

# Hollow fiber cartridge preparation instructions

All GE Healthcare hollow fiber cartridge materials conform to USP XXVII Class VI requirements. Ultrafiltration 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 GE Healthcare's 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

*[Recommended for all UF membranes]*

The New cartridge rinsing procedure should be performed on all ultrafiltration cartridges.

1. Install the cartridge and connect to system.
2. Connect the retentate and the permeate lines to an appropriate waste container.
3. Fill the feed reservoir with clean water (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.
4. Start the pump on slow and adjust transmembrane pressure (TMP) to:
  - 1 barg (15 psig) for 1,000 NMWC and 3,000 NMWC pore sizes
  - 0.7 barg (10 psig) for 5,000 NMWC through 50,000 NMWC pore sizes
  - 0.3 barg (5 psig) for larger pore sizes
5. 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.
6. Continue rinsing for 90 minutes, adding more fluid to the feed reservoir, as needed.
7. If NaOCl is used, thoroughly rinse the cartridge before introducing the process solution.

Alcohol may be used to enhance the glycerol removal from ultrafiltration membranes. Either isopropyl alcohol (IPA) or ethanol (EtOH) may be used.

1. Fill cartridge with 25% alcohol and allow to soak for one hour. This procedure will be more effective if the alcohol is pumped through the cartridge at 0.3 barg (5 psig) TMP for at least 10 minutes prior to soaking.
2. Rinse cartridge per the *New cartridge rinsing procedure* for 90 minutes.

## Microfiltration cartridges

Although microfiltration (MF) membrane cartridges are shipped dry, without preservative solutions, it is prudent to rinse cartridges before first process exposure or heat sterilization. Follow the *New cartridge rinsing procedure* for at least five minutes at 0.3 barg (5 psig) inlet pressure. Longer flush times may be required, depending on the cartridge size.

## Autoclavable/Steam-in-place cartridges

*[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 pre-soak is recommended as an adjunct to the flushing procedure.

1. Rinse cartridge per the *New cartridge rinsing procedure* for 30 minutes.
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 30 minutes.

## Sodium hydroxide sanitization and depyrogenation

Follow the steps below to sanitize and depyrogenate the cartridge.

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 to 50 °C (86 to 122 °F).
3. Thoroughly drain the system.
4. Rinse cartridge per the *New cartridge rinsing procedure* for 30 minutes.



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