length

Code 6 Dimension A

5"

150.5 mm (5.9")

10"

276.0 mm (10.9")

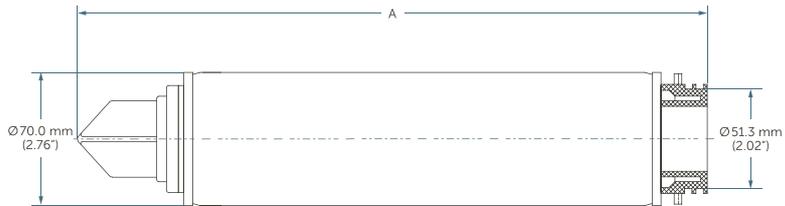
20"

520.0 mm (20.5")

30"

764.5 mm (30.1")

Code 7



Length

Code 7 Dimension A

5"

199.0 mm (7.8")

10"

316.5 mm (12.5")

20"

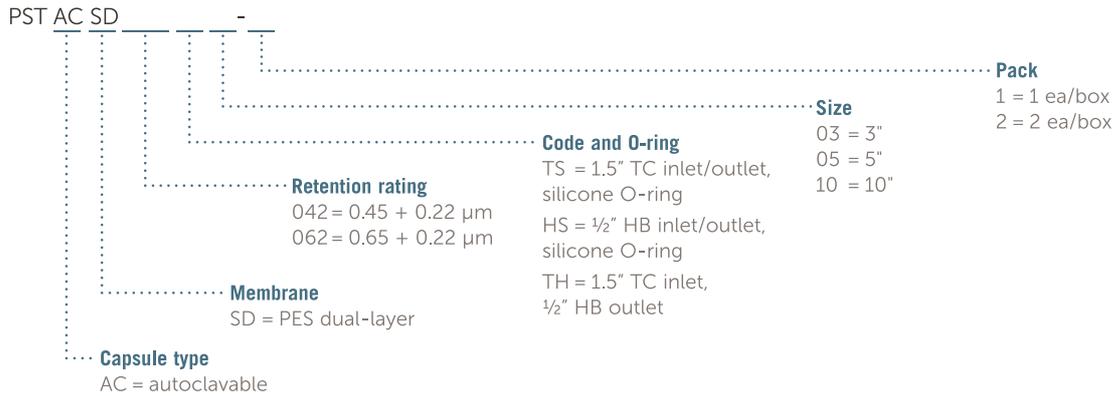
561.0 mm (22.1")

30"

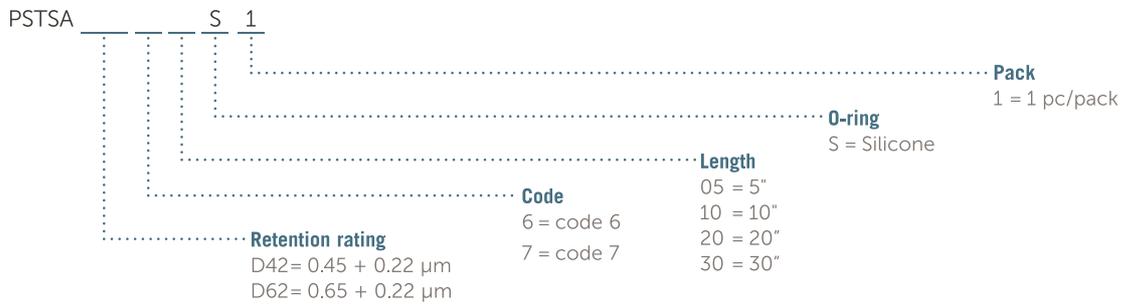
805.5 mm (31.7")

ORDERING INFORMATION

Pharmsteri AHC PES capsule filter: part number



Pharmsteri AHC PES cartridge filter: part number



FOR MORE INFORMATION

Please call your Regional Customer Service Center today to learn what Entegris can do for you. Visit [entegris.com](https://www.entegris.com) and select the [Contact Us](#) link to find the customer service center nearest you.

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