

# Hollow fiber cartridge preparation instructions for 1,000 and 3,000 NMWC membrane filters

## Instructions

All Cytiva hollow fiber (HF) cartridge materials conform to USP XXVII Class VI Biological Test for Plastics requirements. Ultrafiltration (UF) membrane cartridges are treated with a glycerol solution which must be rinsed from the cartridge prior to use. A detailed *Operating Handbook*, *Integrity Test Procedure Handbook*, *Steam Sterilization Handbook*, and *Validation Information Booklet* are available to assist clients with validation and continual quality assurance of Cytiva hollow fiber cartridges. Follow the procedures outlined below to prepare new cartridges for use. More detailed information is provided in the documentation listed above.

### New cartridge rinsing procedure for 1,000 and 3,000 nominal molecular weight cutoff (NMWC) membrane filters

The new cartridge rinsing procedure for 1,000 and 3,000 NMWC membrane filters should be performed on all 1,000 and 3,000 NMWC membrane filters.

| Step | Action                                                                                                                                                                                                                                                                                                          |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1    | Install the cartridge and connect to system.                                                                                                                                                                                                                                                                    |
| 2    | Connect the retentate and the permeate lines to a feed reservoir containing 100% ethanol (EtOH).                                                                                                                                                                                                                |
| 3    | Start the pump on slow and adjust transmembrane pressure (TMP) to 0.34 barg (5 psig). Recirculate the ethanol for 10 minutes.                                                                                                                                                                                   |
| 4    | Turn off the pump and allow the cartridge to soak for 30 minutes.                                                                                                                                                                                                                                               |
| 5    | Drain the ethanol from the feed reservoir and fill with clean water (water-for-injection [WFI] or 10,000 NMWC UF permeate). Use room temperature or warm (up to 50°C [122°F]) water for rinsing. Cold water will be less effective. Addition of 100 ppm NaOCl to the rinse water will enhance glycerol removal. |
| 6    | Connect the retentate and permeate lines to an appropriate waste container.                                                                                                                                                                                                                                     |
| 7    | Start the pump on slow and adjust TMP to 1 barg (15 psig).                                                                                                                                                                                                                                                      |
| 8    | To reduce water consumption, adjust the pump speed and retentate back pressure such that the retentate flow rate is approximately 1/10th of the permeate flow. The pump speed will be set quite low as most of the fluid is passing through the membrane as filtrate.                                           |

| Step | Action                                                                               |
|------|--------------------------------------------------------------------------------------|
| 9    | Continue rinsing for 90 minutes, adding more fluid to the feed reservoir, as needed. |

### Autoclavable/steam-in-place cartridges (3,000 NMWC membrane filters only)

#### [Extended pre-soak]

Before sterilizing ultrafiltration cartridges in an autoclave or in a steam-in-place sterilization procedure, the cartridge must be fully rinsed of glycerol. If UF cartridges are to be autoclaved or steam sterilized, a presoak is recommended as an adjunct to the flushing procedure.

| Step | Action                                                                                                                                                                                       |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1    | Rinse cartridge per the new cartridge rinsing procedure for 1,000 and 3,000 NMWC membrane filter.                                                                                            |
| 2    | Soak cartridge in clean water for at least four hours, preferably overnight. Be certain that both the lumen side and shell side of the cartridge are filled and that air has been displaced. |
| 3    | Rinse cartridge per the new cartridge rinsing procedure for 1,000 and 3,000 NMWC membrane filter.                                                                                            |

### Sodium hydroxide sanitization and depyrogenation

Follow the steps below to sanitize and depyrogenate the cartridge.

| Step | Action                                                                                                                  |
|------|-------------------------------------------------------------------------------------------------------------------------|
| 1    | Thoroughly clean and rinse the cartridge.                                                                               |
| 2    | Recirculate a solution of 0.1 N to 0.5 N sodium hydroxide, pH 13, for 30 to 60 minutes at 30°C to 50°C (86°F to 122°F). |
| 3    | Thoroughly drain the system.                                                                                            |
| 4    | Rinse cartridge per the new cartridge rinsing procedure for 1,000 and 3,000 NMWC membrane filter.                       |

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28910650 AC V:6 02/2021

