Fig 1a

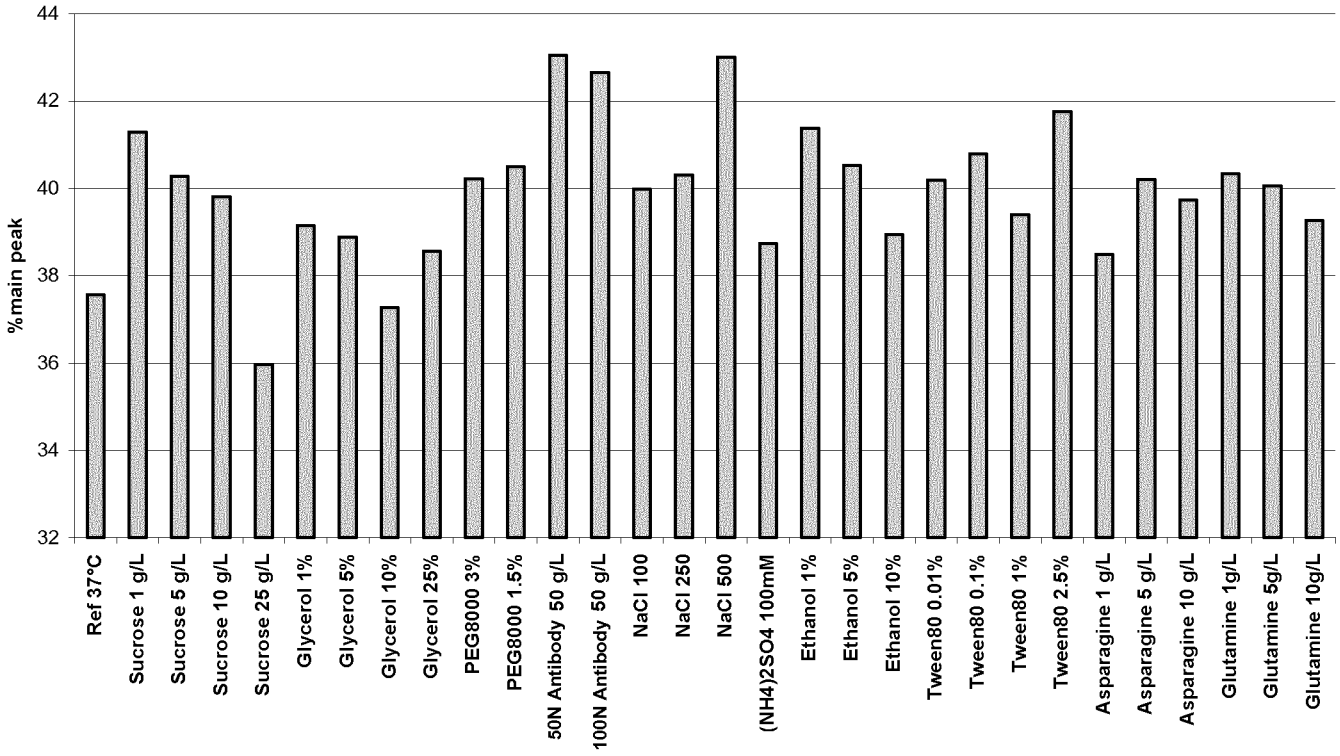

% main peak
44
42
40
38
36
34
32
Ref 37°C
Sucrose 1 g/L
Sucrose 5 g/L
Sucrose 10 g/L
Sucrose 25 g/L
Glycerol 1%
Glycerol 5%
Glycerol 10%
Glycerol 25%
PEG8000 3%
PEG8000 1.5%
50N Antibody 50 g/L
100N Antibody 50 g/L
NaCl 100
NaCl 250
NaCl 500
(NH4)2SO4 100mM
Ethanol 1%
Ethanol 5%
Ethanol 10%
Tween80 0.01%
Tween80 0.1%
Tween80 1%
Tween80 2.5%
Asparagine 1 g/L
Asparagine 5 g/L
Asparagine 10 g/L
Glutamine 1g/L
Glutamine 5g/L
Glutamine 10g/L

Fig 1b

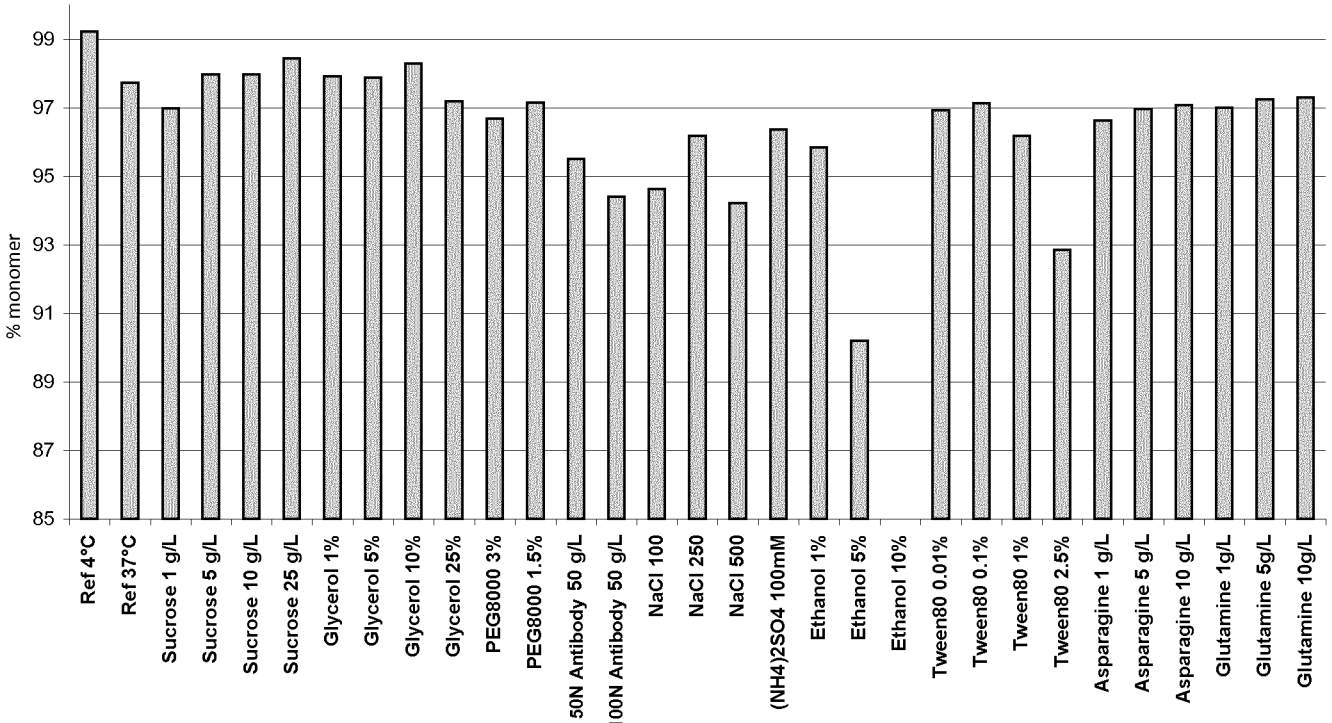

% monomer
99
97
95
93
91
89
87
85
Ref 4°C
Ref 37°C
Sucrose 1 g/L
Sucrose 5 g/L
Sucrose 10 g/L
Sucrose 25 g/L
Glycerol 1%
Glycerol 5%
Glycerol 10%
Glycerol 25%
PEG8000 3%
PEG8000 1.5%
50N Antibody 50 g/L
100N Antibody 50 g/L
NaCl 100
NaCl 250
NaCl 500
(NH4)2SO4 100mM
Ethanol 1%
Ethanol 5%
Ethanol 10%
Tween80 0.01%
Tween80 0.1%
Tween80 1%
Tween80 2.5%
Asparagine 1 g/L
Asparagine 5 g/L
Asparagine 10 g/L
Glutamine 1g/L
Glutamine 5g/L
Glutamine 10g/L

Fig 1c

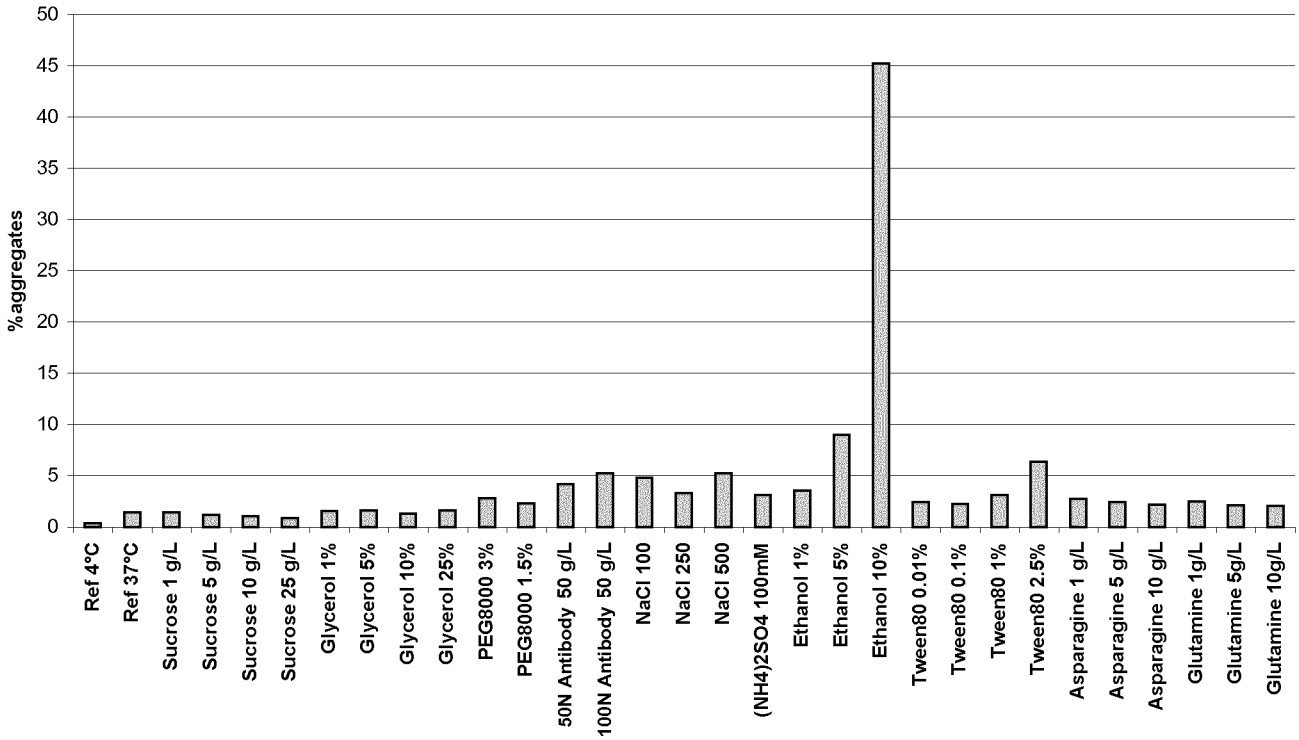

%aggregates
50
45
40
35
30
25
20
15
10
5
0
Ref 4°C
Ref 37°C
Sucrose 1 g/L
Sucrose 5 g/L
Sucrose 10 g/L
Sucrose 25 g/L
Glycerol 1%
Glycerol 5%
Glycerol 10%
Glycerol 25%
PEG8000 3%
PEG8000 1.5%
50N Antibody 50 g/L
100N Antibody 50 g/L
NaCl 100
NaCl 250
NaCl 500
(NH4)2SO4 100mM
Ethanol 1%
Ethanol 5%
Ethanol 10%
Tween80 0.01%
Tween80 0.1%
Tween80 1%
Tween80 2.5%
Asparagine 1 g/L
Asparagine 5 g/L
Asparagine 10 g/L
Glutamine 1g/L
Glutamine 5g/L
Glutamine 10g/L

Fig 1d

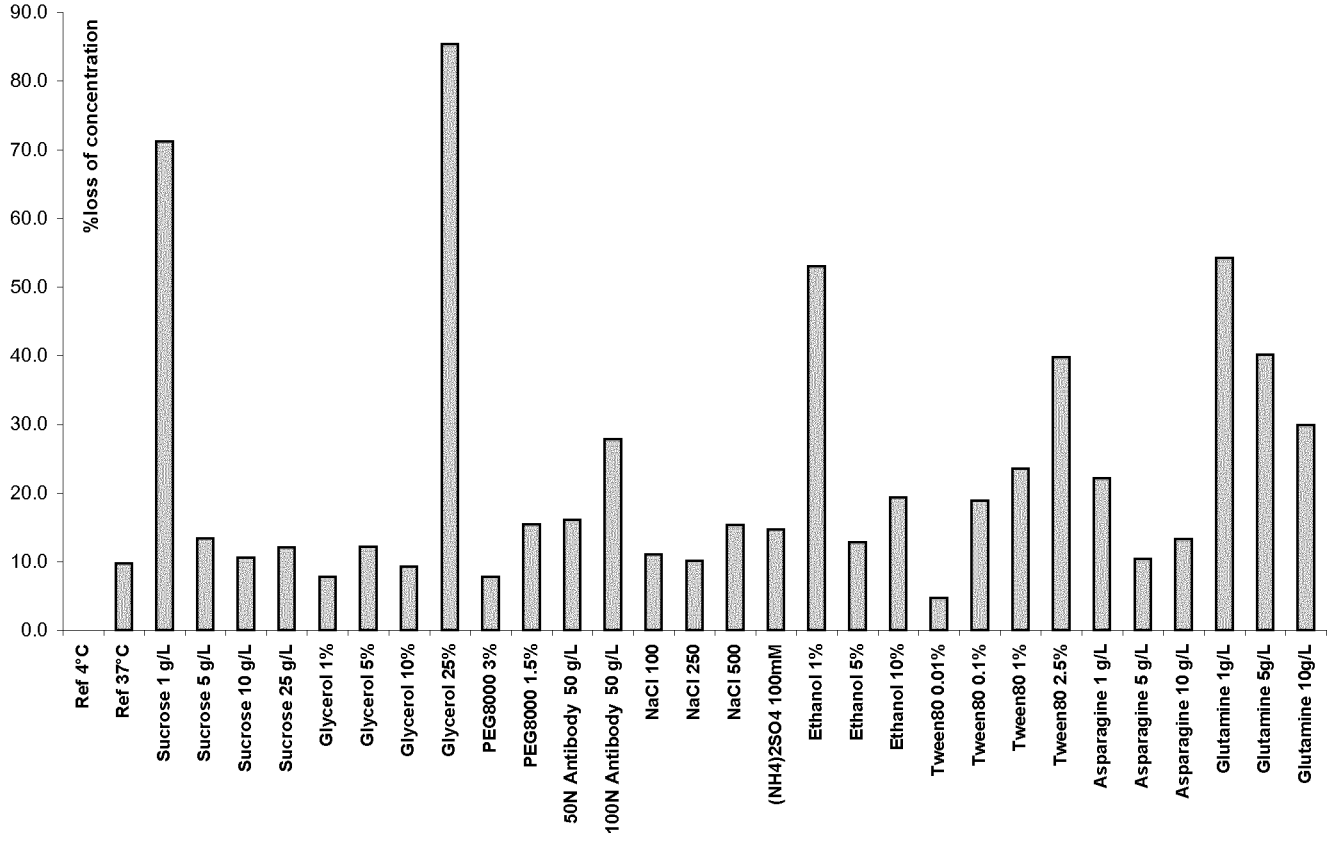

%loss of concentration
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
Ref 4°C
Ref 37°C
Sucrose 1 g/L
Sucrose 5 g/L
Sucrose 10 g/L
Sucrose 25 g/L
Glycerol 1%
Glycerol 5%
Glycerol 10%
Glycerol 25%
PEG8000 3%
PEG8000 1.5%
50N Antibody 50 g/L
100N Antibody 50 g/L
NaCl 100
NaCl 250
NaCl 500
(NH4)2SO4 100mM
Ethanol 1%
Ethanol 5%
Ethanol 10%
Tween80 0.01%
Tween80 0.1%
Tween80 1%
Tween80 2.5%
Asparagine 1 g/L
Asparagine 5 g/L
Asparagine 10 g/L
Glutamine 1g/L
Glutamine 5g/L
Glutamine 10g/L

Fig 2a

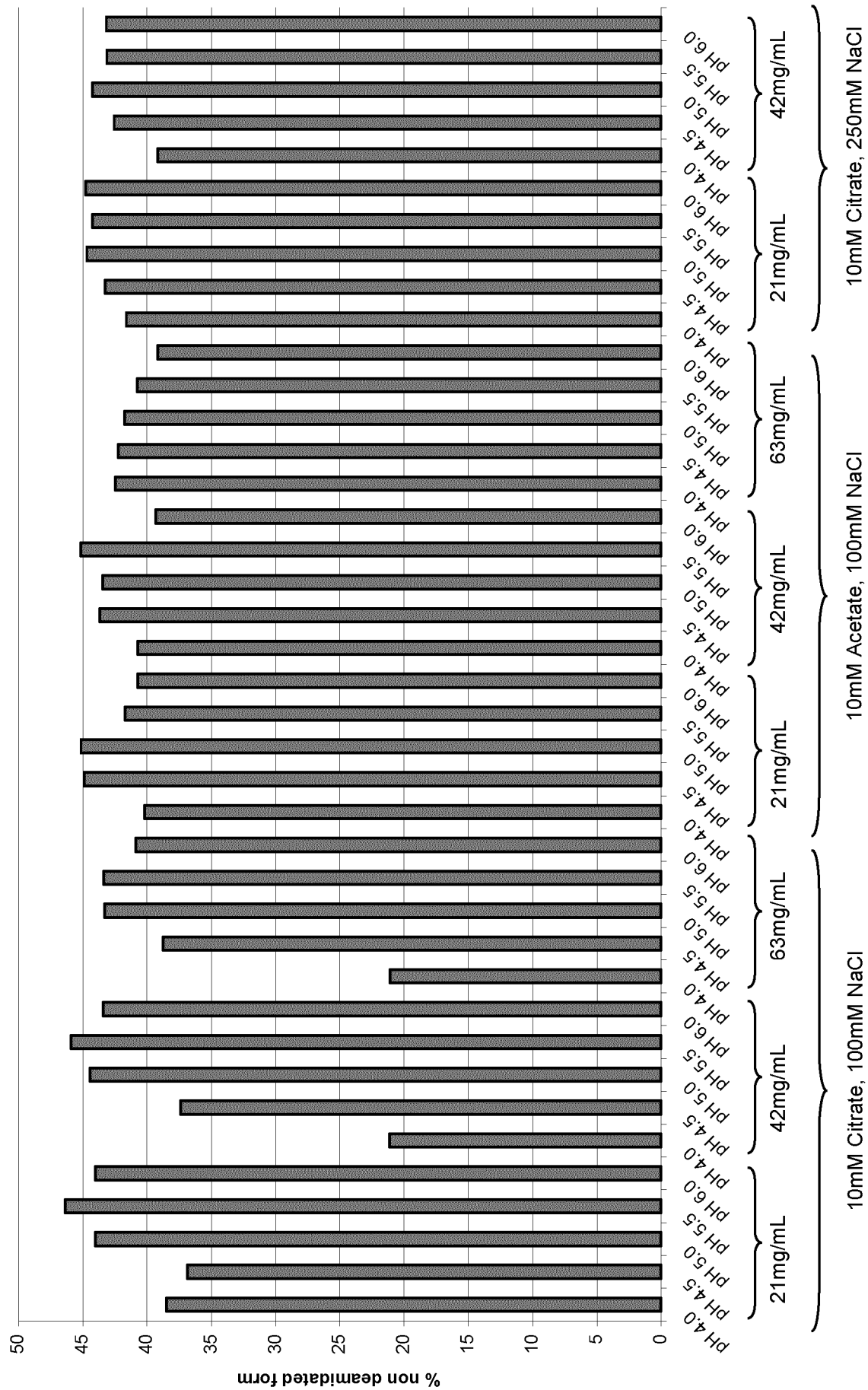

% non deamidated form
50
45
40
35
30
25
20
15
10
5
0
pH 4,0
pH 4,5
pH 5,0
pH 5,5
pH 6,0
21mg/mL
42mg/mL
63mg/mL
21mg/mL
42mg/mL
63mg/mL
10mM Citrate, 100mM NaCl
10mM Acetate, 100mM NaCl
10mM Citrate, 250mM NaCl

Figure 2b

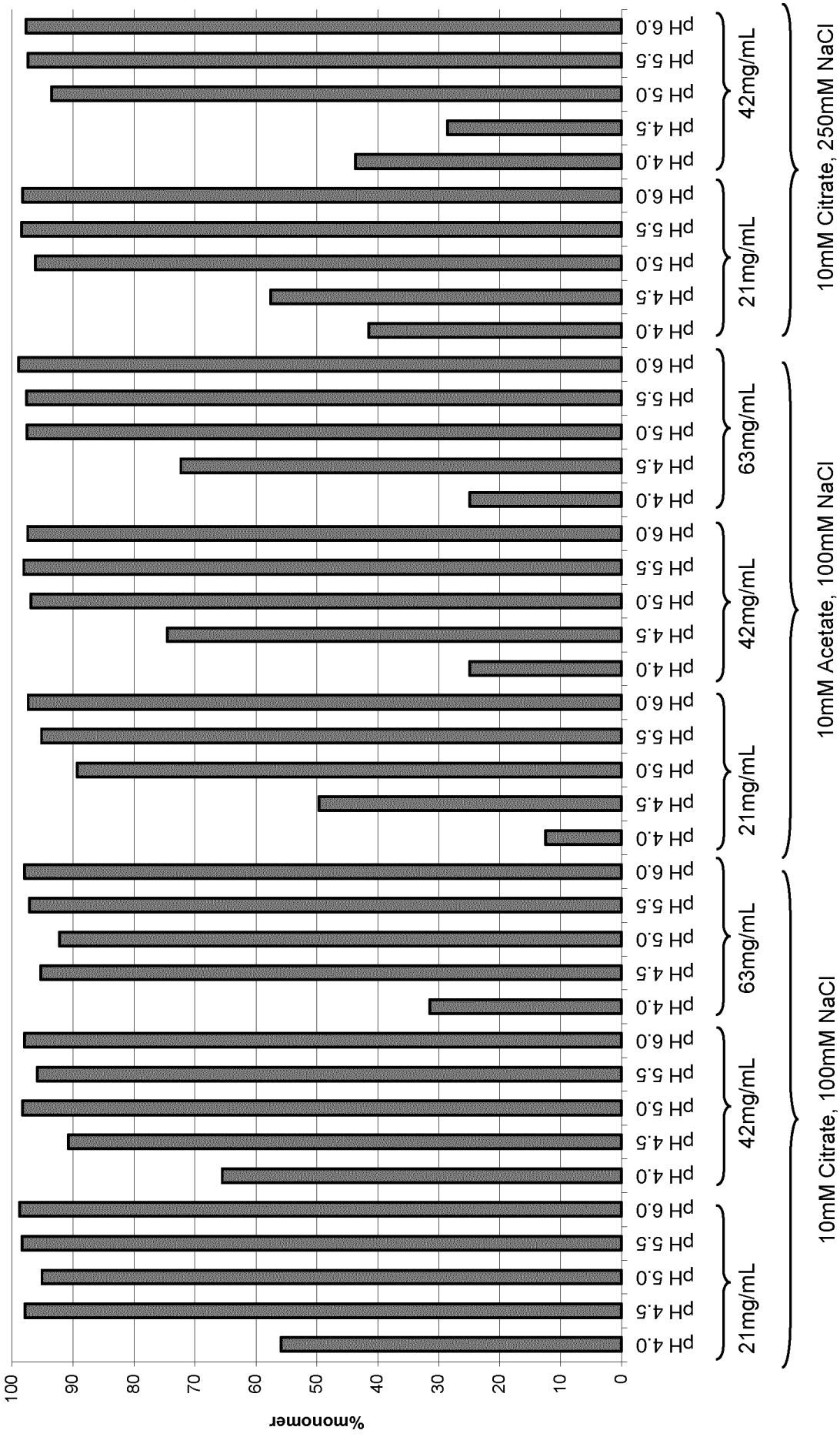

%monomer
100
90
80
70
60
50
40
30
20
10
0
pH 4.0
pH 4.5
pH 5.0
pH 5.5
pH 6.0
21mg/mL
42mg/mL
63mg/mL
10mM Citrate, 100mM NaCl
10mM Acetate, 100mM NaCl
10mM Citrate, 250mM NaCl

Fig 2c

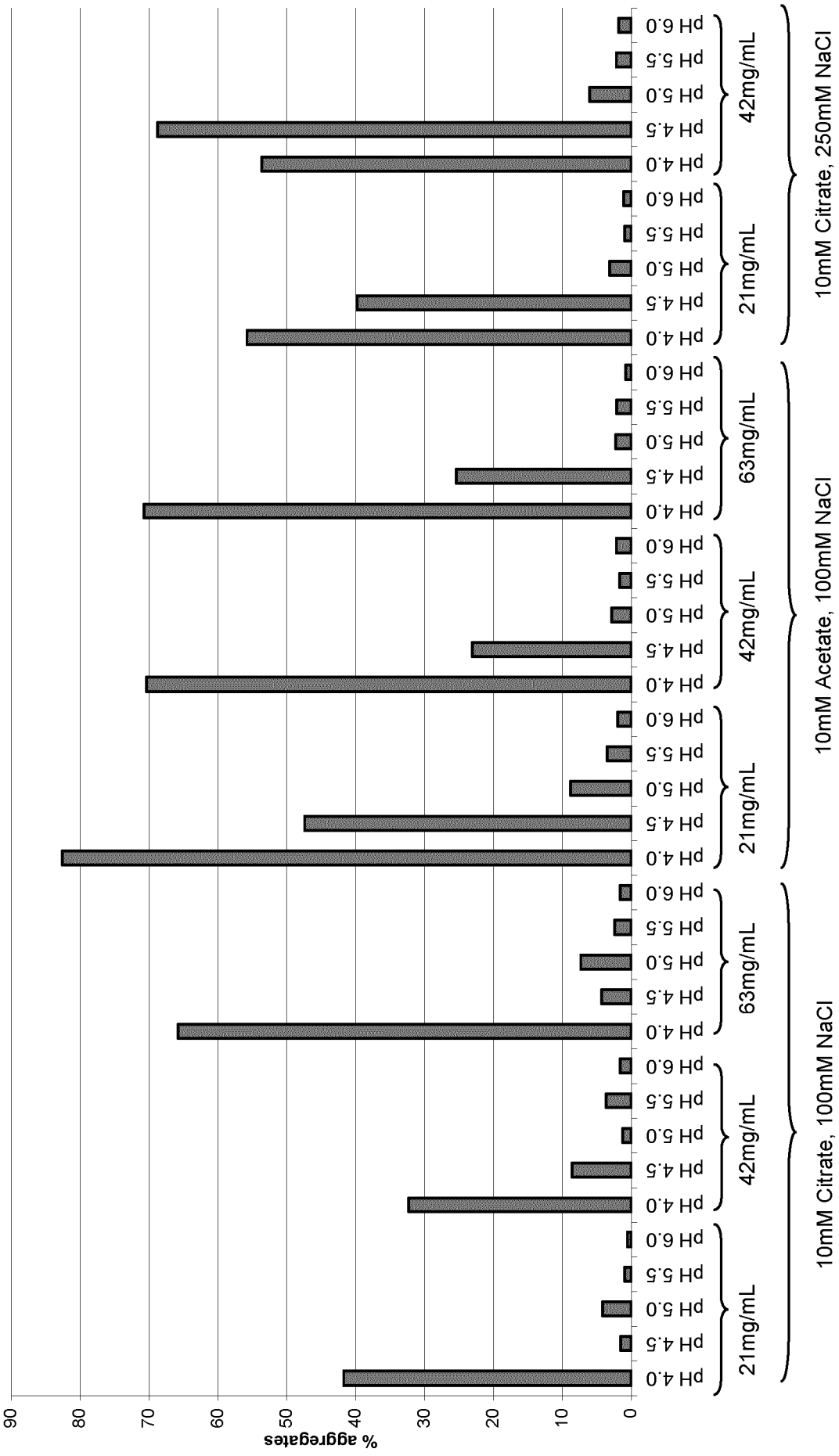

% aggregates
0
10
20
30
40
50
60
70
80
90
pH 4.0
pH 4.5
pH 5.0
pH 5.5
pH 6.0
21mg/mL
42mg/mL
63mg/mL
10mM Citrate, 100mM NaCl
10mM Acetate, 100mM NaCl
10mM Citrate, 250mM NaCl

Figure 2d

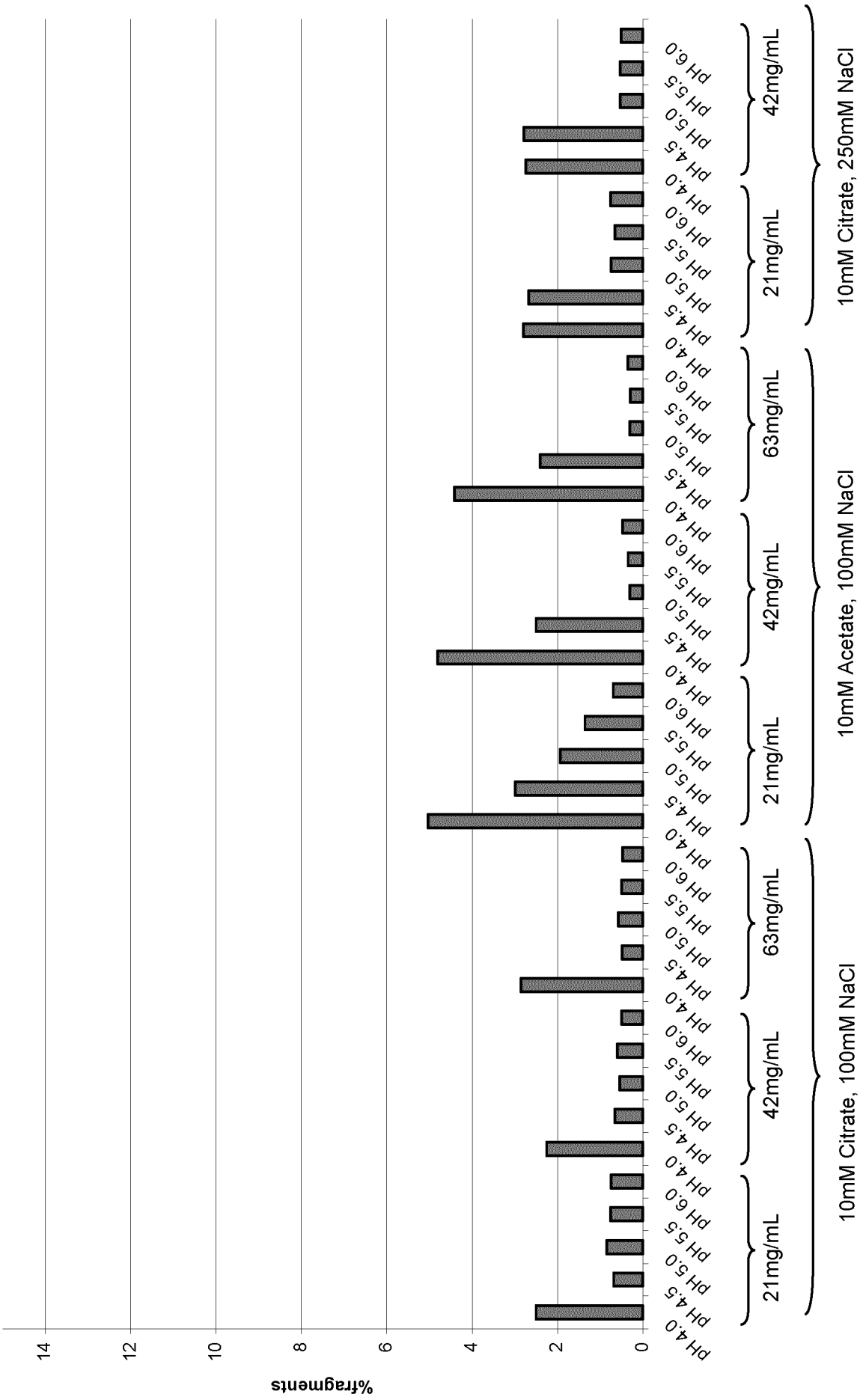

%fragments
0
2
4
6
8
10
12
14
pH 4.0
pH 4.5
pH 5.0
pH 5.5
pH 6.0
21mg/mL
42mg/mL
63mg/mL
10mM Citrate, 100mM NaCl
10mM Acetate, 100mM NaCl
10mM Citrate, 250mM NaCl

Figure 2e

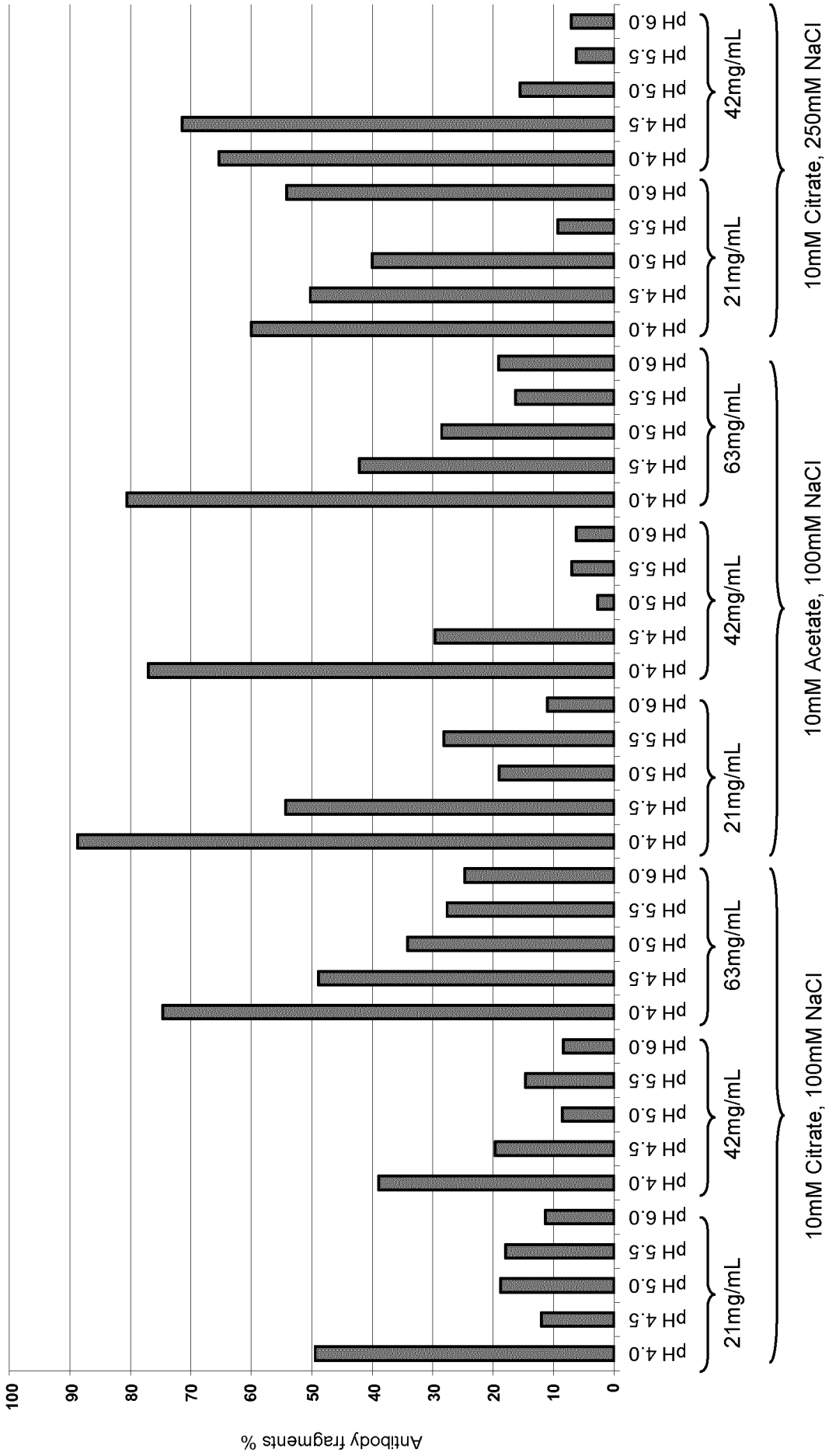

Antibody fragments %
0
10
20
30
40
50
60
70
80
90
100
pH 4.0
pH 4.5
pH 5.0
pH 5.5
pH 6.0
21mg/mL
42mg/mL
63mg/mL
10mM Citrate, 100mM NaCl
10mM Acetate, 100mM NaCl
10mM Citrate, 250mM NaCl

Fig 3a

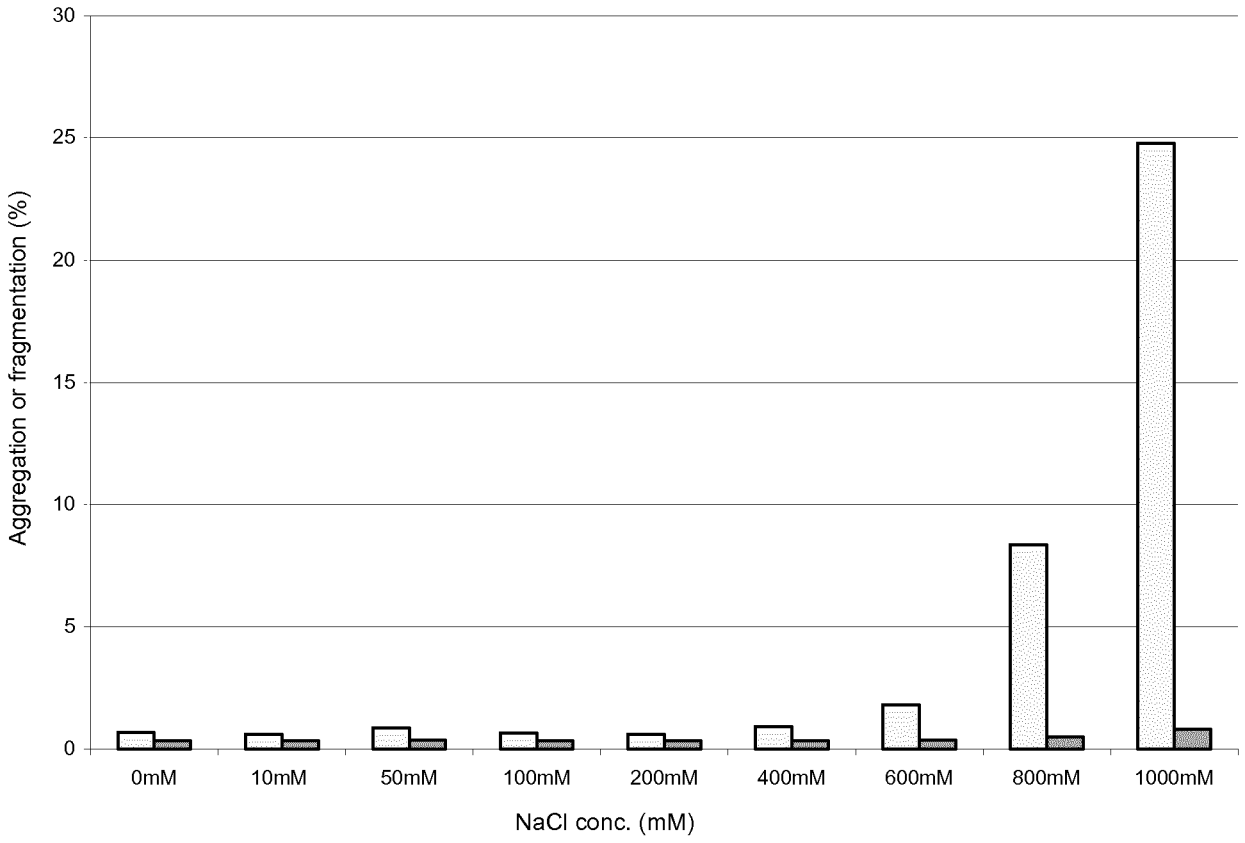

30
25
20
15
10
5
0
Aggregation or fragmentation (%)
0mM
10mM
50mM
100mM
200mM
400mM
600mM
800mM
1000mM
NaCl conc. (mM)

Fig 3b

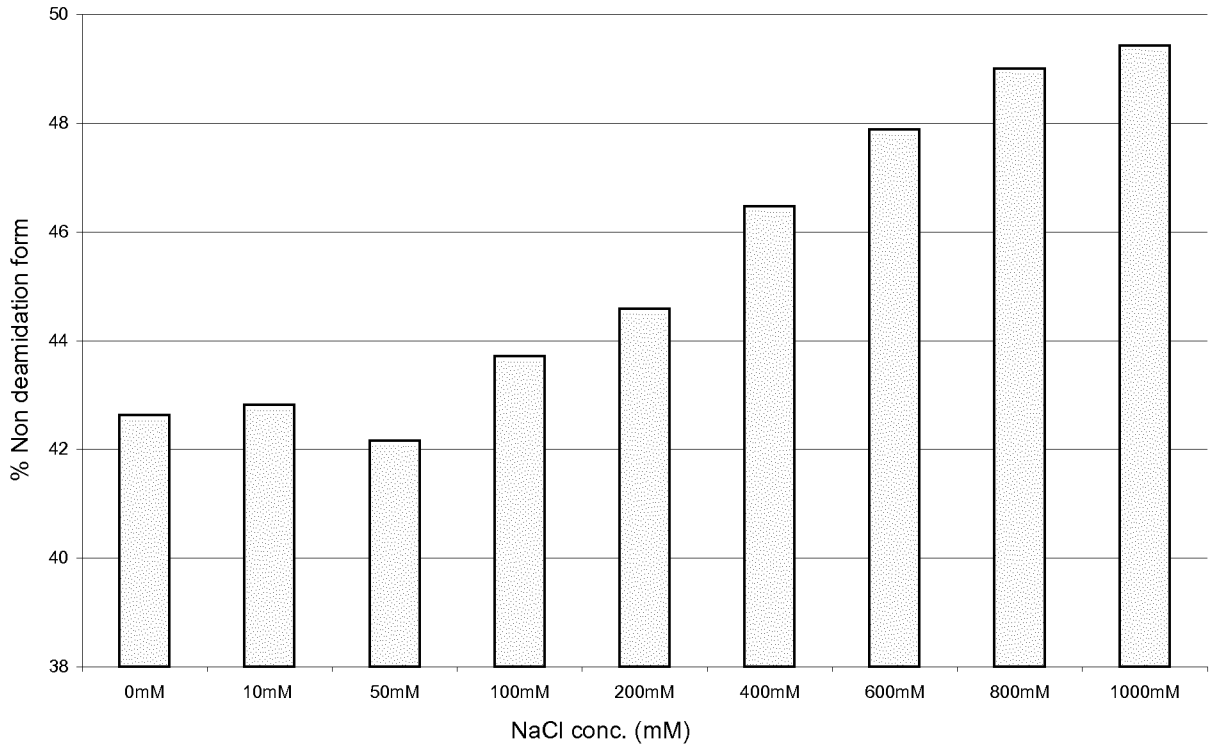
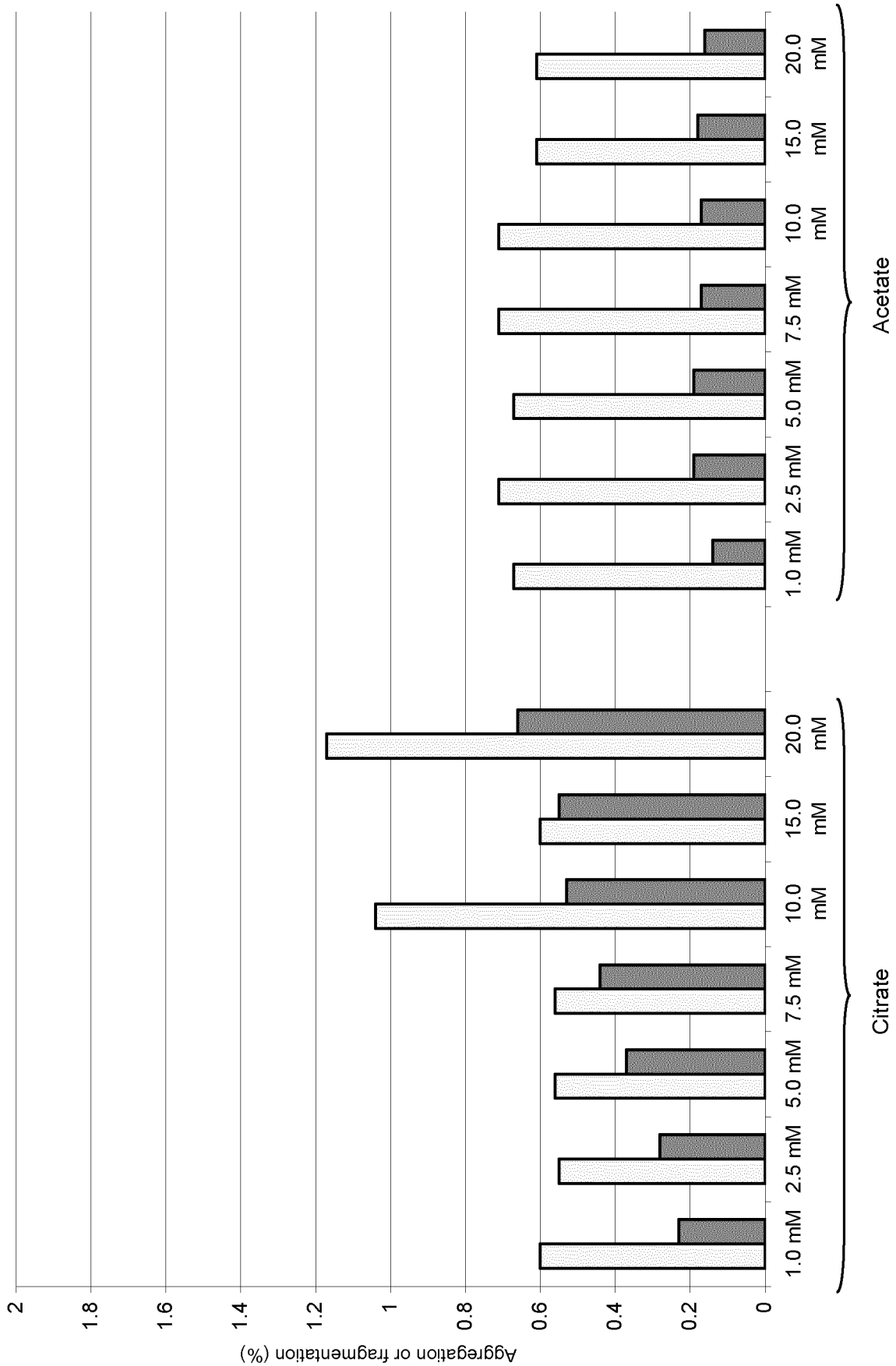

50
48
46
44
42
40
38
% Non deamidation form
0mM
10mM
50mM
100mM
200mM
400mM
600mM
800mM
1000mM
NaCl conc. (mM)

Fig 3c


Aggregation or fragmentation (%)
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2
1.0 mM
2.5 mM
5.0 mM
7.5 mM
10.0 mM
15.0 mM
20.0 mM
Citrate
1.0 mM
2.5 mM
5.0 mM
7.5 mM
10.0 mM
15.0 mM
20.0 mM
Acetate

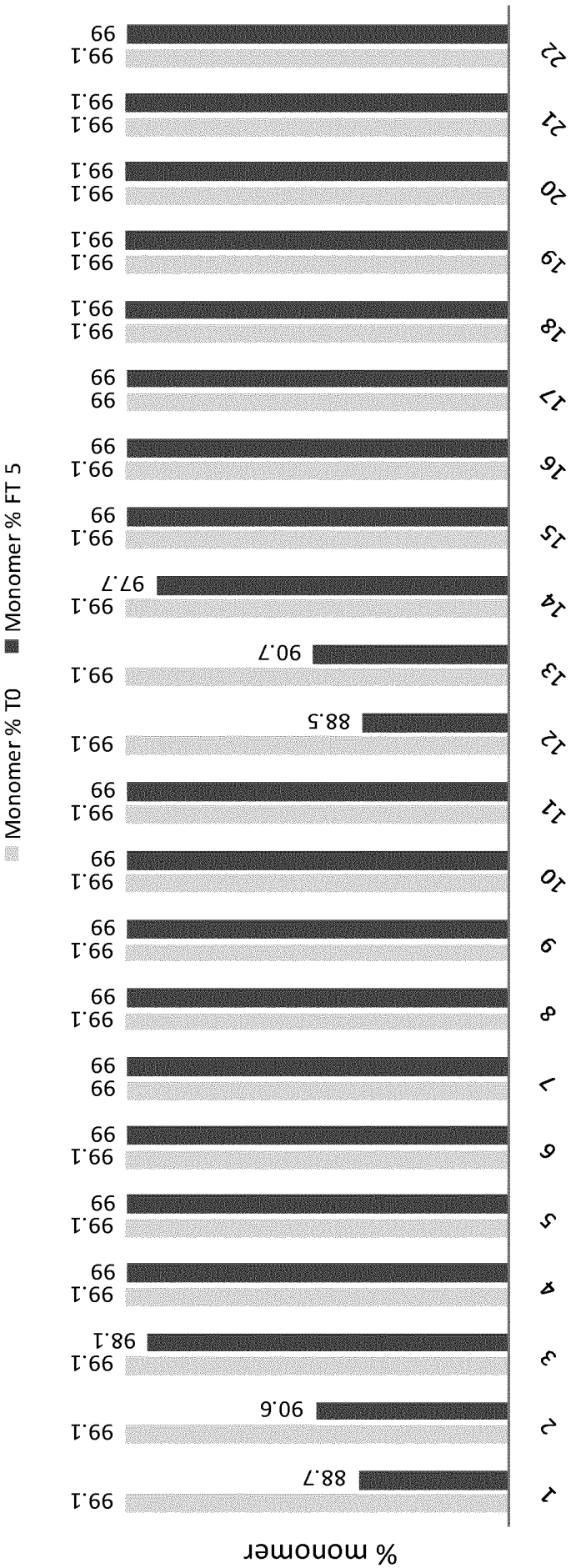

% monomer
Monomer % T0
Monomer % FT 5
1 88.7 99.1
2 90.6 99.1
3 98.1 99.1
4 99 99.1
5 99 99.1
6 99 99.1
7 99 99
8 99 99.1
9 99 99.1
10 99 99.1
11 99 99.1
12 88.5 99.1
13 90.7 99.1
14 97.7 99.1
15 99 99.1
16 99 99.1
17 99 99
18 99.1 99.1
19 99.1 99.1
20 99.1 99.1
21 99.1 99.1
22 99 99.1

Fig 4

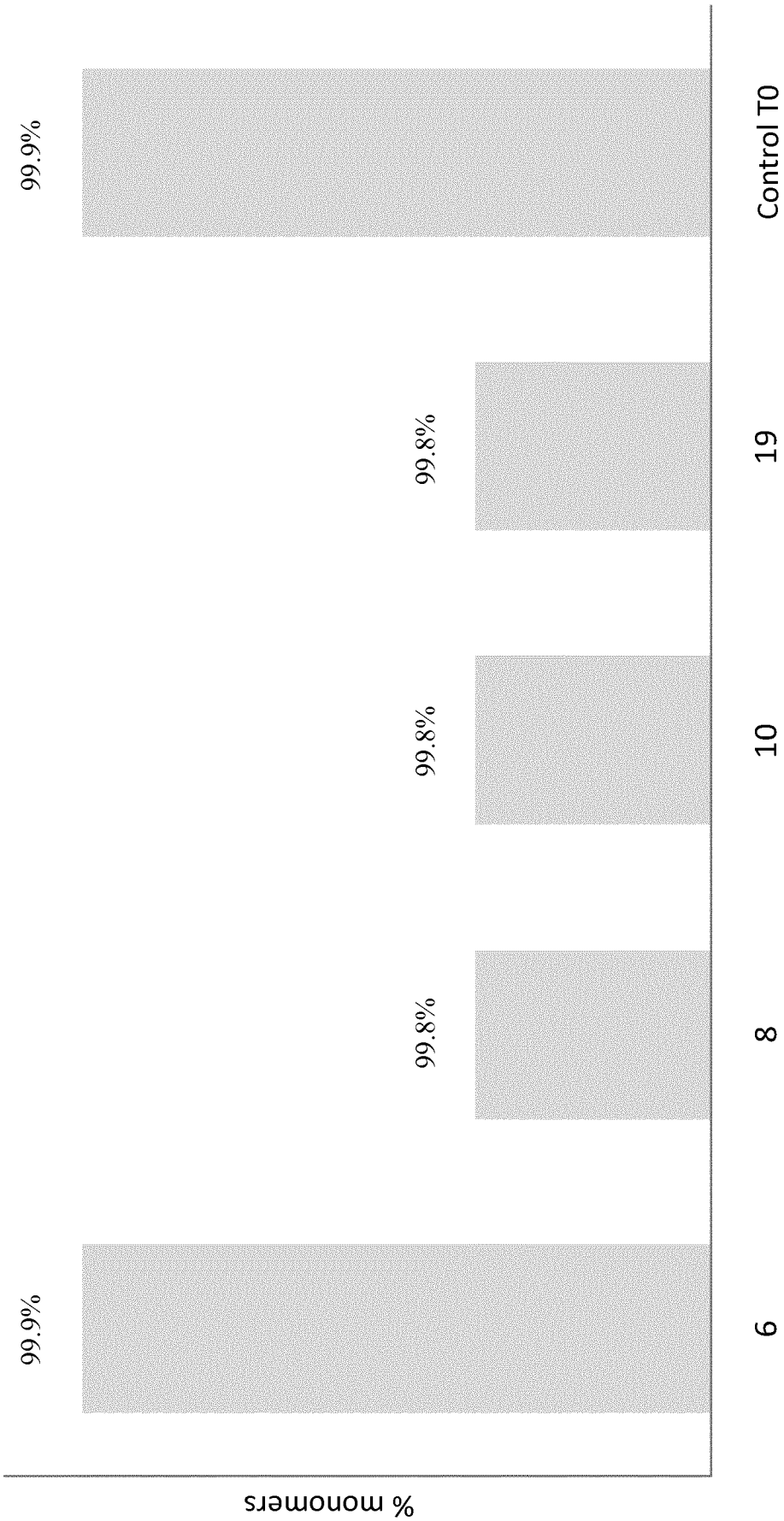


Fig 5

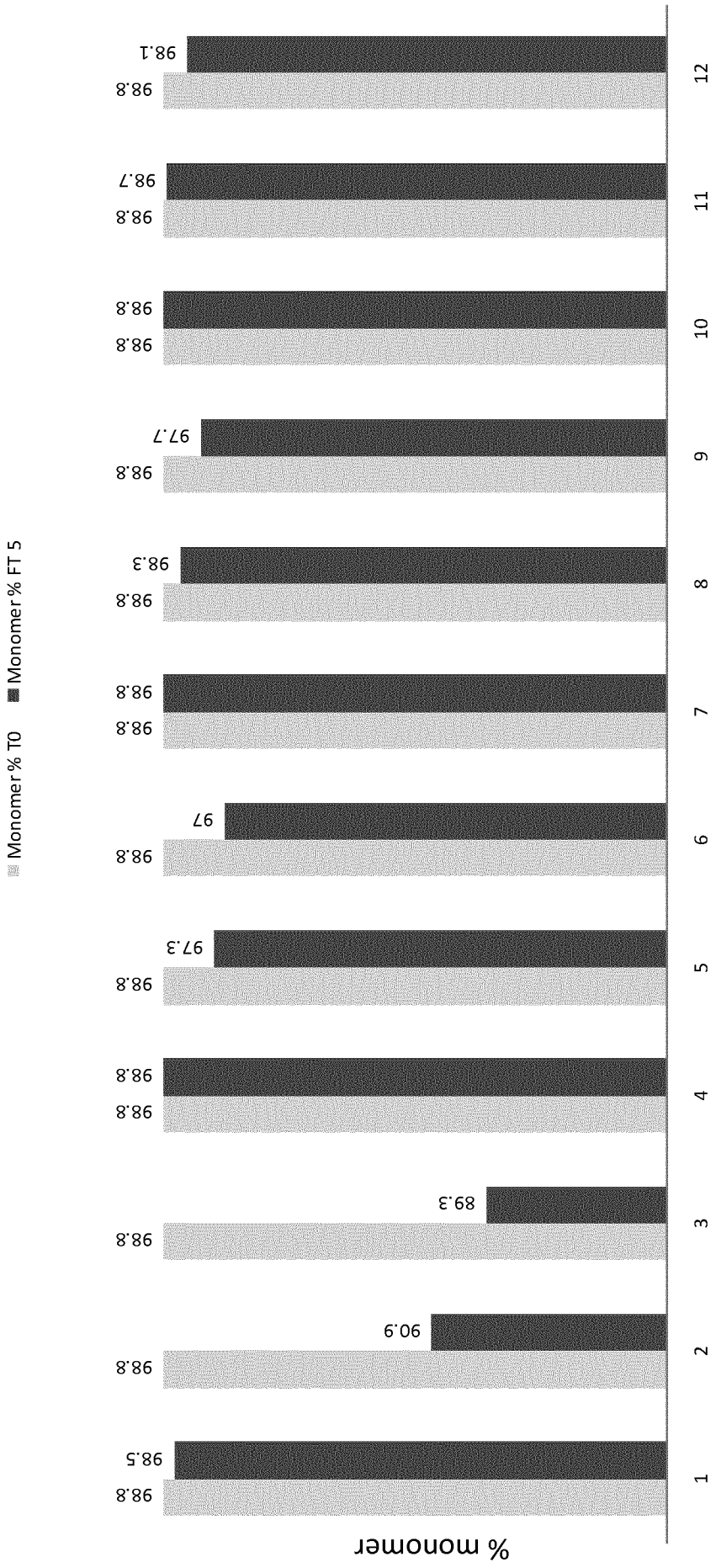

% monomer
Monomer % T0
Monomer % FT 5
1
2
3
4
5
6
7
8
9
10
11
12
98.8
98.5
98.8
90.9
98.8
89.3
98.8
98.8
98.8
97.3
98.8
97
98.8
98.8
98.8
98.3
98.8
97.7
98.8
98.8
98.8
98.7
98.8
98.1

Fig 6

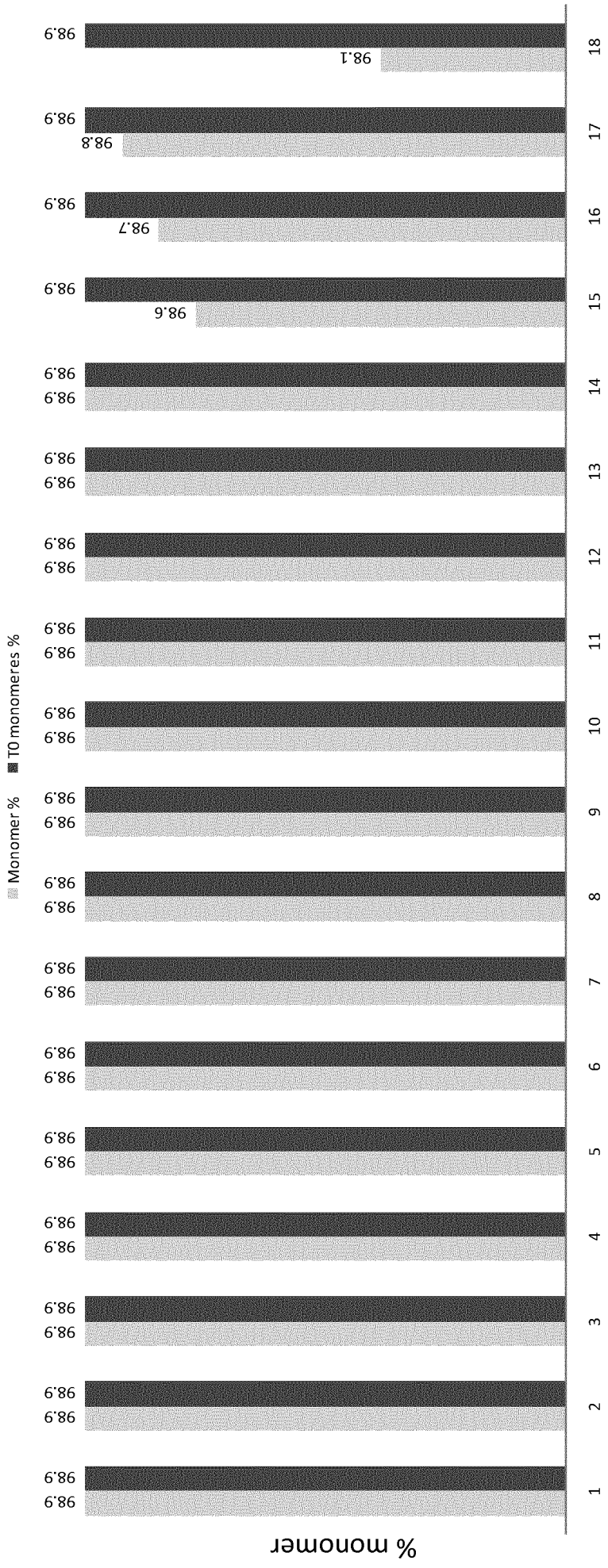

% monomer
Monomer %
T0 monomeres %
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
98.9
98.1
98.8
98.7
98.6

Fig 7

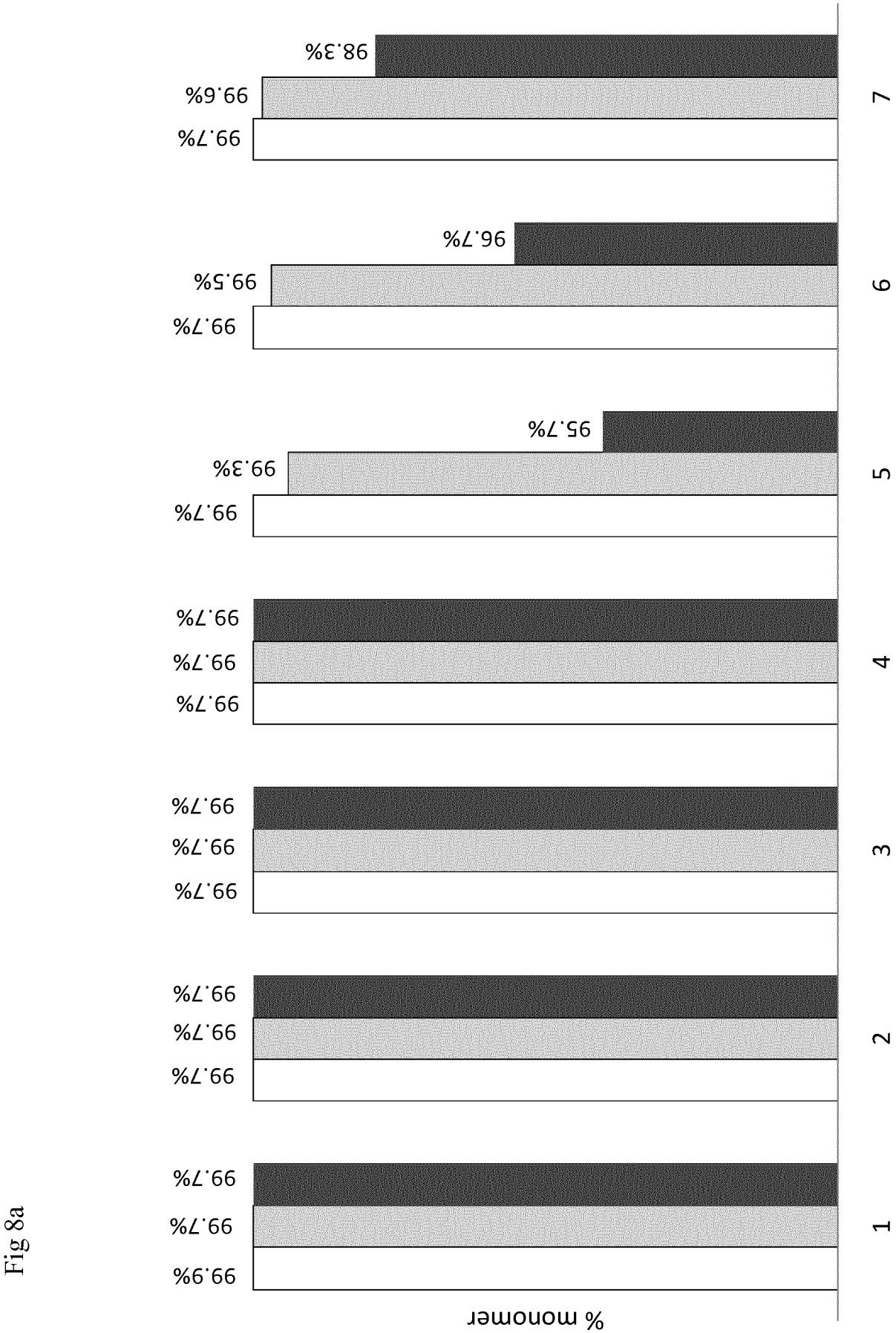
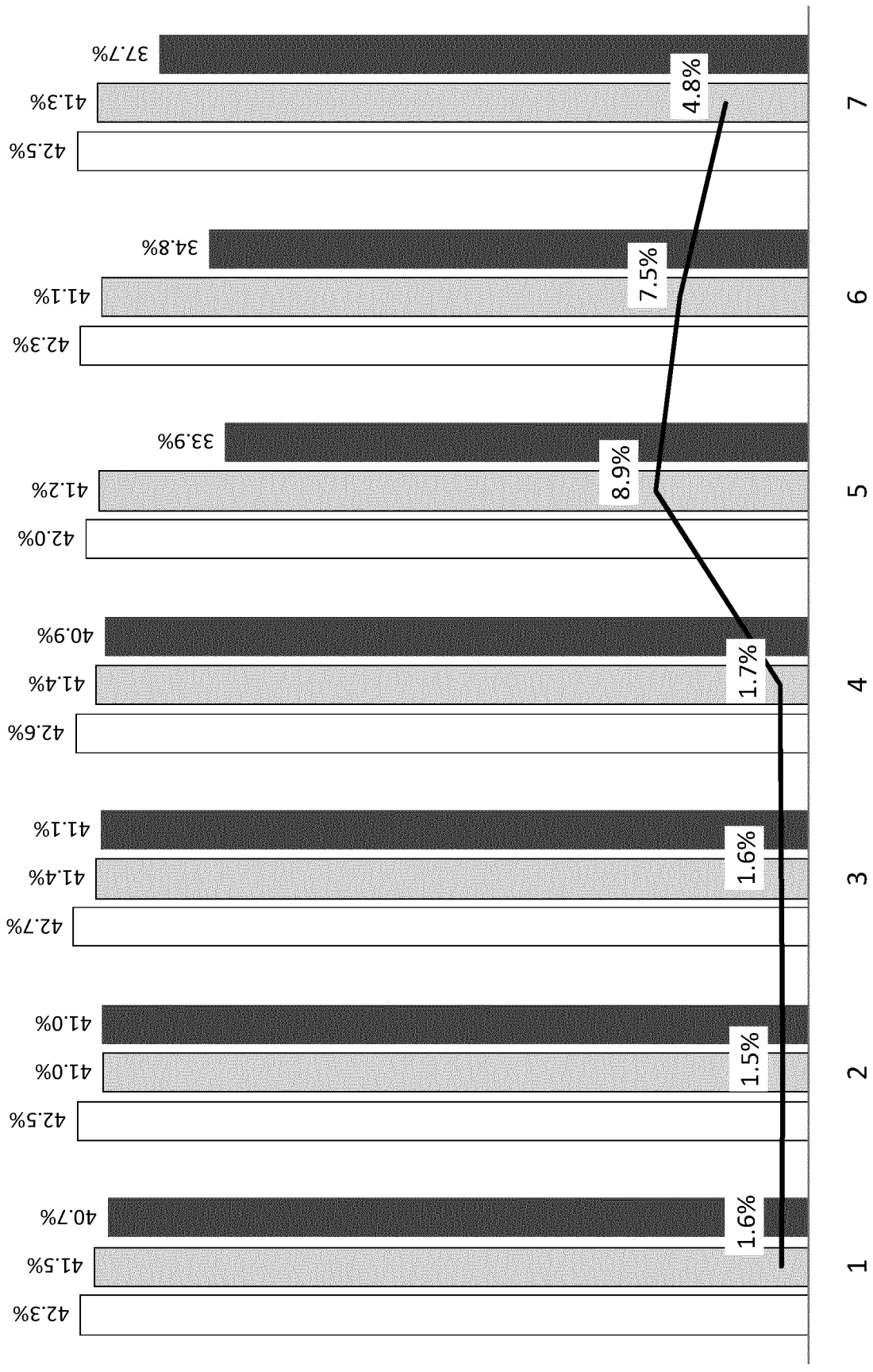

% monomer
1
99.9%
99.7%
99.7%
2
99.7%
99.7%
99.7%
3
99.7%
99.7%
99.7%
4
99.7%
99.7%
99.7%
5
99.7%
99.3%
95.7%
6
99.7%
99.5%
96.7%
7
99.7%
99.6%
98.3%

Fig 8a

Fig 8b


CEX main pic (%)
1
2
3
4
5
6
7
42.3%
41.5%
40.7%
1.6%
42.5%
41.0%
41.0%
1.5%
42.7%
41.4%
41.1%
1.6%
42.6%
41.4%
40.9%
1.7%
42.0%
41.2%
33.9%
8.9%
42.3%
41.1%
34.8%
7.5%
42.5%
41.3%
37.7%
4.8%

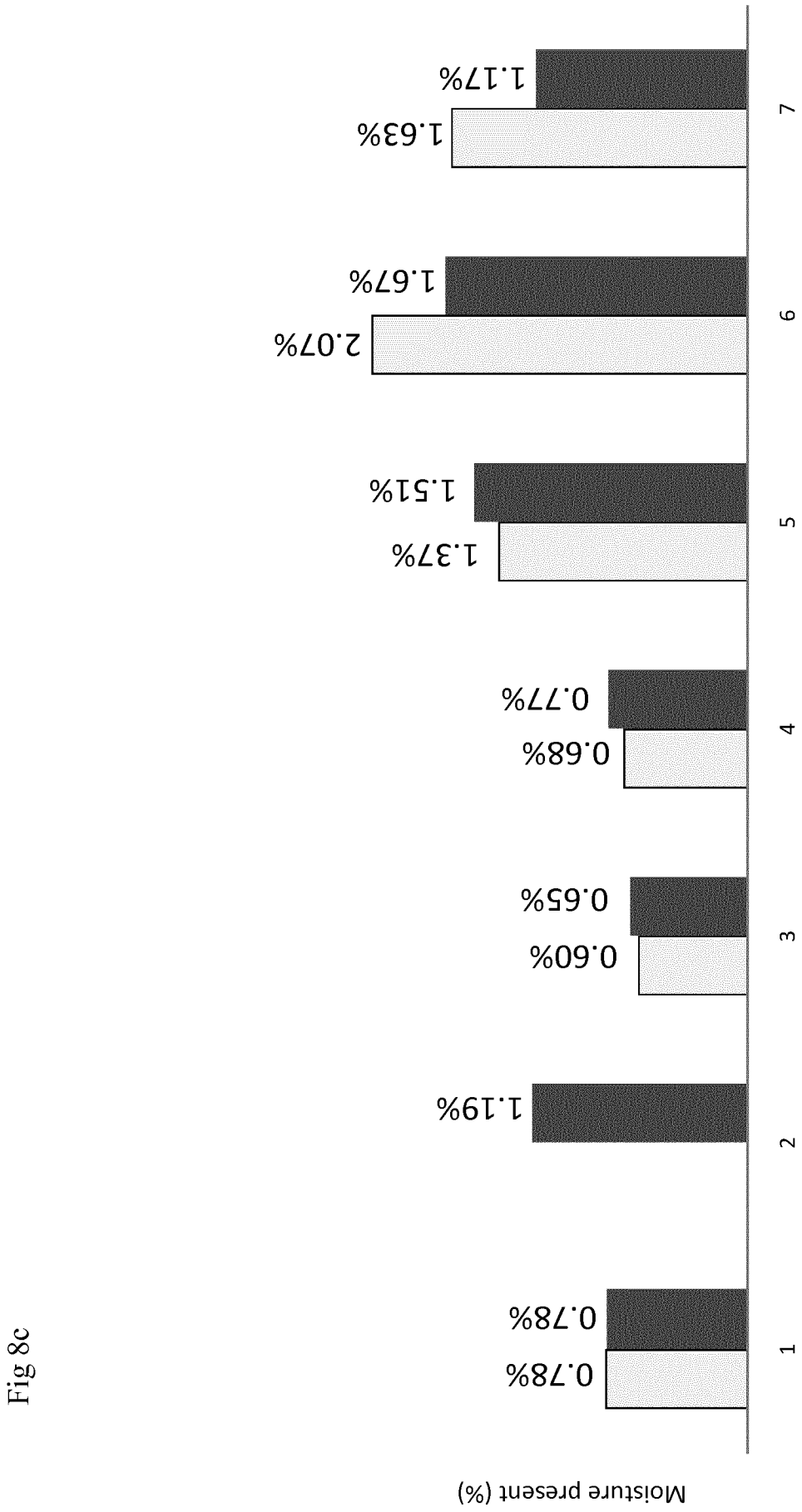

Moisture present (%)
1
2
3
4
5
6
7
0.78%
0.78%
1.19%
0.60%
0.65%
0.68%
0.77%
1.37%
1.51%
2.07%
1.67%
1.63%
1.17%

Fig 8c

Fig 9a

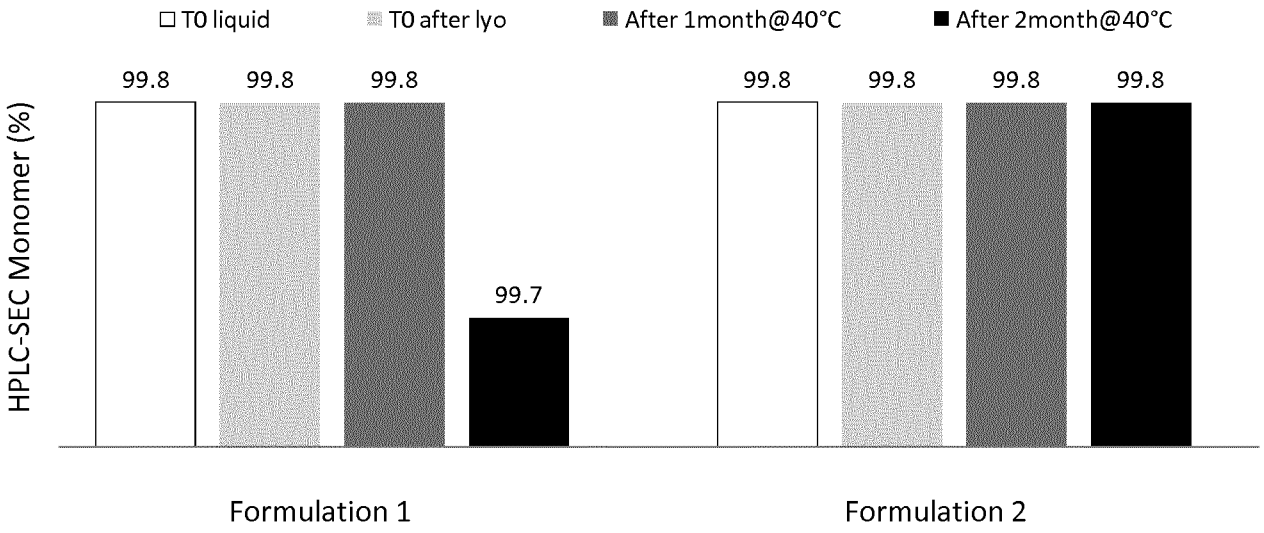

T0 liquid
T0 after lyo
After 1month@40°C
After 2month@40°C
HPLC-SEC Monomer (%)
99.8
99.8
99.8
99.7
99.8
99.8
99.8
99.8
Formulation 1
Formulation 2

Fig 9b

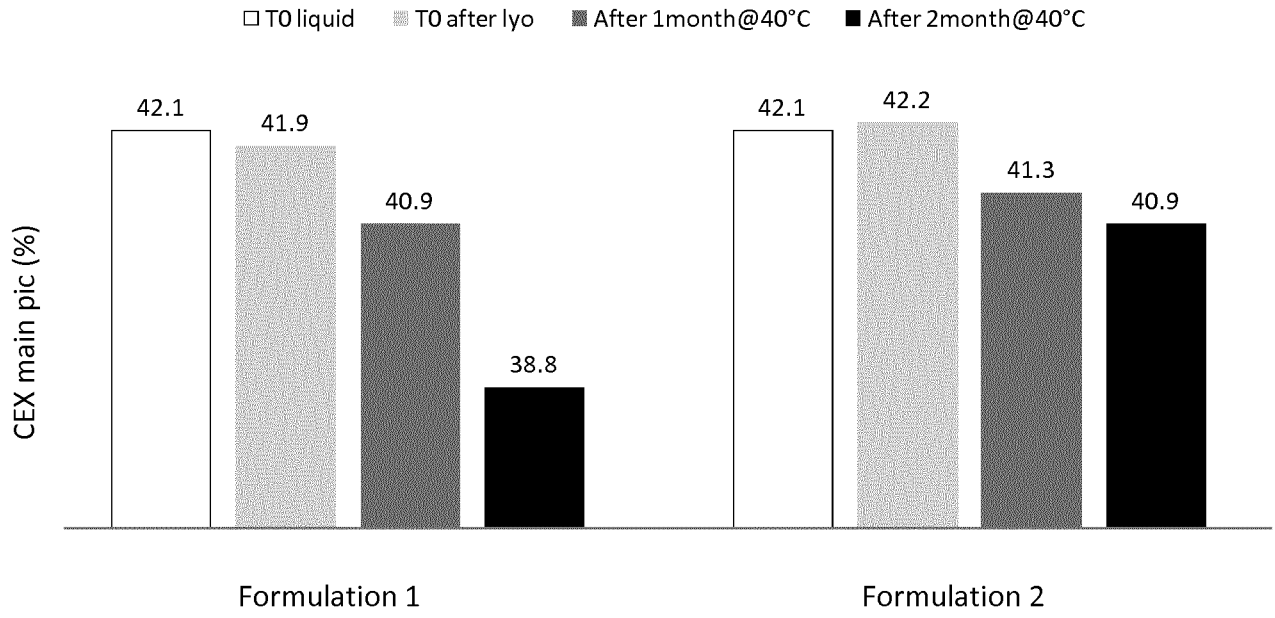

T0 liquid
T0 after lyo
After 1month@40°C
After 2month@40°C
CEX main pic (%)
42.1
41.9
40.9
38.8
42.1
42.2
41.3
40.9
Formulation 1
Formulation 2

Fig 10a

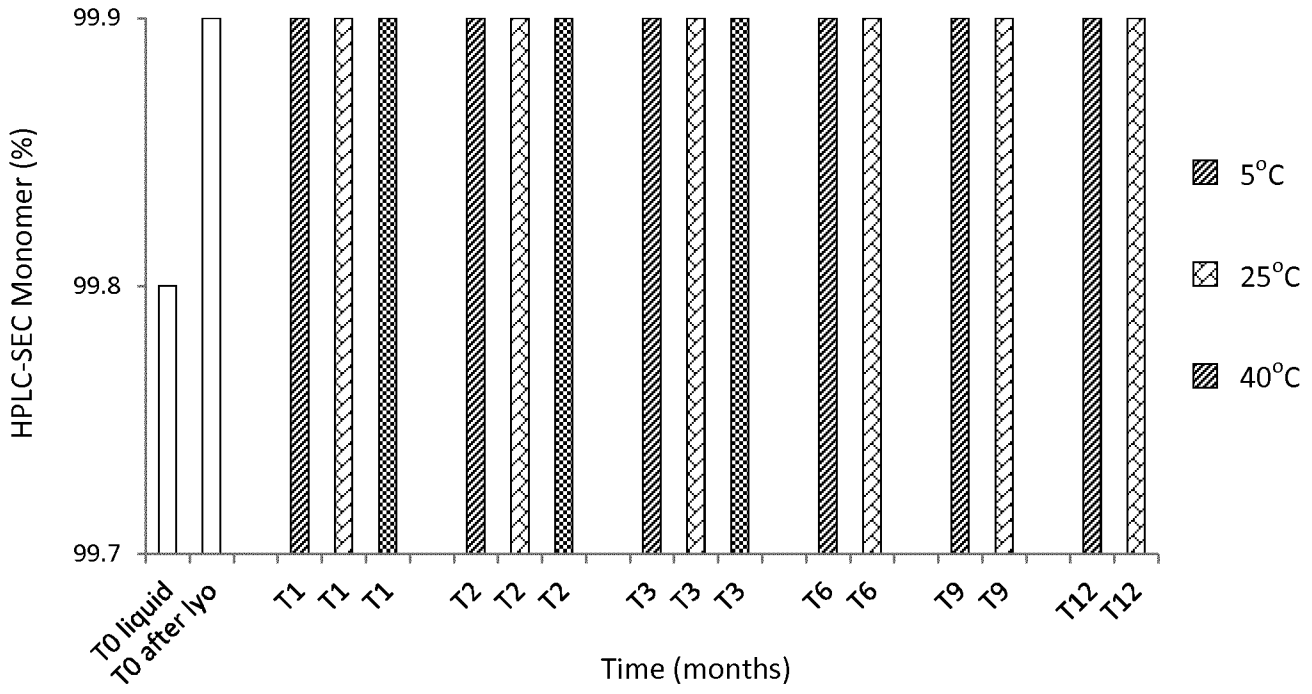


Fig 10b

