Module Preparation and Instructions: Spectrum[®] Hollow Fiber Filters

Module Preparation Flushing and Wetting Protocols by Membrane Type

Modified Polyethersulfone (mPES), UF (3 kD - 750 kD MWCO)

Ultrafiltration modules are made with hydrophilic modified PES membrane contains glycerin to preserve the pore structure. Glycerin is water soluble and readily rinses out.

- Rinse out glycerin with deionized water (DI) water or buffer until a permeate volume of 2 ml/cm² of surface area is reached.
- 2. Drain module and perform module integrity test.

Modified Polyethersulfone (mPES), MF (0.65 µm)

Microfiltration modules are made with hydrophilic mPES membrane.

- Wet out the module with DI water or buffer until a filtrate volume of 2 ml/cm² of surface area is reached.
- 2. Drain module and perform module integrity test.

Polysulfone (PS), Dry

To achieve maximum flux capacity, hydrophobic membranes with a molecular weight cut off (MWCO) of 50 kD or smaller must be completely pre-wetted with alcohol. Dry polysulfone membranes with a MWCO of 500 kD and larger do not require prewetting with alcohol. However, Repligen strongly recommends integrity testing prior to use (skip to Gross leak integrity test).

- Flush the module with 10 20% isopropanol or ethanol for 15 minutes. To conserve alcohol, the permeate can be directed into the retentate reservoir, or the module can be filled with alcohol for 2 hours to thoroughly wet out the pores.
- 2. Drain alcohol from the retentate and filtrate sides of the module and flow path.

- 3. Rinse out remaining alcohol with DI water or buffer until a permeate volume of 2 ml/cm² of surface area is reached.
- 4. Drain water from module and perform integrity test.

Polysulfone (PS), Wet

Hydrophobic polysulfone modules are available pre-wetted for your convenience. The pre-wetted ultrafiltration modules are packaged in DI water containing 1% hydrogen peroxide.

- 1. Drain preservative solution from retentate and permeate sides of module.
- 2. Rinse out remaining solution with DI water or buffer until a permeate volume of 2 ml/cm² of surface area is reached.
- 3. Drain module and perform module integrity test.

Mixed Cellulose Ester (ME)

Microfiltration modules are made with hydrophilic mixed cellulose ester (ME) membrane contains glycerin as a humectant to preserve the membrane durability. Glycerin is water soluble and readily rinses out. Follow the same procedure as the mPES, UF modules.

Polyethersulfone (PES)

Polyethersulfone (PES) Microfiltration modules are made with hydrophilic PES and are provided dry and without preservative. PES modules are ready for use out of the package after integrity testing. Follow the same procedure as the mPES, MF modules.

Gross Leak Integrity Test

All hollow fiber modules are integrity tested prior to shipment. However, Repligen strongly recommends an integrity test be performed prior to use. The following pressure hold test is recommended to verify the integrity of a wetted module. PS modules require alcohol as a wetting agent (see <u>Module</u> <u>preparation</u>):

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- 1. Fully wet the module as described above and ensure that ECS is flooded. Close bottom permeate port, then direct upper permeate line to drain.
- 2. Apply backpressure using Automatic Backpressure Valve or manual backpressure slider on the retentate line to increase the module's TMP. Do not exceed 30 psi TMP at any time.
- 3. Stop the pump and remove feed from DI water source.
- 4. Start the pump to introduce air into module while continuing to monitor the TMP.
- 5. Wait. If after a few minutes bubbles do not appear in the ECS, then module is integral.

Optional: With integrity test equipment, a hollow fiber module may be forward flow diffusion tested. To do so, use the integrity tester to pressurize the retentate port to 20 psi for UF membranes, or 10 psi for MF membranes. After the pressure is reached, the diffusion flow rate can be measured with the integrity tester corrected to room temperature. If the forward flow diffusion reads \leq 2 SCCM / 0.1m² area, then the module is integral. If higher, re-wet module and repeat.

Module Sterilization and Sanitization

Note: UF mPES modules are not steam autoclavable. If application requires sterilized UF mPES module, please purchase a sterile module.

Steam Autoclaving (MF mPES, PS, PES and ME)

- 1. Remove and discard all pouches, as these are not autoclavable; wet the membrane (optional).
- 2. Loosen all module connections to avoid damaging the module during the autoclave cycle.
- 3. Wrap all open ports of the connecting tubing with autoclave paper.
- 4. Pre-warm the module to 102° C at 10 psi for 10 minutes.
- 5. Ramp up the autoclave by increasing pressure approximately 1.5 psi/min for 30 minutes to 121° C.
- 6. Hold the autoclave at 121° C for 50 min, not to exceed124.1° C.
- 7. Slowly ramp down the temperature of the autoclave by exhaust pressure release of approximately 0.75 1 psi/min to 104°C.
- 8. Hold the autoclave at 104° C for at least 20 minutes.
- 9. Bring the module to room temperature.
- 10. Tighten all module connections.
- 11. Perform a module integrity test.

Chemical Compatibility

Visit the Repligen website for Chemical Compatibility Chart: www.repligen.com/resources/knowledge-base/references/chemical-compatibility.

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