# Pharmsteri™ II GSV UPE Vent Capsule Filters

*User manual*

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## INTRODUCTION

Entegris Pharmsteri™ II GSV UPE 0.22 µm vent capsule filters are designed to provide end-users with high flow, sterile barrier, and enhance hydrophobicity properties for use in critical gas and vent applications. Pharmsteri II GSV UPE vent capsule are available in a wide range of sizes from benchtop to production scale. The Pharmsteri II GSV UPE vent filter user guide was designed to allow end-users, both familiar with or unfamiliar with filtration, to wet out a filter safely and effectively and prepare it for integrity testing.

*Figure 1. Pharmsteri II GSV UPE 0.22 um vent capsule filter examples. Flow direction arrows shown moving from top to bottom. Capsule vent ports are shown twisted in the fully open position.*

| MATERIALS OF CONSTRUCTION | |
|---|---|
| **Membrane** | Ultra-high molecular polyethylene (UPE) |
| **Support** | Polyethylene |
| **Core, cage, caps** | Polypropylene (PP) |
| **O-rings** | Silicone |

## 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 "UPE0.22-" (indicating the membrane and retention rating) and ends with the position of that capsule in that lot. Example: UPE0.22-50 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<br>2: 2022<br>3: 2023<br>4: 2024<br>5: 2025<br>6: 2026<br>7: 2027<br>8: 2028<br>9: 2029 | A: January<br>B: February<br>C: March<br>D: April<br>E: May<br>H: June<br>J: July<br>K: August<br>M: September<br>N: October<br>P: November<br>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. Remove the capsule filter from packaging. Inspect Pharmsteri II GSV UPE vent filter for structural damage before use.
2. The filter can be installed either vertically or horizontally, ensuring the flow direction is properly orientated as directed on the filter capsule. See example below:
   a. 
3. Connect the filter's inlet and outlet with corresponding connector types to ensure a complete seal connection.

## BACKGROUND: NON-DESTRUCTIVE INTEGRITY TESTING

A non-destructive integrity test of a sterilizing grade filter can be defined as a test to evaluate if a filter is integral – ensuring a filter membrane's is not defective. A filter that is classified as an integral device ensures it meets guidelines of PDA Technical Report-26 and is bacterial retentive per ASTM F838. The value of non-destructive integrity test allows end-users to retest a filter for integrity without compromising the structure or integrity of the filter during testing. Depending on whether a filter is hydrophilic or hydrophobic, a number of non-destructive integrity test can be used to evaluate the integrity of a filter which include but are not limited to bubble point, diffusional flow, water intrusion, etc. The overview below describes each integrity test in detail and related to the Pharmsteri II GSV UPE vent capsule filter integrity test specifications.

### BUBBLE POINT

Bubble point (BP) test is defined as the minimum pressure to force liquid out from the largest pore of a hydrophilic or hydrophobic filters. The test is comprised of first wetting the filter out and subjecting the upstream side of the filter to gas pressure while measuring gas flow across the membrane. Moreover, when the membrane is wetted, liquid is held within the pores by surface tension and capillary forces. To overcome these forces, the applied gas pressure on the membrane gradually removes liquid within the pores at specific pressures. The bubble point is reached when the largest pore of the membrane has all the liquid remove removed and bulk gas flow is observed at its corresponding applied gas pressure. This minimum bubble point pressure is highlighted by the relationship in equation (1):

$$(1)\ BP = \frac{4 \bullet k \bullet y \bullet \cos\theta}{d}$$

where $k$ is a constant correction factor, $y$ is wetting fluid surface tension, $\theta$ is contact angle, and $d$ is the pore diameter.

### DIFFUSIONAL FLOW

Diffusional flow (DF) rate test is defined by measuring gas flow of a wetted membrane across at a defined differential gas pressure that is below the bubble point. During the DF test, gas molecules pass through filled pores of a wetted membrane and gas flow is measured over a stabilization period. Based on a filter's DF manufacturer specification, integrity of the filter can be determined by comparing the measured DF and filters max DF specification. The gas diffusional flow rate across different filter sizes is proportional to the effective filtration area of a given filter. The DF integrity test can be used to determine if the measured gas flow of filter exceeds the max diffusional flow for a given filter.

### WATER INTRUSION TEST

A water intrusion test (WIT) can be defined as the pressure required to permit water to pass through a hydrophobic membrane and is inversely proportional to a membrane's pore size. A WIT requires that water be introduced on the upstream side of the filter and pressure is gradually increased until the water intrusion specification, either in differential pressure or measure liquid flow rate, is reached to determine integrity of the filter. The WIT can be used a valid integrity test for vent filters when downstream manipulation or requisites of flushing in lower surface tension liquids e.g., IPA, etc. is not possible in a process.

## INTEGRITY TESTING – WETTING PROCEDURE

Entegris recommends proper filter wetting before performing a bubble point or diffusional flow test on Pharmsteri II GSV UPE vent capsule filters. For WIT, no pre-wetting is required to perform the integrity test. Adequate wetting and flushing will ensure a reliable BP or DF measurement to determine the filter integrity and avoid false failure readings. For a wetting fluid, Entegris recommends 60% isopropyl alcohol (IPA) be used prior to performing an integrity test. For any questions in relation to alternative wetting fluids, reach out to your appropriate Entegris representative for additional information.

Entegris recommends end-users to use either of the three wetting methods below to wet Pharmsteri II GSV UPE 0.22 µm capsule filters depending on system setup, wetting fluid availability, and filter size. Figure 3 shows a schematic example of each wetting method systems. A constant pressure or constant flow wetting method can be used for any filter size within Pharmsteri product family.  The manual wetting system is recommended for disc filters when other method is not able to be used for wetting. Entegris recommends proper wetting is done on any Pharmsteri filter to ensure accurate integrity results and to avoid false integrity failures. If a filter does not pass integrity after repeated testing, please reach out to your appropriate Entegris representative for additional technical and troubleshooting support.

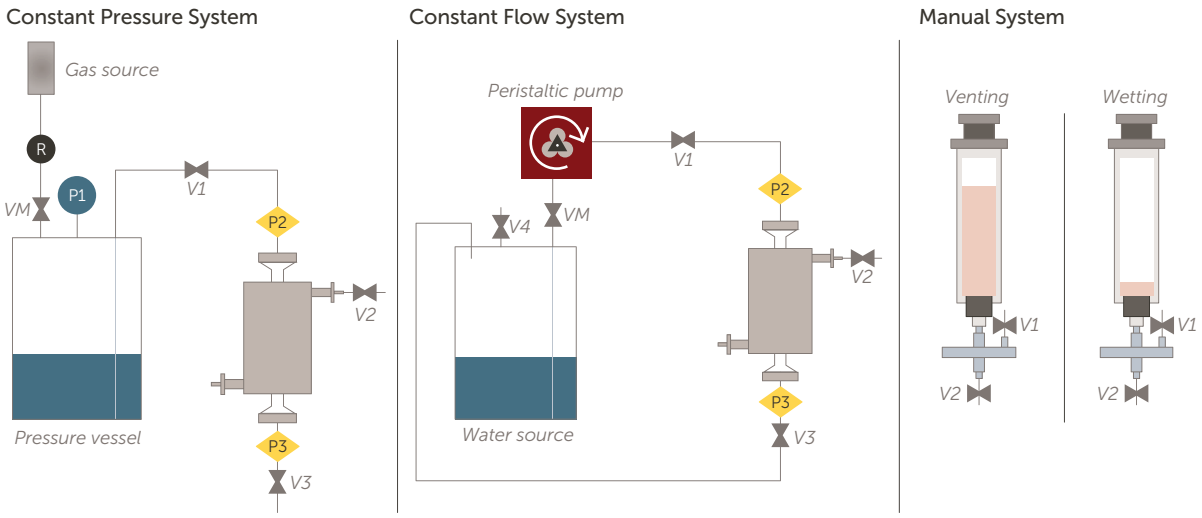
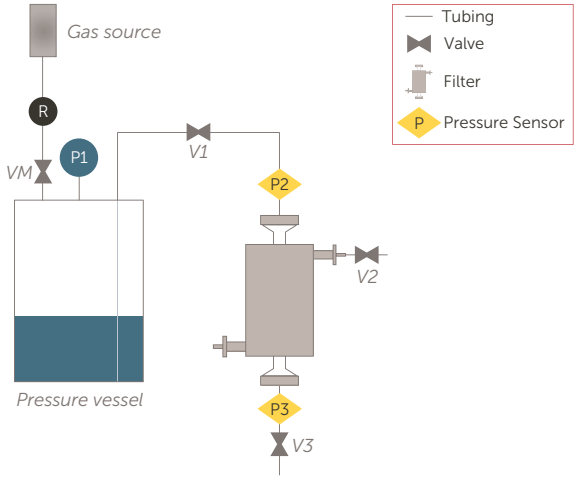



*Figure 3. Example schematic of wetting systems for Pharmsteri II capsule filters.*

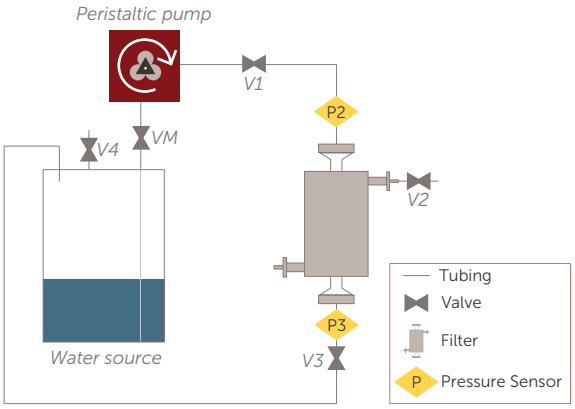
## WETTING METHODS




### Method 1: Constant Pressure

A pressure vessel rated for 60≥ psig with a volume capacity of 2 – 5 L is recommended for the following method of wetting method.

1. Ensure the system is setup in a similar format to the constant pressure system, shown in figure 4, and ensure all valves (VM, V1, V2, and V3) are closed prior to starting test.
2. Set and pressurize the system to at least 45 psig by open the main valve (VM). Ensure the pressure is set accordingly using pressure gauge (P1).
3. Partially open the inlet valve (V1) to fill the upstream side of the filter and ensure the pressure gauge (P2) does not exceed 1 psig.
4. Gradually open the filter vent port and valve (V2) to allow the filter to vent until a steady stream of fluid is observed coming out port.
5. Closed the vent port and valve (V2) once venting is completed.
6. Adjust the inlet valve (V1) to allow the pressure to be set to at least 5 psig by monitoring the pressure gauge (P2).
7. Gradually open the outlet valve (V3) and ensure the target flux rate of 50 LMH is maintain across the filter. The differential pressure (P2 – P3) across the filter should be ≤2 psid.
8. Flush the filter at the target wetting pressure for approximately 1 min.
9. Partially close the outlet valve (V3) to allow for backpressure during flushing for approximately 1 – 2 mins.
10. Fully open the outlet valve (V3), ensuring the target wetting flux rate of 50 LMH is met, and continue flush for an additional 2 mins.
11. Close the inlet valve (V1) and depressurize the pressure vessel using the regulator in system. Once the upstream system is depressurized, close the main valve (VM).
12. Open the inlet valve (V1) to allow the upstream side to drain into the pressure vessel and ensure the rest of system is depressurized.
13. Disconnect the filter from system and connect into filter integrity testing system. Ensure that the pressure gauges are not reading any pressure before disconnecting filter.




### Method 2: Constant Flow

A recirculation wetting system using a peristaltic pump that can set flow rates up to 0.5 LPM is recommended for this wetting method.

1. Ensure the system is setup in a similar format to the constant flow system, shown in figure 5, and ensure all valves (VM, V1, V2, V3, and V4) are closed prior to starting test.
2. Open the main valve (VM), the inlet valve (V1), and the vent valve (V2) before starting the pump.
3. Using the peristaltic pump, set the flux rate to 50 LMH to allow the filter's upstream side fill and remove air. The pressure gauge should be reading <1 psig during this venting process.
4. Once a steady stream of fluid is seen coming from the filter vent port, close the vent valve (V2).
5. Adjust the flow settings on the peristaltic pump and set the target flux rate to 50 LMH to flush and wet the filter.
6. Open the outlet valve (V3) and flush the filter for 1 minute. The differential pressure (P2 – P3) across the filter should be ≤2 psid.
7. Partially close the outlet valve (V3) to allow for backpressure during flushing for approximately 1 – 2 mins.
8. Fully open the outlet valve (V3) and continue flush for an additional 2 mins.
9. Stop the peristaltic pump and close the main and inlet valves.
10. Open water vessel vent port valve (V4) and vent valve (V2). Allow the system to depressurize and drain by ensuring the inlet (P1) and outlet pressure (P2) is at zero.
11. Close all open valves and disconnect the filter from wetting system.
12. Connect to integrity test system to perform filter integrity test.

## INTEGRITY TEST GUIDE

A BP, DF, or WIT can be performed on the Pharmsteri II GSV UPE vent capsule filters with appropriate wetting discussed in the previous section. For a BP or DF test, a 60% IPA-based pre-wet filter can be integrity tested as described in the corresponding sections below. Note that no pre-wetting is required for a WIT test but a purified water source e.g., DI, etc. is required to perform the test. All test methods assume the use of an automatic integrity tester or a custom system that allows for integrity testing of filters. Pharmsteri II GSV UPE vent capsule filters integrity test specifications can be found in datasheet or validation guide for each filter size. For any questions in relation to alternative wetting fluids, please contact Entegris Life Sciences Customer Service for help if needed.

### BUBBLE POINT

1. Ensure the filter has been wetted using one of wetting methods in previous section before connecting the filter to integrity test system.
2. Connect the filter into integrity test system using an automated integrity tester. Ensure the system uses a regulated air or nitrogen gas source that has the capacity to reach at least 70 psig.
3. Input the integrity test parameters into automated integrity tester. For the minimum bubble point test specification, refer to Pharmsteri II GSV UPE vent datasheet or validation guide.
4. A filter can be considered integral if the measured bubble point above the minimum bubble point specification of the Pharmsteri II GSV UPE vent capsule filter.
5. Once the test is completed, depressurize the integrity test system and disconnect the filter from the system.
6. If the filter fails the integrity test, refer to trouble-shooting schematic repeat the integrity test. If the filter does not pass integrity test after repeated tests, please contact your Entegris representative for additional support.

### DIFFUSIONAL FLOW TEST

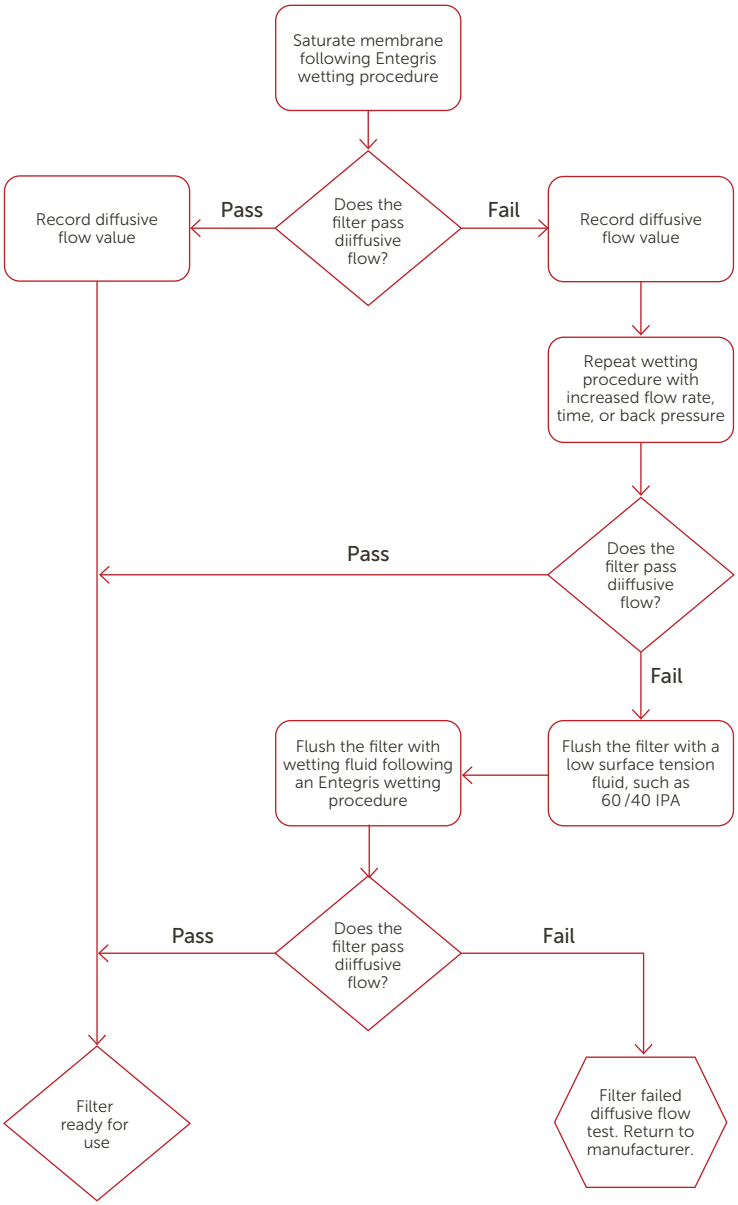
1. Ensure the filter has been wetted using one of wetting methods in previous section before connecting the filter to integrity test system.
2. Connect the filter into integrity test system using an automated integrity tester. Ensure the system uses a regulated air or nitrogen gas source that has the capacity to reach at least 70 psig.
3. Input the integrity test parameters into automated integrity tester. The test pressure is at 40 psig and for the max diffusional flow, refer to Pharmsteri II GSV UPE vent datasheet or validation guide.
4. A filter can be considered integral if the measured diffusional flow is below the max diffusional flow specification of the given filter size.
5. Once the test is completed, depressurize the integrity test system and disconnect the filter from the system.
6. If the filter fails the integrity test, refer to trouble-shooting schematic repeat the integrity test. If the filter does not pass integrity test after repeated tests, please contact your Entegris representative for additional support.

## WATER INTRUSION TEST:

1. Ensure the filter has water filled on the upstream side of the capsule prior to starting the integrity test. This can be achieved using a pump or manually pouring into the filter until water has filled up to the fitting.
2. Connect the filter into integrity test system using an automated integrity tester. Ensure the system uses a regulated air or nitrogen gas source that has the capacity to reach at least 70 psig.
3. Input the integrity test parameters into automated integrity tester. For the max water intrusion pressure, refer to Pharmsteri II GSV UPE vent datasheet or validation guide.
4. A filter can be considered integral if the measured if no differential pressure is observed at max water intrusion pressure specification of the Pharmsteri II GSV UPE vent capsule filter.
5. Once the test is completed, depressurize the integrity test system and disconnect the filter from the system.
6. If the filter fails the integrity test, refer to trouble-shooting schematic repeat the integrity test. If the filter does not pass integrity test after repeated tests, please contact your Entegris representative for additional support.

## 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.

For pre-sterilized filters via gamma sterilization, a visual inspection to ensure the gamma indicator change from orange to red and the integrity of packaging bag is needed to ensure the filter is sterile.

## 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. Ensure the filter has been flushed and decontaminated accordingly if filter has been used with 60% IPA. Note that IPA is flammable and exposed filters should be decontaminated accordingly. Please check with local EHA for further instructions.
5. Adhere to local regulations

## 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.

## 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:

Hangzhou Anow Filtration and Materials Co., Ltd.
No. 22, Qing Quan Road, Xindeng New Area, Zindeng
Fuyang District, Hangzhou 311404 P.R. China
EPA Est. No.: 97725-CHN-002

## 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.

### LIMITED WARRANTY

Entegris' products are subject to the Entegris, Inc. General Limited Warranty. To view and print this information, visit entegris.com and select the Legal & Trademark Notices link in the footer. Entegris does not warrant any failure in the case of customers using unapproved foreign components.

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Entegris

Corporate Headquarters
129 Concord Road
Billerica, MA 01821
USA

Customer Service
Tel +1 952 556 4181
Fax +1 952 556 8022
Toll Free 800 394 4083