# Pharmsteri™ II GHF PES Liquid Capsule Filter

*Delivers superior flow rates in a broad range of chemical conditions to deliver significant economic advantages*

*Fully validated for gamma compatibility up to 45 kGy*

As biological manufacturing rapidly increases in capacity, end users are challenged to purify a diverse array of new biologics such as monoclonals, antibody-drug conjugates, and new modalities in gene therapies in a risk-free and economical environment. Entegris is a leading expert in controlling particles and impurities and we are leveraging our extensive knowledge in purity manufacturing for strict semiconductor applications into the life sciences market.

Pharmsteri™ II GHF PES liquid capsule filters are made of a high-grade, gamma-stable polypropylene (PP) shell and a hydrophilic, polyethersulfone (PES) membrane with nominal pore rating at 0.22 µm.

Single-use capsules provide end users unparalleled flexibility and adaptability in a smaller footprint than traditional cartridges in a stainless steel housing. This flexibility allows end users to scale their templates up and out, improves process economics, enables multiuse facilities, and reduces the risk of contamination entering the manufacturing process.

## APPLICATIONS

- Buffers
- Chemical or small molecule solutions
- Small or large volume parenterals
- Chemical drug formulations, such as eye drops
- Cleaning and sanitizing solutions
- Wafer for injection
- Other low-fouling fluids

## FEATURES & BENEFITS

| | |
|---|---|
| **Gamma stable and autoclavable materials of construction** | Enable sterilization using caustics or autoclaving, or for optimal bioprocessing, integrate into single-use assemblies for gamma irradiation |
| **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 |
| **On site or integrator compatible** | Autoclave claims allow users the advantage of choosing to integrate buffer filters in situ to meet their own specific templates and needs |
| | Gamma capability ensures that integrators can connect these filters into any customer-specific, single-use assembly and provide it as a sterile final assembled product |
| **Broad chemical compatibility** | pH 1~14, allows use in a range of chemicals including acids and bases |
| **Best-in-class flow rates** | Meets or exceeds other commercially available filters allowing increased volumes to be processed in a limited time |

## SPECIFICATIONS

| | | 50mm Disc | 3"/5"/10" In-line Capsules | |
|---|---|---|---|---|
| **Materials** | Media | Polyethersulfone (PES) | Polyethersulfone (PES) | |
| | Support | Polyester | Polyester | |
| | Film edge | NA | Polypropylene/polyethylene copolymer | |
| | Core, cage, end caps | Polypropylene | Polypropylene | |
| | O-ring | NA | Silicone | |
| **Sealing technology** | | Mechanical sealing with O-ring | Thermal bonding without adhesives | |
| **Pore size** | | 0.22 µm | 0.22 µm | |
| **Filtration area** | | 17.3 $cm^2$ | 3" | 0.19 $m^2$ |
| | | | 5" | 0.36 $m^2$ |
| | | | 10" | 0.72 $m^2$ |
| **Integrity** | Bubble point | NA | ≥3.65 bar (53 psi) air with water | |
| | Water Diffusion | NA | 3" | ≤6.5 mL/min @ 40 psi at 25°C (77°F) |
| | | | 5" | ≤13.0 mL/min @ 40 psi at 25°C (77°F) |
| | | | 10" | ≤25.0 mL/min @ 40 psi at 25°C (77°F) |
| **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) | 40 psi (2.8 bar) @ 60°C (140°F) | |
| | Maximum differential pressure | Forward 60 psi (4.1 bar) @ 25°C (77°F) | Forward 60 psi (4.1 bar) @ 25°C (77°F) | |
| | | Forward 30 psi (2.1 bar) @ 60°C (140°F) | Forward 30 psi (2.1 bar) @ 60°C (140°F) | |
| | | Reverse 10 psi (0.7 bar) @25°C (77°F) | Reverse 10 psi (0.7 bar) @ 25°C (77°F) | |
| **Bacteria Retention** | | Sterilizing grade membrane | >$10^7$ CFU/$cm^2$ B. diminuta per the ASTM F838. | |
| **Multiple sterilization cycles** | 2 cycles of autoclave, 30 min at 130°C (266°F) | | | |
| **Gamma stability** | Gamma irradiation stable up to 45 kGy | | | |
| **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 gamma and after a water flush, meeting the requirements of USP <643> | | | |
| **Conductivity*** | ≤1.3 µS/cm post gamma 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 | | | |

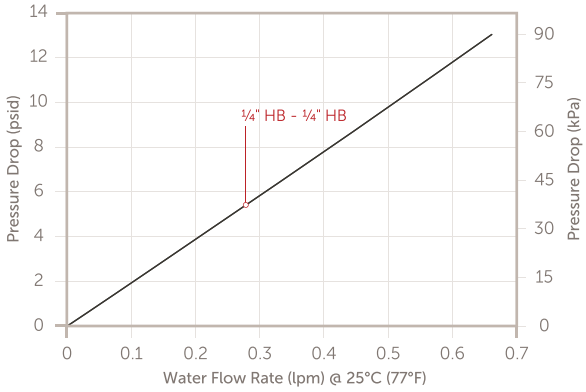
## SPECIFICATIONS

| | |
|---|---|
| **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 |

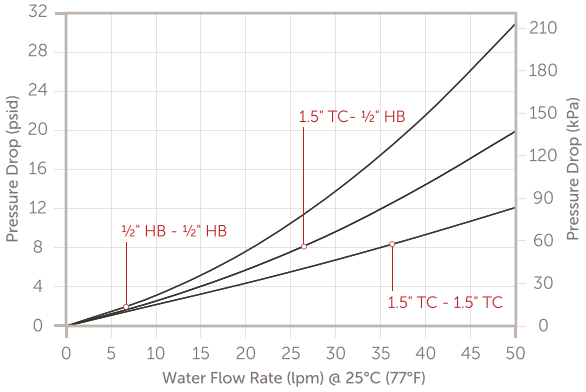
*Test post-gamma irradiation. Refer to our validation guide for details.

## PERFORMANCE DATA

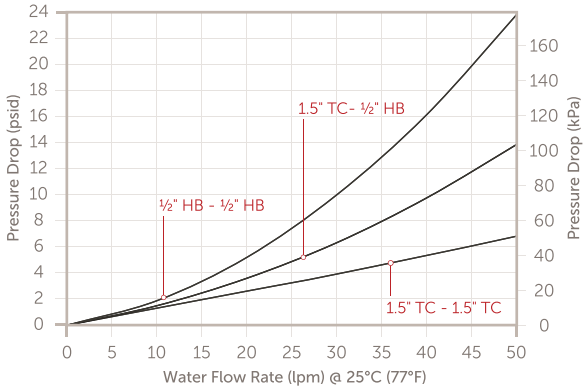
50 mm Disc



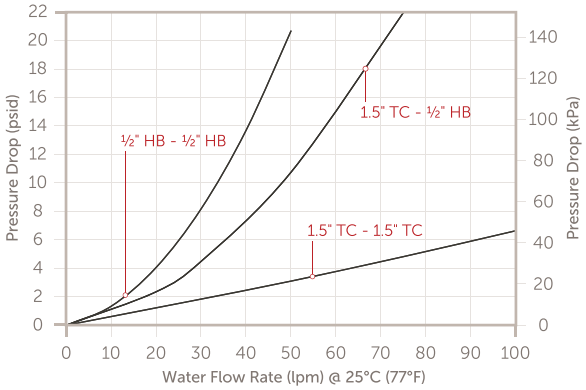

3-inch Capsules



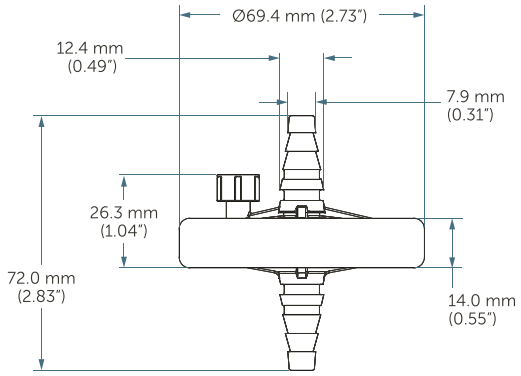

5-inch Capsules

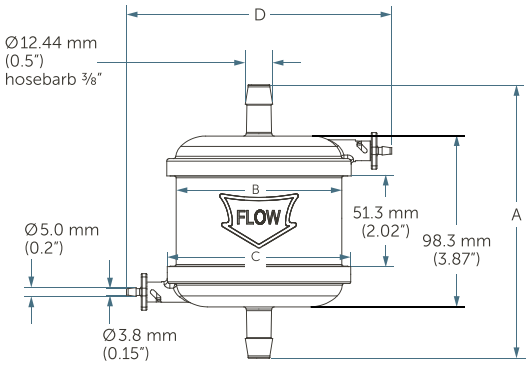



10-inch Capsules




## DIMENSIONS

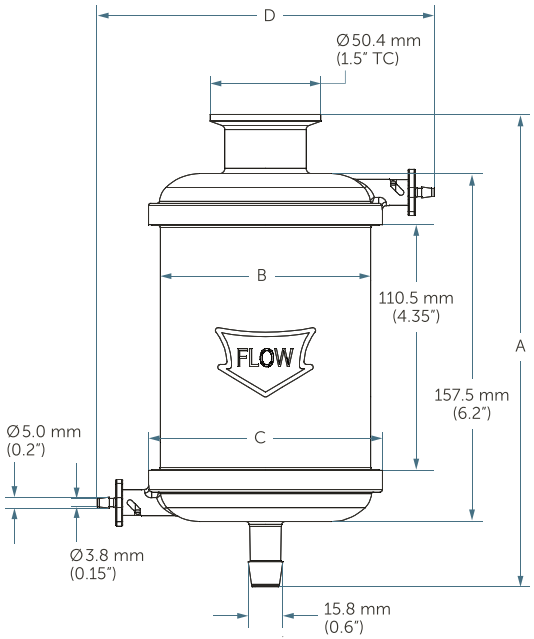


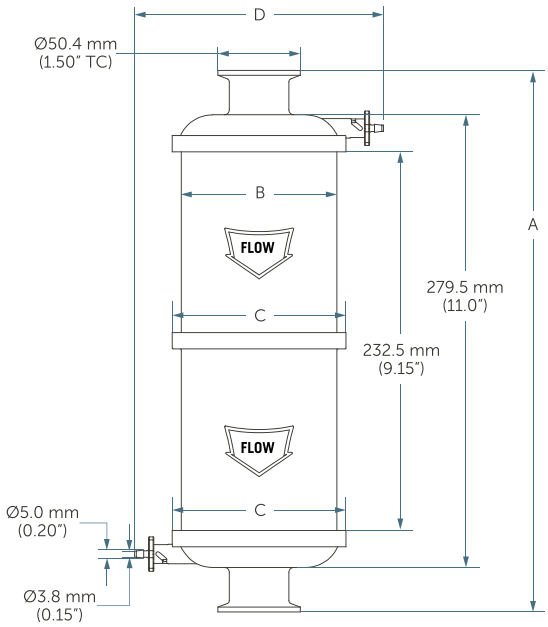




| Size - Connections | Total Length - A | Body Diameter - B | Min Width - C | Max Width - D |
|---|---|---|---|---|

## DIMENSIONS

| | | | | |
|---|---|---|---|---|
| 3-inch 1.5" TC-1.5" TC | 154.5 mm (6.08") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 3-inch 1.5" TC-1/2" HB | 156.7 mm (6.17") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 3-inch 1/2" HB-1/2" HB | 159.7 mm (6.29") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 3-inch 1.5" TC-3/8" HB | 152.5 mm (6.00") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 3-inch 3/8" HB-3/8" HB | 150.5 mm (5.93") | 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 |
|---|---|---|---|---|
| 5-inch 1.5" TC-1.5" TC | 213.2 mm (8.39") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 5-inch 1.5" TC-1/2" HB | 216.5 mm (8.52") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 5-inch 1/2" HB-1/2" HB | 219.5 mm (8.96") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 5-inch 1.5" TC-3/8" HB | 211.6 mm (8.33") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 5-inch 3/8" HB-3/8" HB | 210.0 mm (8.27") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 10-inch 1.5" TC-1.5" TC | 335.5 mm (13.21") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 10-inch 1.5" TC-1/2" HB | 339.0 mm (13.35") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |
| 10-inch 1/2" HB-1/2" HB | 342.0 mm (13.46") | 96.0 mm (3.78") | 107.0 mm (4.21") | 153.0 mm (6.02") |

## ORDERING INFORMATION

Pharmsteri II GHF PES: part number

PST__ SA 022 __ __ - __

**Single use**
SU = gamma compatible
GS = gamma sterilized

**Membrane**
SA = PES single-layer

**Pore rating**
022 = 0.22 µm

**Code and O-ring**
TS = 1.5" TC inlet/outlet, silcone O-ring
HS = ½" HB inlet/outlet, silcone O-ring
TH = 1.5" TC inlet, ½" HB outlet
RS = ⅜" HB inlet/outlet, silicone O-ring
TR = 1.5" TC inlet, ⅜" HB outlet
SH = ¼" HB inlet/outlet, disc only

**Size**
00 = 50 mm disc
03 = 3"
05 = 5"
10 = 10"

**Pack**
1 = 1 ea/box
2 = 2 ea/box
3 = 3 ea/box

Notes:
1. TS/HS/TH code for 3"/5"/10", RS/TR code for 3"/5", SH code for 50mm disc
2. 5"/10" as 1 ea/box, 3" as 2 ea/box, 50mm disc as 3 ea/box

### FOR MORE INFORMATION

Please call your Regional Customer Service Center today to learn what Entegris can do for you. Visit entegris.com and select the Contact Us link to find the customer service center nearest you.

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