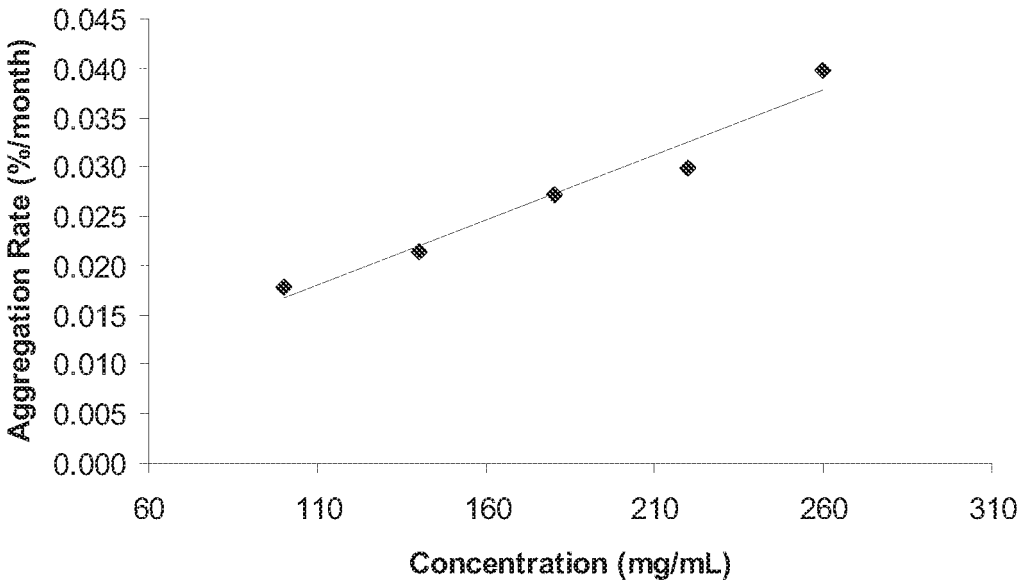

Aggregation Rate (%/month)
0.045
0.040
0.035
0.030
0.025
0.020
0.015
0.010
0.005
0.000
60
110
160
210
260
310
Concentration (mg/mL)

Figure 1

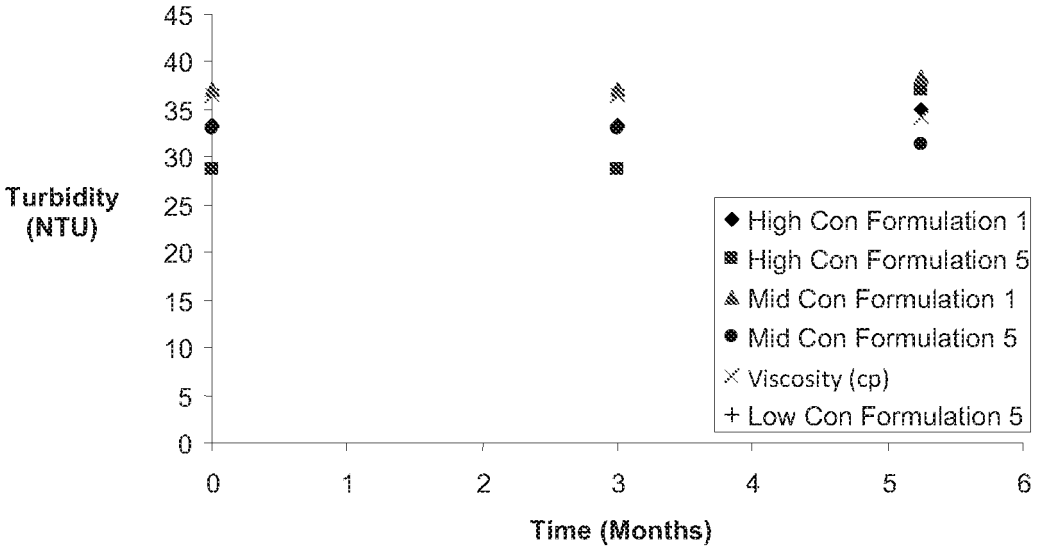

45
40
35
30
25
20
15
10
5
0
Turbidity (NTU)
0
1
2
3
4
5
6
Time (Months)
High Con Formulation 1
High Con Formulation 5
Mid Con Formulation 1
Mid Con Formulation 5
Viscosity (cp)
Low Con Formulation 5

Figure 2

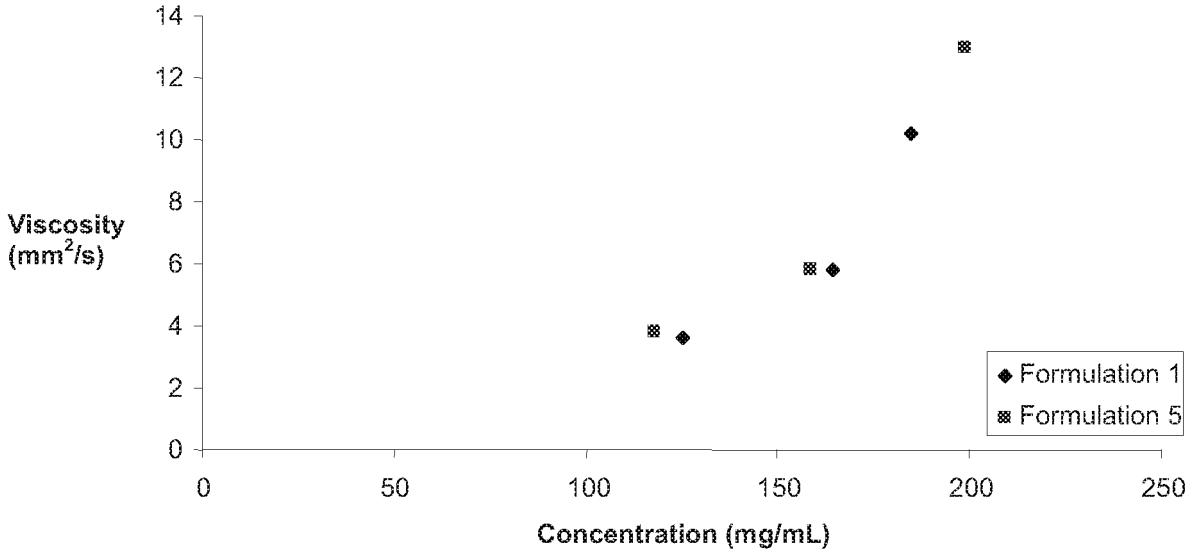

14
12
10
8
6
4
2
0
Viscosity (mm²/s)
0
50
100
150
200
250
Concentration (mg/mL)
Formulation 1
Formulation 5

Figure 3

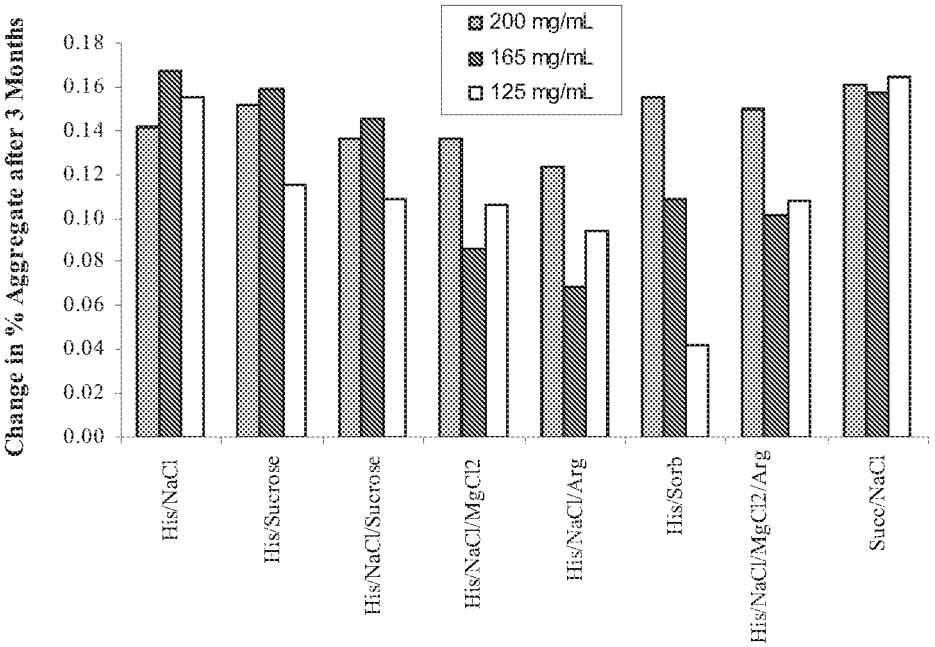

Change in % Aggregate after 3 Months
0.18
0.16
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0.00
200 mg/mL
165 mg/mL
125 mg/mL
His/NaCl
His/Sucrose
His/NaCl/Sucrose
His/NaCl/MgCl2
His/NaCl/Arg
His/Sorb
His/NaCl/MgCl2/Arg
Succ/NaCl

Figure 4

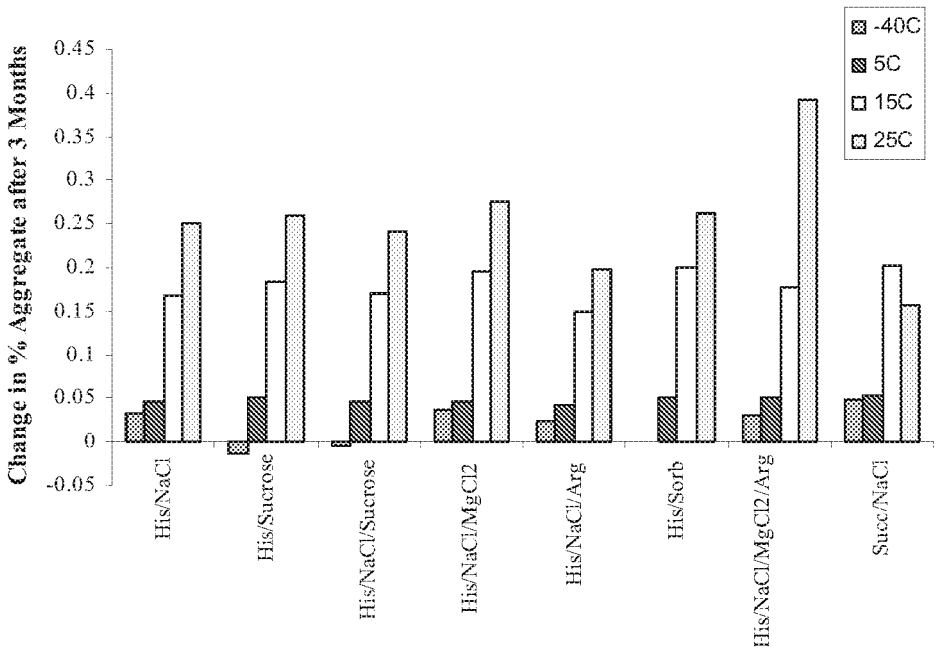

Change in % Aggregate after 3 Months
0.45
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
-0.05
-40C
5C
15C
25C
His/NaCl
His/Sucrose
His/NaCl/Sucrose
His/NaCl/MgCl2
His/NaCl/Arg
His/Sorb
His/NaCl/MgCl2/Arg
Succ/NaCl

Figure 5

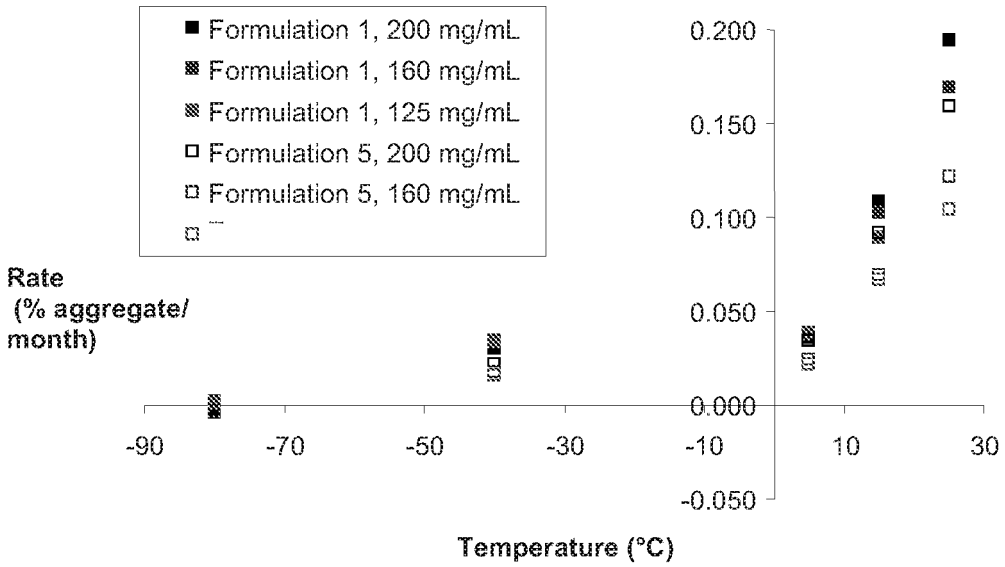

Formulation 1, 200 mg/mL
Formulation 1, 160 mg/mL
Formulation 1, 125 mg/mL
Formulation 5, 200 mg/mL
Formulation 5, 160 mg/mL
Rate
(% aggregate/
month)
0.200
0.150
0.100
0.050
0.000
-0.050
-90
-70
-50
-30
-10
10
30
Temperature (°C)

Figure 6

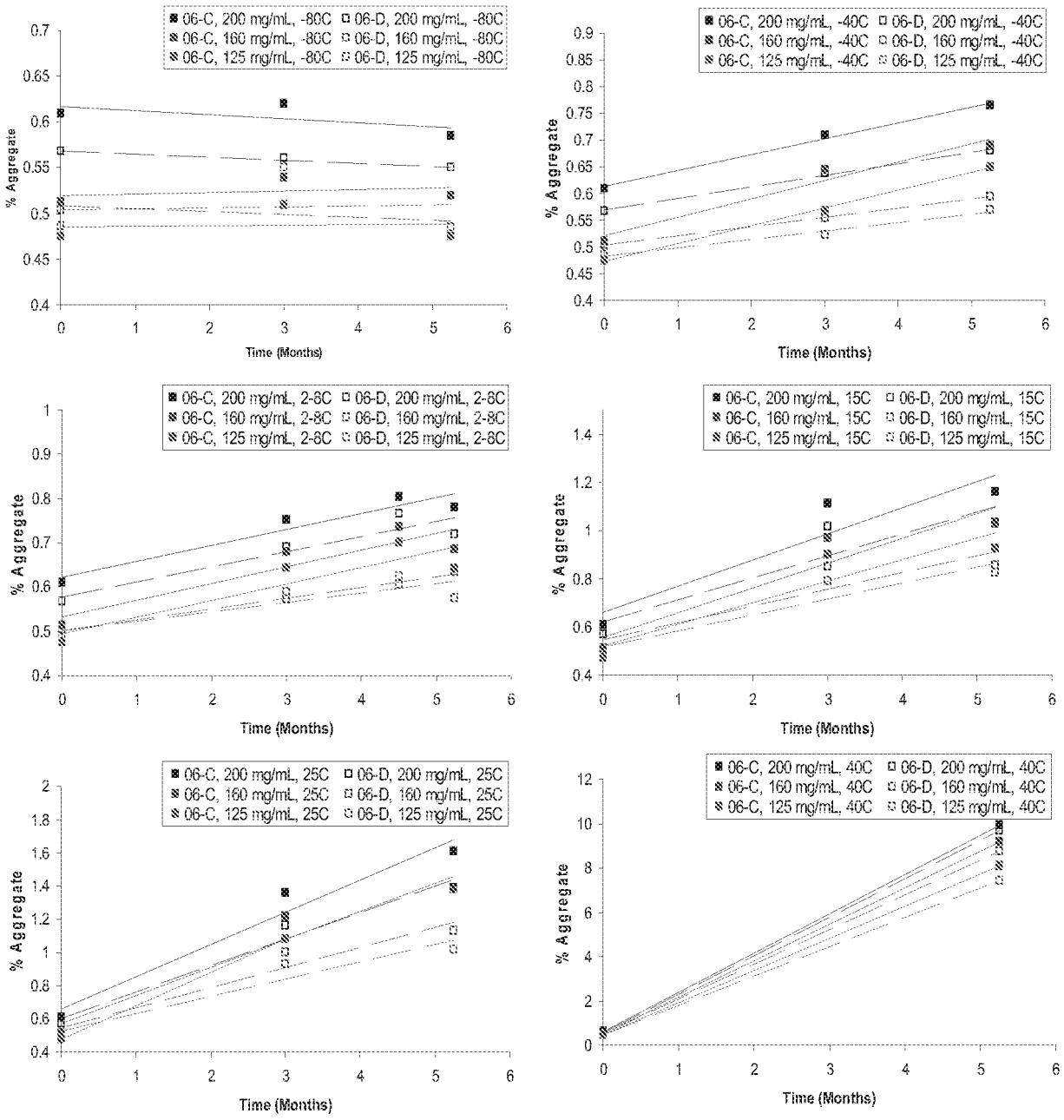

06-C, 200 mg/mL, -80C
06-D, 200 mg/mL, -80C
06-C, 160 mg/mL, -80C
06-D, 160 mg/mL, -80C
06-C, 125 mg/mL, -80C
06-D, 125 mg/mL, -80C
% Aggregate
Time (Months)
06-C, 200 mg/mL, -40C
06-D, 200 mg/mL, -40C
06-C, 160 mg/mL, -40C
06-D, 160 mg/mL, -40C
06-C, 125 mg/mL, -40C
06-D, 125 mg/mL, -40C
% Aggregate
Time (Months)
06-C, 200 mg/mL, 2-8C
06-D, 200 mg/mL, 2-8C
06-C, 160 mg/mL, 2-8C
06-D, 160 mg/mL, 2-8C
06-C, 125 mg/mL, 2-8C
06-D, 125 mg/mL, 2-8C
% Aggregate
Time (Months)
06-C, 200 mg/mL, 15C
06-D, 200 mg/mL, 15C
06-C, 160 mg/mL, 15C
06-D, 160 mg/mL, 15C
06-C, 125 mg/mL, 15C
06-D, 125 mg/mL, 15C
% Aggregate
Time (Months)
06-C, 200 mg/mL, 25C
06-D, 200 mg/mL, 25C
06-C, 160 mg/mL, 25C
06-D, 160 mg/mL, 25C
06-C, 125 mg/mL, 25C
06-D, 125 mg/mL, 25C
% Aggregate
Time (Months)
06-C, 200 mg/mL, 40C
06-D, 200 mg/mL, 40C
06-C, 160 mg/mL, 40C
06-D, 160 mg/mL, 40C
06-C, 125 mg/mL, 40C
06-D, 125 mg/mL, 40C
% Aggregate
Time (Months)

Figure 7

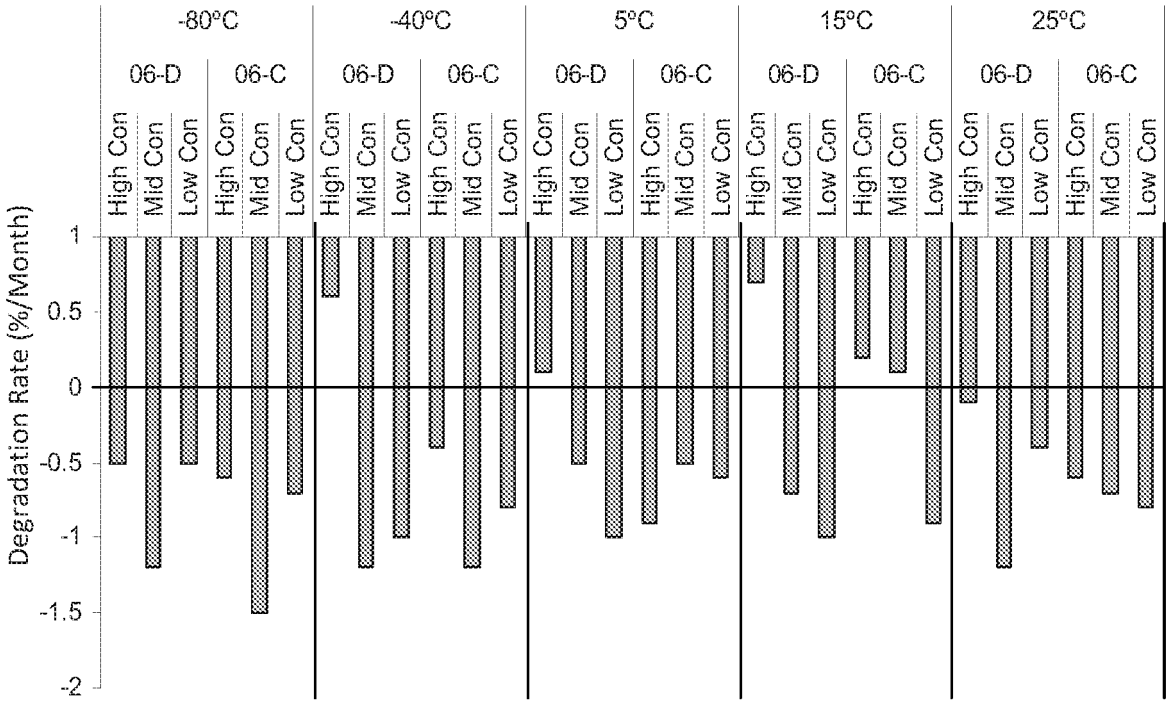

-80°C
-40°C
5°C
15°C
25°C
06-D
06-C
High Con
Mid Con
Low Con
Degradation Rate (%/Month)
1
0.5
0
-0.5
-1
-1.5
-2

Figure 8

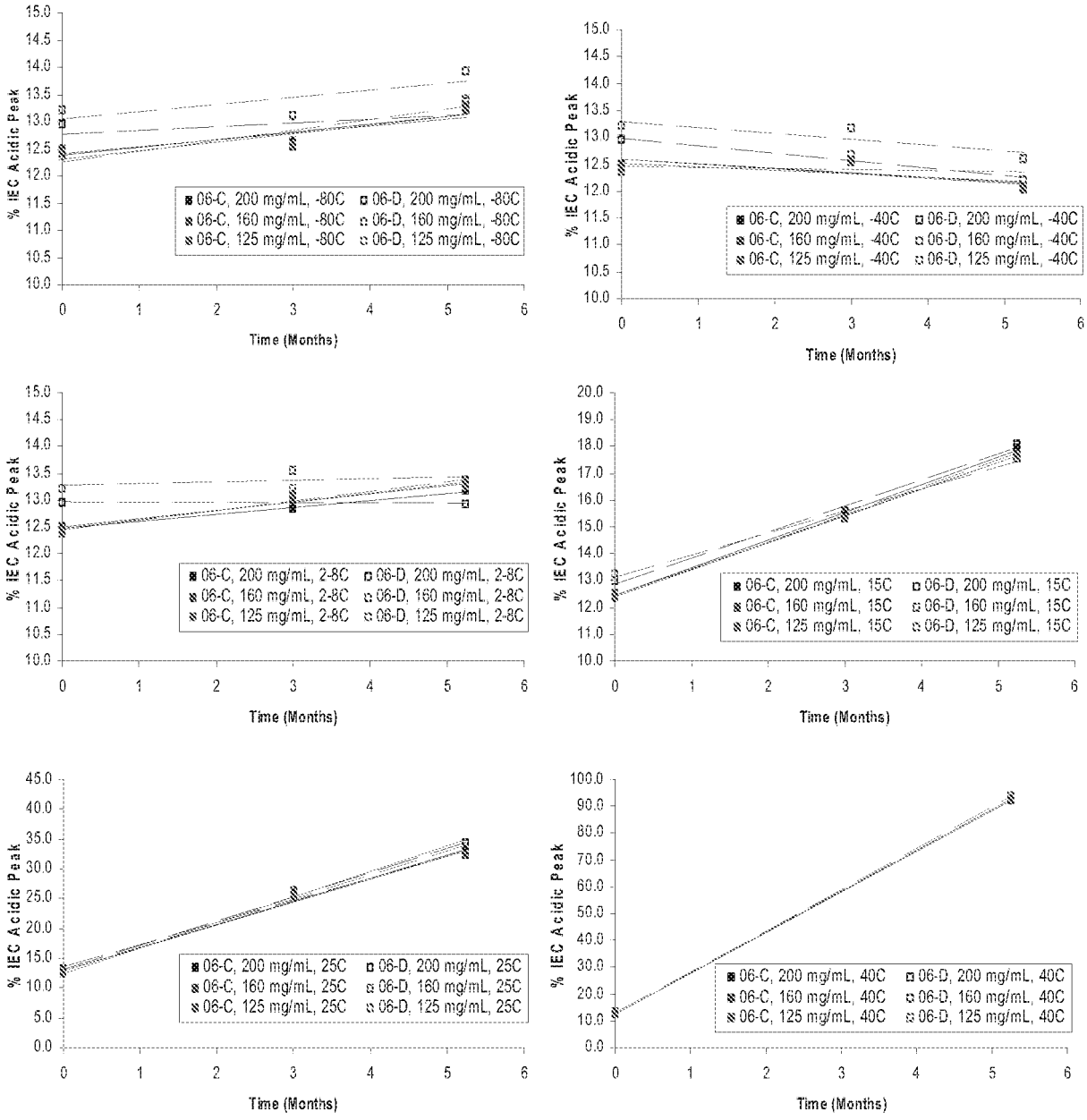

% IEC Acidic Peak
Time (Months)
06-C, 200 mg/mL, -80C
06-D, 200 mg/mL, -80C
06-C, 160 mg/mL, -80C
06-D, 160 mg/mL, -80C
06-C, 125 mg/mL, -80C
06-D, 125 mg/mL, -80C
06-C, 200 mg/mL, -40C
06-D, 200 mg/mL, -40C
06-C, 160 mg/mL, -40C
06-D, 160 mg/mL, -40C
06-C, 125 mg/mL, -40C
06-D, 125 mg/mL, -40C
06-C, 200 mg/mL, 2-8C
06-D, 200 mg/mL, 2-8C
06-C, 160 mg/mL, 2-8C
06-D, 160 mg/mL, 2-8C
06-C, 125 mg/mL, 2-8C
06-D, 125 mg/mL, 2-8C
06-C, 200 mg/mL, 15C
06-D, 200 mg/mL, 15C
06-C, 160 mg/mL, 15C
06-D, 160 mg/mL, 15C
06-C, 125 mg/mL, 15C
06-D, 125 mg/mL, 15C
06-C, 200 mg/mL, 25C
06-D, 200 mg/mL, 25C
06-C, 160 mg/mL, 25C
06-D, 160 mg/mL, 25C
06-C, 125 mg/mL, 25C
06-D, 125 mg/mL, 25C
06-C, 200 mg/mL, 40C
06-D, 200 mg/mL, 40C
06-C, 160 mg/mL, 40C
06-D, 160 mg/mL, 40C
06-C, 125 mg/mL, 40C
06-D, 125 mg/mL, 40C

Figure 9

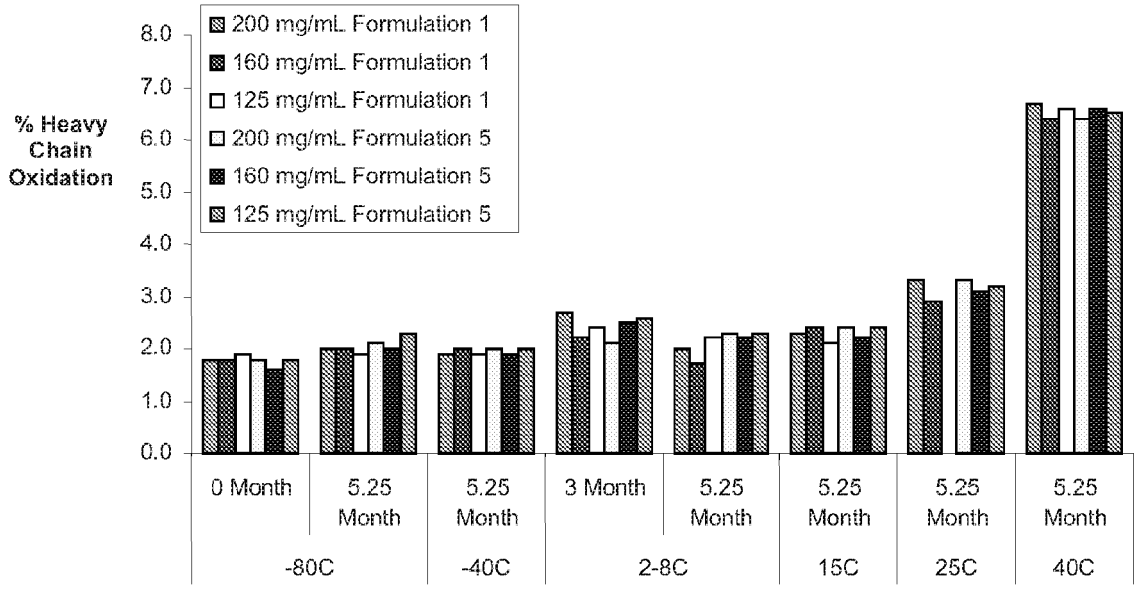

% Heavy Chain Oxidation
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
200 mg/mL Formulation 1
160 mg/mL Formulation 1
125 mg/mL Formulation 1
200 mg/mL Formulation 5
160 mg/mL Formulation 5
125 mg/mL Formulation 5
0 Month
5.25 Month
5.25 Month
3 Month
5.25 Month
5.25 Month
5.25 Month
5.25 Month
-80C
-40C
2-8C
15C
25C
40C

Figure 10

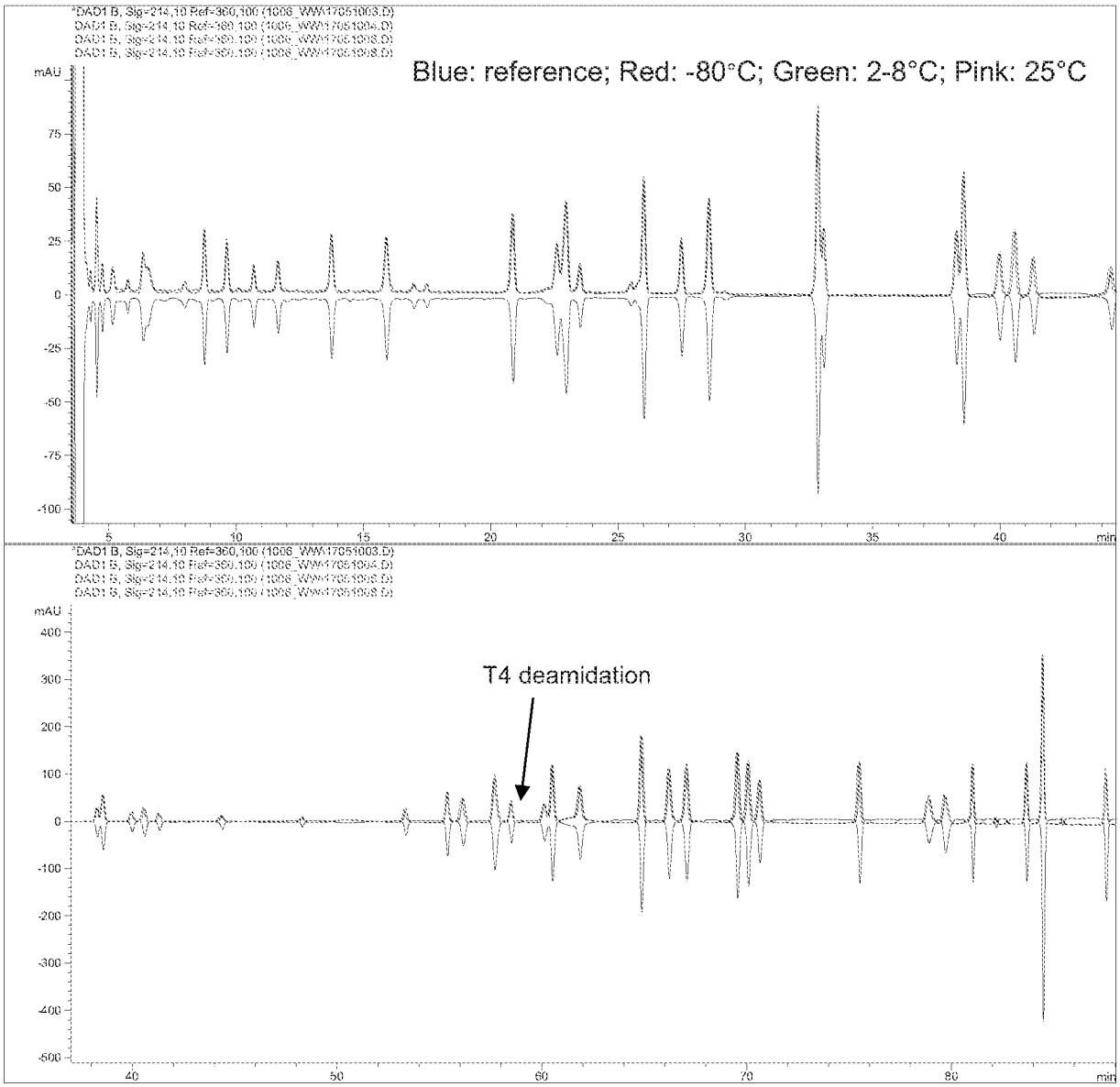

Blue: reference; Red: -80°C; Green: 2-8°C; Pink: 25°C
mAU
min
T4 deamidation

Figure 11

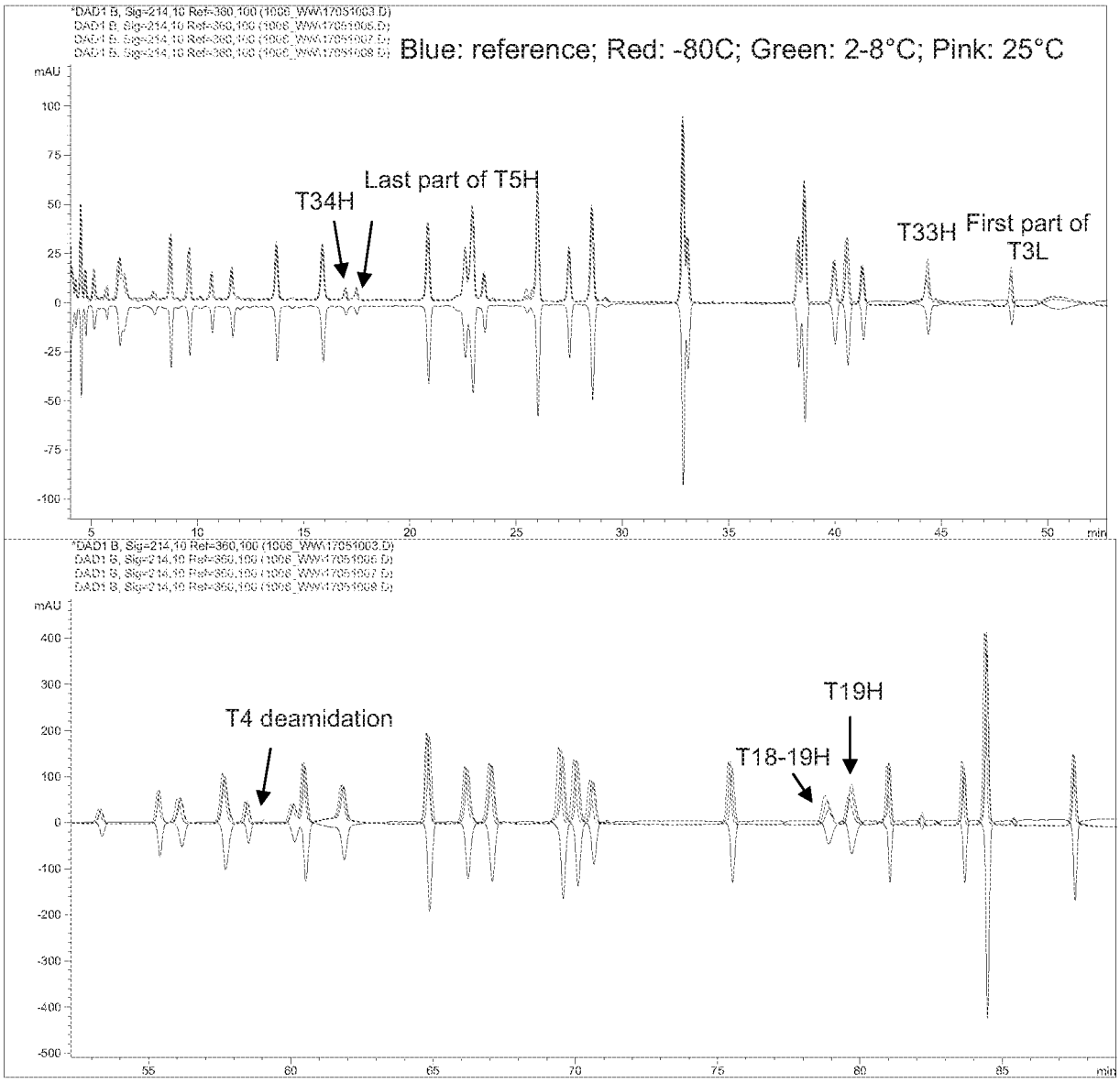

Blue: reference; Red: -80C; Green: 2-8°C; Pink: 25°C
mAU
T34H
Last part of T5H
T33H
First part of T3L
min
T4 deamidation
T18-19H
T19H

Figure 12

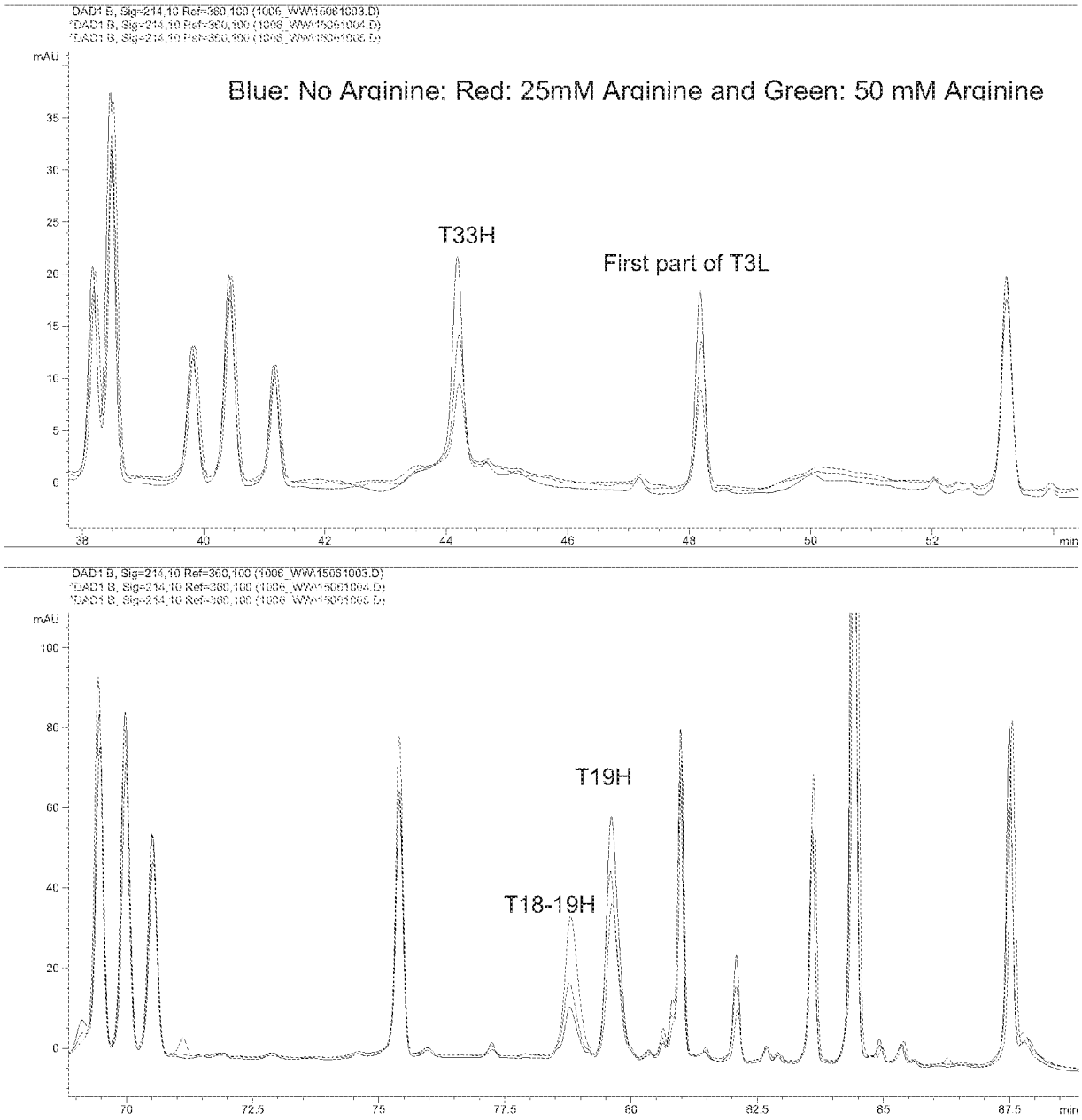

Blue: No Arginine: Red: 25mM Arginine and Green: 50 mM Arginine
T33H
First part of T3L
T19H
T18-19H
mAU
min

Figure 13

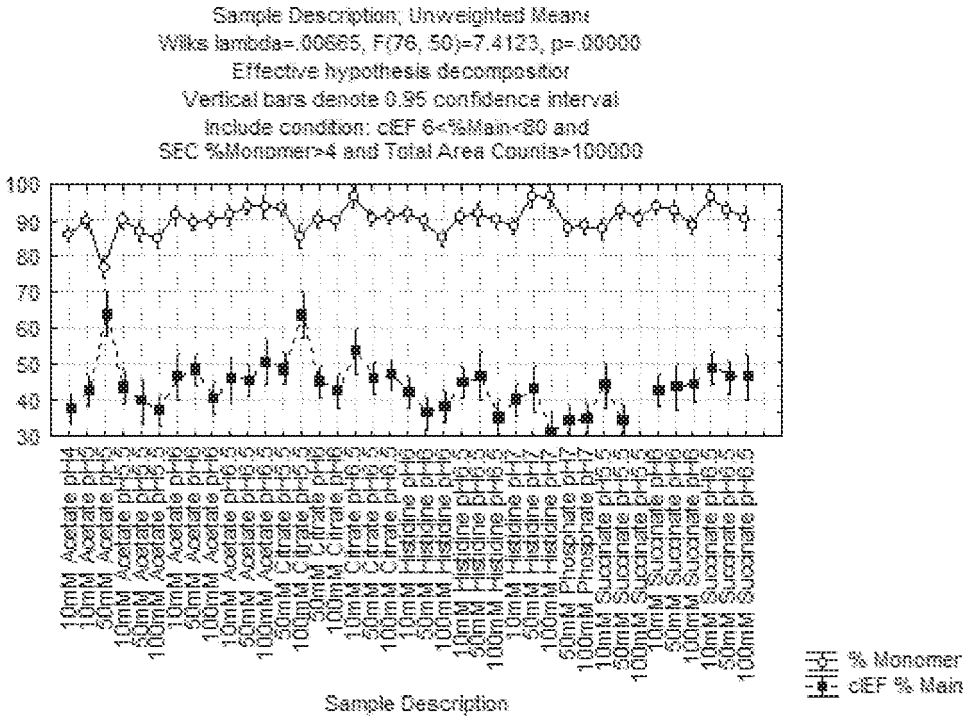

Sample Description; Unweighted Means
Wilks lambda=.00665, F(76, 50)=7.4123, p=.00000
Effective hypothesis decomposition
Vertical bars denote 0.95 confidence interval
Include condition: cEF 6<%Main<80 and
SEC %Monomer>4 and Total Area Counts>100000
100
90
80
70
60
50
40
30
10mM Acetate pH4
10mM Acetate pH5
50mM Acetate pH4
50mM Acetate pH5
100mM Acetate pH4
100mM Acetate pH5
10mM Citrate pH5
50mM Citrate pH5
100mM Citrate pH5
10mM Histidine pH5.5
50mM Histidine pH5.5
100mM Histidine pH5.5
10mM Histidine pH6
50mM Histidine pH6
100mM Histidine pH6
10mM Phosphate pH7
50mM Phosphate pH7
100mM Phosphate pH7
10mM Succinate pH5.5
50mM Succinate pH5.5
100mM Succinate pH5.5
10mM Succinate pH6
50mM Succinate pH6
100mM Succinate pH6
10mM Succinate pH6.5
50mM Succinate pH6.5
100mM Succinate pH6.5
Sample Description
% Monomer
cEF % Main

Figure 14

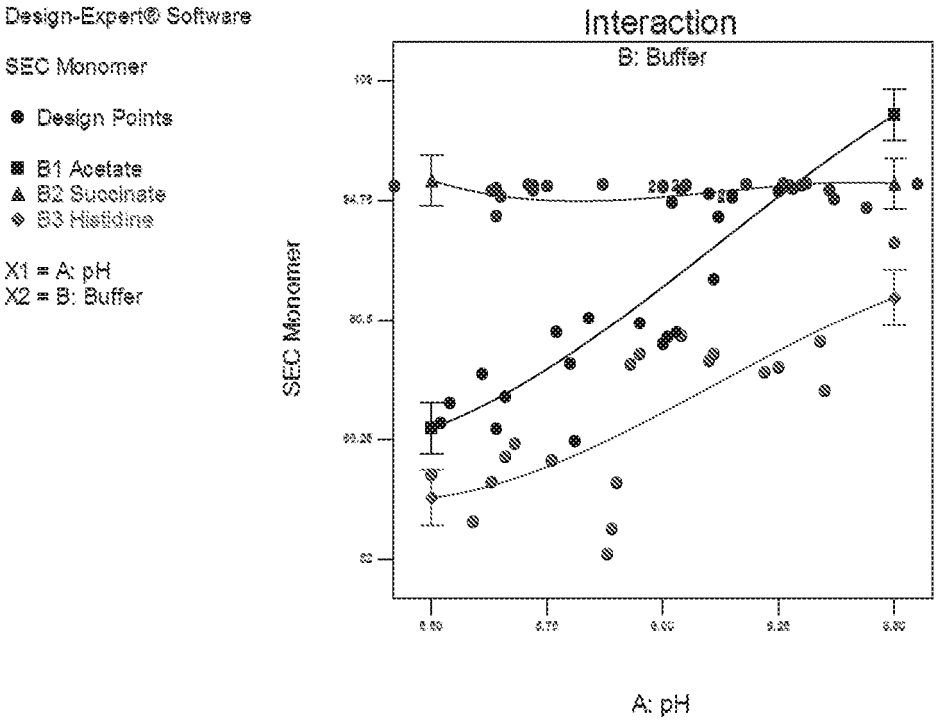

Design-Expert® Software
SEC Monomer
Design Points
B1 Acetate
B2 Succinate
B3 Histidine
X1 = A: pH
X2 = B: Buffer
Interaction
B: Buffer
SEC Monomer
A: pH

Figure 15

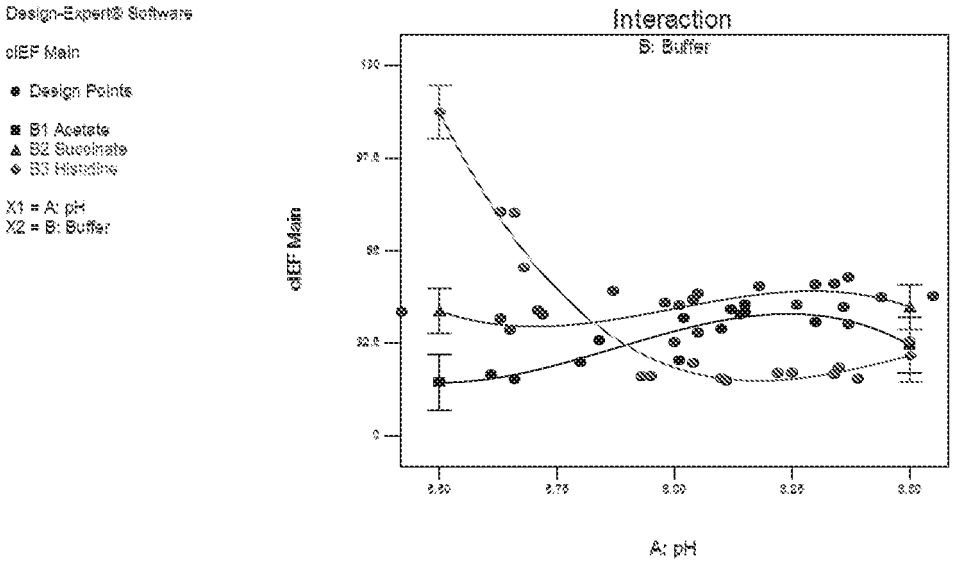

Design-Expert® Software
cIEF Main
Design Points
B1 Acetate
B2 Succinate
B3 Histidine
X1 = A: pH
X2 = B: Buffer
Interaction
B: Buffer
cIEF Main
A: pH

Figure 16

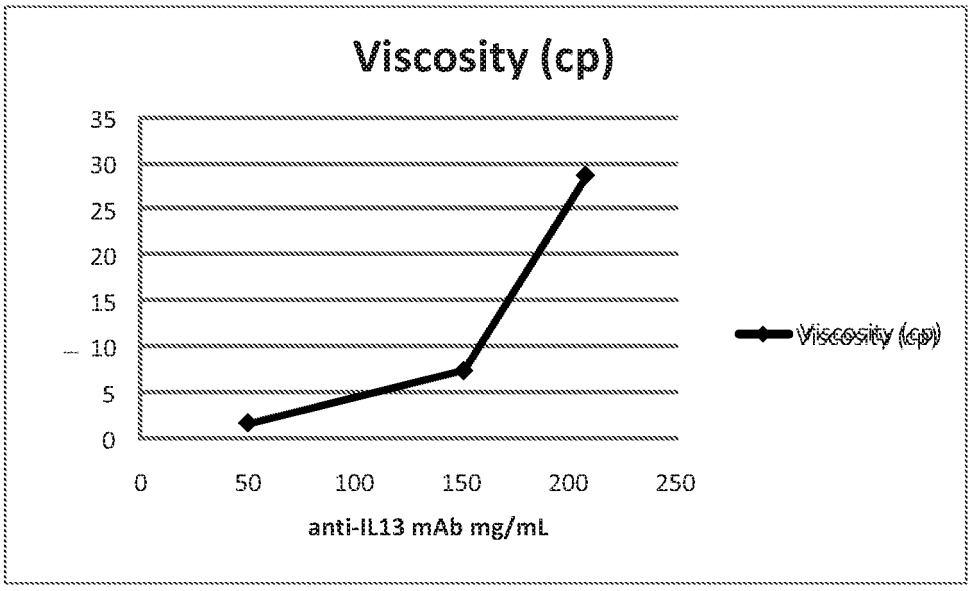
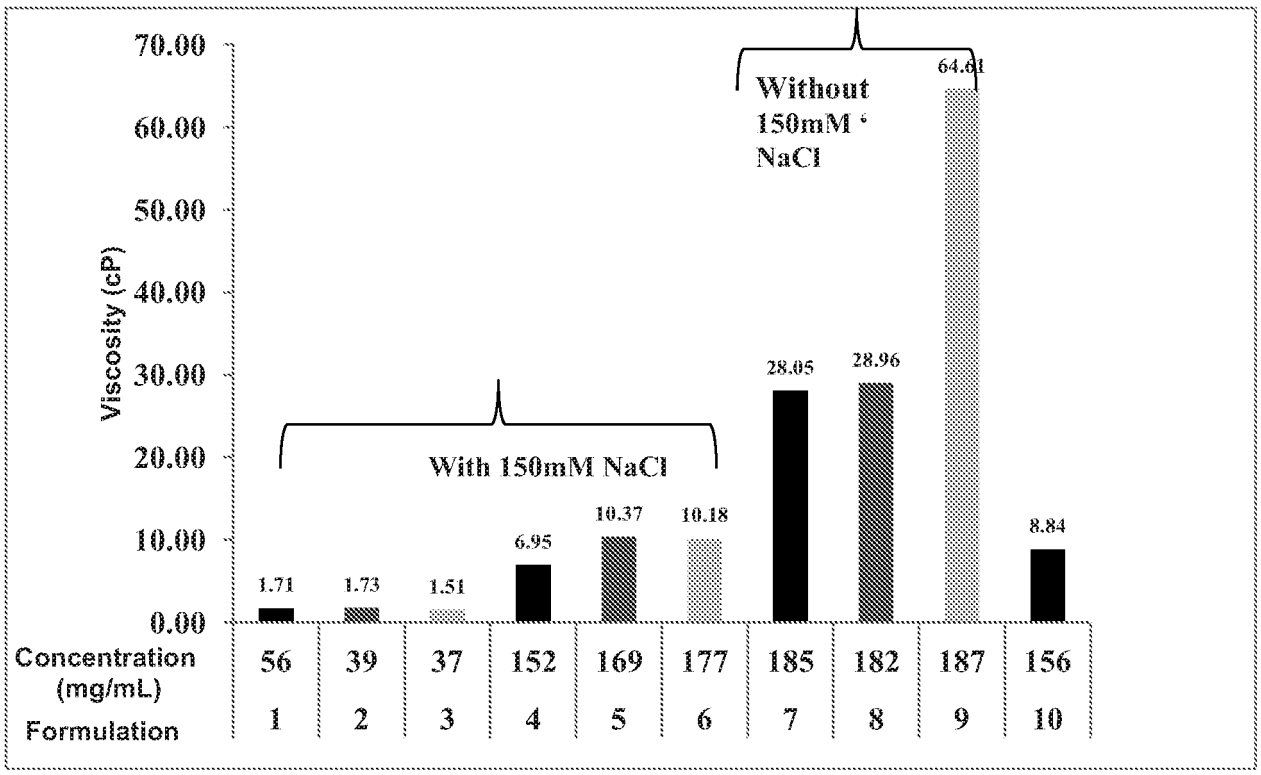

Viscosity (cp)
35
30
25
20
15
10
5
0
0
50
100
150
200
250
anti-IL13 mAb mg/mL
Viscosity (cp)

Figure 17



Black- acetate
Grey- succinate
Light Grey- histidine

Figure 18

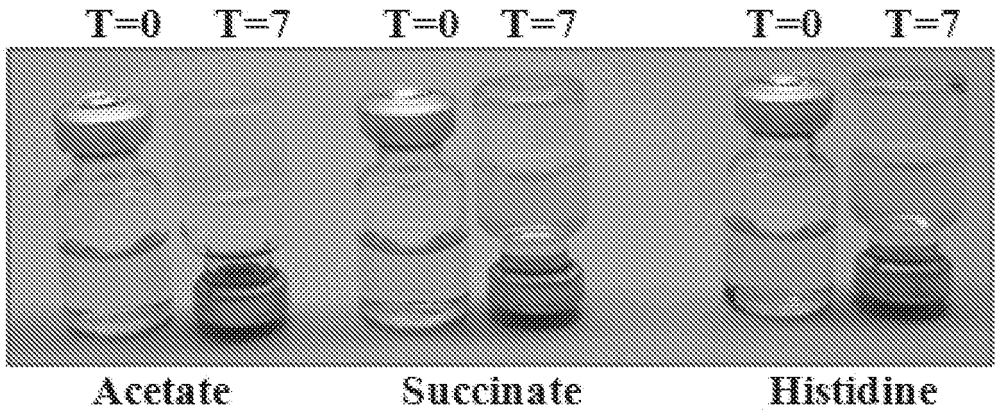


Figure 19

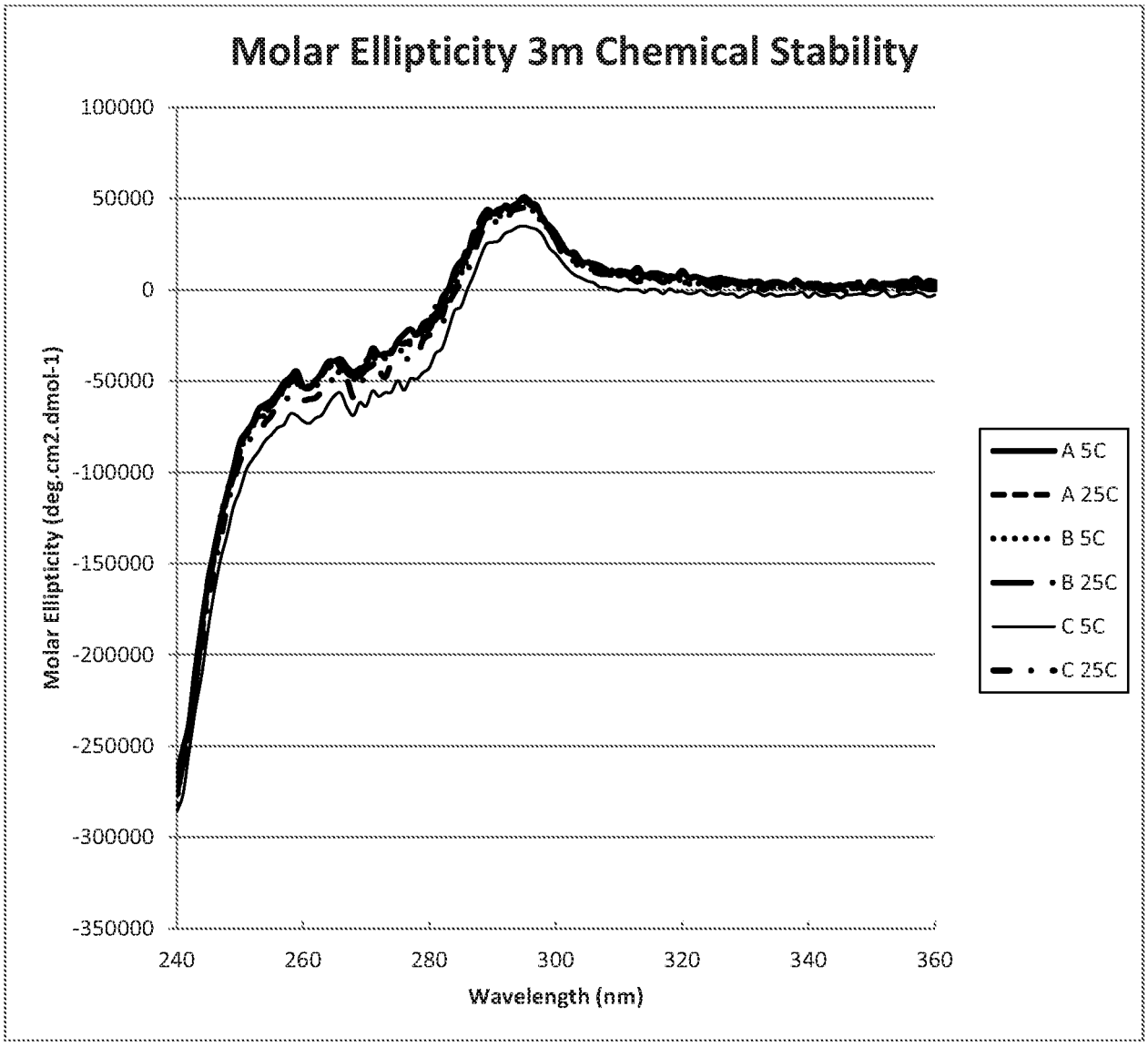

Molar Ellipticity 3m Chemical Stability
100000
50000
0
-50000
-100000
-150000
-200000
-250000
-300000
-350000
Molar Ellipticity (deg.cm2.dmol-1)
240
260
280
300
320
340
360
Wavelength (nm)
A 5C
A 25C
B 5C
B 25C
C 5C
C 25C

Figure 20