Life Sciences

Instructions For Use

USD3140

Pall® Microdisc Filter Capsules with Pegasus™ Prime Virus Removal Filter Membrane

*Filtration. Separation. Solution.*SM

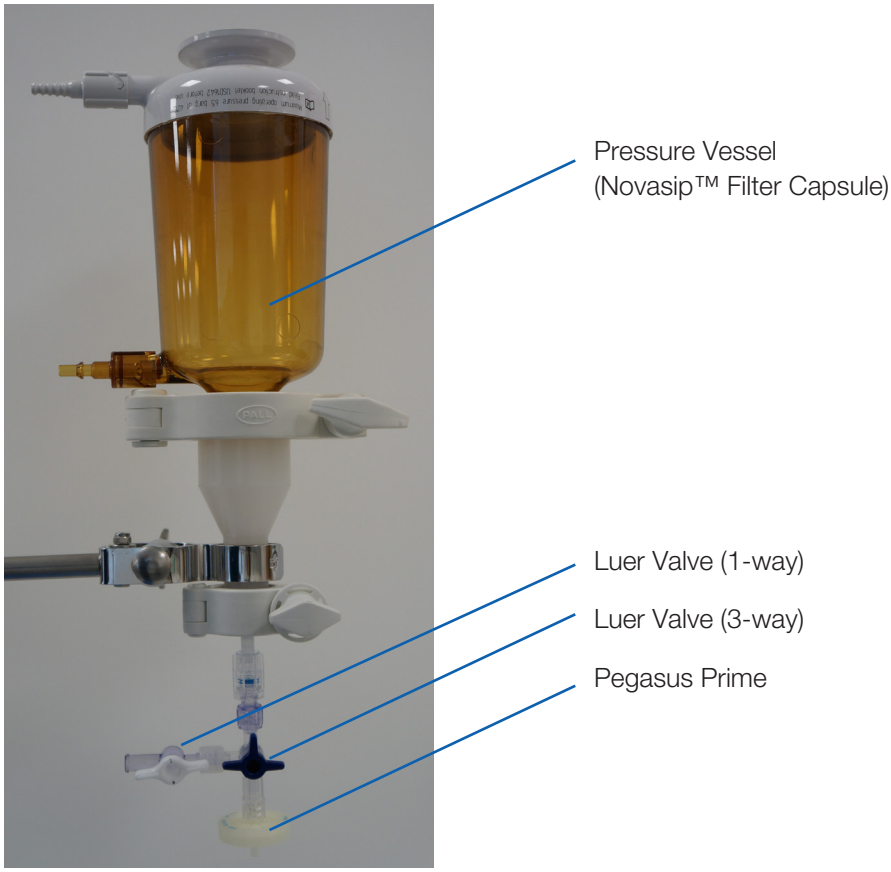
1. Introduction

The following guide details procedures for the assembly and testing of Pall Microdisc Filter Capsules with Pegasus Prime virus removal filter membrane (part number 3MCFPRM4 (Pack of 4) and 3MCFPRM12 (Pack of 12 (3 lots)).

2. Filterability Test System

Any filtration system capable of supplying a constant pressure or appropriate constant flow to the Microdisc Filter Capsule can be used. The system must be rated to at least the maximum pressure to be applied during the test.

Figure 1
Typical Filterability and Challenge Test System



3. Assembly

1. Assemble your filterability test system (e.g. Figure 1).
2. Pall recommends using a 3-way Luer Lock valve and 1-way Luer Lock valve upstream of the Microdisc Filter Capsule (see Figure 1).

• Note: a 1-way valve may be used on its own, but this gives reduced safety and control.

3. Ensure that the Microdisc Filter Capsule is isolated. In the assembly shown in figure 1 this is achieved by turning the 3-way Luer Lock with ‘off’ pointing towards the capsule.
4. Fill the system with sufficient water to complete the test without air entering the Microdisc Filter Capsule (at least 60 mL)
5. Purge the air from the system lines and valves through the 1-way valve.

4. Pre-Challenge Installation Test

1. Ensure the 1-way Luer valve is in the ‘off’ position.
2. Adjust the pressure to the value specified in Table 1: Pre-Challenge Installation Test Parameters.
3. Open the 3-way Luer valve upstream of the Microdisc Filter Capsule by turning the ‘off’ position towards the 1-way valve.
4. Once the flow is steady, collect the filtrate using a graduated cylinder or balance for the time specified in Table 1: Pre-Challenge Installation Test Parameters.
5. Calculate and record the flow rate.
6. Normalize the water flow rate to an equivalent value at 20 °C. The following equation should be used in conjunction with the temperature correction factor (TCF) at the test temperature (T °C) from Table 2.

   Water Flow Rate 20 °C = Water Flow Rate T °C x TCFT °C
7. If the normalized water flow rate of the Microdisc Filter Capsule does not meet the water flow rate in Table 1 check all parameters and repeat the test. If the water flow is still outside the range shown in Table 1 please contact your local Pall representative.

Warning:
Do not allow air to enter the upstream of the capsule as this will risk an air-lock in the capsule. If air enters the Microdisc Filter Capsule then purge the system of air and ensure the Luer valves are completely full of water before reconnecting the capsule and repeating the installation test. Only use the Microdisc Filter Capsule if it meets the installation test parameter range and matches the original water flow measured. A reduction in water flow is indicative of an irreversible air-lock.

Table 1
Pre-Challenge Installation Test Parameters

Pressure	Water Flow Collection Time	Water Flow Rate at 20°C
2.1 bar (30 psi)	≥ 10 minutes	1.4 - 2.6 mL/min

These data are solely valid for Microdisc Filter Capsules with Pegasus Prime virus removal filter membrane, which are supplied by Pall for filterability trials, virus validation studies and for general studies requiring down-scaling.

Table 2
Temperature Correction Factors (TCF) for Normalizing Water Flow Rates to 20°C

T °C	$TCF_{T°C}$	T °C	$TCF_{T°C}$	T °C	$TCF_{T°C}$	T °C	$TCF_{T°C}$
		11	1.27	21	0.98	31	0.78
		12	1.24	22	0.95	32	0.76
		13	1.20	23	0.93	33	0.75
4	1.57	14	1.17	24	0.91	34	0.73
5	1.52	15	1.14	25	0.89	35	0.72
6	1.47	16	1.11	26	0.87	36	0.70
7	1.43	17	1.08	27	0.85	37	0.69
8	1.39	18	1.05	28	0.83	38	0.68
9	1.35	19	1.03	29	0.81	39	0.66
10	1.31	20	1.00	30	0.80	40	0.65

5. Filterability Test Procedure

1. Depressurise the filterability test system.
2. Isolate the Microdisc Filter Capsule is by turning the 3-way Luer valve ‘off’ towards the capsule.
3. Remove any residual water from the system by opening the 1-way Luer valve. Close the 1-way Luer valve when complete
4. Fill the feed reservoir with buffer or challenge solution as required.
5. Purge the air from the tubing, through the 1-way Luer valve.
6. Close the 1-way Luer valve.
7. Apply the desired challenge pressure and then open the 3-way Luer valve upstream of the Microdisc Filter Capsule by turning the ‘off’ position to towards the 1-way valve.
   - Note: If using a pump, ensure the valve is opened before starting the pump.
8. Record the time, pressure, temperature and throughput as required.
9. Run the challenge until the desired endpoint based on volume, time or flux decay.

6. Virus Challenge Test Procedure

1. Contact your local Pall representative for additional assistance with virus validation design.
2. Repeat the steps as per the Filterability Test Procedure (Section 5).
3. Effluent should be collected in individual sterile containers to the appropriate aliquot volume.

7. Post-Challenge Installation Test

1. The post-challenge installation test is recommended for all virus challenge studies and is optional for all other studies.
2. Connect the challenged capsule directly to the pressure source and increase the pressure to 3.1 bar (45 psi).
3. Allow the system to stabilise for about 5 minutes or until no liquid comes out of the filter. The upstream of the capsule should now be drained of all liquid.
4. Connect a clean piece of tubing to the capsule outlet and hold the open end of the tubing under water for 60 seconds. Check for any bubbles emerging from the tubing. The absence of bubbles indicates an integral system.

NOTE: One or two isolated bubbles in 60 seconds may be a false signal due to trapped air or residual flow. You may repeat step 7.3 before retesting to confirm the bubble signal.

8. Specifications

8.1 Viral (Bacteriophage) Retention

> 4 log TR based on challenge with parvovirus model bacteriophage (bacterial virus) PP7.

8.2 Packaging

Box containing 4 filter capsules or box containing 12 filter capsules (3 different lots x 4 filter capsules).

8.3 USP Bacterial Endotoxins

Pall Microdisc Filter Capsules have met the current USP requirements under Section <85> Bacterial Endotoxins Test as determined using the Limulus Amebocyte Lysate (LAL) reagent with an aliquot from a soak solution.

8.4 Materials

Pall Microdisc Filter Capsule fluid contact components have met the specifications under Section <88> Biological Reactivity Tests, *in vivo*, listed in the current revision of the United States Pharmacopeia (USP) for Class VI plastics at 121 °C.

Table 3

Materials of construction

Materials of Construction	
Membrane	Hydrophilic polyethersulfone (PES)
Support disc	Polypropylene
Capsule Inlet and Outlet	Polypropylene
Connection	Luer Lock
Filter Area	2.8 cm^2 (0.43 $in.^2$)
Wetting / Installation Test	Refer to Section 4: Pre-Challenge Installation Test

Pressure Rating
Maximum operating pressure 3.1 bar.g (45.0 psi.g) at 40 °C for 6 h
Maximum differential pressure 3.1 bar.d (45.0 psi.d) at 25 °C for 12 h

Technical Addendum for ATEX 94/9/EC Pall Encapsulated Filter Assemblies

Installation and maintenance should be undertaken by a competent person. National and local codes of practice, environmental regulations and Health and Safety directives must be adhered to and take precedence over any stated or implied practices within this document.

For fluids having low conductivity, there exists the possibility of the generation of static electricity during use with polymeric components. This could potentially lead to a static electricity discharge resulting in the ignition of a potentially explosive atmosphere where such an atmosphere is present. These Pall products are not suitable for use with such low conductivity fluids in an environment that includes flammable liquids or a potentially explosive atmosphere.

Where flammable or reactive fluids are being processed through a Pall capsule assembly, the user should ensure that spillages during filling, venting, depressurizing, draining and capsule change operations are minimized, contained or directed to a safe area. In particular, the user should ensure that flammable fluids are not exposed to surfaces at a temperature that may ignite the fluid, and that reactive fluids cannot contact incompatible materials that may lead to reactions generating heat, flame or that are otherwise undesirable.

Pall capsule assemblies do not generate heat, but during the processing of high temperature fluids, including steam sterilization operations and process upset conditions, it will take on the temperature of the fluid being processed. The user should ensure that this temperature is acceptable for the area in which the filter is to be operated, or that suitable protective measures are employed.

When processing flammable fluids, the user should ensure that any air is fully purged from within the assembly during filling and subsequent operation to prevent the formation of a potentially flammable or explosive vapor/air mixture inside the equipment.

This can be achieved through careful venting of the assembly or system as detailed in the user instructions.

To prevent damage or degradation which may result in leakage of fluids from this equipment it is imperative that the end user check the suitability of all materials of construction (including seals on the connections where appropriate) with the process fluid and conditions. The user should ensure that the assembly is regularly inspected for damage and leaks, which should be promptly corrected, and that seals (where appropriate) are renewed after every capsule change.

Leakage of flammable or reactive fluids from this assembly, arising through incorrect installation or damage to the equipment (including any seals), may generate a source of ignition if flammable fluids are exposed to a heated surface, or if reactive fluids contact incompatible materials that may lead to reactions generating heat, flame or that are otherwise undesirable. The user should ensure that the assembly is regularly inspected for damage and leaks, which should be promptly corrected, and that any seals are renewed after every filter change. The user should ensure that these products are protected from foreseeable mechanical damage that might cause such leakage, including impact and abrasion.

Should you have any questions, please contact your local Pall office or distributor.

PALL Life Sciences

Corporate Headquarters
Port Washington, NY, USA
+1.800.717.7255 toll free (USA)
+1.516.484.5400 phone
biopharm@pall.com e-mail

European Headquarters
Fribourg, Switzerland
+41 (0)26 350 53 00 phone
LifeSciences.EU@pall.com e-mail

Asia-Pacific Headquarters
Singapore
+65 6389 6500 phone
sgcustomerservice@pall.com e-mail

Visit us on the Web at www.pall.com/biopharm

E-mail us at biopharm@pall.com

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