



Life Sciences

Instructions For Use

USD3139

Mini Kleenpak™ Capsule Filterability Tool with Pegasus™ Prime Virus Removal Filter Membrane

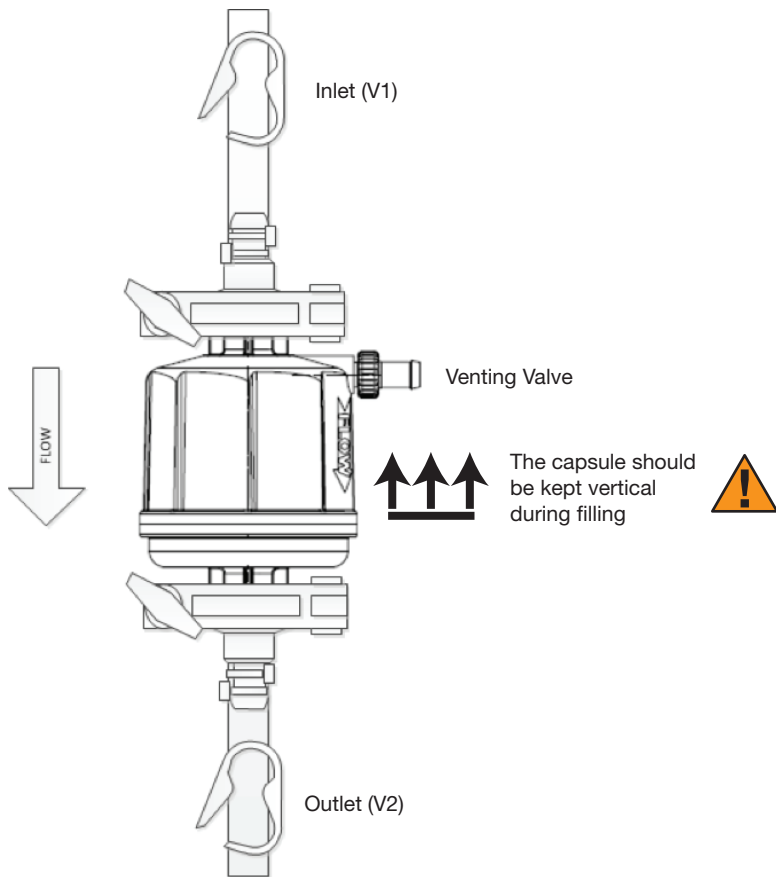


Mini Kleenpak Capsule Filterability Tools are for filter-sizing studies and evaluation during process development only. They are not qualified for virus removal.

Pall Corporation provides filters for use during drug manufacture or for animal, human therapeutic or diagnostic needs. Please contact Pall for details of these filters where needed as Mini Kleenpak Capsule Filterability Tools are not intended for these purposes.

Figure 1

Mini Kleenpak Capsule Filterability Tool



Operating Parameters

Maximum Operating Pressure	3.1 barg (45 psig)
Recommended Operating Pressure	2.1 – 3.1 barg (30 – 45 psid)
Operating Temperature Range	2 °C to 38 °C

Please refer to the product datasheet (Pall publication USD3142) or technical specifications for materials of construction and effective filtration area.

It is recommended that the Mini Kleenpak Capsule Filterability Tool is used under expected production conditions.

Pall’s Scientific and Laboratory Services (SLS) Global Technical Support team can assist with filtration tests either at customer sites or in our own facilities.

**Attention:**

- Please observe the operating parameters and guidelines for use
- Use the Mini Kleenpak Capsule Filterability Tool exclusively for liquids
- Assess the compatibility of your fluid with the Mini Kleenpak Capsule Filterability Tool
- Keep the Mini Kleenpak Capsule Filterability Tool in an upright, vertical position during filling steps (see Figure 1).
- Make sure that no system pressure prevails during connection or disconnection of the Mini Kleenpak Capsule Filterability Tool

Operation and Guidelines for Use (Refer to Figure 1)

1. Prepare the Mini Kleenpak Capsule Filterability Tool, connecting to ancillary tubing.

NOTE: The Mini Kleenpak is provided gamma irradiated in line with the production scale Pegasus Prime capsules and cartridges for optimal scalability. Where beneficial, aseptic connection to sterile tubing will minimize contamination risk.

2. Connect upstream tubing to an appropriate pump or pressure source, depending on anticipated operating conditions at process scale
3. Close the valves V1 and V2 (see Figure 1)
4. Open the venting valve
5. Slowly open valve V1 and fill the Mini Kleenpak Capsule Filterability Tool with fluid until fluid escapes at the venting valve
 - First contact fluid should be 0.2 µm filtered DI water (or finer grade)
 - Fill rate should be up to 80 mL / min
 - If using a pump, stop the pump before closing the vent valve to avoid over-pressurization
6. Close the venting valve
7. Now open valve V2 and increase the pressure or adjust the flow rate to reach a differential pressure of 2.1 bard (30 psid)
8. Run initial water flush for 5 minutes
9. Measure the water flow rate
10. Stop the pump/depressurize the system
11. Drain excess liquid through the vent valve (invert the capsule)
12. Repeat the slow fill procedure above (steps 3-6) for subsequent fluids (buffer, product)
13. Open valve V2, adjusting to the required flow rate or operating pressure as guided by small scale disc studies and/or production scale system specifications
14. Process for the required throughput and time, recording the flow rate
15. Safely stop the test (repeat steps 10-11)
16. Following use, rinse if necessary and dispose of in accordance with local regulations

Consult Pall for more detailed guidance on filter sizing under conditions of constant flow or constant pressure.

**Important note:**

All information contained is based on today's knowledge. It does not claim to be complete, therefore no liability can be accepted. All users are advised to test Pall products to ensure they meet their specific requirements and to exercise all necessary care when in use.

The information in the instruction manuals issued by Pall should be strictly observed. Departure any specific instructions means Pall cannot accept any responsibility for damage which may result. Should you encounter specific problems, please contact our specialists. Pall reserves the right to make alterations without prior notice.



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