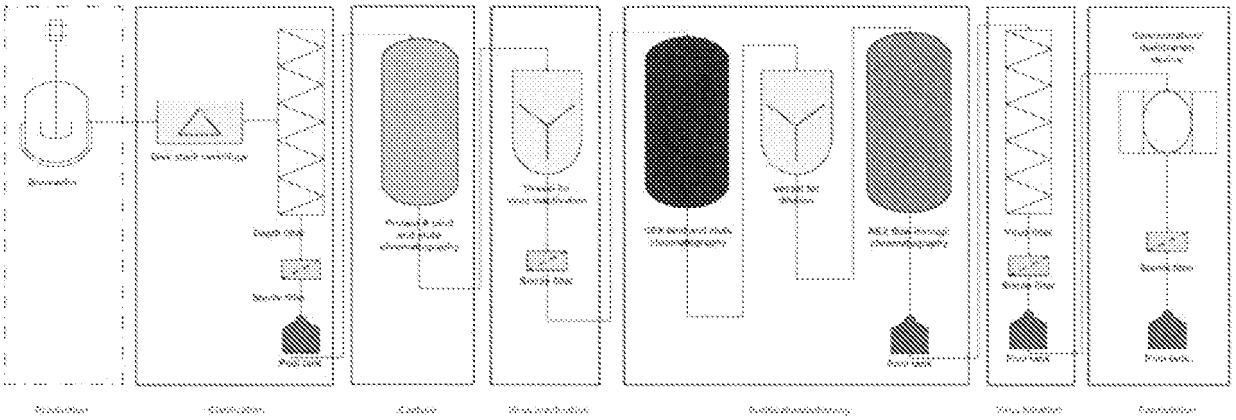


Figure 1

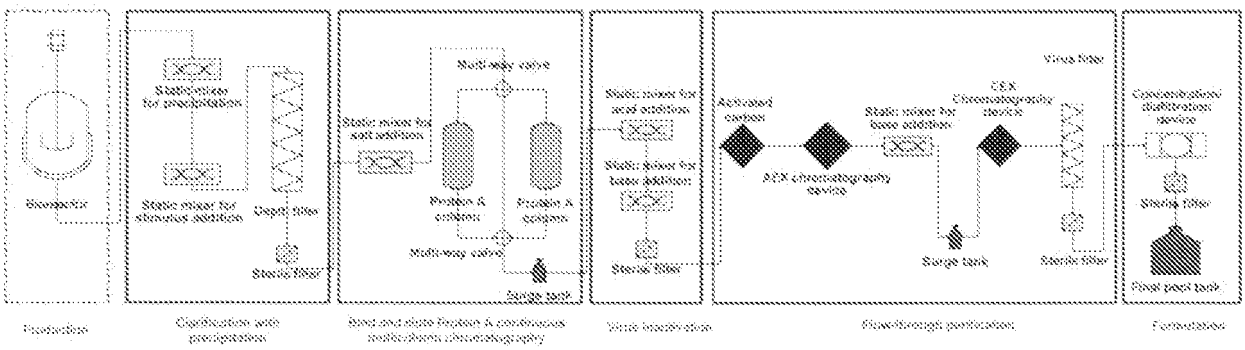


Figure 2

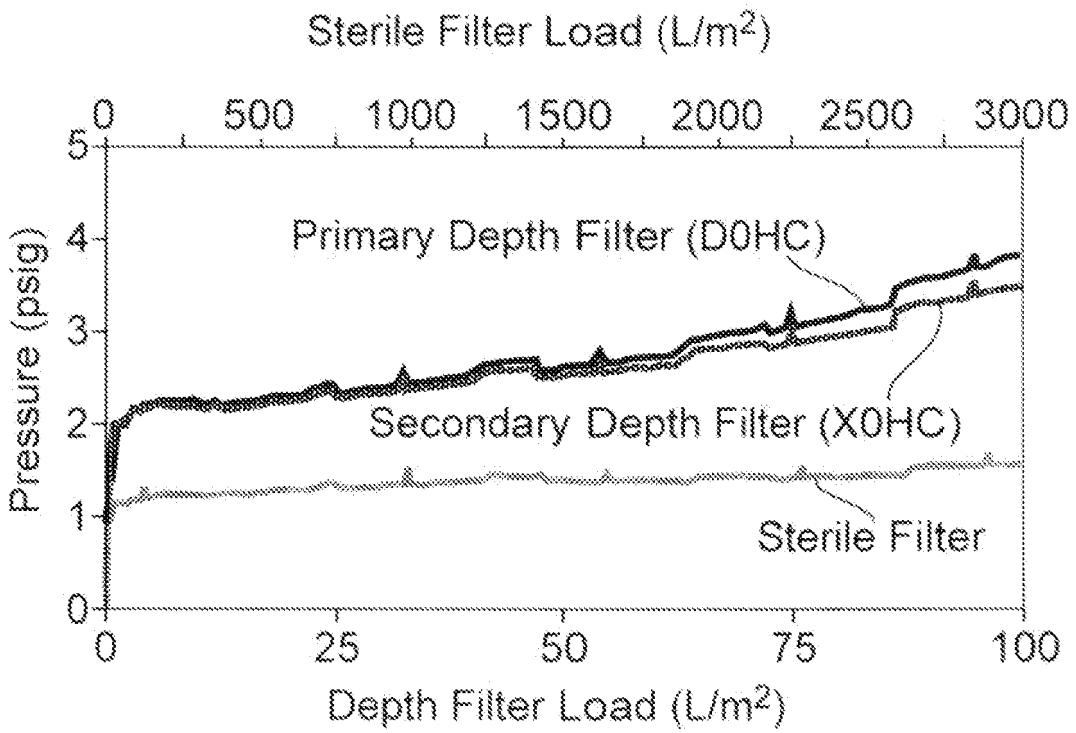

Sterile Filter Load (L/m²)
0
500
1000
1500
2000
2500
3000
5
4
3
2
1
0
Pressure (psig)
Primary Depth Filter (D0HC)
Secondary Depth Filter (X0HC)
Sterile Filter
0
25
50
75
100
Depth Filter Load (L/m²)

Figure 3

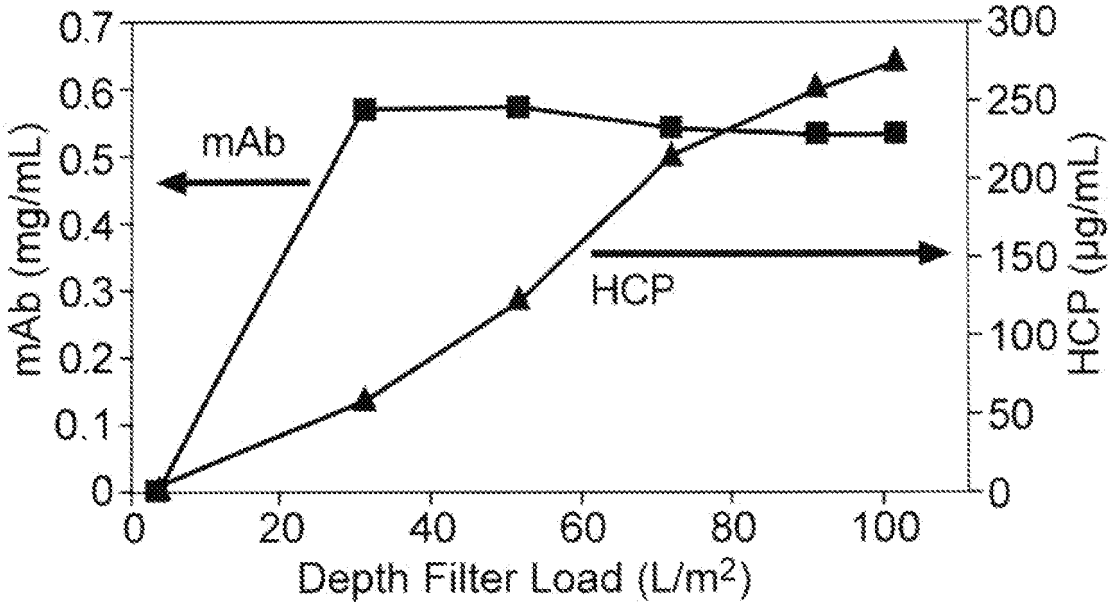

0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
mAb (mg/mL)
mAb
300
250
200
150
100
50
0
HCP (µg/mL)
HCP
0
20
40
60
80
100
Depth Filter Load (L/m2)

Figure 4

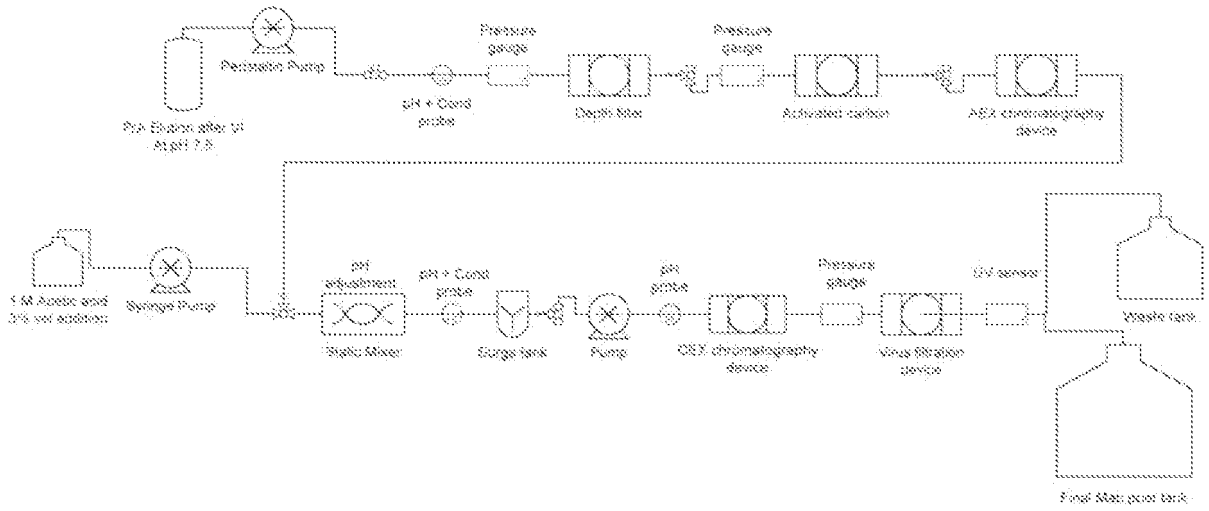

Peristaltic Pump
Pressure gauge
Depth filter
Pressure gauge
Activated carbon
Pressure gauge
Waste tank
Peristaltic Pump
Static Mixer
Surge tank
Pump
Pressure gauge
Waste tank

Figure 5

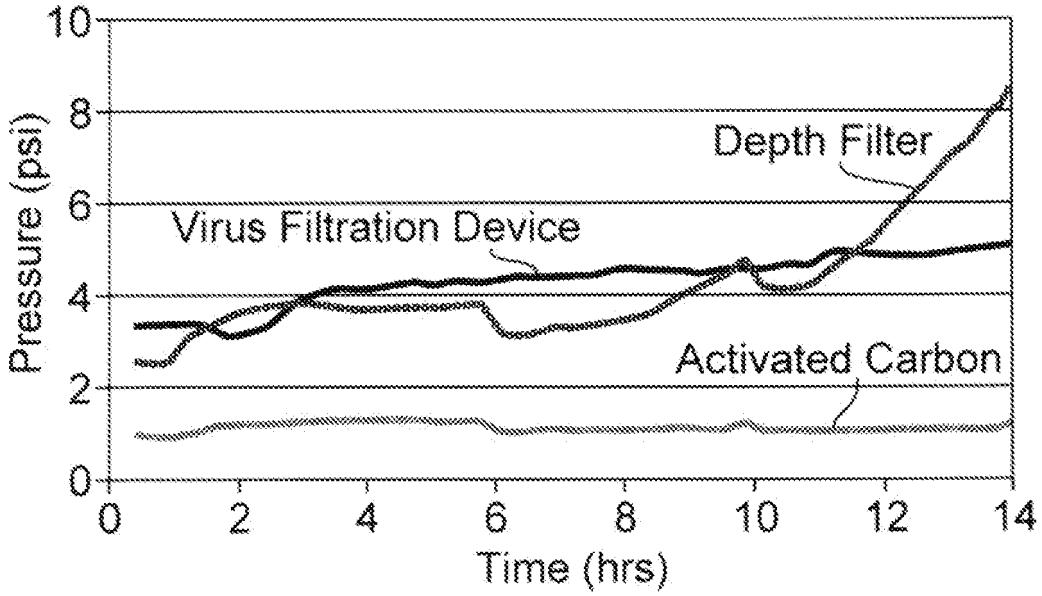

Pressure (psi)
10
8
6
4
2
0
0
2
4
6
8
10
12
14
Time (hrs)
Depth Filter
Virus Filtration Device
Activated Carbon

Figure 6

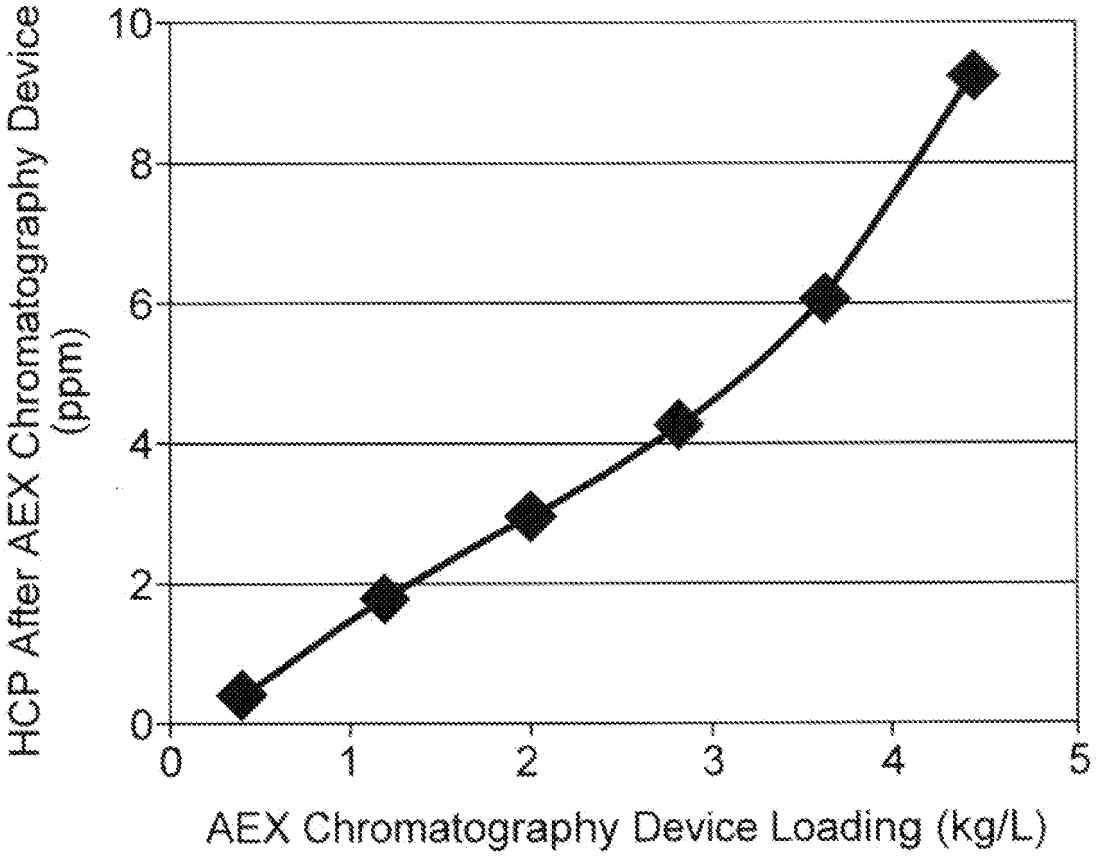

HCP After AEX Chromatography Device (ppm)
10
8
6
4
2
0
0
1
2
3
4
5
AEX Chromatography Device Loading (kg/L)

Figure 7

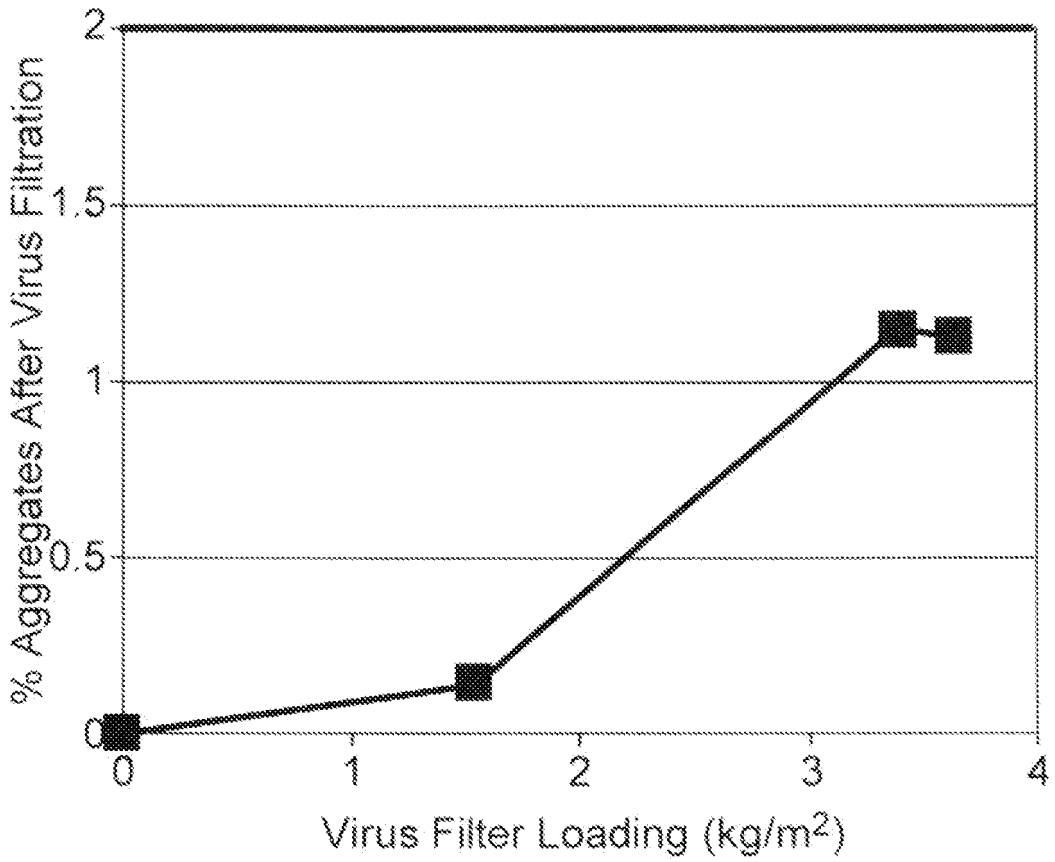

% Aggregates After Virus Filtration
2
1.5
1
0.5
0
0
1
2
3
4
Virus Filter Loading (kg/m2)

Figure 8

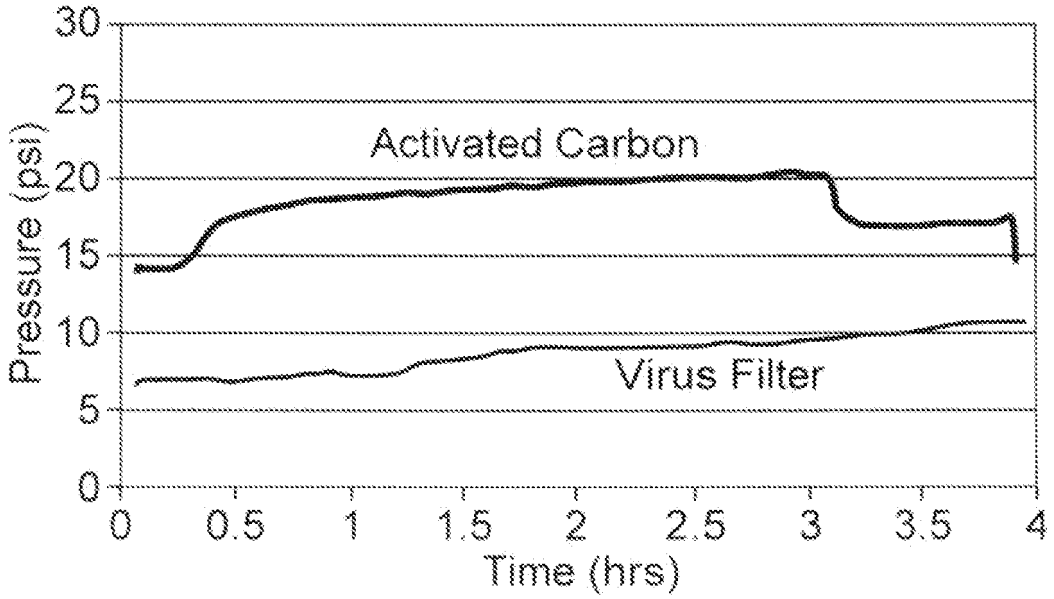

30
25
20
15
10
5
0
Pressure (psi)
Activated Carbon
Virus Filter
0
0.5
1
1.5
2
2.5
3
3.5
4
Time (hrs)

Figure 9

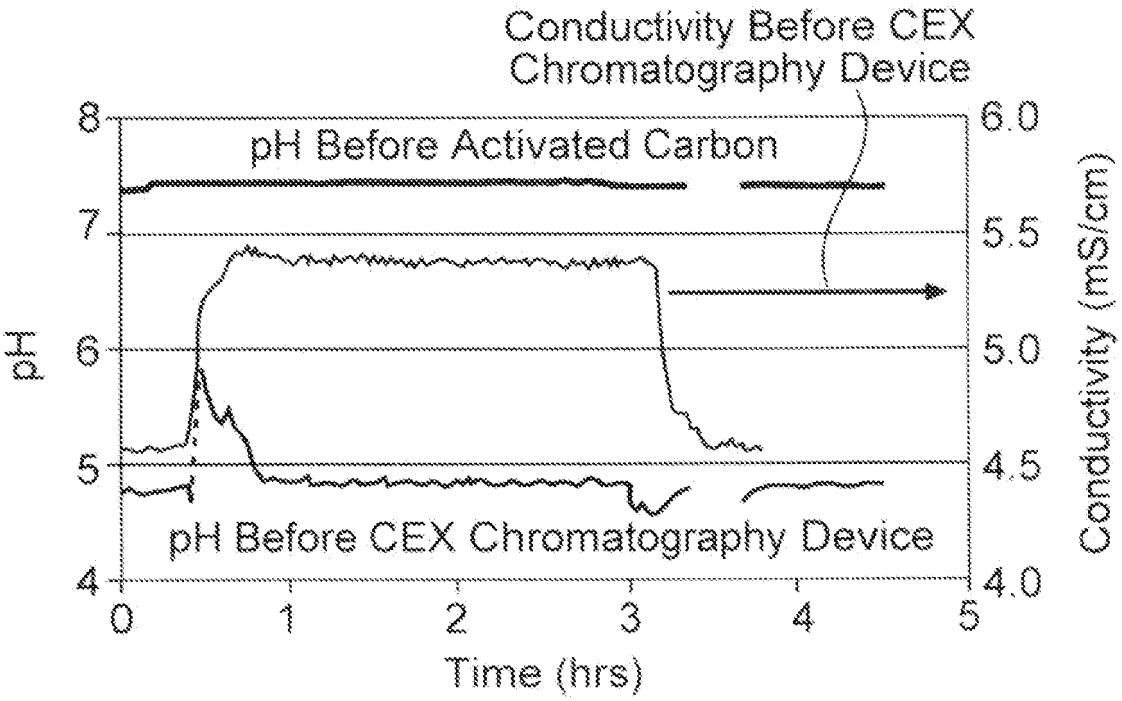

Conductivity Before CEX Chromatography Device
pH Before Activated Carbon
pH Before CEX Chromatography Device
pH
Conductivity (mS/cm)
Time (hrs)
8
7
6
5
4
6.0
5.5
5.0
4.5
4.0
0
1
2
3
4
5

Figure 10

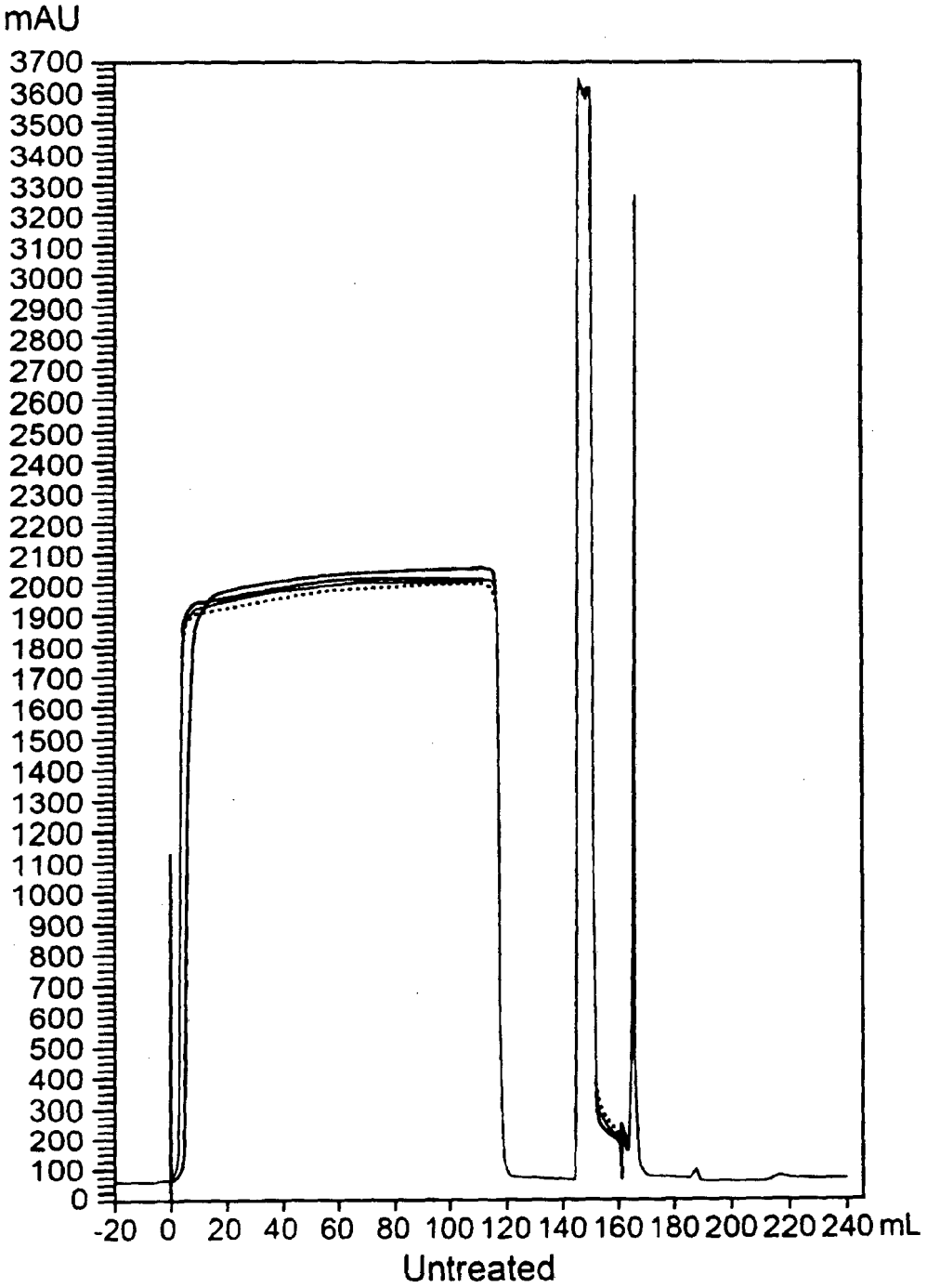

mAU
3700
3600
3500
3400
3300
3200
3100
3000
2900
2800
2700
2600
2500
2400
2300
2200
2100
2000
1900
1800
1700
1600
1500
1400
1300
1200
1100
1000
900
800
700
600
500
400
300
200
100
0
-20 0 20 40 60 80 100 120 140 160 180 200 220 240 mL
Untreated

Figure 11

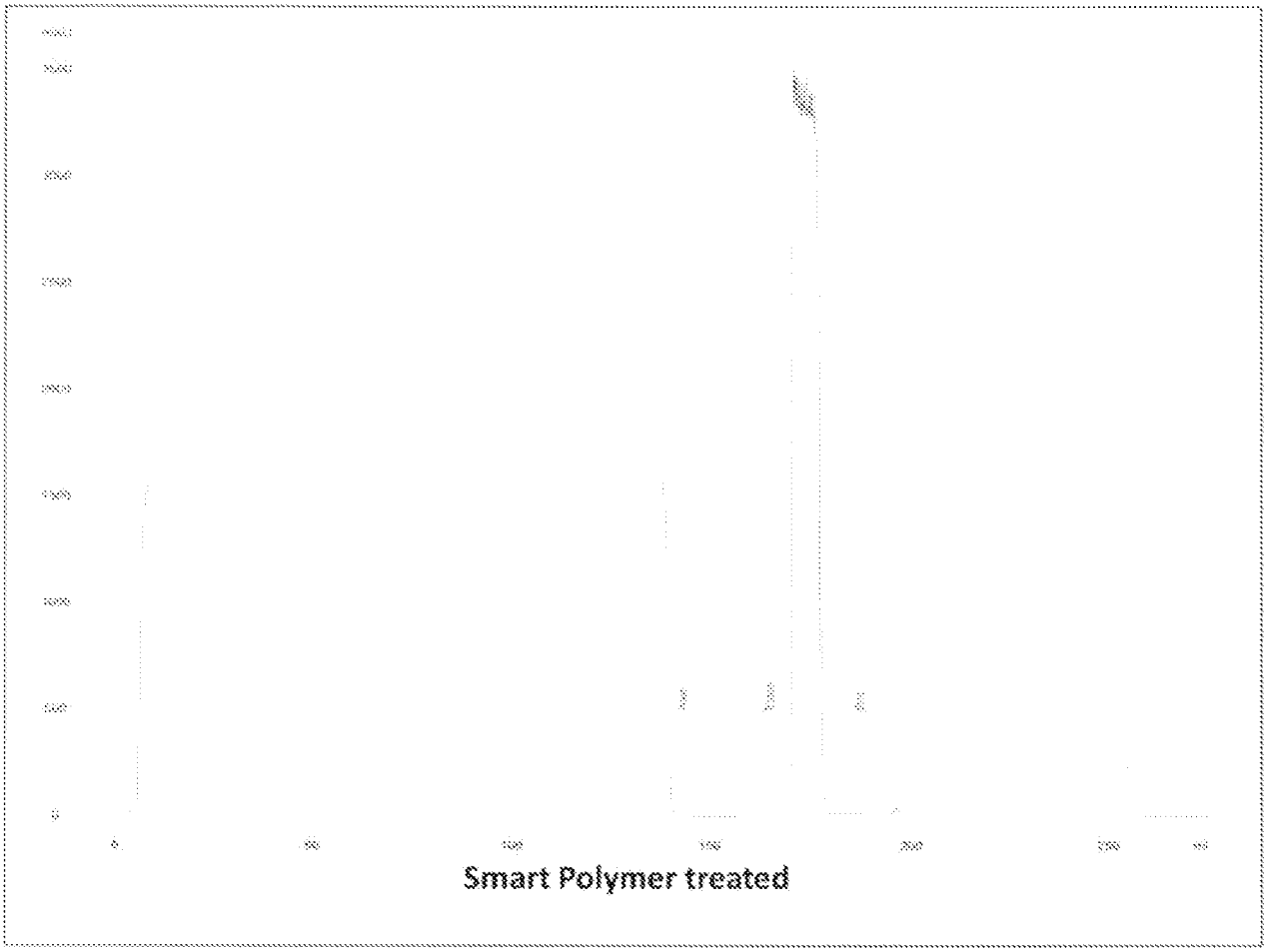


Figure 12

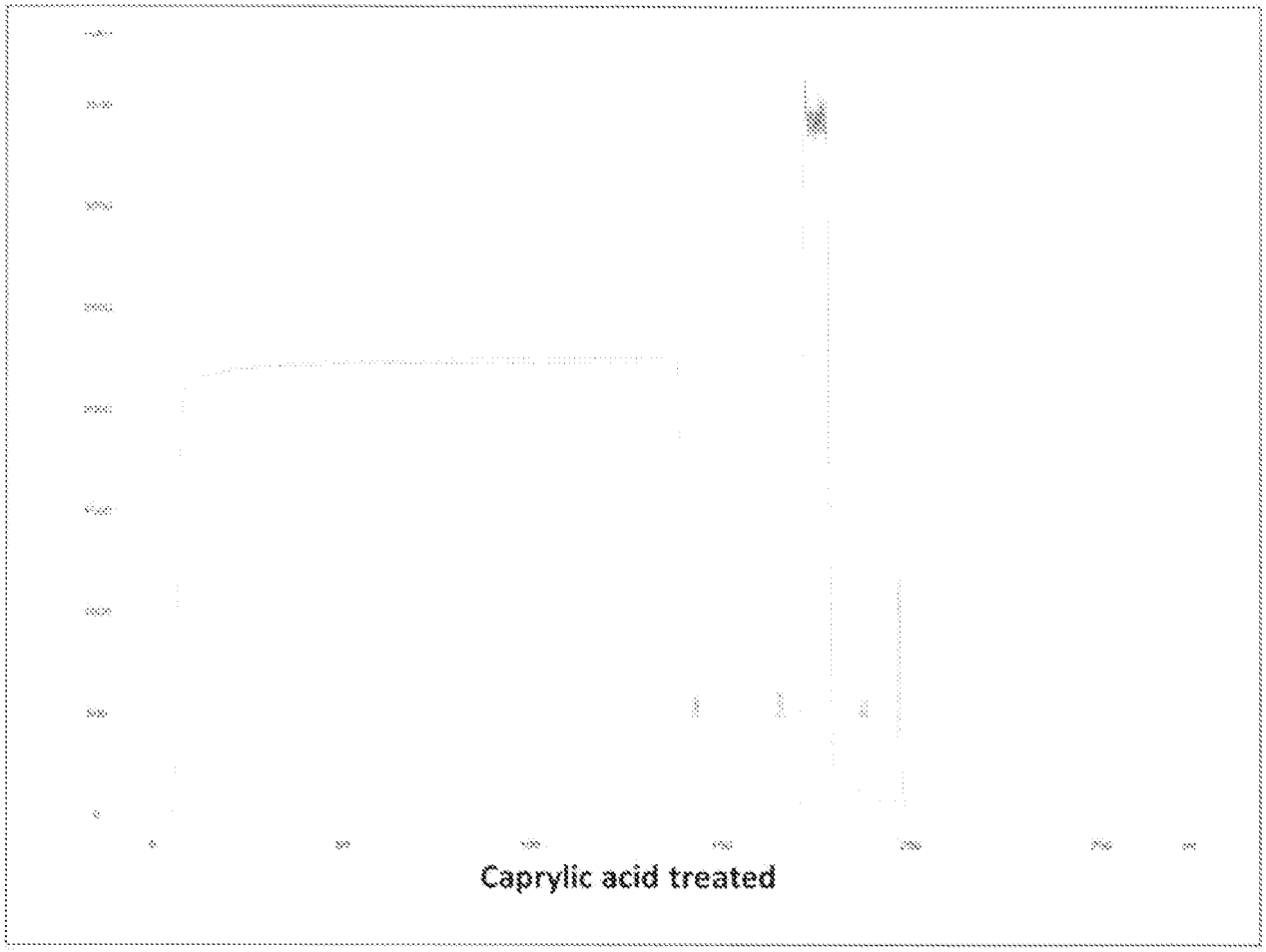


Figure 13

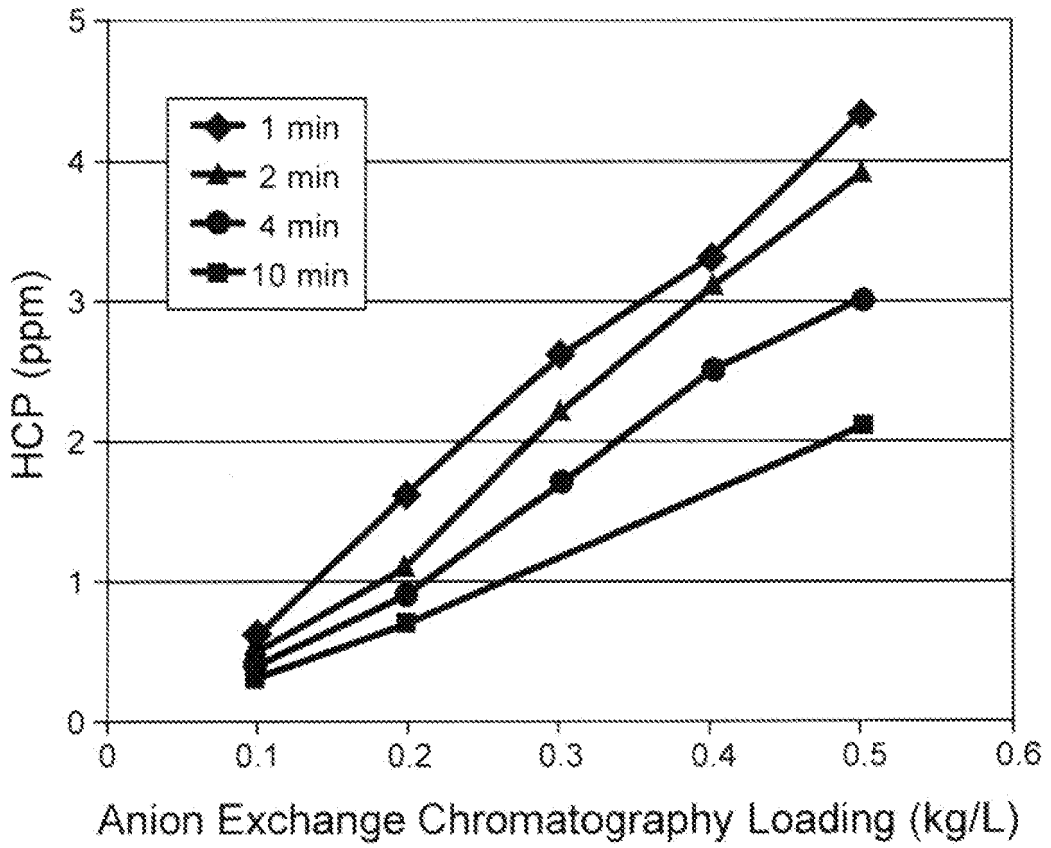

5
4
3
2
1
0
HCP (ppm)
1 min
2 min
4 min
10 min
0
0.1
0.2
0.3
0.4
0.5
0.6
Anion Exchange Chromatography Loading (kg/L)

Figure 14

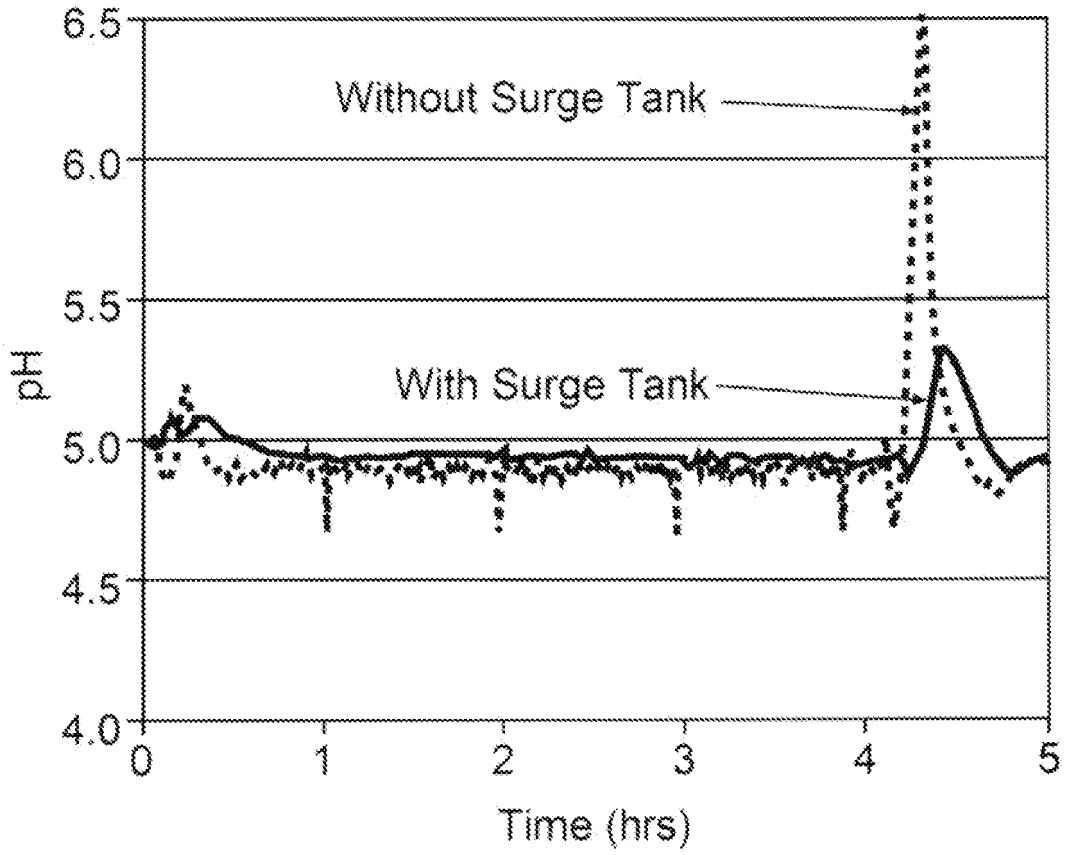

6.5
6.0
5.5
5.0
4.5
4.0
pH
Without Surge Tank
With Surge Tank
0
1
2
3
4
5
Time (hrs)

Figure 15

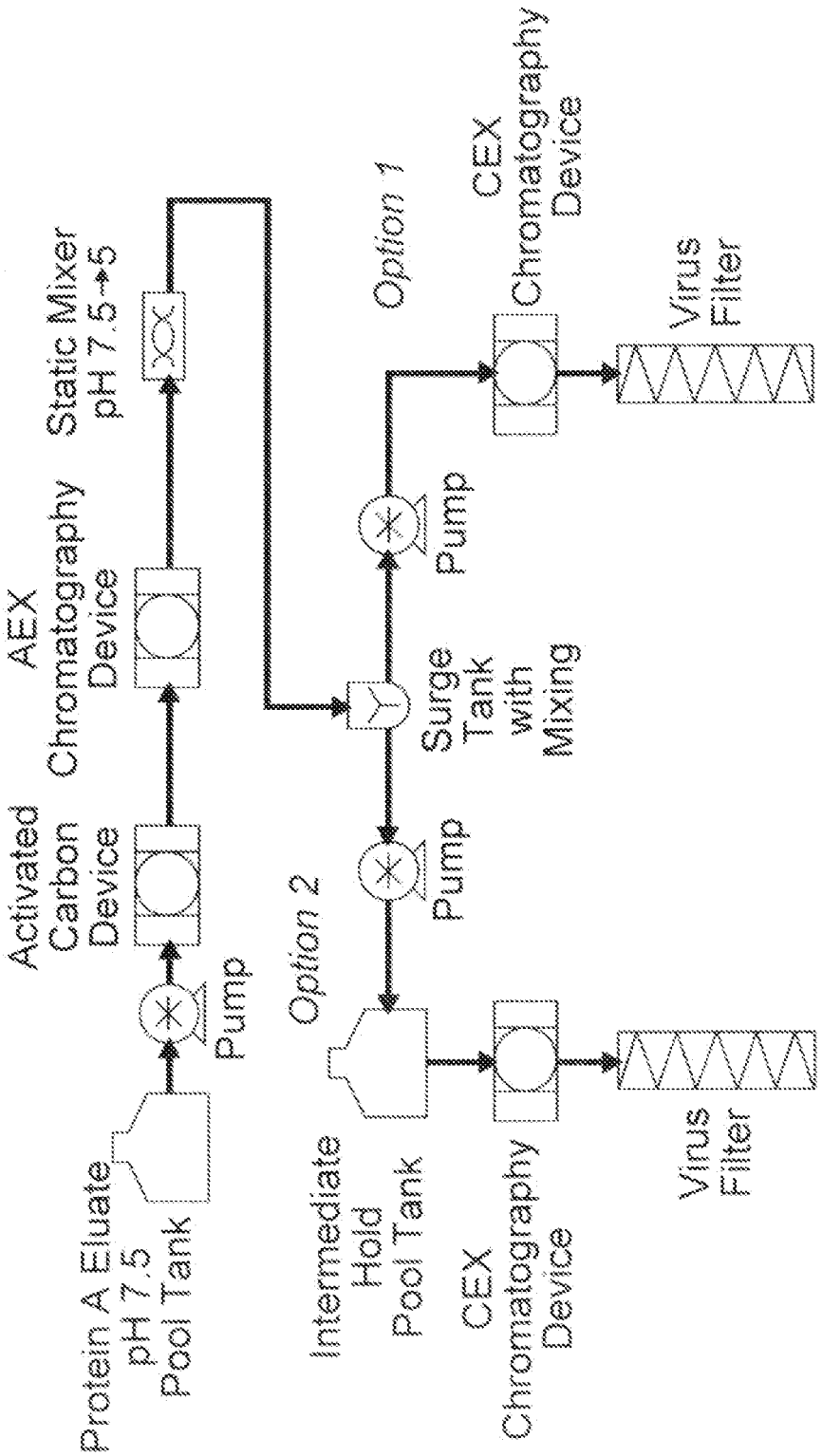

Protein A Eluate pH 7.5 Pool Tank
Pump
Activated Carbon Device
AEX Chromatography Device
Static Mixer pH 7.5→5
Option 2
Intermediate Hold Pool Tank
Pump
Surge Tank with Mixing
Option 1
Pump
CEX Chromatography Device
Virus Filter
CEX Chromatography Device
Virus Filter

Figure 16

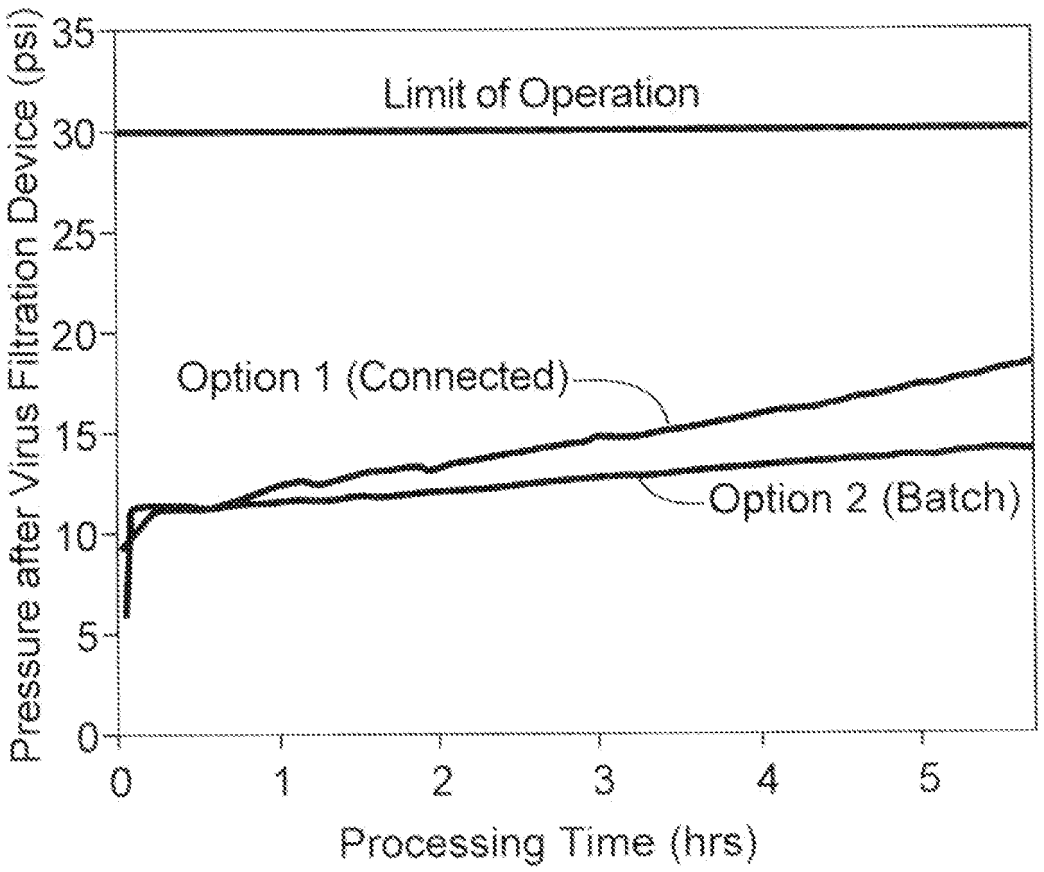

Pressure after Virus Filtration Device (psi)
35
30
25
20
15
10
5
0
Limit of Operation
Option 1 (Connected)
Option 2 (Batch)
0
1
2
3
4
5
Processing Time (hrs)

Figure 17

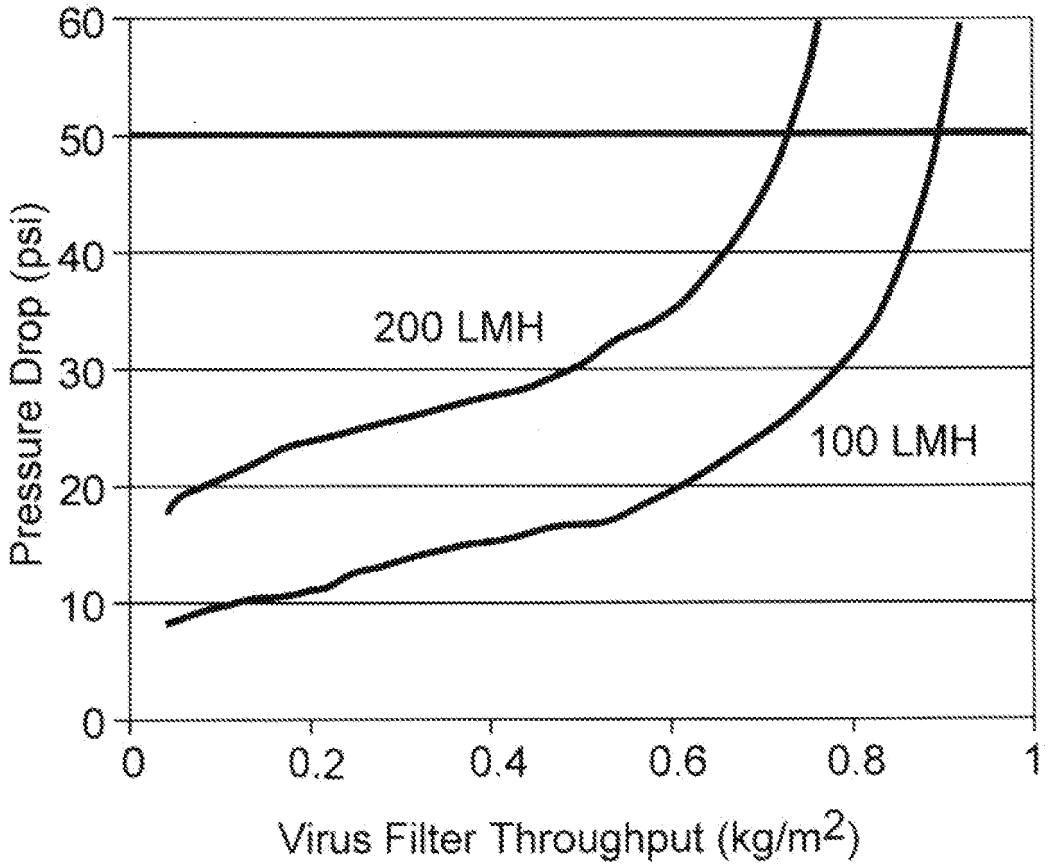

60
50
40
30
20
10
0
Pressure Drop (psi)
200 LMH
100 LMH
0
0.2
0.4
0.6
0.8
1
Virus Filter Throughput (kg/m2)

Figure 18

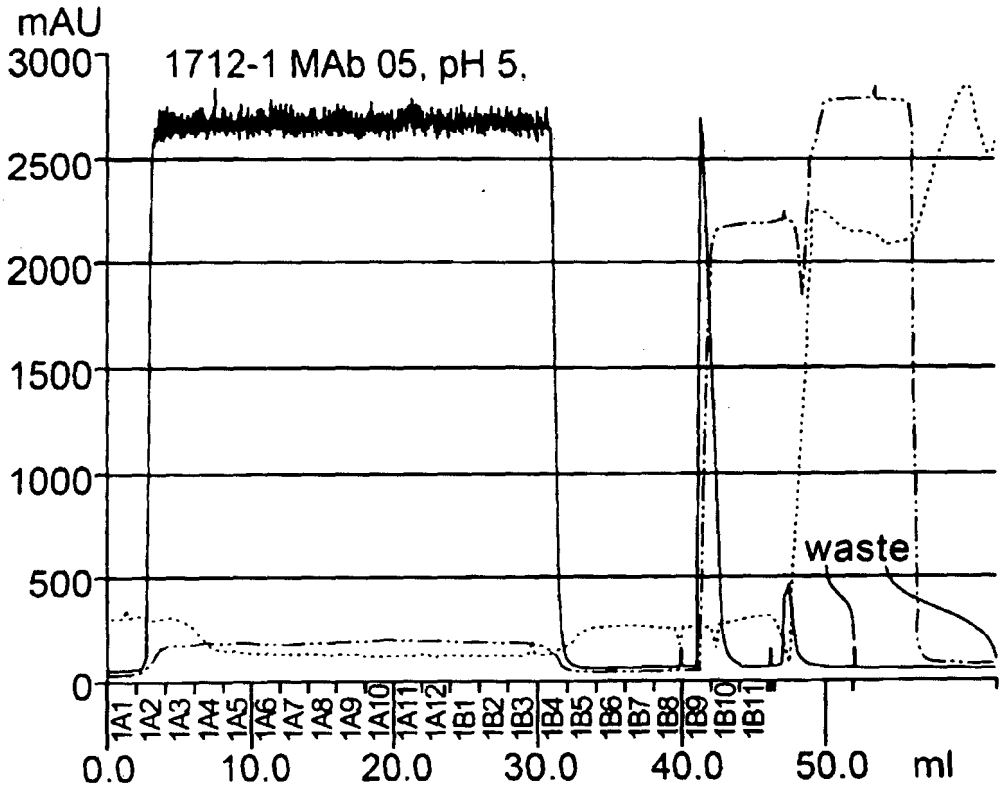

mAU
3000
2500
2000
1500
1000
500
0
1712-1 MAb 05, pH 5.
waste
1A1
1A2
1A3
1A4
1A5
1A6
1A7
1A8
1A9
1A10
1A11
1A12
1B1
1B2
1B3
1B4
1B5
1B6
1B7
1B8
1B9
1B10
1B11
0.0
10.0
20.0
30.0
40.0
50.0
ml

Figure 19

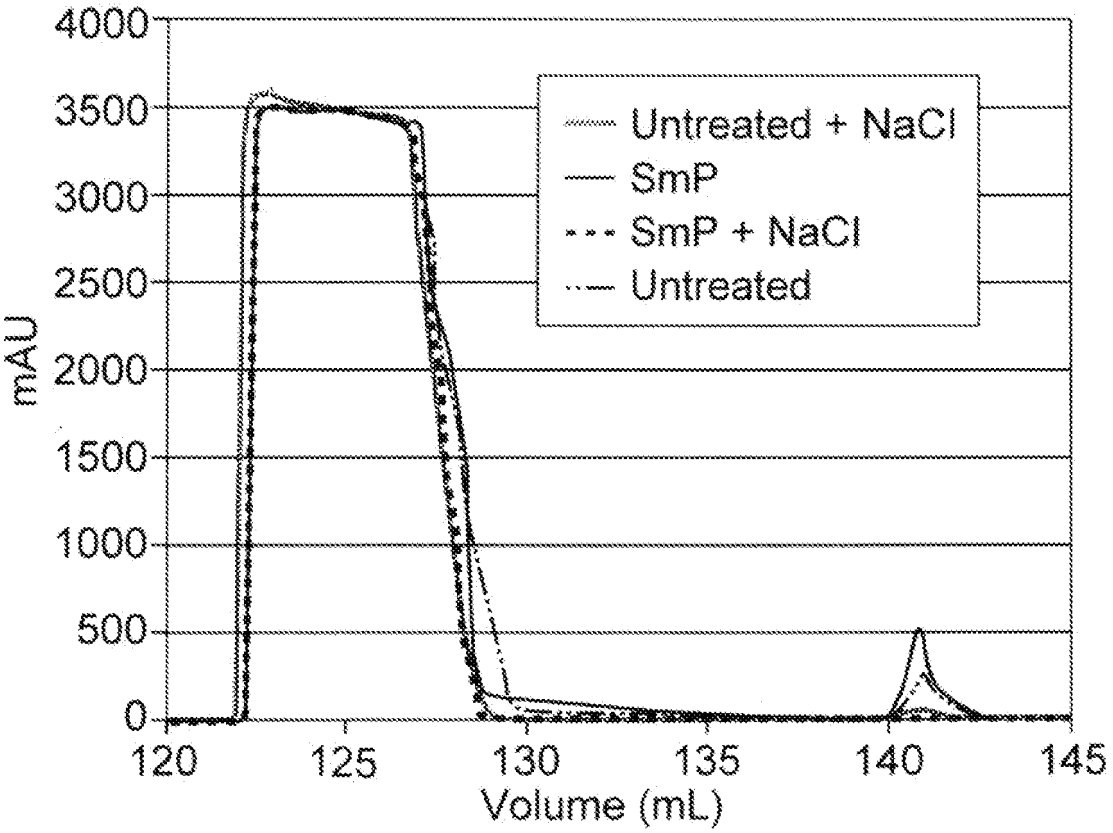

4000
3500
3000
2500
2000
1500
1000
500
0
mAU
120
125
130
135
140
145
Volume (mL)
Untreated + NaCl
SmP
SmP + NaCl
Untreated

Figure 20

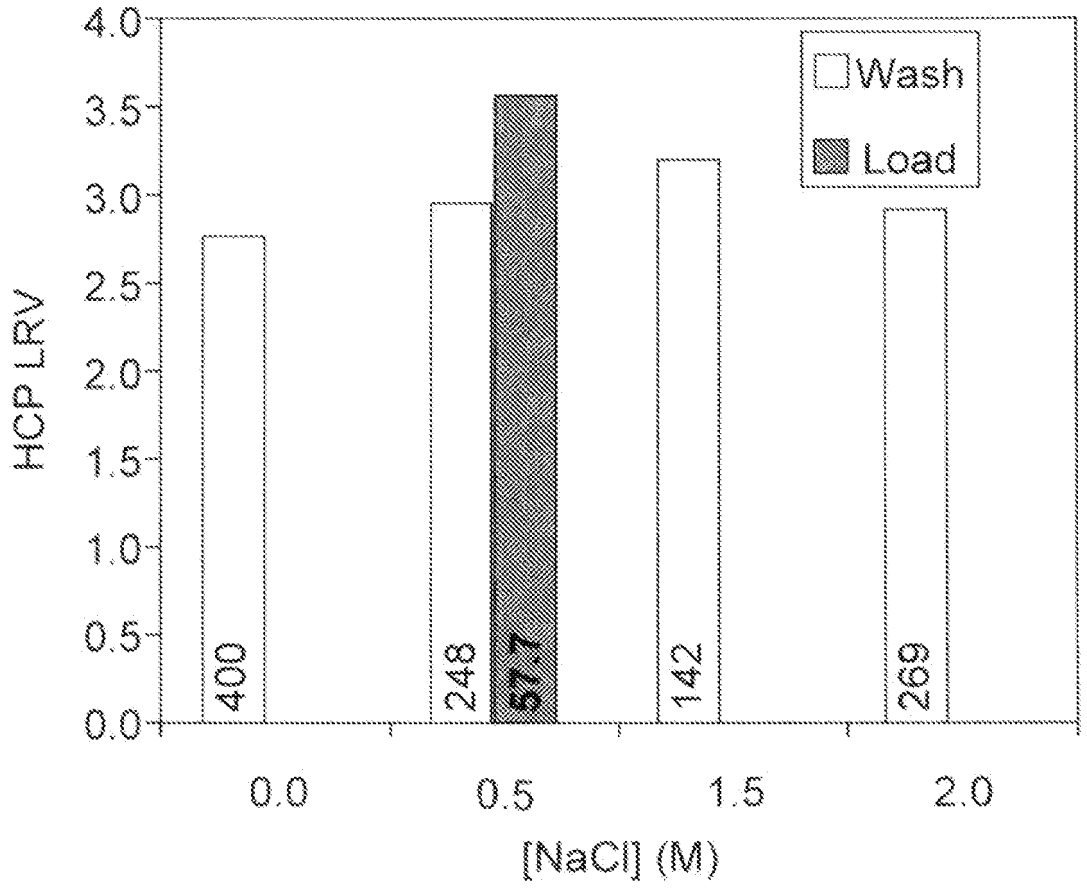

4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
HCP LRV
Wash
Load
400
248
57.7
142
269
0.0
0.5
1.5
2.0
[NaCl] (M)

Figure 21

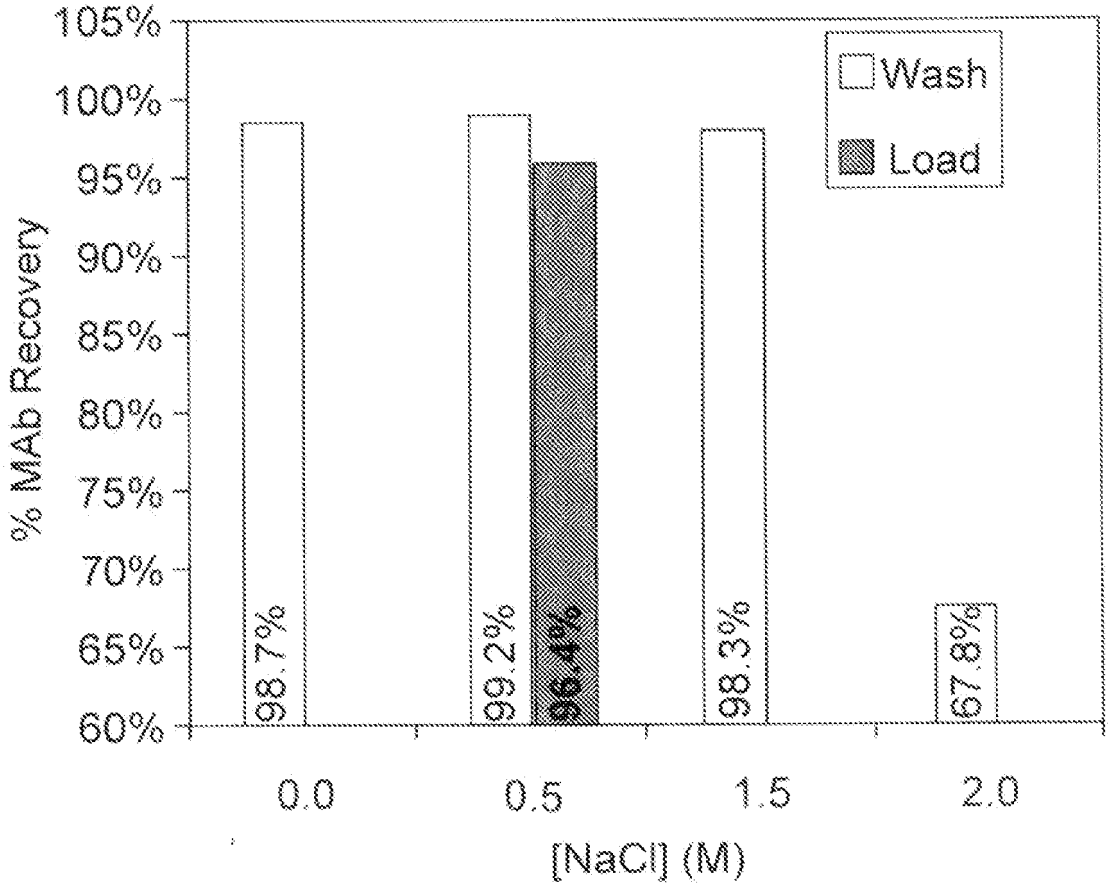

105%
100%
95%
90%
85%
80%
75%
70%
65%
60%
% MAb Recovery
Wash
Load
98.7%
99.2%
96.4%
98.3%
67.8%
0.0
0.5
1.5
2.0
[NaCl] (M)

Figure 22

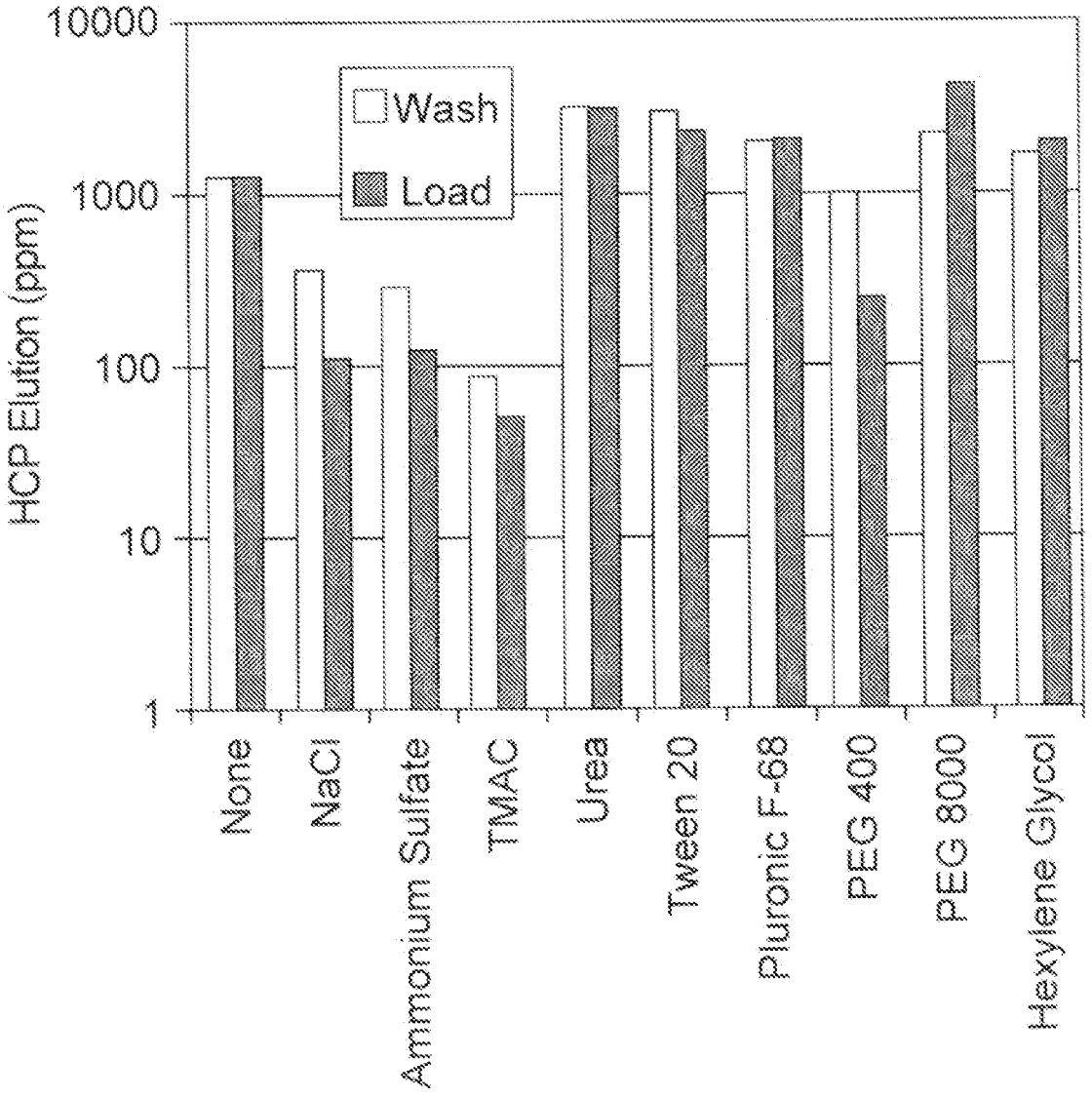

10000
1000
100
10
1
HCP Elution (ppm)
Wash
Load
None
NaCl
Ammonium Sulfate
TMAC
Urea
Tween 20
Pluronic F-68
PEG 400
PEG 8000
Hexylene Glycol

Figure 23

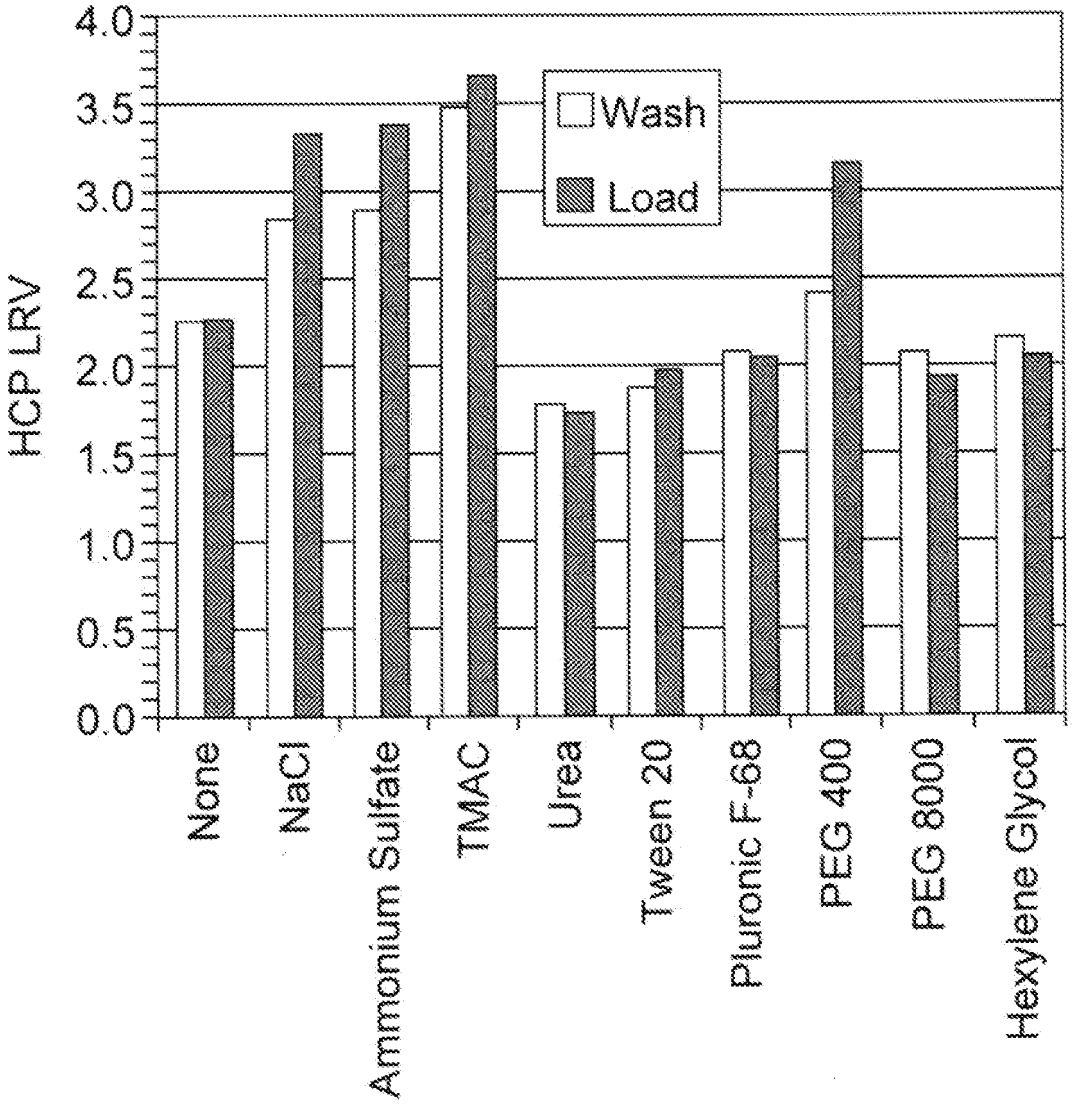

HCP LRV
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
Wash
Load
None
NaCl
Ammonium Sulfate
TMAC
Urea
Tween 20
Pluronic F-68
PEG 400
PEG 8000
Hexylene Glycol

Figure 24

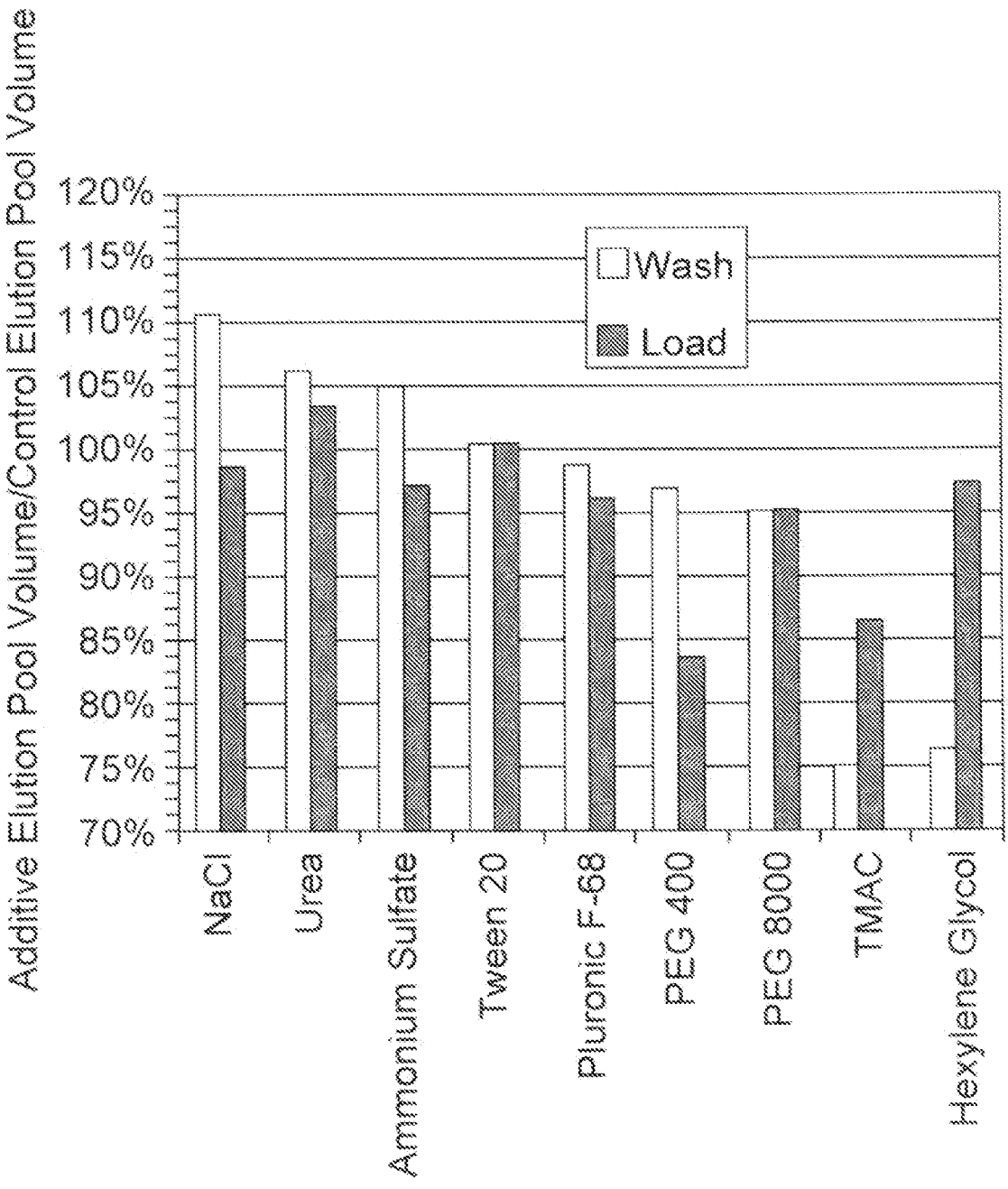

Additive Elution Pool Volume/Control Elution Pool Volume
120%
115%
110%
105%
100%
95%
90%
85%
80%
75%
70%
Wash
Load
NaCl
Urea
Ammonium Sulfate
Tween 20
Pluronic F-68
PEG 400
PEG 8000
TMAC
Hexylene Glycol

Figure 25