



Comparison of Kwick cassettes and two competitive cassettes for the concentration and diafiltration of Human Serum Albumin (HSA)

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The situation

Cross flow trial filtration runs were undertaken to compare the performance of three 10 kD molecular weight cutoff cassettes, one manufactured by GE Healthcare and two from different suppliers, for the concentration and diafiltration of Human Serum Albumin (HSA).

The three primary areas of interest were as follows: (1) to determine the final concentration achieved with each type of cassette; (2) to determine the final yield from each type of cassette; and (3) to note the time required to reach that concentration. In the trial using the GE Healthcare Kwick™ cassette, a final concentration was reached of 36.9% HSA with a yield of 98.53% in ~75 minutes. Final concentrations attained using competitive cassettes were 35.9% with a yield of 95.72% in ~90 minutes.; and 36.4% with a yield of 97% in ~103 minutes.

Equipment setup for the trial run

The cross flow ultrafiltration trial runs were performed using the GE Healthcare Kwick lab system, catalog no. KLSY 0105 RLPSS20. The Kwick lab system utilizes a low shear rotary lobe pump. Three test cassettes were selected, each with a 10 kD molecular weight cutoff. One was a Kwick lab 1.2 ft² cassette, catalog no. UFELA 0010010 ST, the second a cassette from supplier X, and the third a cassette from supplier Z. The medium used for this test was pure Human Serum Albumin at 2.5% initial concentration.



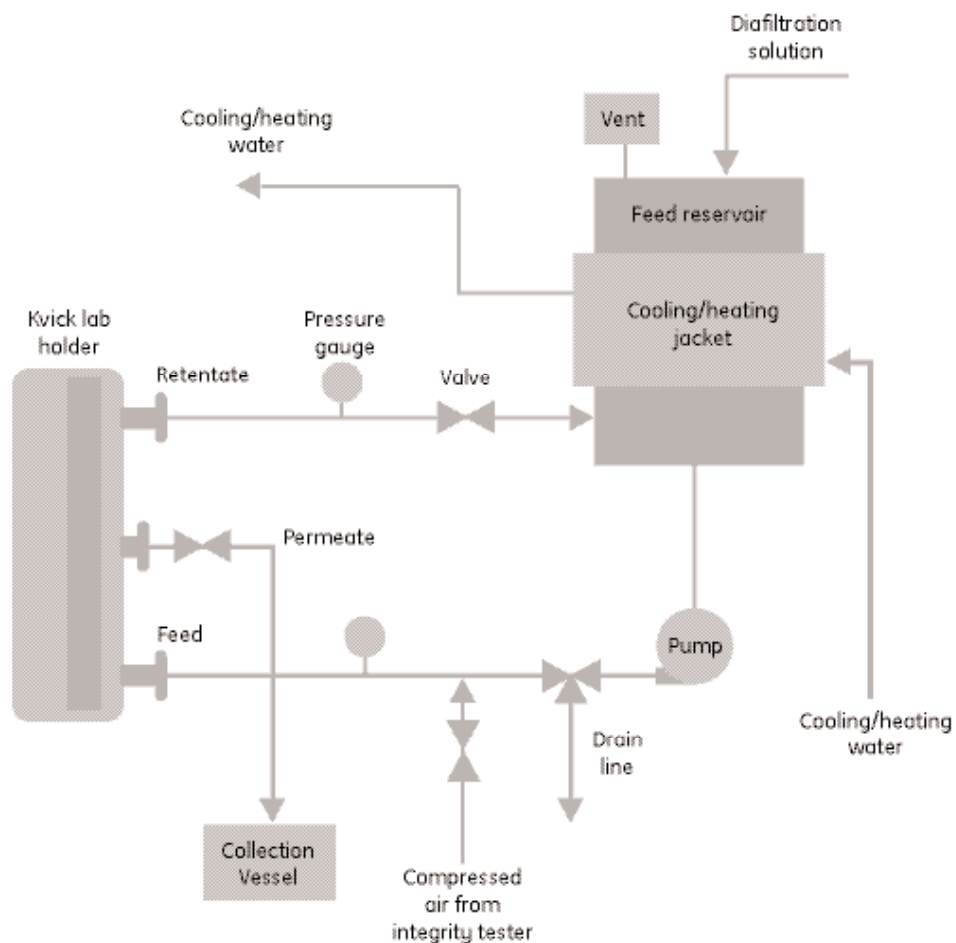


Figure 1. Schematic flow diagram of the Kwick lab cross flow system used for the trial runs

Method

For each trial, the cassette undergoing the test was placed in the Kwick lab holding device, and the clamping plates tightened to the required torque.

The cassettes were prepared and an HSA solution was concentrated using the following steps:

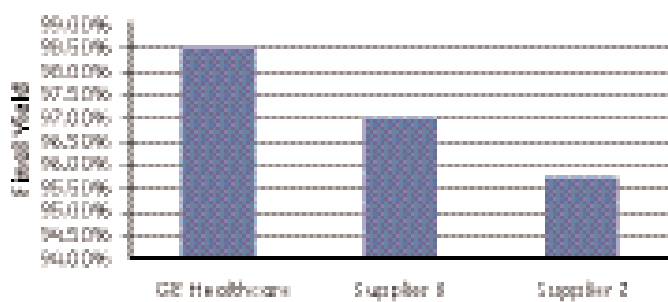
1. System and cassette rinsed with deionized water (DI-water) to remove storage solution
2. Cassette pre-conditioned with isotonic NaCl solution
3. 1st concentration step, 6× concentration, 3000 ml down to 500 ml
4. Diafiltration step, 5× 500 ml
5. Final concentration step, 15× concentration, 3000 ml to 200 ml
6. Product recovery with buffer
7. Cleaning and storage

Results

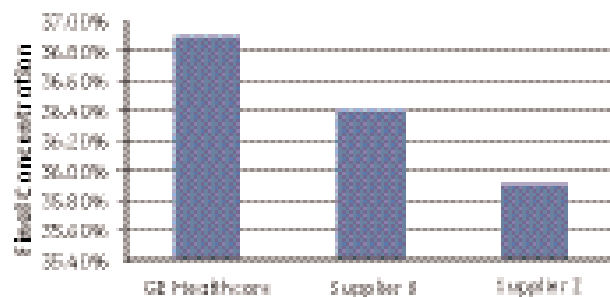
Table 1. Shows the process parameters and comparative performance of the cassettes studied. Certain process parameters are the same for all three cassettes: the comparison medium used is HSA, 2.5% initial concentration, membrane molecular weight cutoff is 10 kD, area is 0.1 meters (Kvick cassette is 0.11), batch volume is 3.00 liters, and the diafiltration volumes are 5× 500 ml.

Process condition	Kvick cassette (UFELA0010010ST)	Cassette from supplier Z	Cassette from supplier X
Temperature, 1st concentration	26°C	24°C	26°C
Temperature, diafiltration	24°C	18°C	22°C
Feed inlet pressure, 1st concentration	2.5 bar	2.5 bar	3.2 bar
Feed inlet pressure, diafiltration	2.5 bar	2.5 bar	3.2 bar
Feed inlet pressure, final concentration	2.5 bar up to 3.0 bar	2.5 bar up to 2.9 bar	3.2 bar
Retentate pressure, final concentration	1.5 bar, down to 1.2 bar	1.5 bar, down to 1.2 bar	1.2 bar, down to 0.8 bar
Permeate pressure	0.0 bar	0.0 bar	0.0 bar
Transmembrane pressure (TMP), final concentration	2.0 bar, up to 2.1 bar	2.0 bar, up to 2.2 bar	2.2 bar, up to 2.35 bar
Recirculation rate, first concentration and diafiltration	900 ml/min	820 ml/min	850 ml/min
Recirculation rate, final concentration	700 ml down to 420 ml	600 ml down to 310 ml	640 ml down to 380 ml

Comparison of HSA Final Yield

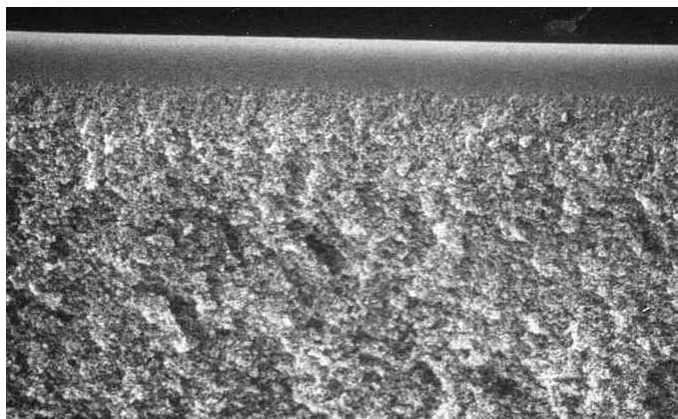


Comparison of HSA Final Concentration



Conclusions

1. Kwick cassettes incorporate a proprietary polyether-sulfone membrane that combines a macrovoid-free structure with low protein binding characteristics.
2. This macrovoid-free structure, coupled with the high selectivity of the membrane, results in overall increased performance of the membrane and higher yields for the end user, as demonstrated in this trial.
3. In this comparison, the Kwick cassette demonstrated superior performance over the competition. The final yield for the HSA product was 2.81% more than supplier Z and 1.53% greater than supplier X.



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