



ReadyToProcess hollow fiber filters: reduced rinse-up requirements as compared to standard hollow fiber filters

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Abstract

GE Healthcare's hollow fiber filters are available in two formats:

- ReadyToProcess™ hollow fiber filters (pre-wetted, pre-rinsed and gamma-sterilized)
- Standard hollow fiber filters (untreated).

This Application Note shows a comparison of preparation time between using ReadyToProcess and Standard hollow fiber filters. Using Total Organic Carbon (TOC) determination as a sensitive means of assessing filter extractables, we concluded the benefits of using the ReadyToProcess filters are the following:

- There is a 40 L/m² difference in WFI rinse requirement between the ReadyToProcess and Standard filter (60 L/m² for standard versus 20 L/m² for ReadyToProcess filters) to reach TOC levels of < 0.5 ppm*.
- Shortened preparation time and a corresponding reduction in labor requirement.

There is no need for pretreatment with 25% alcohol when using the ReadyToProcess low molecular weight cut off filters (NMWC < 100 kD); they come pre-wetted.

* The user of GE Healthcare filters is not required to rinse them to a 0.5 ppm TOC endpoint. This endpoint was chosen for experimental purposes because it is stringent and it represents a recognizable water quality standard.

Introduction

Use of hollow fiber filtration devices usually involve the following pretreatment steps. This is to meet the desired TOC levels of 0.5 ppm.

- NMWC < 100 kD: wet-out the filter with approximately 10 L/m² of 25% alcohol for 70 min, then rinse it with WFI for 90 min to prepare it for use.
- 100 kD ≤ NMWC ≤ 750 kD: remove glycerol stabilizer from the filter by rinsing it with WFI for 90 min to prepare it for use.
- 0.1 µm ≤ pore size rating ≤ 0.65 µm: rinse the filter with WFI for 5 min to prepare it for use.

For more details, see GE Healthcare document #18-1165-30 entitled, "Operating Handbook, Hollow Fiber Cartridges for Membrane Separations."

ReadyToProcess and Standard filter pre-use processing requirements are summarized in Table 1.



Table 1. ReadyToProcess hollow fiber filters vs standard hollow fiber filters: pre-use processing requirements

Step	Pre-Use Processing Requirement	Standard Filter			RTP Filter
		<100kD	100-750 kD	0.1-0.65µm	All Pore Sizes
P	Pretreatment (alcohol wet)	Yes	No	No	No
1	Water rinse to remove alcohol or glycerol	Yes	Yes	No	No
2	Water rinse only	No	No	Yes	Yes

Rinsing procedure for this study

1. Standard filters (< 100 kD NMWC only):

- Fill the filter and system with room temperature 25% isopropyl alcohol.
- Recirculate the alcohol solution through both the retentate and permeate sides of the filter at 0.3–1.0 barg TMP (depending upon pore size rating) for 10 min.
- Stop recirculation and allow the filter to soak in alcohol solution for 1 h.
- Drain the retentate and permeate sides of the filter. Continue to Step 2 (below).

2. ReadyToProcess and Standard filters:

- Fill the filter with room temperature WFI.
- Pump WFI through both the retentate and permeate sides of the filter to drain at 0.3–1.0 barg TMP (depending upon pore size rating) until filter rinse water quality reaches the USP's WFI specification for TOC (< 0.5 ppm). Control the ratio of permeate flow to retentate flow at 10:1 (approx.).

Results

In each figure below, vertical arrows designate where the quality of permeate reached the USP WFI specification for TOC (< 0.5 ppm):

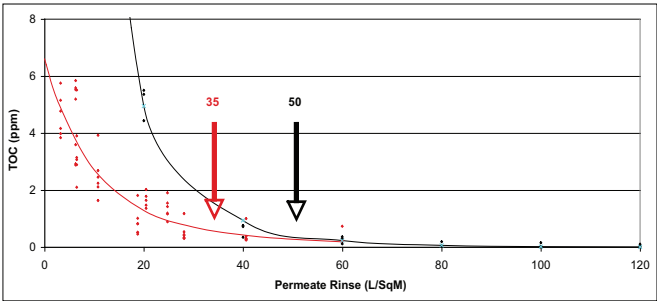


Figure 1. ReadyToProcess (Red) Vs. Standard (Black) UFP-10-C-3X2M TOC Rinse-Up (10 kD, size 3X2)

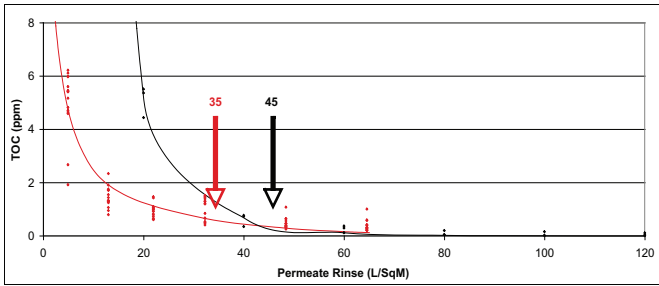


Figure 4. ReadyToProcess (Red) Vs. Standard (Black) CFP-1-E-3M TOC Rinse-Up (0.1µm, size 3)

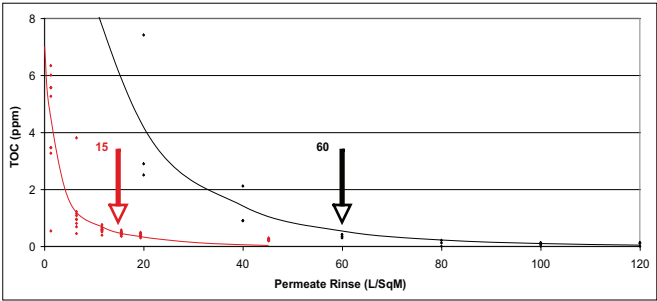


Figure 2. ReadyToProcess (Red) Vs. Standard (Black) UFP-30-C-4X2M TOC Rinse-Up (30 kD, size 4X2)

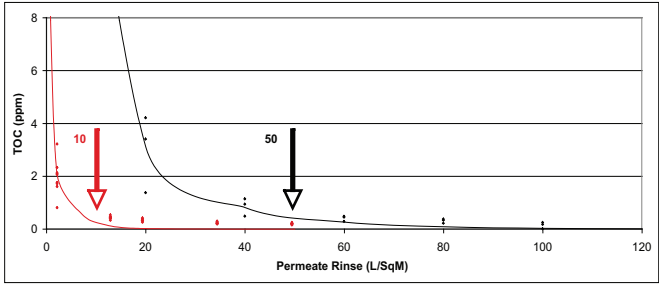


Figure 5. ReadyToProcess (Red) Vs. Standard (Black) CFP-4-E-8 TOC Rinse-Up (0.45 µm, size 8)

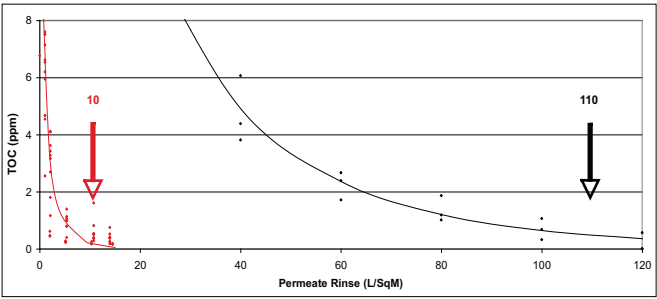


Figure 3. ReadyToProcess (Red) Vs. Standard (Black) UFP-500-C-6 TOC Rinse-Up (500 kD, size 6)

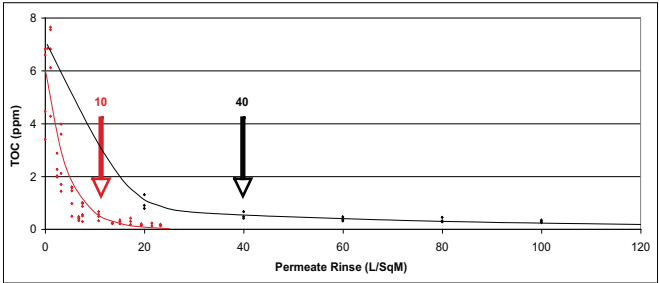


Figure 6. ReadyToProcess (Red) Vs. Standard (Black) CFP-6-D-9 TOC Rinse-Up (0.65µm, size 9)

Conclusions

The average ReadyToProcess hollow fiber filter rinse-up requirement to reach 0.5 ppm TOC in permeate is 20 L/m². The average Standard hollow fiber filter rinse-up requirement to reach 0.5 ppm TOC in permeate is 60 L/m². Of course, there is no intrinsic requirement that hollow fiber filters be rinsed to

such a stringent endpoint. The choice of pre-use permeate rinse endpoint is normally based upon product quality requirements. Based upon overall TOC result averages from Figures 1-6 and Table 2 details rinse endpoint options available to the user:

Table 2. ReadyToProcess filters vs. standard filters average permeate quality as a function of permeate rinse endpoint

Permeate Rinse (L/m ²)	TOC (ppm) in Permeate Rinse	
	RTP Filter	Non-RTP Filter
10*	1.5	9.5
20	0.5	4.5
40	< 0.5	1.5
60	< 0.5	0.5

*A minimum of 10 L/m² of permeate rinse is usually required to prepare a hollow fiber filter for use.

ReadyToProcess filter rinsing recommendation

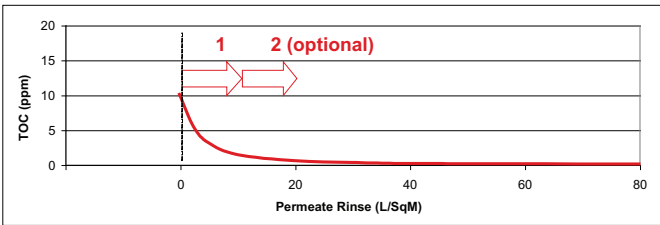


Figure 7. Recommended ReadyToProcess filter rinse (all NMWC and micron-rated filters)

A single rinsing regimen is recommended for all RTP hollow fiber filters regardless of NMWC or micron rating:

1. Rinse system with water (to 10 L/m² permeate rinse).
2. Optional: Continue rinsing system until reaching 0.5 ppm TOC in permeate (at 20 L/m²).

Standard filter rinsing recommendations

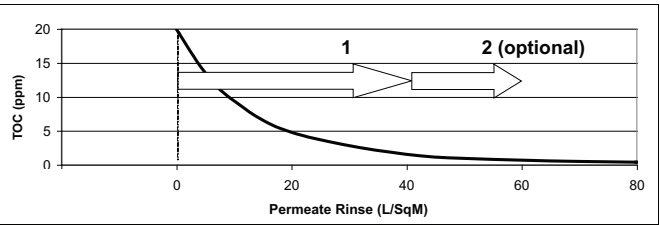


Figure 8. Recommended standard filter rinse ≥ 100 kD and micron-rated filters

A similar rinsing regimen is recommended for Standard microporous filters and ultrafilters with NMWC ≥ 100 kD:

1. Rinse system with water until most extractables (glycerol, etc.) have been removed (to 40 L/m²).
2. Optional: Continue rinsing system until reaching 0.5 ppm TOC in permeate (at 60 L/m²).

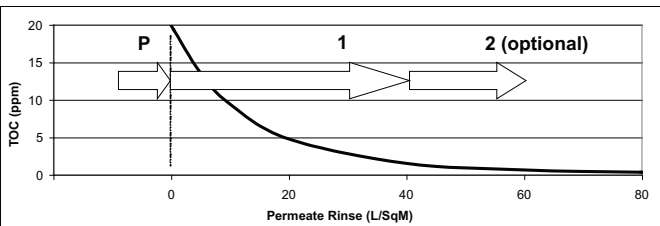


Figure 9. Recommended standard filter rinse (< 100 Kd filters)

A different rinsing regimen is recommended for all standard hollow fiber filters with NMWC < 100 kD:

- P. Pretreatment. Wet-out filter with 25% alcohol.
1. Rinse system with water until most extractables (glycerol, etc.) have been removed (to 40 L/m²).
 2. Optional: Continue rinsing system until reaching 0.5 ppm TOC in permeate (at 60 L/m²).

Hidden costs associated with standard filter use

The process of pretreatment of standard filters to rinse storage solutions such as alcohol or glycerol means significant manpower costs and at larger scale also the costs for water. This can be eliminated by using ReadyToProcess filters.

Table 3. Standard hollow fiber filter: incremental processing time and water requirements (versus ReadyToProcess filter)

Cost Factor	<100kD	100-750 kD	0.1-0.65µm
Incremental processing time requirement as compared to corresponding ReadyToProcess filter	+3 hr	+1 hr	+1 hr
Incremental water requirement as compared to corresponding ReadyToProcess filter	30 - 40 L/m², depending upon choice of endpoint		

While labor costs (\$100–\$200 per manhour) and WFI costs (\$1–\$5 per liter) and the methods of accounting for them vary widely from company to company, knowledge of the additional cost factors associated with using Standard filters allows one to compare operational alternatives. In equation form:

$$M \text{ [manhours saved]} \times L \text{ [$/manhour]} + V \text{ [liters/m}^2 \text{ saved]} \times A \text{ [m}^2\text{]} \times W \text{ [$/liter]} = C \text{ [hidden cost, $]}$$

Using median rates, the hidden cost associated with the use of a Standard (non-RTP), Size 9 (1 m²), 30 kD filter is:

$$[3 \text{ manhours} \times \$150 / \text{manhour}] + [35 \text{ L/m}^2 \times 1 \text{ m}^2 \times \$3 / \text{liter}] = \$555.$$

For contact information for your local office,
please visit: www.gelifesciences.com/contact

GE Healthcare Bio-Sciences AB
Björkgatan 30
751 84 Uppsala
Sweden

www.gelifesciences.com



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GE Healthcare Bio-Sciences AB, Björkgatan 30, 751 84 Uppsala, Sweden

GE Healthcare Bio-Sciences Corp., 800 Centennial Avenue, P.O. Box 1327, Piscataway, NJ 08855-1327 USA

GE Healthcare Europe, GmbH, Munzinger Strasse 5, D-79111 Freiburg, Germany

GE Healthcare Bio-Sciences KK, Sanken Bldg., 3-25-1, Hyakunincho, Shinjuku-ku, Tokyo 169-0073 Japan