Pall® Minidisc filter capsules with Pegasus™ SV4 virus removal filter membrane

Instructions for Use

1 Introduction

The following Instructions for Use details procedures for the assembly and testing of Pall® Minidisc filter capsules with Pegasus™ SV4 virus removal filter membrane (part number 10MCFSV4).

2 Parts required

- Source that can supply air up to a pressure of 3.1 bar (45.0 psi).
- Pressure gauges.
- Male and female Luer-Lok to tubing adaptors capable of withstanding 3.1 bar (45.0 psi) or the required test pressure.
- A 3-way Luer-Lok valve (2 x female Luer-Lok, 1 x male Luer-Lok).
- Graduated cylinder or collection vessel.
- Balance (optional).
- Appropriate tubing capable of withstanding 3.1 bar (45.0 psi) or the required test pressure.
- Capsule to be tested.
- Pressure vessel capable of operating at 3.1 bar (45.0 psi).

Pressure vessels	Part number
Novasip™ vessel[1]	C3EP1
Sealkleen™ vessel	ZLK702G23LHKH4

[1] See *Fig. 3.1, on page 4*

Pressure vessel accessories	Part number
Adapter 1 in. TC/male Stäubli connector	GFX0290 (two recommended for inlet and outlet)
TC clamp + silicone gasket (two each per part number)	SLK1TC23H4
Female Stäubli fitting for inlet pressure tubing (6 mm O.D.)	GFX0236

3 Assembly

Step	Action
1	Attach pipework with the male Luer-Lok to the downstream side of the pressure vessel.
2	Connect the inlet of the capsule to the 3-way Luer-Lok valve.
3	Connect the valve to the pressure vessel via the male Luer-Lok.
4	Make sure that the unconnected female Luer port is shut off by the valve.
5	Insert and hold the capsule so that the outlet of the filter points upward (see *Fig. 4.1, on page 5*).

Step	Action
6	Fill the pressure vessel with clean de-ionized (DI) water to at least the minimum fill volume specified in *Table 4.1, on page 5*.

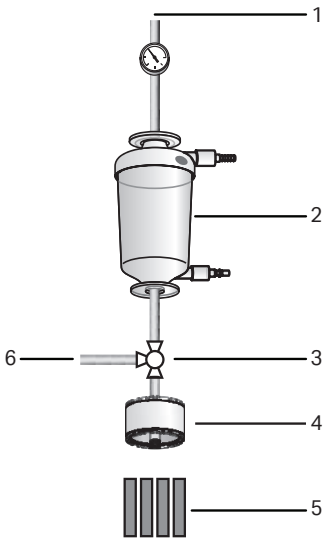


Figure 3.1: Filterability and challenge test setup

Part	Description
1	Pressure source
2	Pressure vessel (Novasip)
3	3-way Luer-Lok valve
4	Minidisc filter capsules
5	Filtrate samples
6	Temporary waste line tubing

4 Pre-challenge wetting

Step	Action
1	Make sure that the capsule remains inverted as shown in the image below.



Figure 4.1: Recommended wetting procedure

2 Adjust the air pressure to the pressure vessel containing water to the approximate wetting pressure specified in the table below.

Table 4.1: Pre-challenge wetting parameters

Parameter	Specification
Capsule	10MCFSV4
Minimum fill volume of water	40 mL
Approximate wetting pressure	2.1 bar (30 psi)
Typical wetting time	< 2 minutes

3 Admit DI water (or similar grade) into the inlet of the capsule until water begins to come out of the outlet.

Note:
Do this slowly to make sure that there is no air trapped upstream of the filter membrane.

Result:
Once water starts to come through the outlet, wetting is complete.

Step	Action
4	Return the capsule to its original position with the outlet facing down as shown in the image below.



Figure 4.2: Capsule in original position

5 Pre-challenge installation test

Step	Action
1	Adjust the water pressure to the value specified in the table below.

Table 5.1: Pre-challenge installation test parameters

Parameter	Specification
Capsule	10MCFSV4
Pressure	2.1 bar (30 psi)
Water flow collection time	≥ 10 minutes
Water flow rate mL/min at 20°C	0.48 to 0.7

Note:
This data is solely valid for Minidisc capsules with virus removal filter membrane, which are supplied by Cytiva for filterability trials and virus validation studies respectively, for the purpose of down-scaling.

2 Once the flow is steady, collect the filtrate using a graduated cylinder or balance for the water flow collection time specified in the table above.

Step	Action
3	Calculate and record the flow rate. Due to variation in the viscosity of water at different temperatures, it is recommended that all water flow rates are normalized to an equivalent value at 20°C. The following equation must be used in conjunction with the temperature correction factor (TCF) at the test temperature (T°C) shown in the following table. Water flow rate$_{20°C}$ = Water flow rate$_{T°C}$ × TCF$_{T°C}$

Table 5.2: 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 $_{T°C}$
4	1.57	11	1.27	21	0.98	31	0.78
5	1.52	12	1.24	22	0.95	32	0.76
6	1.47	13	1.20	23	0.93	33	0.75
7	1.43	14	1.17	24	0.91	34	0.73
8	1.39	15	1.14	25	0.89	35	0.72
9	1.35	16	1.11	26	0.87	36	0.70
10	1.31	17	1.08	27	0.85	37	0.69
		18	1.05	28	0.83	38	0.68
		19	1.03	29	0.81	39	0.66
		20	1.00	30	0.80	40	0.65

4	If the normalized water flow rate of the capsule does not meet the water flow rate, check all parameters and repeat the test. If the water flow is still outside the range, contact your local Cytiva representative.
5	Raise the water pressure to 3.1 bar (45.0 psi) and check for leaks. If any leaks are evident: **a.** Tighten the tubing connections. **b.** If the leak persists, replace the tubing and check for any gross leaks.

Step	Action
	c. If this does not resolve the problem, record any leaks and use another filter sample.



NOTICE
Do not allow air to enter the upstream of the capsule.

6 Filterability and viral challenge test procedure

Step	Action
1	Once the pre-challenge wetting procedure has been completed (*Pre-challenge wetting, on page 5*), remove the remaining water from the reservoir and from the tubing upstream of the capsule.



NOTICE
Do not allow air to enter the upstream of the capsule.

a. Connect a piece of tubing with a male Luer-Lok connector to the free valve port to give a waste line.

b. Place the free end of the waste line in an appropriate collection vessel.

c. Turn off the valve port to the capsule inlet, opening up flow from the pressure vessel to the waste line.

d. Adjust the pressure in the pressure vessel to approximately 0.2 bar (3 psi) and drain all the water from the pressure vessel and tubing.

e. Depressurize the system.

f. Turn off the valve port to the waste line.

2 Fill the pressure vessel with the test fluid.

3 Bleed the remaining air from the tubing.

a. Turn off the valve port to the capsule inlet.

b. Once the air is bled from the tubing and test fluid starts to exit the waste line, turn off the valve port to the waste line.

c. Disconnect the waste line, taking care not to spill residual fluid in the tube.

4 Adjust the pressure in the pressure vessel containing the test fluid to 2.1 bar (30.0 psi) or to another operating pressure (maximum 3.1 bar (45.0 psi)) and run the challenge until the desired volume is collected.

5 Effluent can be collected in 20 mL aliquots or in another convenient volume.

6 Record the time, pressure, temperature and throughput as required.

7 Post-challenge installation test

Step	Action
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 air source and increase the pressure to 3.1 bar (45.0 psi).
3	Hold the system as recommended for about 5 minutes or until no liquid comes out of the filter. *Result:* The upstream of the capsule is now drained of all the liquid.
4	Hold the open end of the outlet tubing under water, with the capsule outlet pointing up, for about 30 seconds and check for any bubbles emerging from the tubing. The absence of bubbles indicates an integral system. Only a continuous stream of bubbles is significant. One or two isolated bubbles in 30 seconds can be a false signal due to trapped air in the lines.

8 Scaling calculation

Parameter	Specification
Capsule	10MCFSV4
47 mm disc (used with FTK200) Effective filter area (m^2)	1.11×10^{-3}
Minidisc filter capsules Effective filter area (m^2)	9.6×10^{-4}
10 inch cartridges Effective filter area (m^2)	2.25

9 Specifications

9.1 Viral (bacteriophage) retention

Refer to the Validation Guide for the corresponding virus removal filter grade.

9.2 Packaging

Box containing 3 filter capsules. All included.

9.3 USP bacterial endotoxins

Minidisc 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.

9.4 Materials

Minidisc virus filter fluid path 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.

Materials of construction

Parameter	Specification
Membrane	Virus-retentive membrane (refer to capsule label for filter membrane grade)
Support disc	Polypropylene (non-woven)
O-ring	EPDM
Capsule inlet and outlet	Polycarbonate
Connection	Luer-Lok
Filter area	9.6 cm^2 (1.49 $inch^2$)
Wetting	Refer to *Pre-challenge wetting, on page 5*
Installation test	Refer to *Pre-challenge wetting, on page 5* and *Post-challenge installation test, on page 11*

Pressure rating

Pressure level[1]	Specification
Maximum operating pressure	3.1 barg (45.0 psig) at 25°C

Pressure level[1]	Specification
Maximum differential pressure	3.1 bard (45.0 psid) at 25°C

[1] Temporary pressures up to 3.4 barg (50 psig) are acceptable, but the target operating and differential pressures must not exceed 3.1 bar (45 psi) to allow for pressure fluctuations during testing.

9.5 Additional safety considerations

Installation and maintenance must be undertaken by a competent person. National and local codes of practice, environmental regulations and Health & 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 all- 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 Cytiva 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 Cytiva capsule assembly, the user must make sure that spillages during filling, venting, depressurizing, draining and capsule change operations are minimized, contained, or directed to a safe area. In particular, the user must make sure that flammable fluids are not exposed to surfaces at a temperature that can ignite the fluid, and that reactive fluids cannot contact incompatible materials that may lead to reactions generating heat, flame or that are otherwise undesirable.

Cytiva 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 must make sure 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 must make sure 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 must make sure that the assembly is regularly inspected for damage and leaks, which must 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), can generate a source of ignition if flammable fluids are exposed to a heated surface, or if reactive fluids contact incompatible materials that can lead to reactions generating heat, flame or that are other- wise undesirable. The user must make sure that the assembly is regularly inspected for damage and leaks, which must be promptly corrected, and that any seals are renewed after every filter change.

The user must make sure that these products are protected from foreseeable mechanical damage that might cause such leakage, including impact and abrasion.

Regular cleaning with an anti-static material is required to avoid the build-up of dust on the filter assembly. Should you have any queries, contact your local Cytiva office or distributor.

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