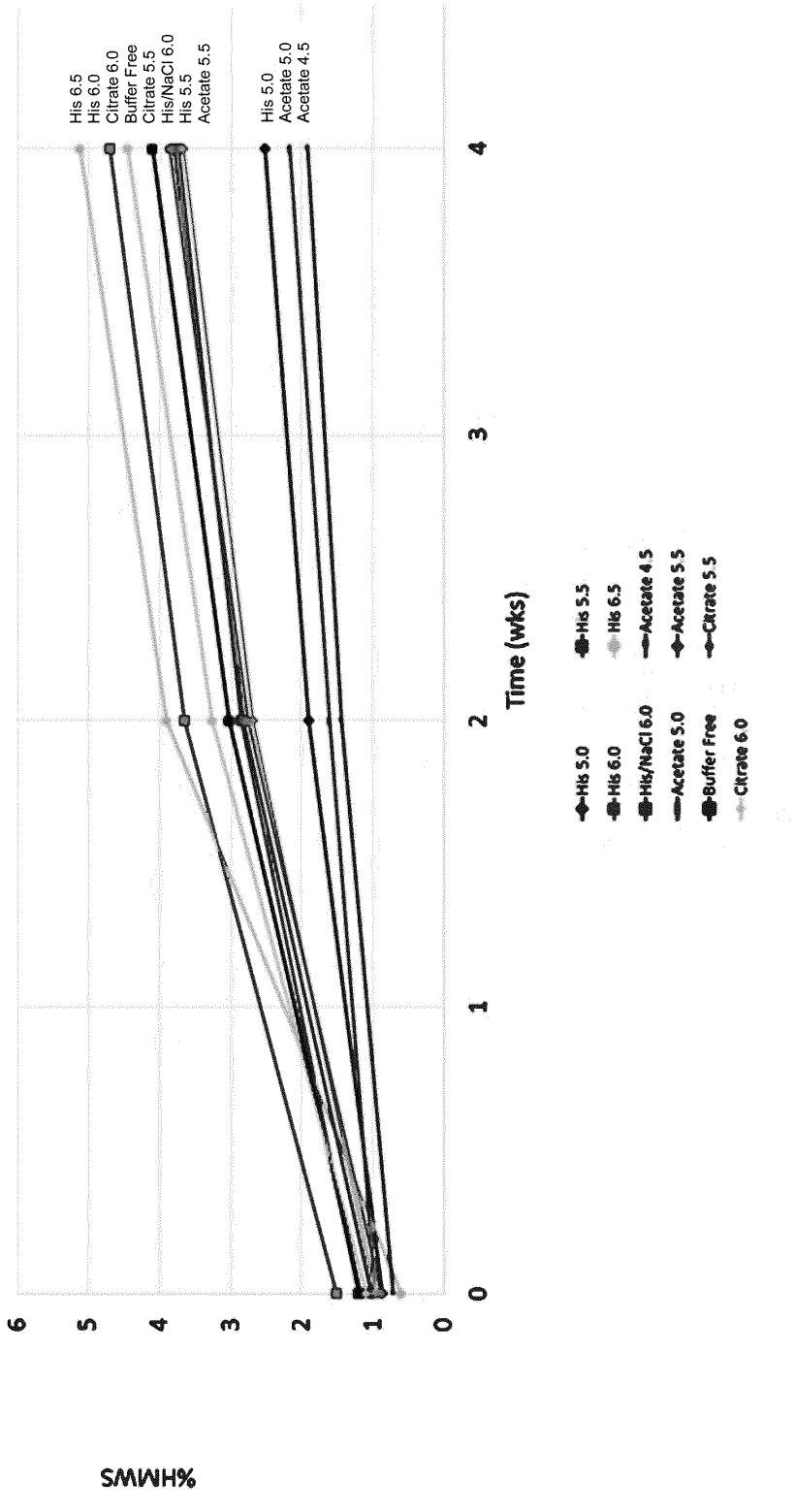

His 6.5
His 6.0
Citrate 6.0
Buffer Free
Citrate 5.5
His/NaCl 6.0
His 5.5
Acetate 5.5
His 5.0
Acetate 5.0
Acetate 4.5
Time (wks)
SMWH%
His 5.0
His 6.0
His/NaCl 6.0
Acetate 5.0
Buffer Free
Citrate 6.0
His 5.5
His 6.5
Acetate 4.5
Acetate 5.5
Citrate 5.5

Figure 1

Figure 2

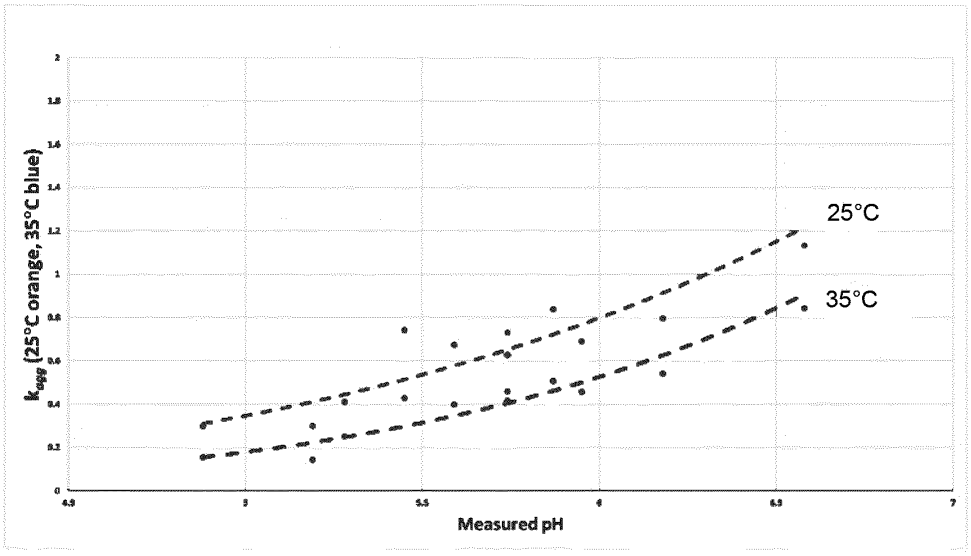


Figure 3

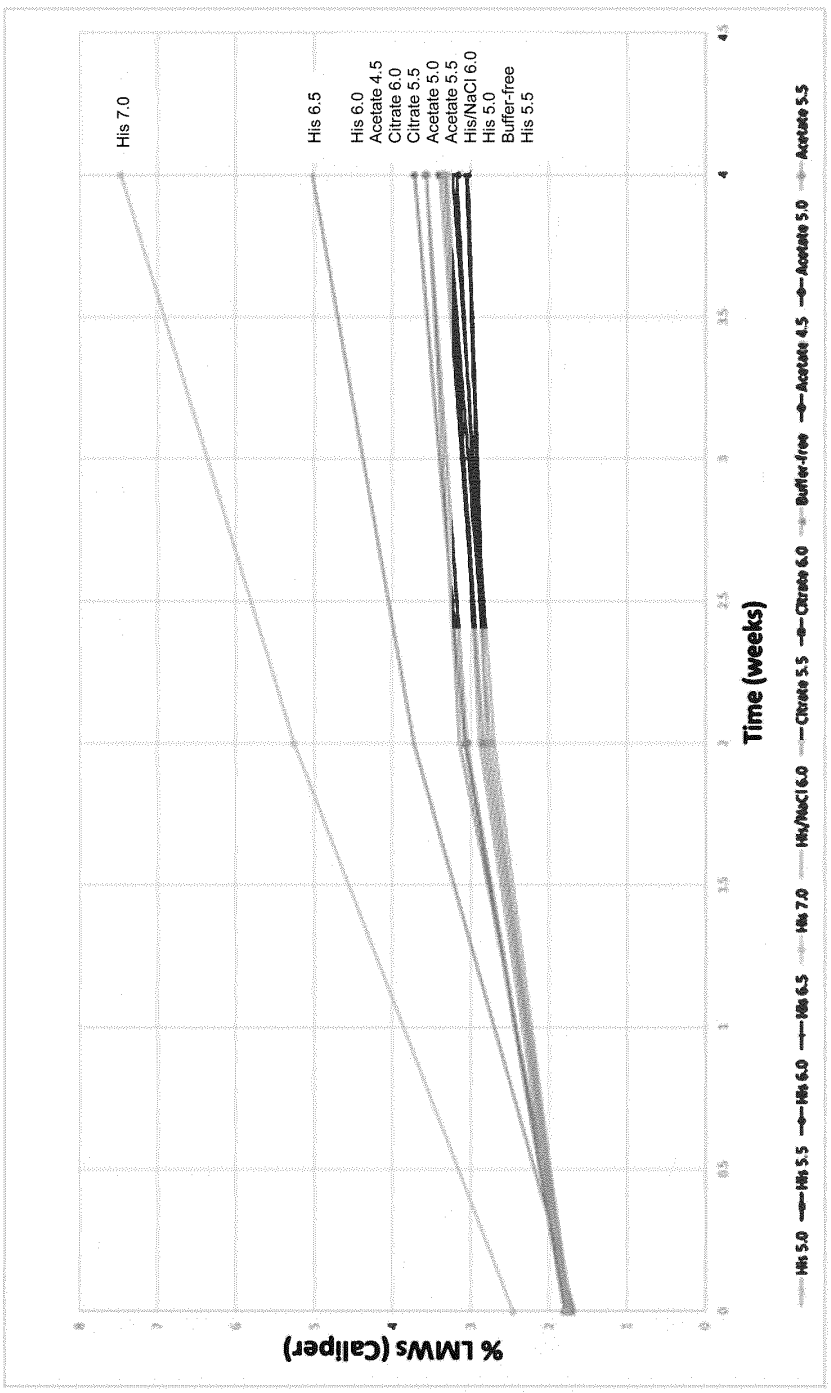

His 7.0
His 6.5
His 6.0
Acetate 4.5
Citrate 6.0
Citrate 5.5
Acetate 5.0
Acetate 5.5
His/NaCl 6.0
His 5.0
Buffer-free
His 5.5
% LMWs (Caliper)
Time (weeks)
His 5.0
His 5.5
His 6.0
His 6.5
His 7.0
His/NaCl 6.0
Citrate 5.5
Citrate 6.0
Buffer-free
Acetate 4.5
Acetate 5.0
Acetate 5.5

Figure 4

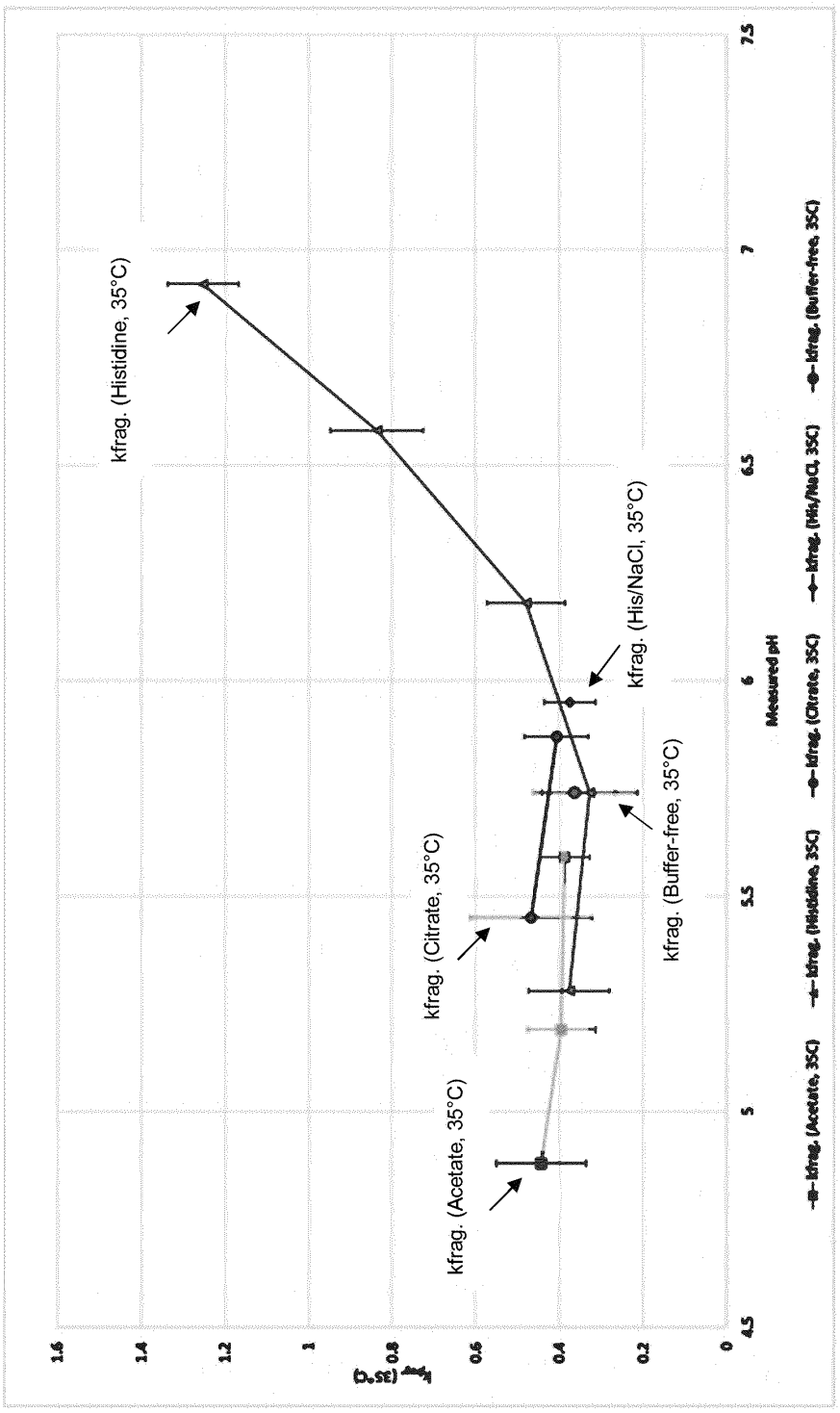
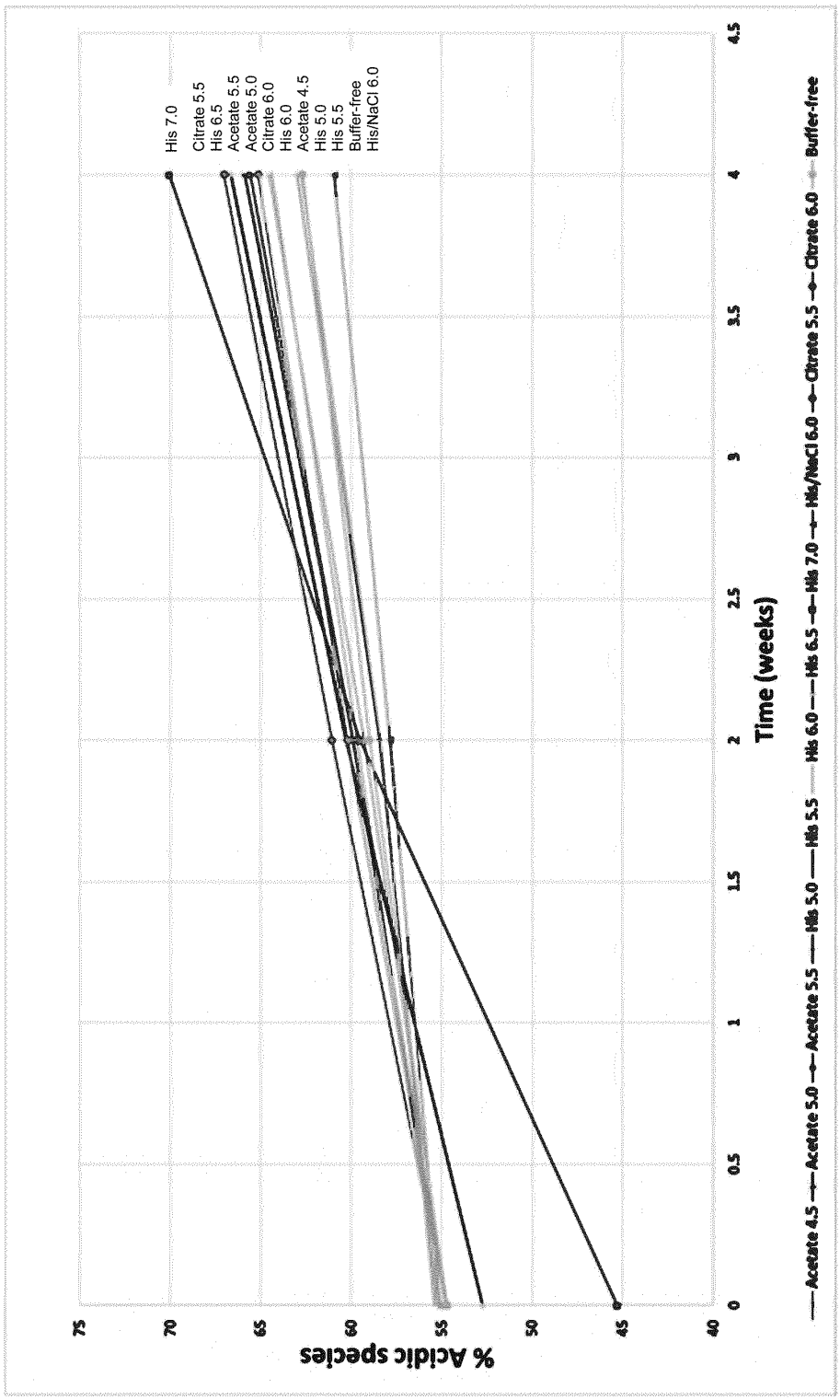

kfrag. (Histidine, 35°C)
kfrag. (His/NaCl, 35°C)
kfrag. (Citrate, 35°C)
kfrag. (Buffer-free, 35°C)
kfrag. (Acetate, 35°C)
Measured pH
kfrag. (Acetate, 35C)
kfrag. (Histidine, 35C)
kfrag. (Citrate, 35C)
kfrag. (His/NaCl, 35C)
kfrag. (Buffer-free, 35C)

Figure 5


His 7.0
Citrate 5.5
His 6.5
Acetate 5.5
Acetate 5.0
Citrate 6.0
His 6.0
Acetate 4.5
His 5.0
His 5.5
Buffer-free
His/NaCl 6.0
% Acidic species
Time (weeks)
Acetate 4.5
Acetate 5.0
Acetate 5.5
His 5.0
His 5.5
His 6.0
His 6.5
His 7.0
His/NaCl 6.0
Citrate 5.5
Citrate 6.0
Buffer-free

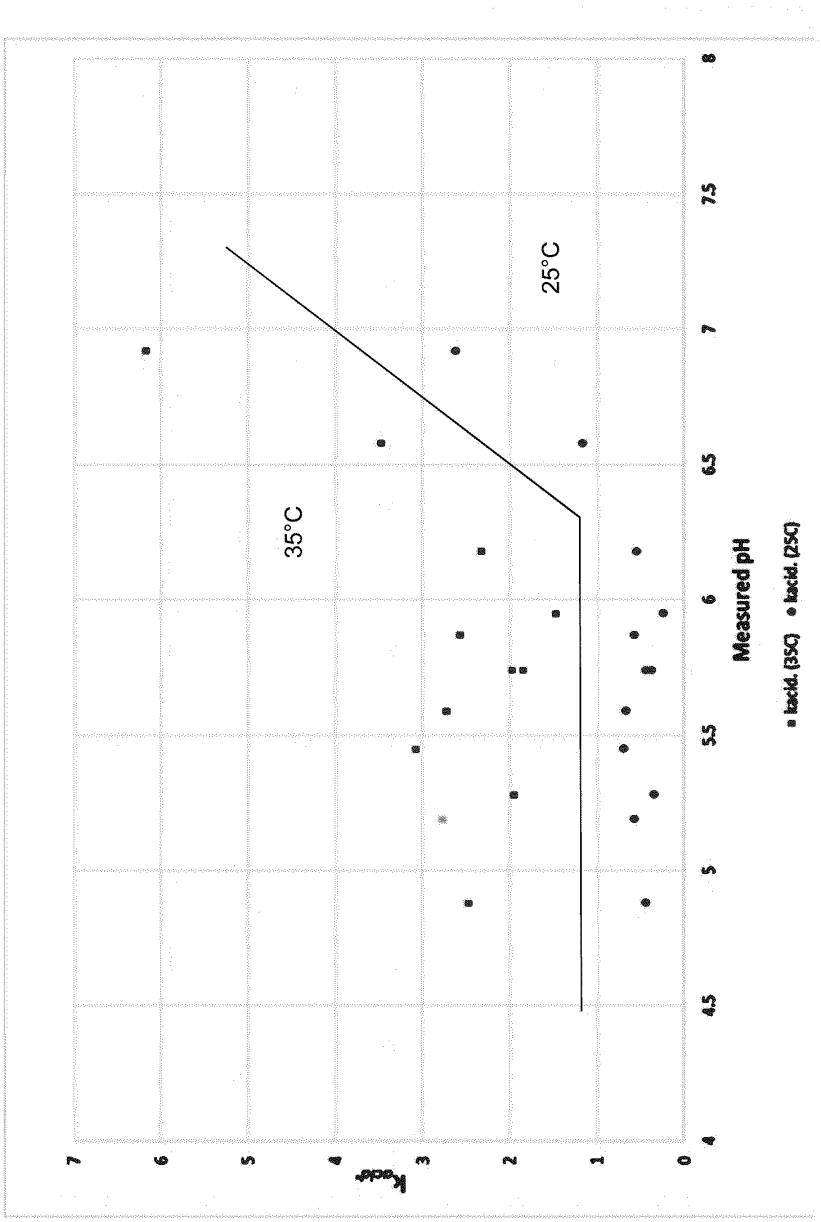
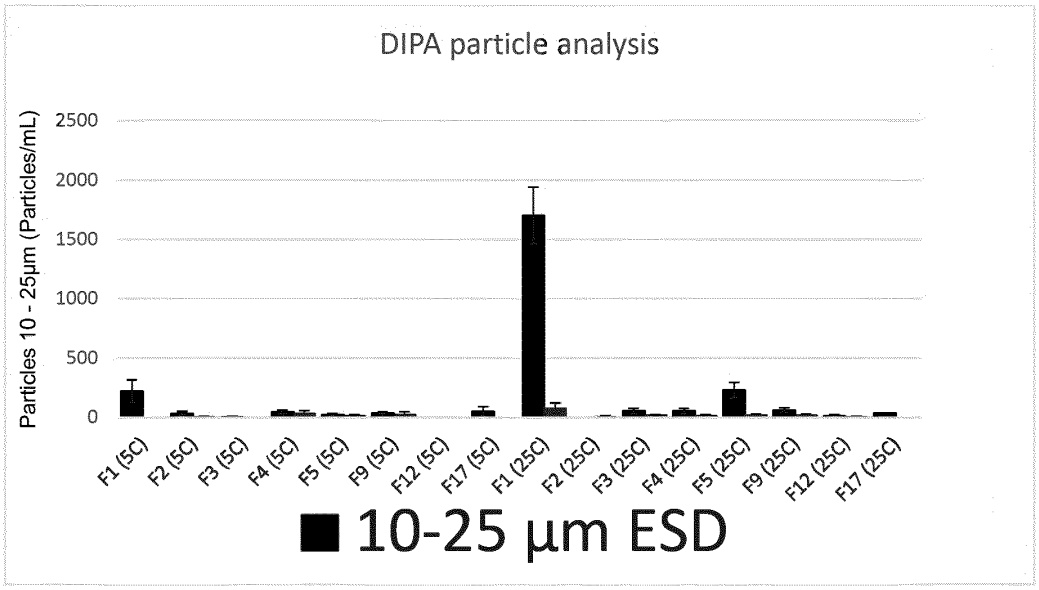

35°C
25°C
Measured pH
lacid. (35C)
lacid. (25C)
4
4.5
5
5.5
6
6.5
7
7.5
8
0
1
2
3
4
5
6
7

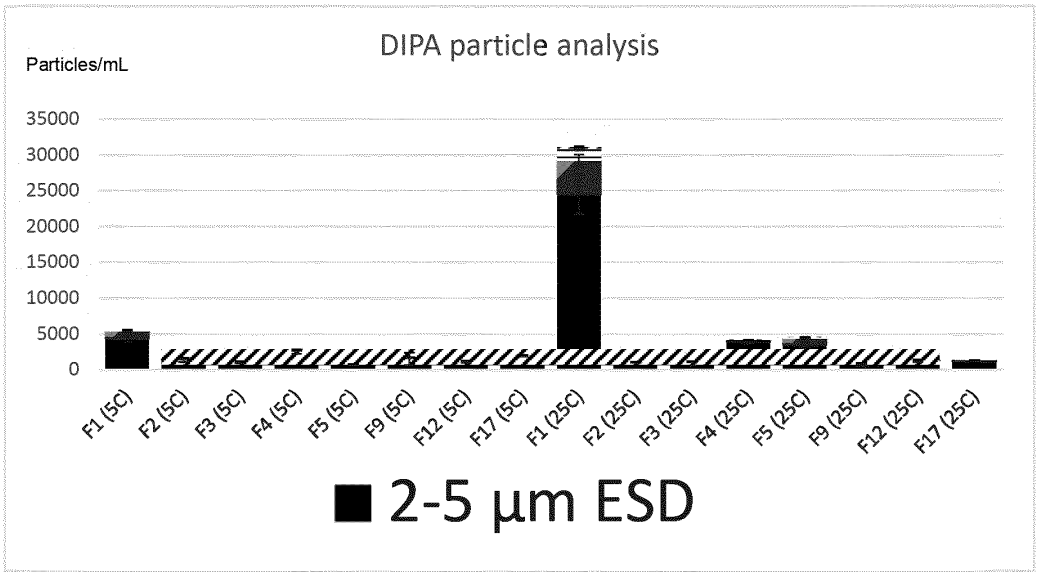
Figure 6

Figure 7

A


DIPA particle analysis
Particles 10 - 25µm (Particles/mL)
2500
2000
1500
1000
500
0
F1 (5C)
F2 (5C)
F3 (5C)
F4 (5C)
F5 (5C)
F9 (5C)
F12 (5C)
F17 (5C)
F1 (25C)
F2 (25C)
F3 (25C)
F4 (25C)
F5 (25C)
F9 (25C)
F12 (25C)
F17 (25C)
10-25 µm ESD

B


DIPA particle analysis
Particles/mL
35000
30000
25000
20000
15000
10000
5000
0
F1 (5C)
F2 (5C)
F3 (5C)
F4 (5C)
F5 (5C)
F9 (5C)
F12 (5C)
F17 (5C)
F1 (25C)
F2 (25C)
F3 (25C)
F4 (25C)
F5 (25C)
F9 (25C)
F12 (25C)
F17 (25C)
2-5 µm ESD

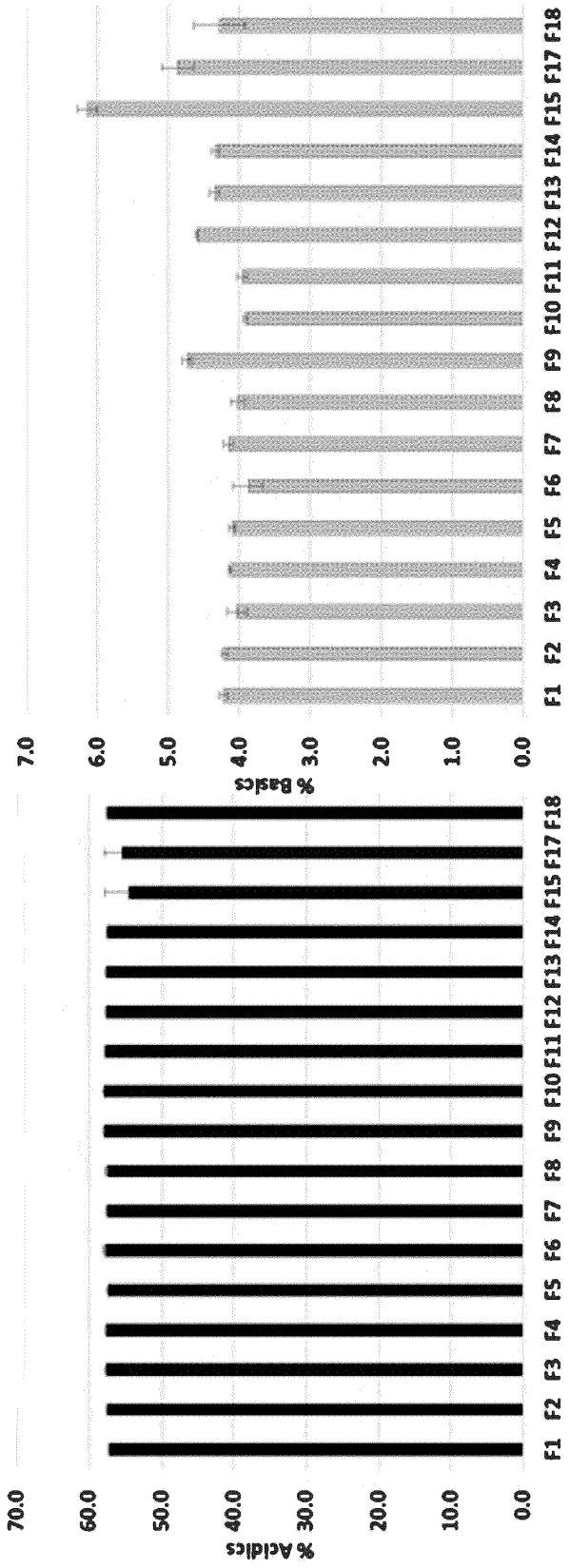
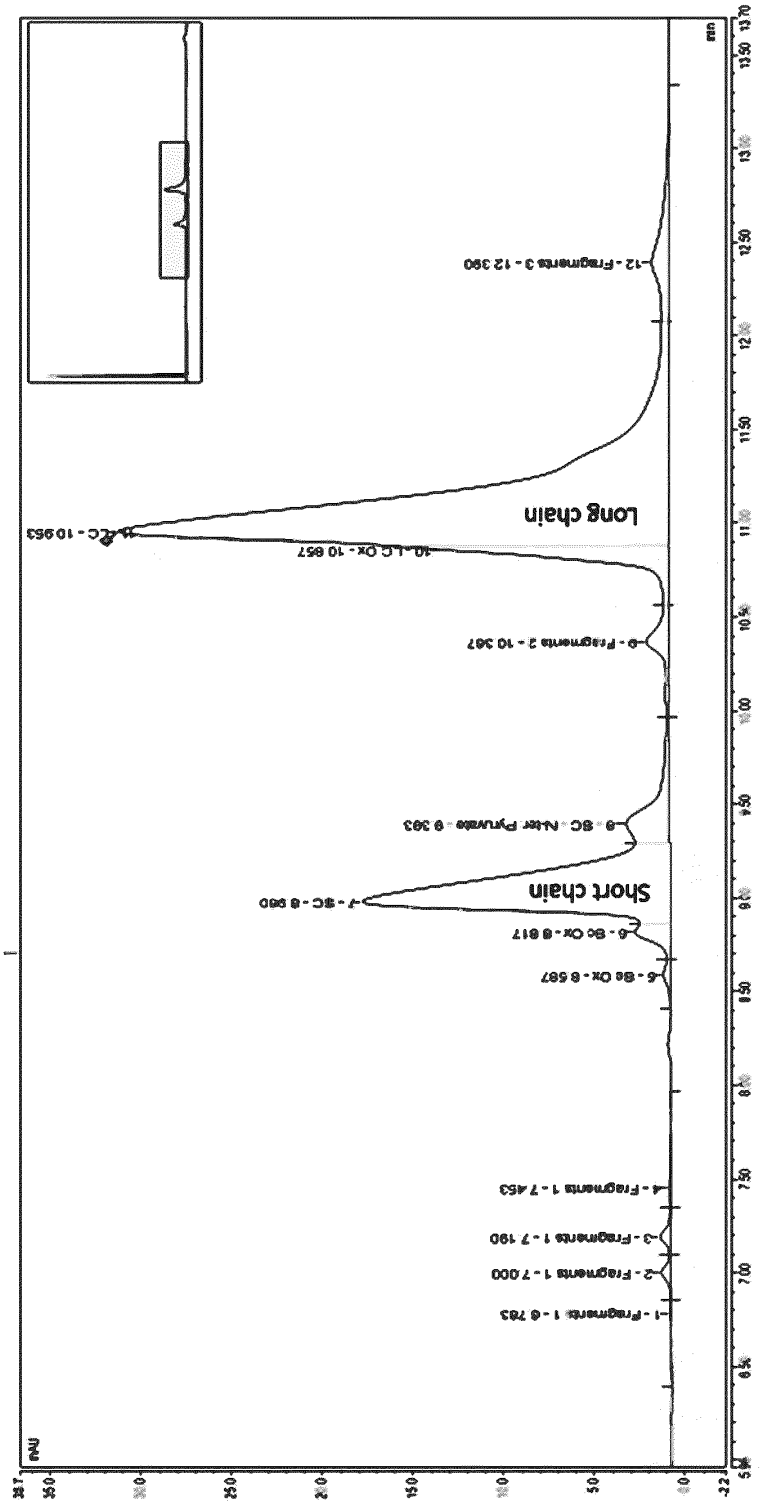

% Basics
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
F1 F2 F3 F4 F5 F6 F7 F8 F9 F10 F11 F12 F13 F14 F15 F17 F18
% Acidics
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
F1 F2 F3 F4 F5 F6 F7 F8 F9 F10 F11 F12 F13 F14 F15 F17 F18

Figure 8

Figure 9


mAU
min
Short chain
Long chain
1 - Fragments 1 - 6 783
2 - Fragments 1 - 7 000
3 - Fragments 1 - 7 190
4 - Fragments 1 - 7 453
5 - Ba Ox - 8 587
6 - Bc Ox - 8 817
7 - BC - 8 980
8 - BC - Ester Pyruvate - 9 393
9 - Fragments 2 - 10 367
10 - LC Ox - 10 857
11 - LC - 10 953
12 - Fragments 3 - 12 390

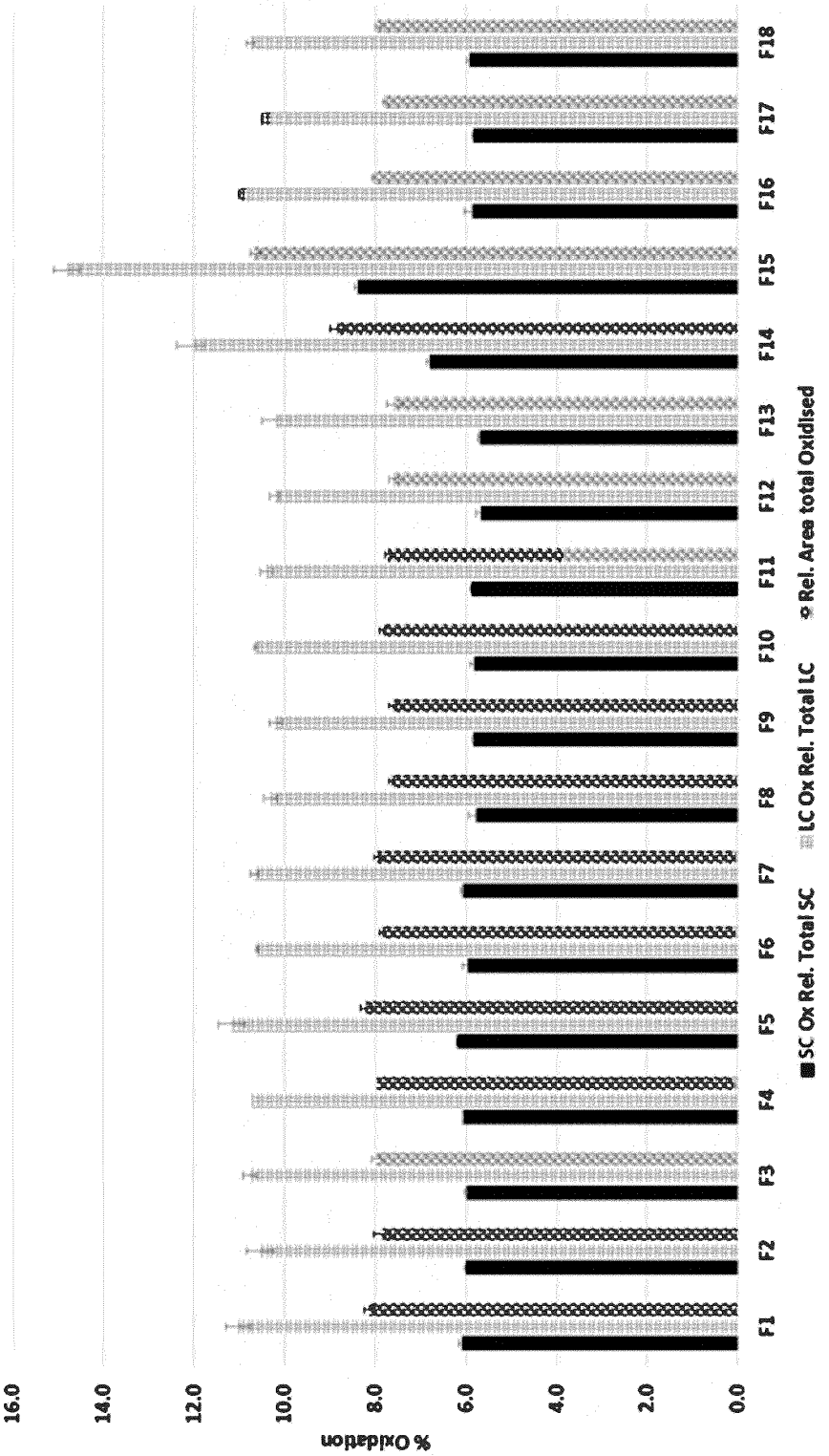

% Oxidation
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
F1
F2
F3
F4
F5
F6
F7
F8
F9
F10
F11
F12
F13
F14
F15
F16
F17
F18
SC Ox Rel. Total SC
LC Ox Rel. Total LC
Rel. Area total Oxidised

Figure 10

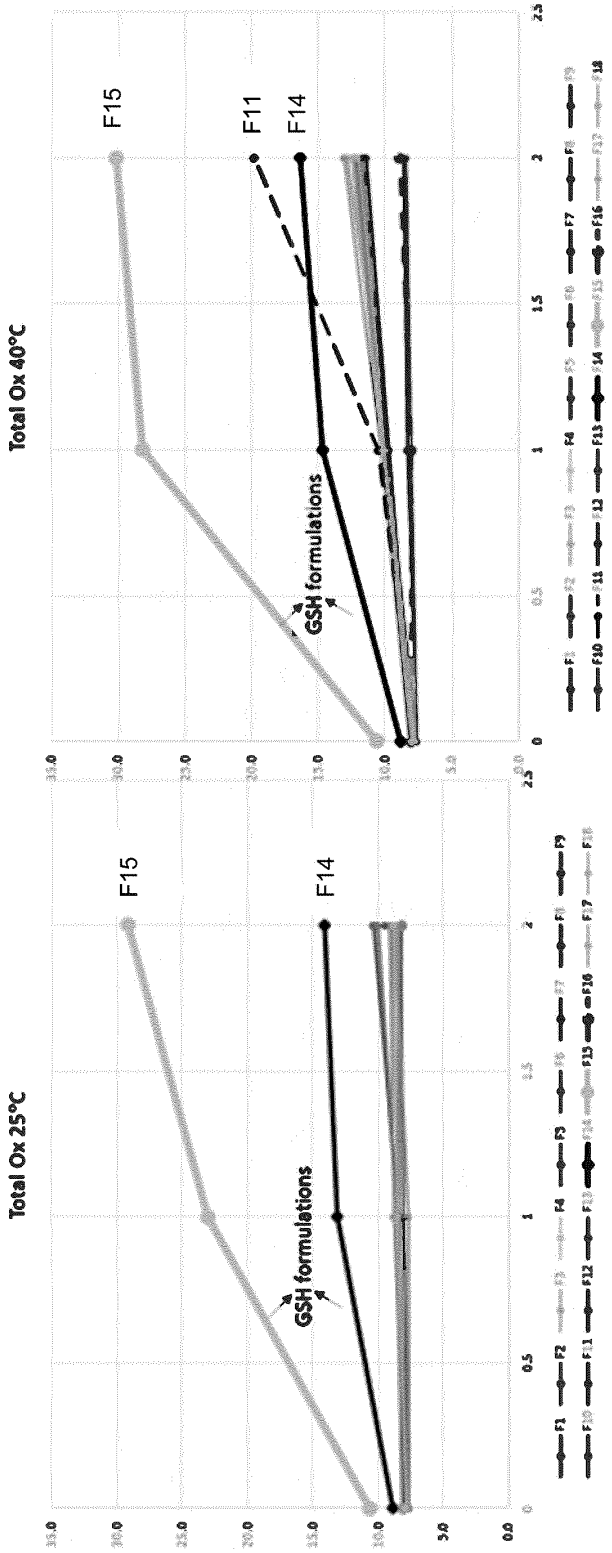

Total Ox 40°C
F15
F11
F14
GSH formulations
Total Ox 25°C
F15
F14
GSH formulations

Figure 11

Figure 12

