Pharmsteri™ II PES 0.22 Buffer Capsule Filter

User manual

TABLE OF CONTENTS

INTRODUCTION

Pharmster™ II PES 0.22 buffer capsule filters are designed to provide biopharma manufacturing customers with high flow, low flush buffer filters. The filters are developed for the sterile or bioburden reduction filtration of process fluids in biopharma and pharma industries, including buffers, media, intermediates, etc. This user manual allows users, both familiar with or unfamiliar with filtration, to wet out a filter safely and effectively and prepare it for diffusive flow testing and manufacturing.

Figure 1. 10" Pharmsteri II PES 0.22 buffer capsule filter. Flow direction arrows shown moving from right to left. Capsule vent ports are shown twisted in the fully open position.

MATERIALS OF CONSTRUCTION	
Membrane	Polyethersulfone (PES)
Support	Polyester
Core, cage, caps	Polypropylene (PP)
O-rings	Silicone

Note: net weight of a single unit ~1.4 kg (3.1 lb), a typical package of 8 ea/box ~12 kg (26.5 lb).

ACCEPTANCE

Please check product's specifications and material number after receiving. Besides material number, each product has its own serial number and lot number as shown in Figure 2.

The serial number and lot number are laser marked near the mid-section of the filter capsule. The serial number appears below the material number and is separate from the lot number.

For this buffer capsule- the serial number always begins with "PES0.22-" (indicating the membrane and retention rating) and ends with the position of that capsule in that lot. Example: PES0.22-50 is the 50th capsule built in that lot. Below the serial number is the lot number. The lot number indicates when and where the filter was built and provides traceability to the batch record.

G	Year	Month	SAP lot number
G: Hangzhou	1: 2021 2: 2022 3: 2023 4: 2024 5: 2025 6: 2026 7: 2027 8: 2028 9: 2029	A: January B: February C: March D: April E: May H: June J: July K: August M: September N: October P: November S: December	Last 6 numbers of the work order

Example: *Lot number G2A471270 was manufactured at Entegris Hangzhou China in January 2022, under work order ending in 471270.*

Figure 2. Annotation for lot number.

INSTALLATION

Each user is responsible for verifying that the filter is technically suitable for use in combination with their process fluid and specific application. Please review entire procedure prior to use and follow all instructions in this manual. Entegris recommends that the user wear personal protective equipment (PPE) appropriate to the chemical hazards associated with the applicable process fluids.

1. Filters are double-wrapped for cleanroom use. Handle filter according to installation facility's cleanroom procedures. Dust-free gloves are recommended. Please inspect packaging prior to use to ensure filter has not been tampered with and is in good condition. Take care in unpacking, especially the inner bag, to avoid damaging the filter. Inspect filter for structural damage prior to use.
2. The filter can be installed either vertically or horizontally. Properly orient the capsule filter so that fluid flow direction in the chosen wetting method follows the flow indicators on the capsule.
3. Connect the filter inlet and outlet with corresponding connectors (either 1.5" sanitary fittings or hose barb).

WETTING PROCEDURE

Entegris strongly recommends properly wetting the filter before its first use. Flushing will greatly reduce residual extractable within the filter, as well as ensure a reliable BP/diffusion flow measurement to determine the filter integrity and avoid false failure readings.

The PES membrane used in the buffer filter is hydrophilic and easily wettable by DI water or similar aqueous liquids.

Depending on your system setup and process fluid availability, Entegris recommends three methods to wet the capsule.

- Method 1: Pressurized Flow – is recommended if you have limited IPA, DI water, or process fluids supply, but good control of system pressures.
- Method 2: Constant Flow with Peristaltic Pump – is recommended if you do not have accurate control of system pressures but can provide a high flow rate or large supply of IPA, DI water, or process fluids.
- Method 3: Constant Flow with Centrifugal Recirculating Flow Pump – is recommended if you do not have a high flow rate or access to pressurized air of 30 psi minimum.

METHOD 1: PRESSURIZED FLOW

A pressure pot (vessel) rated for 100 psi with a volume of at least 10 gallons (~38 liters) minimum is recommended for the following method of wetting.

1. Fill the pressure pot with a minimum of 32 liters of wetting fluid (WFI, DI water, etc.) and close all pressure pot valves.
2. Connect the capsule filter to the pressure pot following the system flow direction arrows on the capsule. The capsule can be oriented horizontally with the downstream vent port facing down (rotate capsule and orient as necessary). Make sure you have a valve installed on the downstream side of the capsule.

   NOTE: The pressure pot must be pressurized to a minimum of 30 psi (this procedure takes roughly 30 L and 16 minutes).
3. Open both capsule vent ports and leave the secured downstream valve open before beginning the procedure.
4. When ready, slowly open the upstream pressure pot flow valve to allow fluid to travel from the pressure pot into the capsule, aiming to achieve ~3 lpm (0.8 gpm).
5. Once the upstream valve (V1) is fully open, close the downstream valve (V4) and the downstream vent port, leaving only the upstream top facing vent port open to allow excess air to escape.
6. After about 1 – 2 minutes, close the remaining upward oriented vent port to allow the capsule to pressurize with fluid.
7. Hold the capsule under pressure with no flow for 2 minutes, then slowly open the downstream valve (or use alternative flow-restricting device) to allow for ~3 lpm (0.8 gpm) of flow for 3 minutes. Repeat this procedure (step 7) another time, then repeat (step 7) one final time for 4 minutes instead of 3 minutes. This should result in a total of 10 minutes of 3 lpm flow.
8. Shut down the upstream valve then remove the capsule from the setup and tilt the capsule to drain residual fluid from both ends of the capsule. Properly transport the filter without aggressively introducing air into the system for the next step in the process.

Capsule Filter Pressure Setup

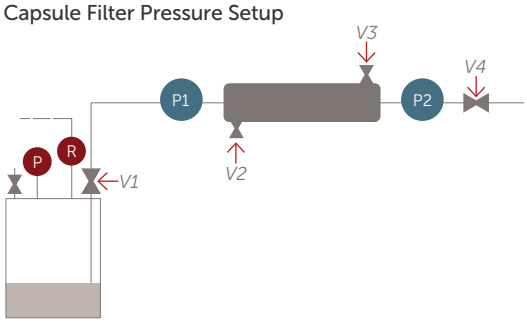


Figure 3. Necessary equipment for capsule filter pressure setup (Method 1) includes a pressure pot, air-flow regulator, pressure gauges, valves, minimum of 30 psi air flow, sanitary fittings, gaskets, and clamps.

METHOD 2: CONSTANT FLOW WITH PERISTALTIC PUMP

A peristaltic pump is recommended for this method.

Before attempting this method, determine the flow rate of your peristaltic pump in accordance with the rpm available with your machine, as well as with selected tubing.

1. Connect the capsule to the peristaltic pump system by securing an industry standard peristaltic pump hose inside the pump that can withstand a minimum of 20 psi, connecting both sides of the capsule to separate hoses and placing each end of the hose into the fluid container to allow for recirculation.
2. Ensure the peristaltic pump is rotating properly to pull the water from the container, into the capsule, and out into the container following the flow indicators.
3. Power on the peristaltic pump using one of two procedures. The first procedure reduces fluid requirements by ~6 L but requires personnel to operate and attend to. The second procedure requires ~33 L of fluid but can be initiated to run without the need for manual attention until completion.

Capsule Filter Peristaltic Pump Setup

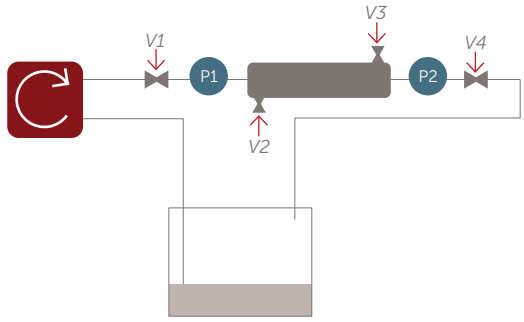


Figure 4. Necessary equipment for capsule filter peristaltic pump setup (Method 2) includes peristaltic pump that can supply 2.1+ lpm (0.6 gpm), peristaltic pump tubing, pressure gauges, adjustable valve, fluid recirculation reservoir, sanitary fittings, gaskets, and clamps.

Procedure 1

a. Power on the peristaltic pump and run at a low rpm until the capsule is full of fluid and spraying fluid through the venting ports.

b. Stop the pump, close valves 2, 3, and 4, and pressurize the capsule with the pump to 15 psi. The pump should be stopped at 15 psi to allow the fluid to sit pressurized in the capsule for 1 minute.

c. After 1 minute, slowly depressurize by opening the downstream valve (V4) and turn the pump up to the rpm of your machine that correlates to 2.1 lpm (0.6 gpm). Run at this flow rate for 6 minutes.

d. After 6 minutes, repeat the procedure once more. After these steps have been completed, the capsule is ready for diffusive flow testing or use.

Procedure 2

a. Power on the peristaltic pump and run at a low rpm until the capsule is full of fluid and spraying fluid through the venting ports.

b. Stop the pump, close valves 2, 3, and 4, and pressurize the capsule with the pump to 15 psi. The pump should be stopped at 15 psi to allow the fluid to sit pressurized in the capsule for 1 minute.

c. After 1 minute, slowly depressurize by opening the downstream valve (V4) and turn the pump up to the rpm of your machine which correlates to 2.1 lpm (0.6 gpm). Run at this flow rate for 15 minutes. After 15 minutes, the capsule is ready for diffusive flow testing or use.

METHOD 3: CONSTANT FLOW WITH CENTRIFUGAL RECIRCULATING FLOW PUMP

A large recirculation tub with a high flow pump is recommended for this method.

1. Connect the capsule to the recirculation system following the properly labeled flow direction, and make sure the capsule is secured into the system.
2. Ensure the adjustable downstream valve is open and keep both capsule venting ports open. Fill the capsule slowly with DI water by turning the pump on the lowest flow setting possible.
3. Purge air inside the capsule by allowing DI water to stream out from both capsule vent ports for about 5 seconds. Close both capsule venting ports.
4. Slowly increase the pump operating speed. Increase the flow rate using the adjustable downstream valve until it flows through the capsule at a rate between 30 – 75 lpm (8 – 20 gpm.) Run the system and recirculate fluid for at least 30 minutes. Allow for a partially closed downstream valve to build back pressure between 14 – 18 psi.
5. After 30 minutes of wetting, lower the operating speed of the pump, turn the pump off, and take out the capsule to drain residual fluid.

Capsule Filter Centrifugal Recirculating Flow Pump Setup

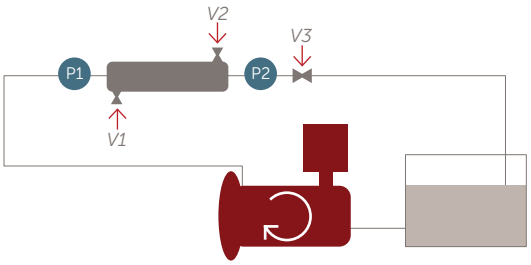


Figure 5. Necessary equipment for capsule filter centrifugal recirculating flow pump setup (Method 3) includes centrifugal pump, flowmeter, pressure gauges, adjustable valve, large fluid recirculation reservoir, sanitary fittings, gaskets, and clamps.

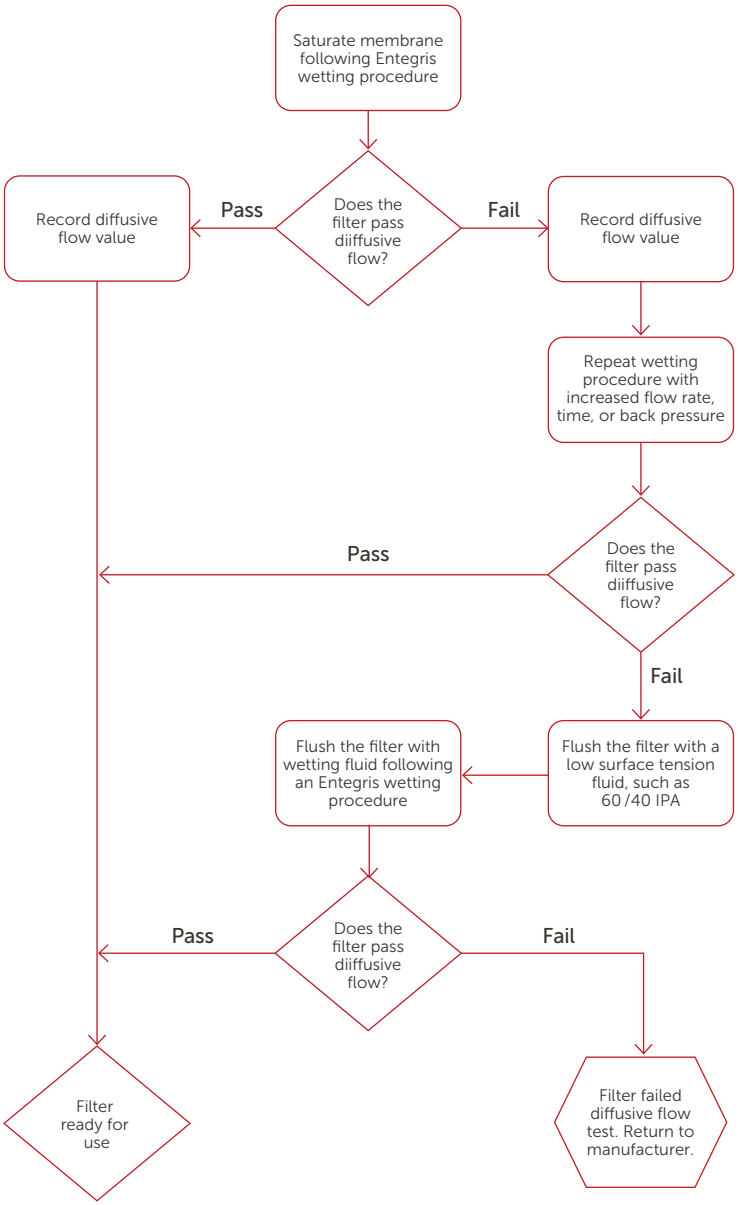
INTEGRITY TEST GUIDE

Entegris recommends integrity testing the Pharmsteri II PES 0.22 buffer capsule filter using a diffusion flow test method. There are two types of post-use integrity testing: water-based and product fluids-based. If all the process fluids can be thoroughly flushed from the capsule, a DI water-based integrity test method can be used below. For process fluids-based post-use integrity testing, please contact Entegris Customer Service for help if needed.

1. Wet the capsule according to the wetting procedures above with DI water, or thoroughly flush the capsule with DI water post use, then drain the capsule.
2. Connect the capsule to a regulated air or nitrogen pressure source according to your diffusion flow testing system setup. Utilizing an industry standard diffusive flow tester is the most accurate method to find your diffusive flow value. An automated diffusive flow tester is recommended for the most accurate results.
3. Set the system to measure the diffusive flow at 40 psi.
4. The maximum acceptable diffusion flow reading is 25 mL/min (0.006 gpm), 20° – 25°C (68° – 77°F) for an integral 10" capsule.

TROUBLESHOOTING GUIDE

Entegris Integrity Troubleshooting Guide to Diffusive Flow Measurements



STERILIZATION

Unless marked on label, all Entegris disposable filters and membrane components are shipped unsterilized.

This product was manufactured with gamma compatible raw materials and testing on final filters confirmed product performance was maintained after exposure of 45 kGy. If sterilization by autoclave is required, the validation test showed integrity and performance was preserved after 2 cycles @ 130°C (266°F) for 30 minutes.

STORAGE AND DISPOSAL

1. Store the filters in a cool dry area away from the sun, rain, or heat.
2. To keep disposable filters in good condition do not store them with toxic, corrosive, volatile, or pungent materials.
3. Handle filters gently during shipment and unpack only when ready to use.
4. Adhere to local regulations when disposing of used capsule filters.

FIRST AID

1. **Ingestion:** These devices are not likely to be hazardous by ingestion. Consult a physician if necessary.
2. **Eyes:** Because of the size and solid nature of these devices they are not expected to present an eye injury hazard.
3. **Inhalation:** These devices do not present an inhalation hazard because of the non-volatile nature of the polymeric component materials.
4. **Skin:** These devices are not likely to be hazardous by skin contact but cleansing the skin is advisable.

HAZARD IDENTIFICATION

1. **Appearance:** Porous white membrane encased in a solid polymer (plastic) housing with silicon O-rings on end cap subassembly.
2. **Health Hazard:** Under normal operating temperature and pressure conditions, these devices do not present a health hazard.
3. **Physical Hazard:** Under normal operating temperature and pressure conditions, these devices do not present a physical hazard. If removed from its housing, the membrane and nonwoven fabric are considered a combustible solid.

WARNING

To reduce the risk associated with choking, do not allow children under three years of age to have access to small parts during the installation of this product.

This is designed as a single-use product and Entegris recommends replacing a capsule filter after each product filtration batch. If any of the following situations occur, this product should not be used:

1. The filter fails integrity test.
2. The differential pressure in normal operation is above 2 bar.
3. The flow rate cannot meet production requirements.
4. The filter is beyond its verified lifetime.

WARRANTY AND CLAIMS

Entegris warrants that all products are manufactured in accordance with their specifications and quality standards. A certificate of quality will also be issued by quality upon lot release and attached to product package. Date of manufacture of all products is indicated on label and the shelf-life claim validated.

To ensure the capsule filter is not damaged during transportation, carefully check that the product packaging corrugated cartons are not damaged.

EPA INFORMATION

PRODUCED BY:

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Hangzhou Anow Filtration and Materials Co., Ltd. is a subsidiary of Entegris, Inc.

SERVICES

Entegris provides a variety of technical services including filter selection, system design, process verification, and more. Contact us or visit our website www.entegris.com to learn more.

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