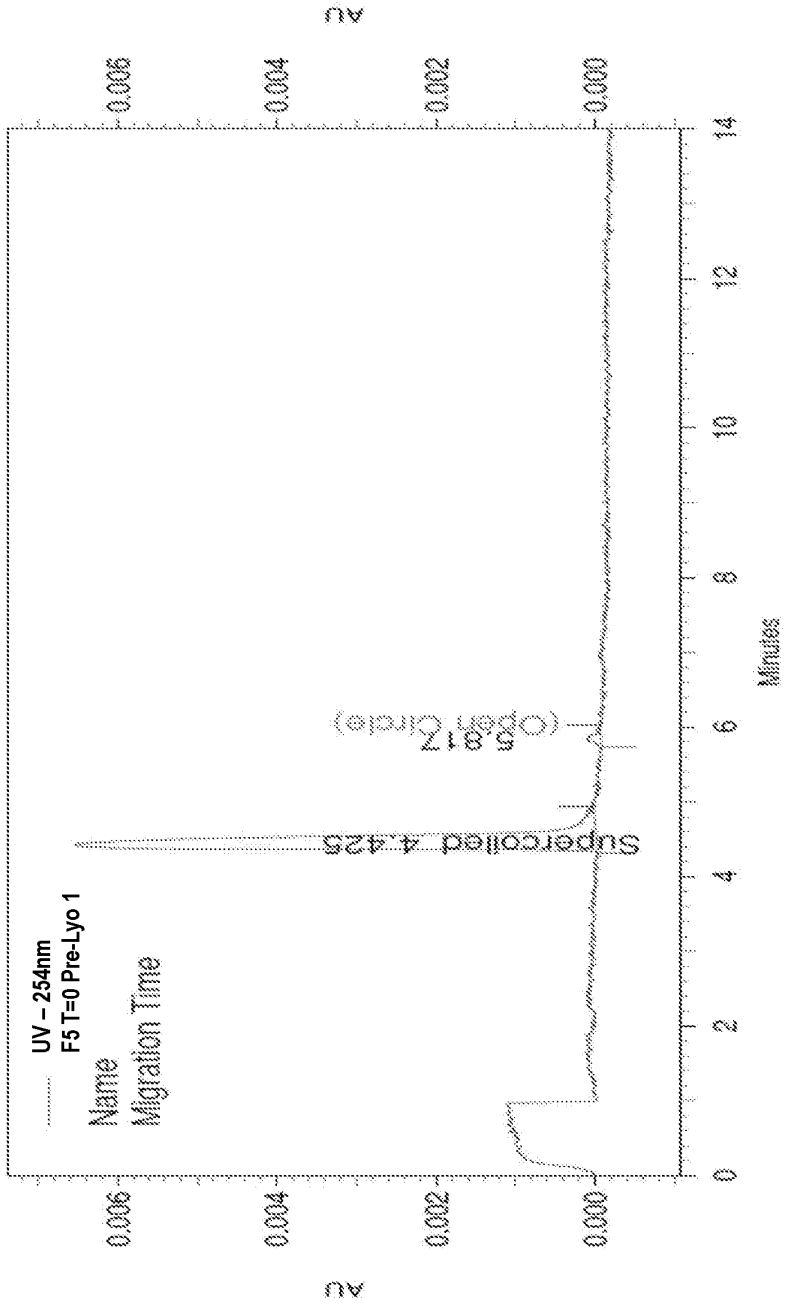

AU
0.006
0.004
0.002
0.000
0
2
4
6
8
10
12
14
Minutes
Supercoiled 4.425
Open Circle
UV – 254nm
F5 T=0 Pre-Lyo 1
Name
Migration Time

Figure 1

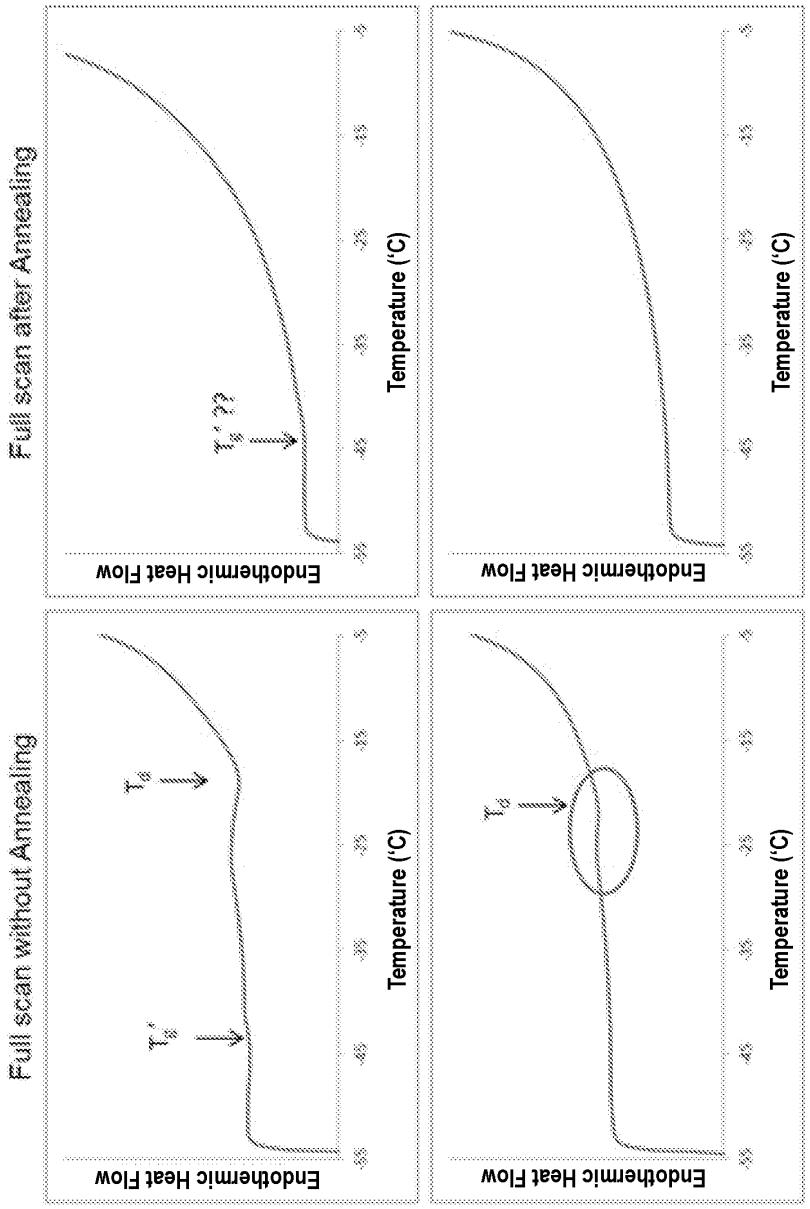


Figure 2A

Figure 2B

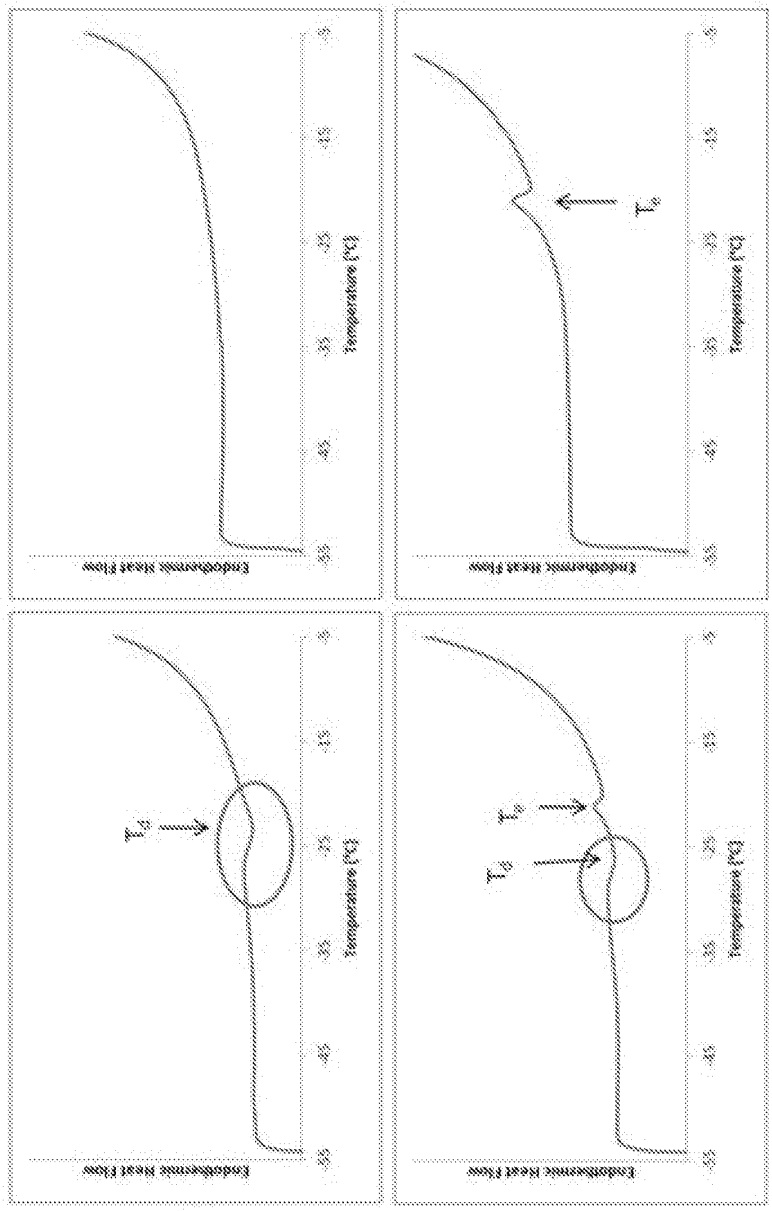


Figure 2C

Figure 2D

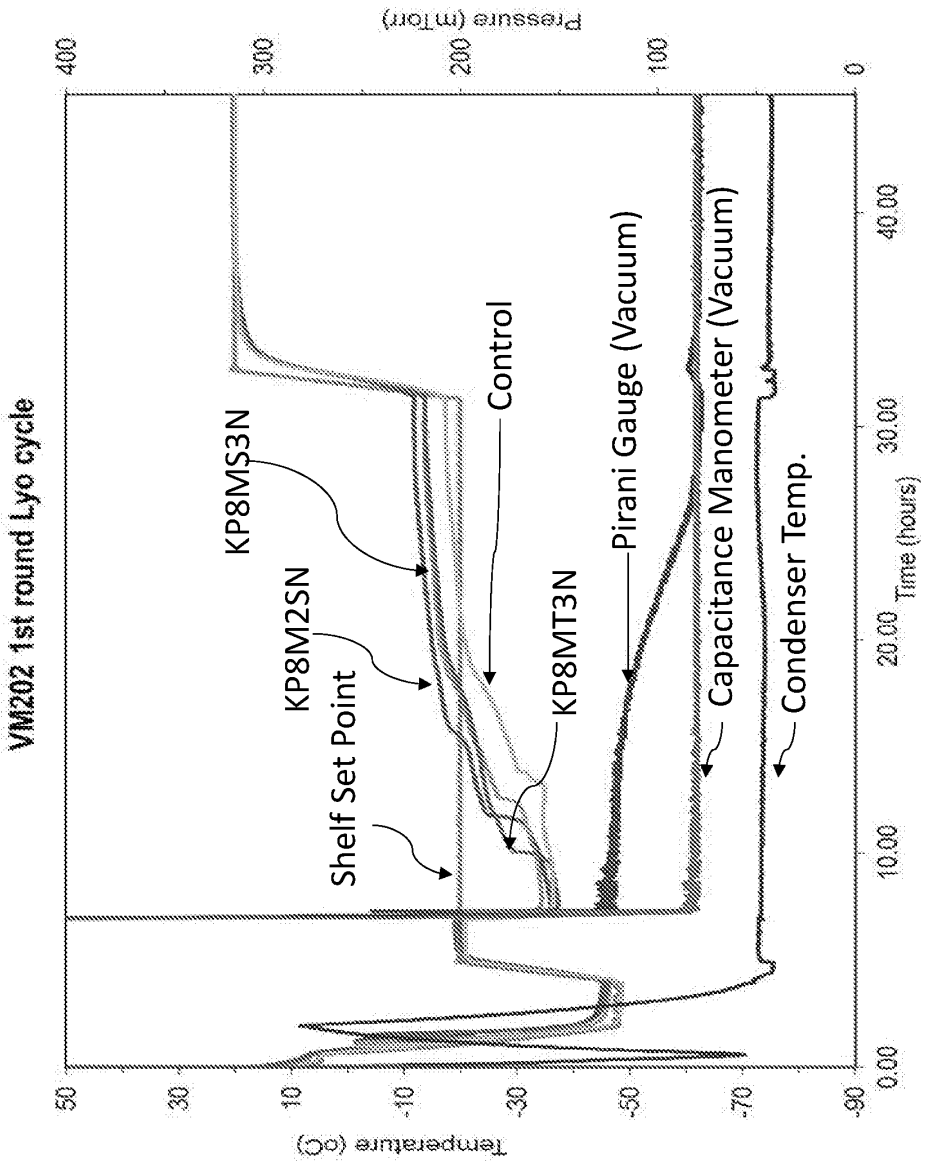

VM202 1st round Lyo cycle
Temperature (oC)
Pressure (mTorr)
Time (hours)
KP8MS3N
KP8M2SN
Shelf Set Point
Control
KP8MT3N
Pirani Gauge (Vacuum)
Capacitance Manometer (Vacuum)
Condenser Temp.

Figure 3

Figure 4A

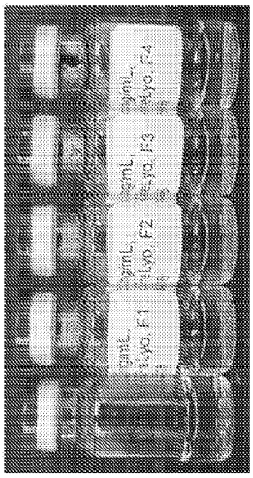


Figure 4B

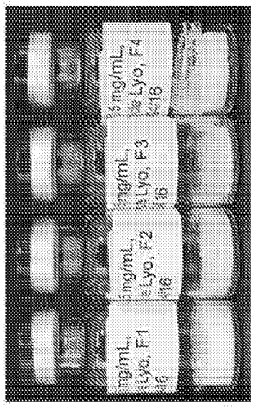


Figure 4C

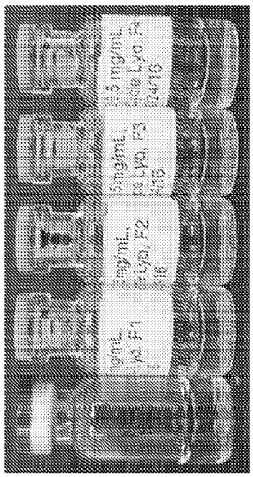
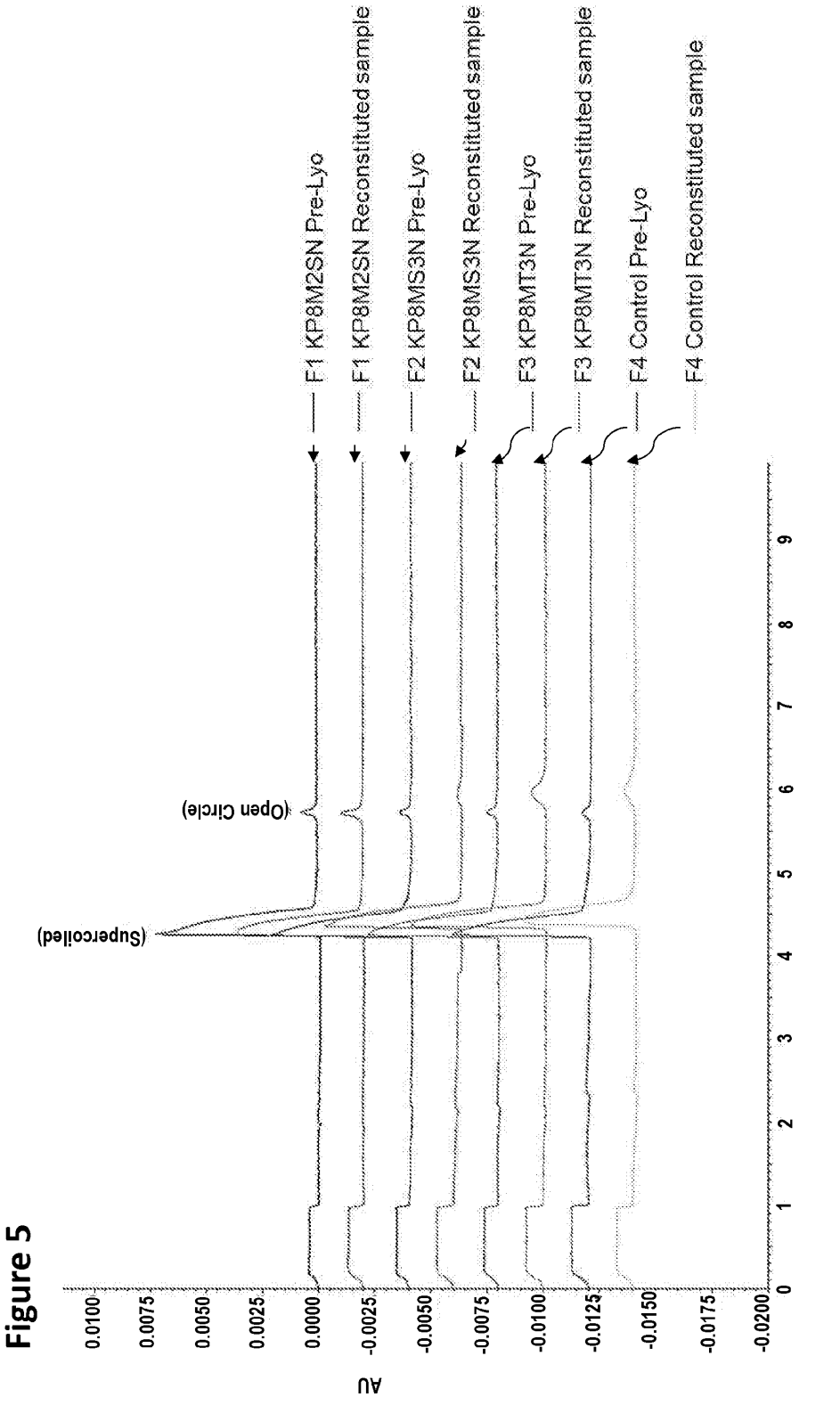


Figure 5


F1 KP8M2SN Pre-Lyo
F1 KP8M2SN Reconstituted sample
F2 KP8MS3N Pre-Lyo
F2 KP8MS3N Reconstituted sample
F3 KP8MT3N Pre-Lyo
F3 KP8MT3N Reconstituted sample
F4 Control Pre-Lyo
F4 Control Reconstituted sample
(Open Circle)
(Supercoiled)
AU
0.0100
0.0075
0.0050
0.0025
0.0000
-0.0025
-0.0050
-0.0075
-0.0100
-0.0125
-0.0150
-0.0175
-0.0200
0
1
2
3
4
5
6
7
8
9

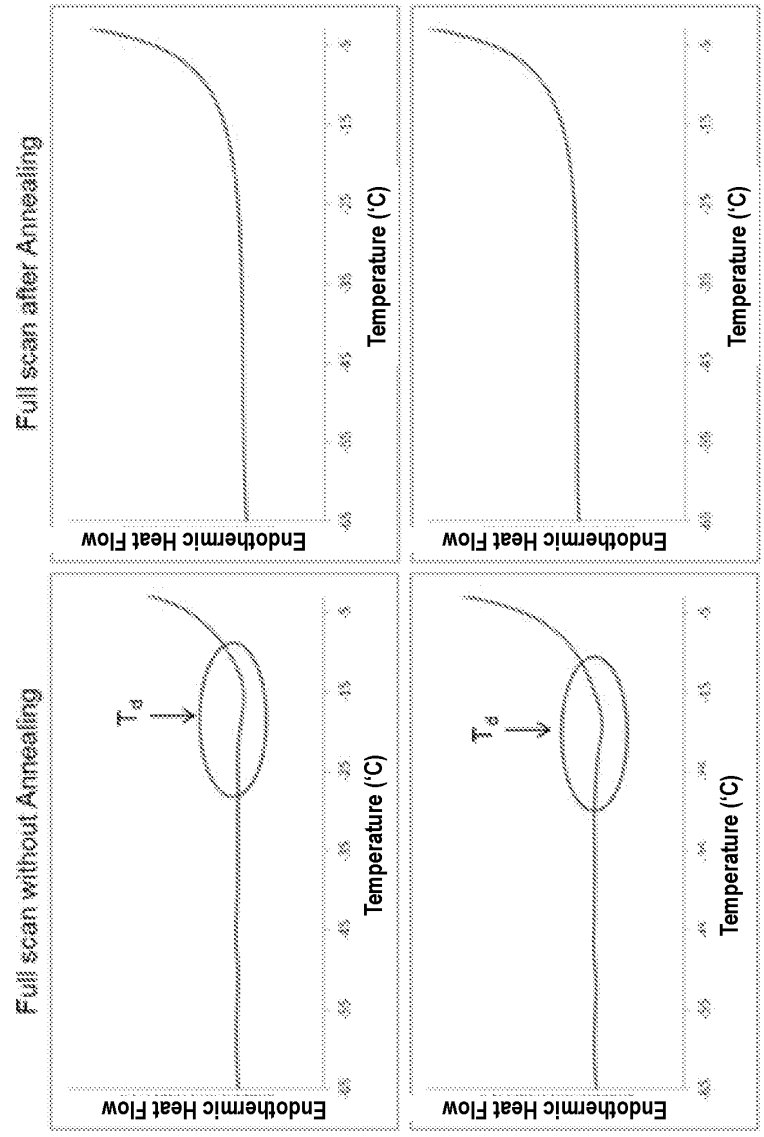


Figure 6A

Figure 6B

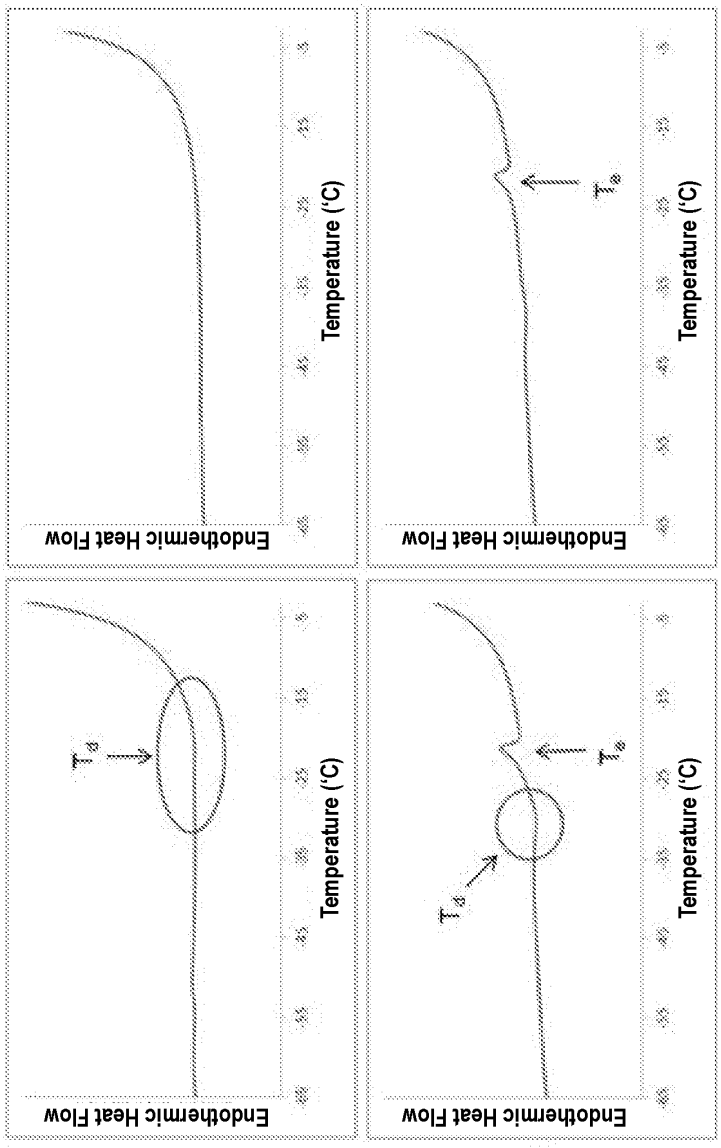


Figure 6C

Figure 6D

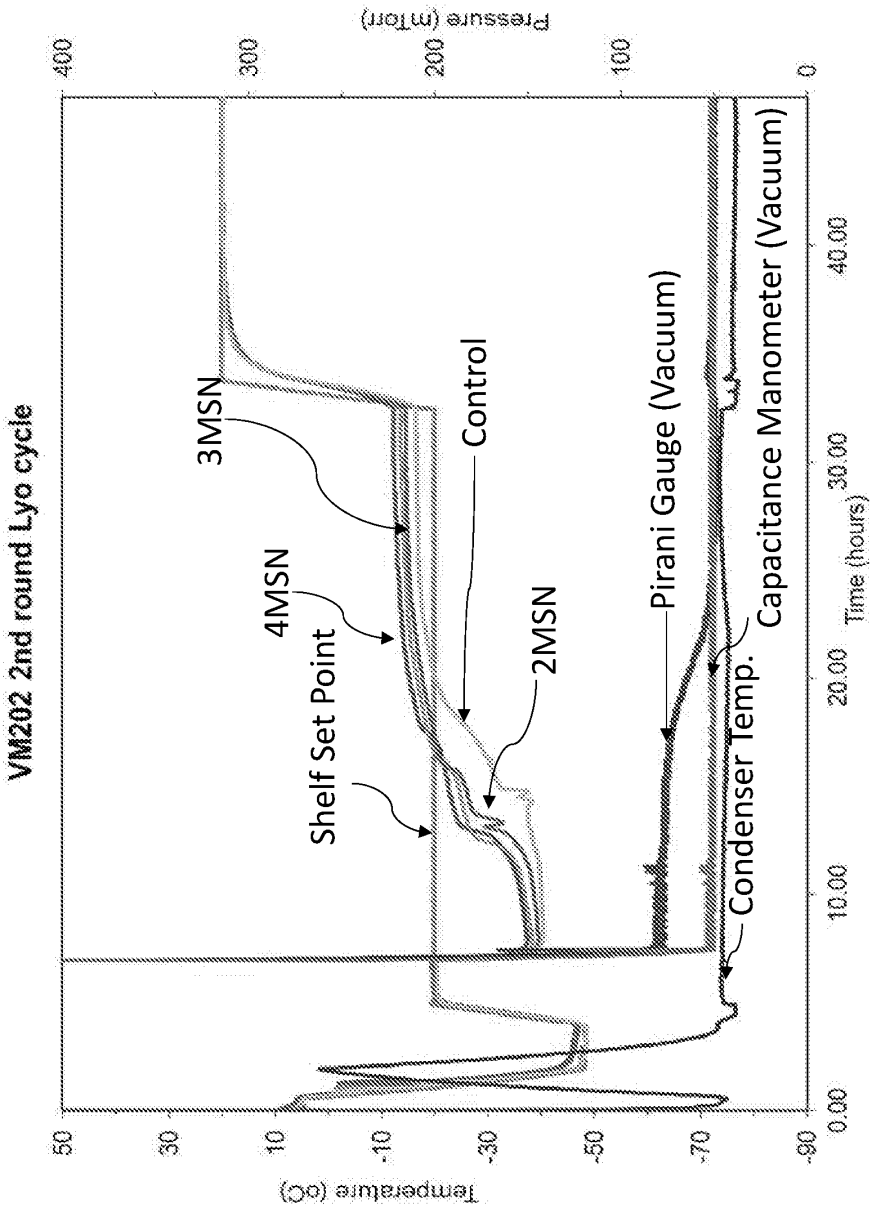

VM202 2nd round Lyo cycle
Temperature (oC)
Pressure (mTorr)
Time (hours)
3MSN
4MSN
Shelf Set Point
Control
2MSN
Pirani Gauge (Vacuum)
Capacitance Manometer (Vacuum)
Condenser Temp.

Figure 7

Figure 8A



Figure 8B



Figure 8C

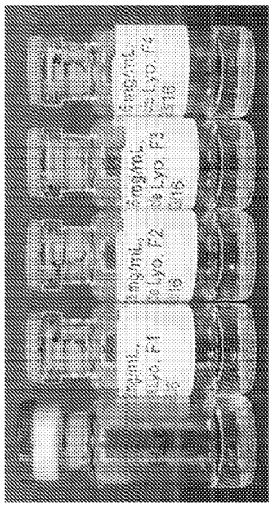
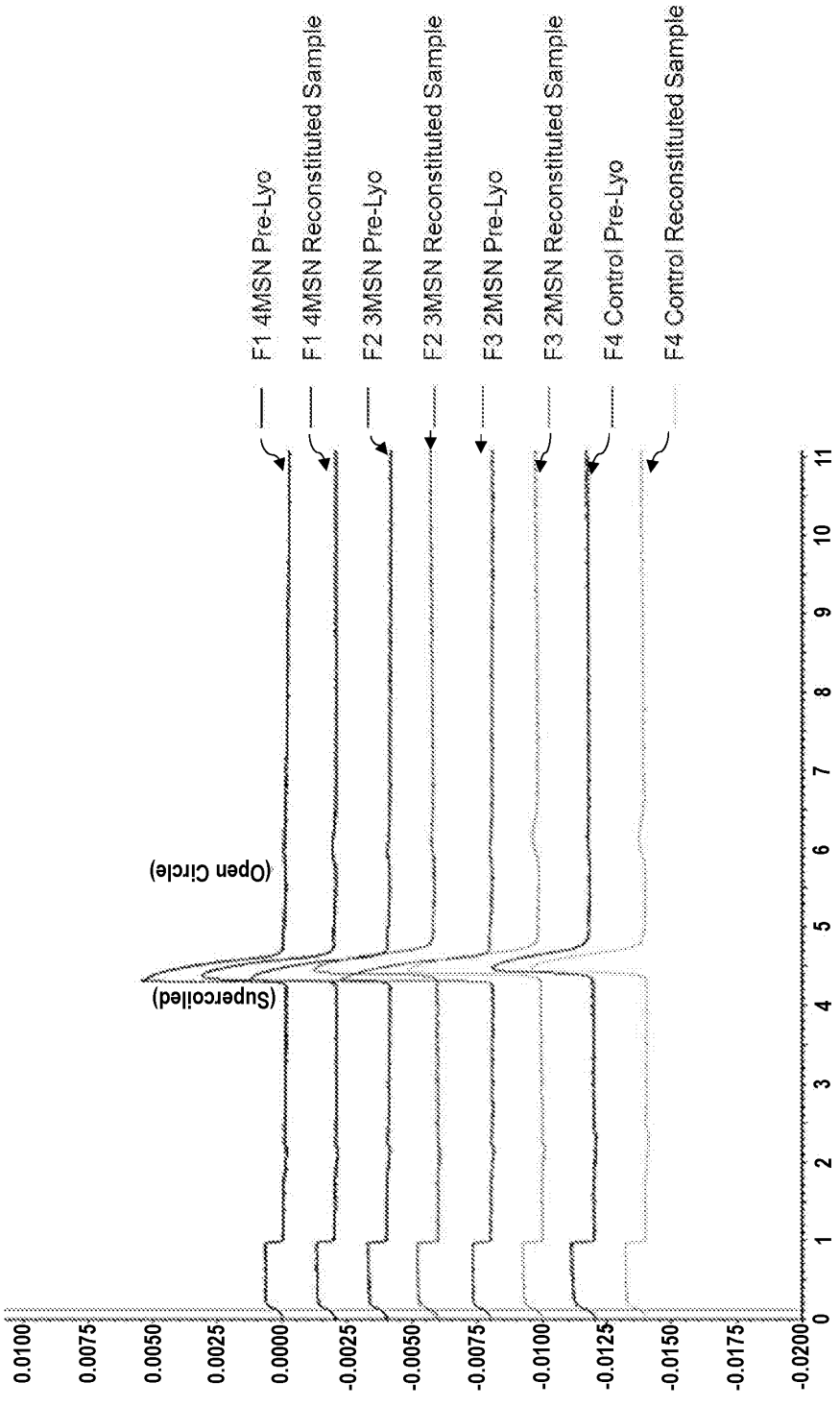


Figure 9


F1 4MSN Pre-Lyo
F1 4MSN Reconstituted Sample
F2 3MSN Pre-Lyo
F2 3MSN Reconstituted Sample
F3 2MSN Pre-Lyo
F3 2MSN Reconstituted Sample
F4 Control Pre-Lyo
F4 Control Reconstituted Sample
(Open Circle)
(Supercoiled)
0.0100
0.0075
0.0050
0.0025
0.0000
-0.0025
-0.0050
-0.0075
-0.0100
-0.0125
-0.0150
-0.0175
-0.0200
0
1
2
3
4
5
6
7
8
9
10
11

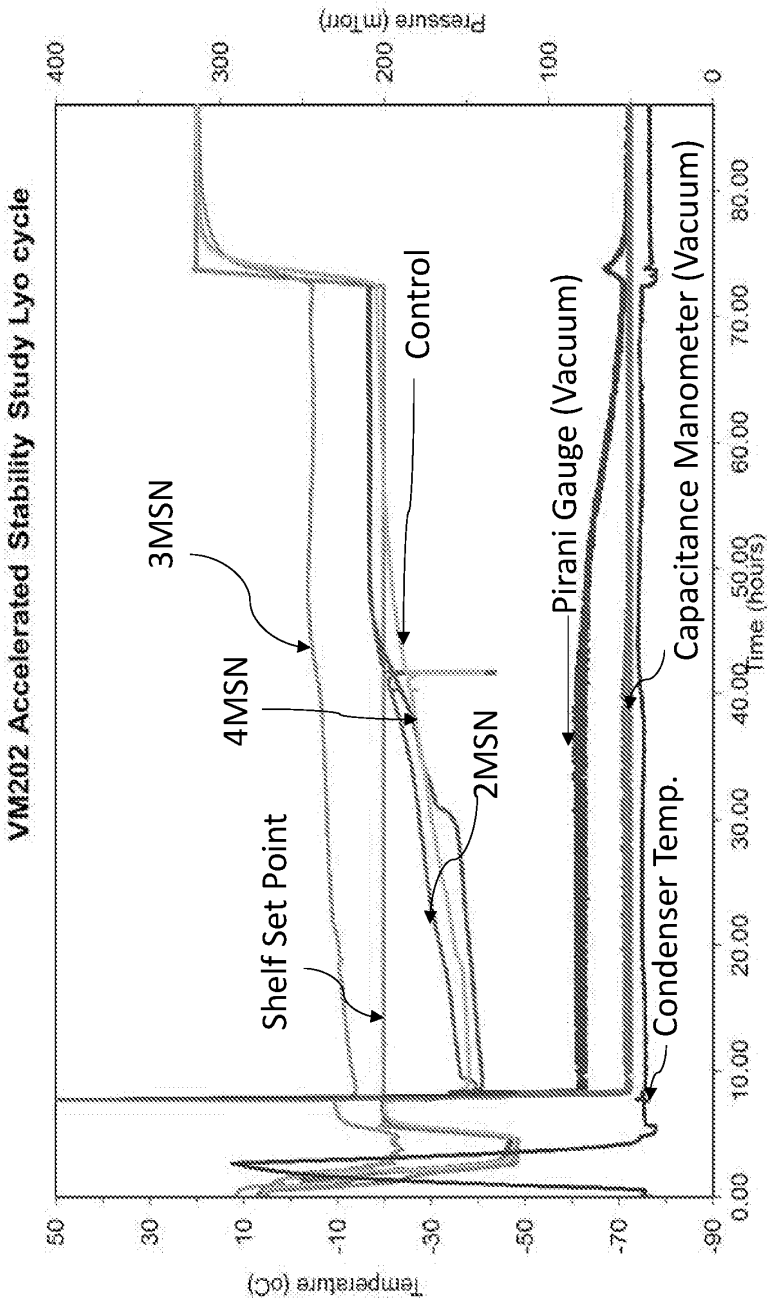

VM202 Accelerated Stability Study Lyo cycle
Temperature (oC)
Pressure (mTorr)
Time (hours)
3MSN
4MSN
2MSN
Control
Shelf Set Point
Pirani Gauge (Vacuum)
Capacitance Manometer (Vacuum)
Condenser Temp.

Figure 10

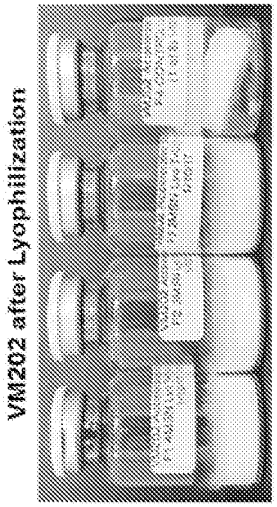


Figure 11B

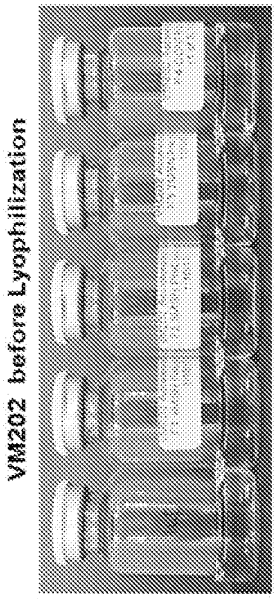


Figure 11A

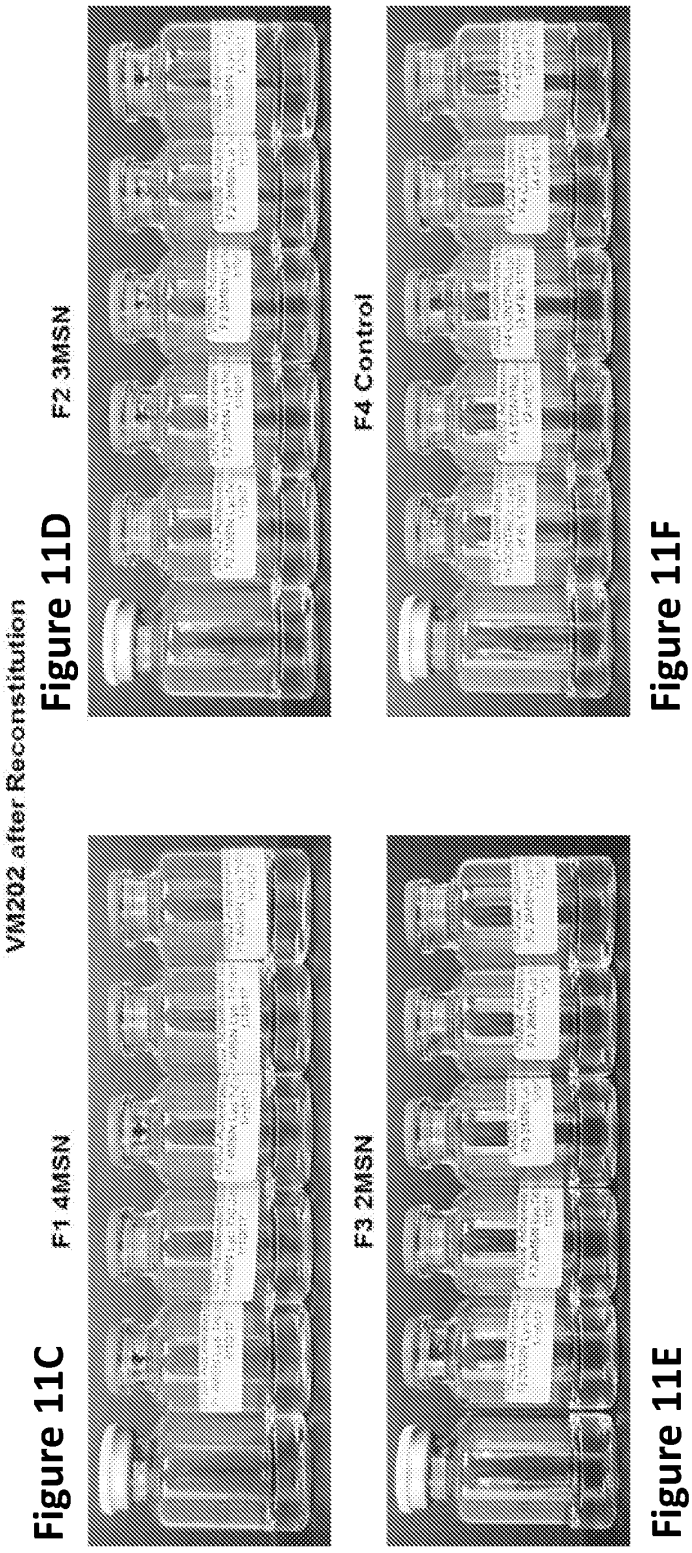


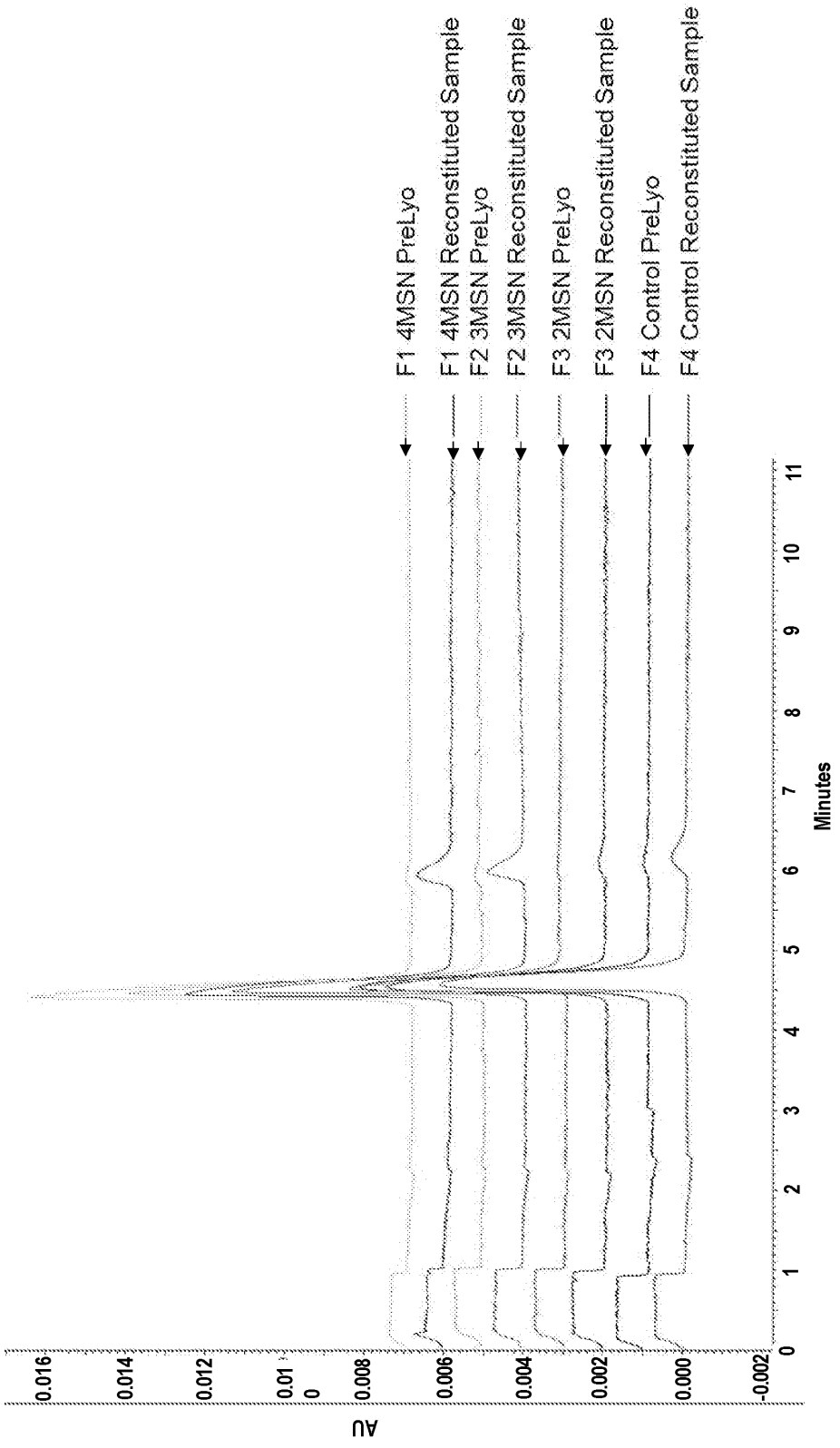
Figure 11C

Figure 11D

Figure 11E

Figure 11F

Figure 12


F1 4MSN PreLyo
F1 4MSN Reconstituted Sample
F2 3MSN PreLyo
F2 3MSN Reconstituted Sample
F3 2MSN PreLyo
F3 2MSN Reconstituted Sample
F4 Control PreLyo
F4 Control Reconstituted Sample
AU
0.016
0.014
0.012
0.01
0
0.008
0.006
0.004
0.002
0.000
-0.002
0
1
2
3
4
5
6
7
8
9
10
11
Minutes

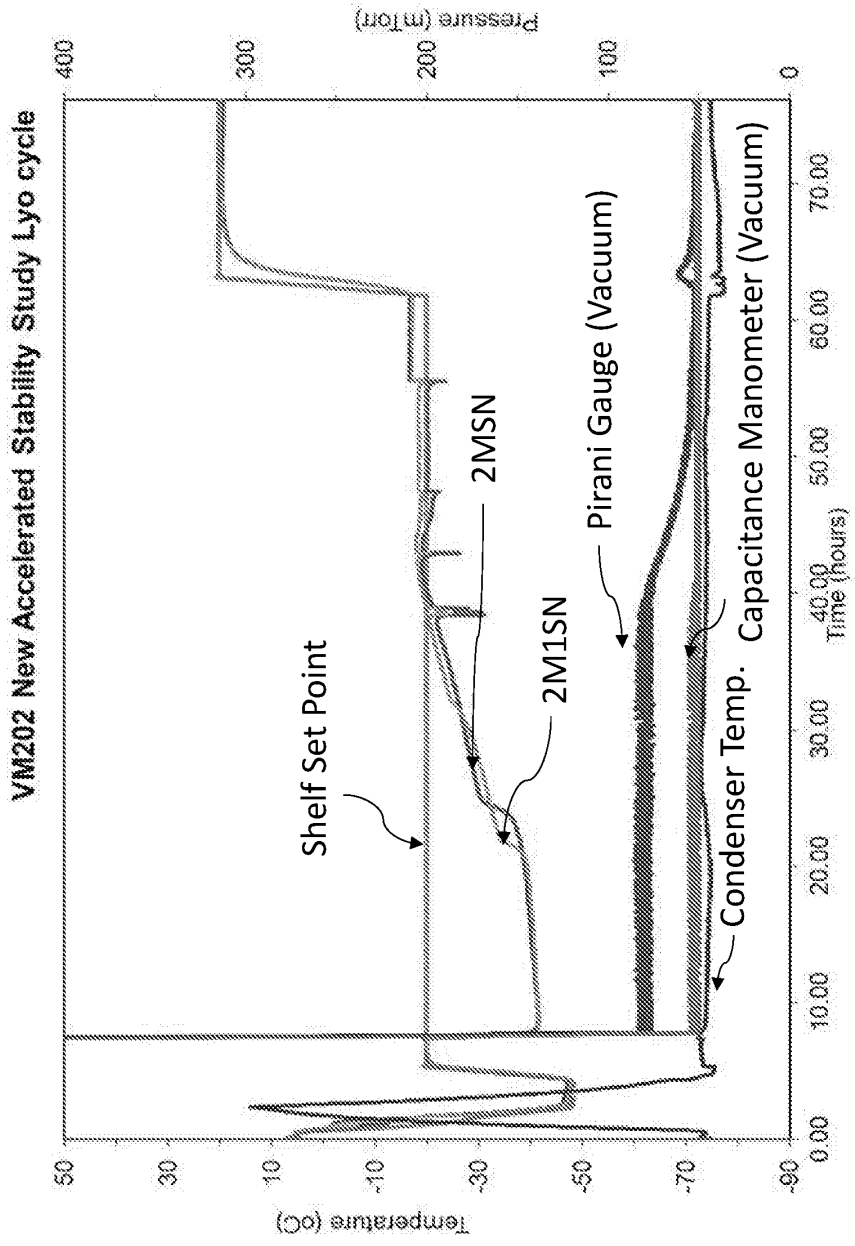

VM202 New Accelerated Stability Study Lyo cycle
Temperature (oC)
Pressure (mTorr)
Time (hours)
Shelf Set Point
2MSN
2M1SN
Pirani Gauge (Vacuum)
Capacitance Manometer (Vacuum)
Condenser Temp.

Figure 13

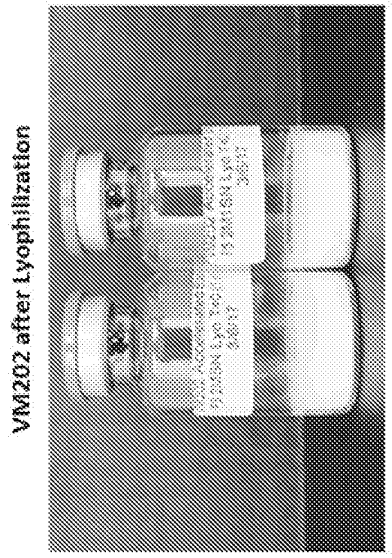


Figure 14B

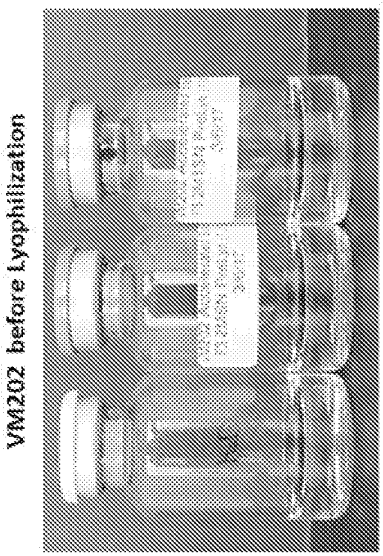


Figure 14A

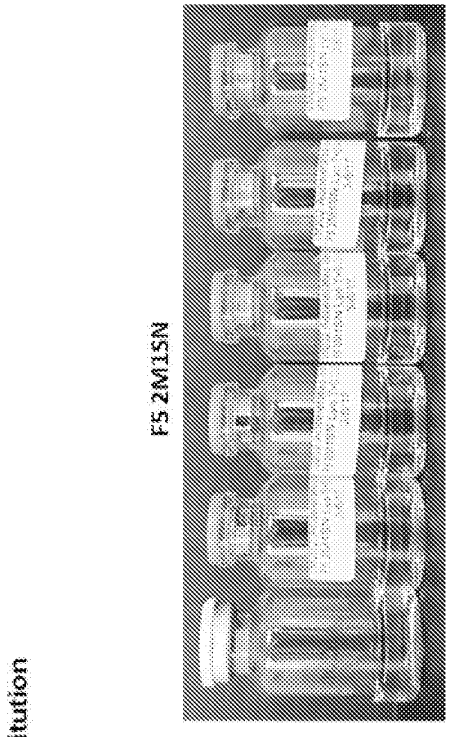


Figure 14D

VM202 after Reconstitution

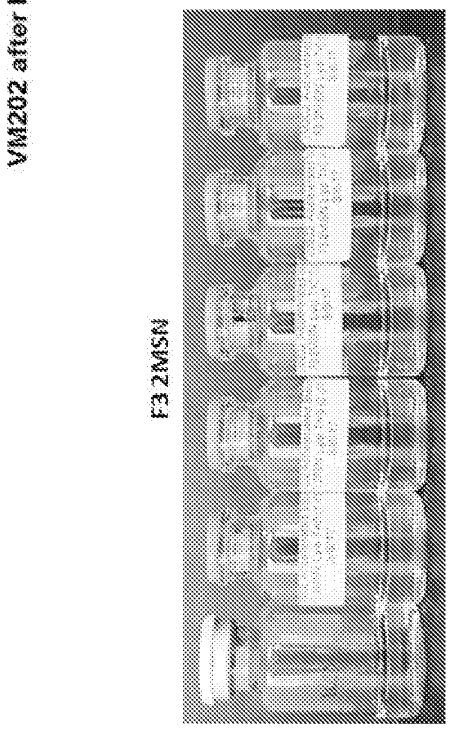


Figure 14C

Figure 15

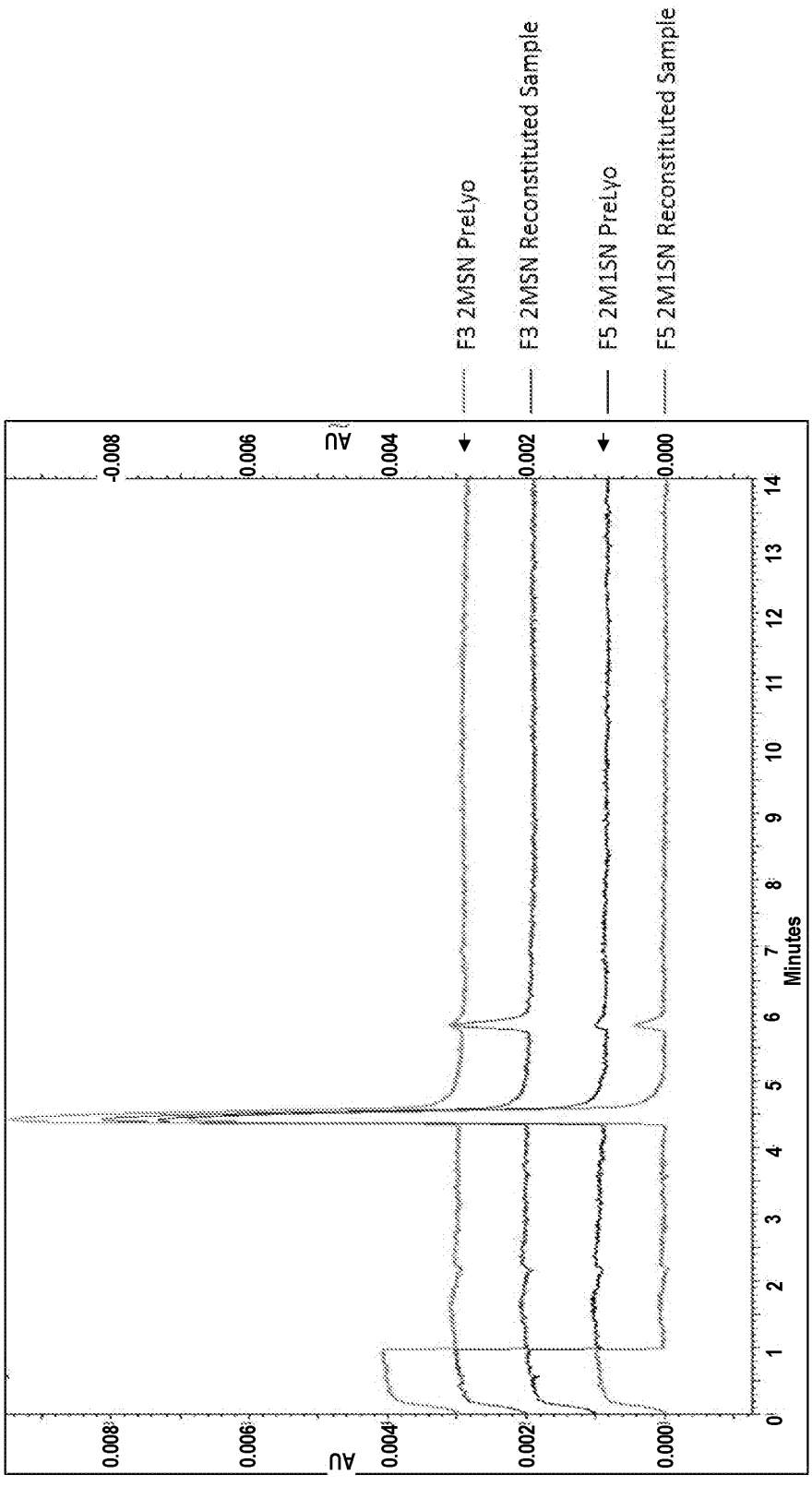

F3 2MSN PreLyo
F3 2MSN Reconstituted Sample
F5 2M1SN PreLyo
F5 2M1SN Reconstituted Sample
AU
Minutes
0.008
0.006
0.004
0.002
0.000
-0.008
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14

Figure 16A

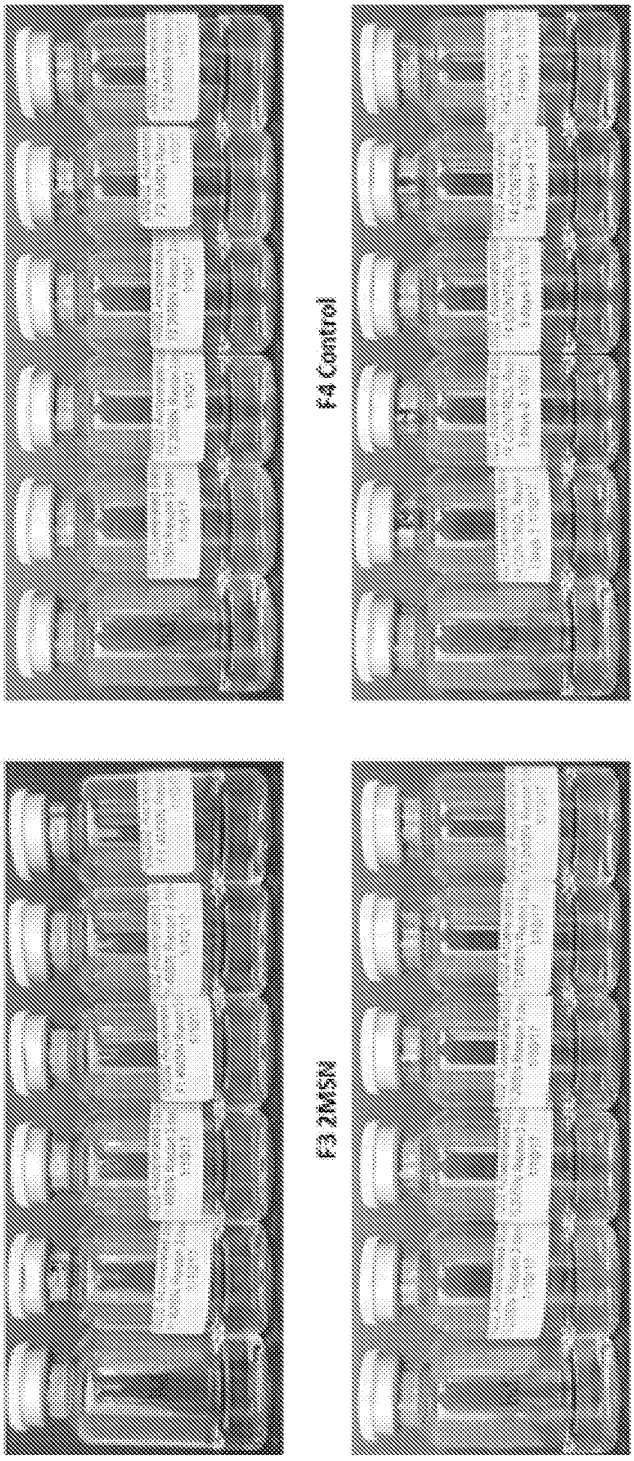

(a) Storage at 25°C for 3 days after Reconstitution
F1 4MSN
F2 3MSN
F3 2MSN
F4 Control

Figure 16B

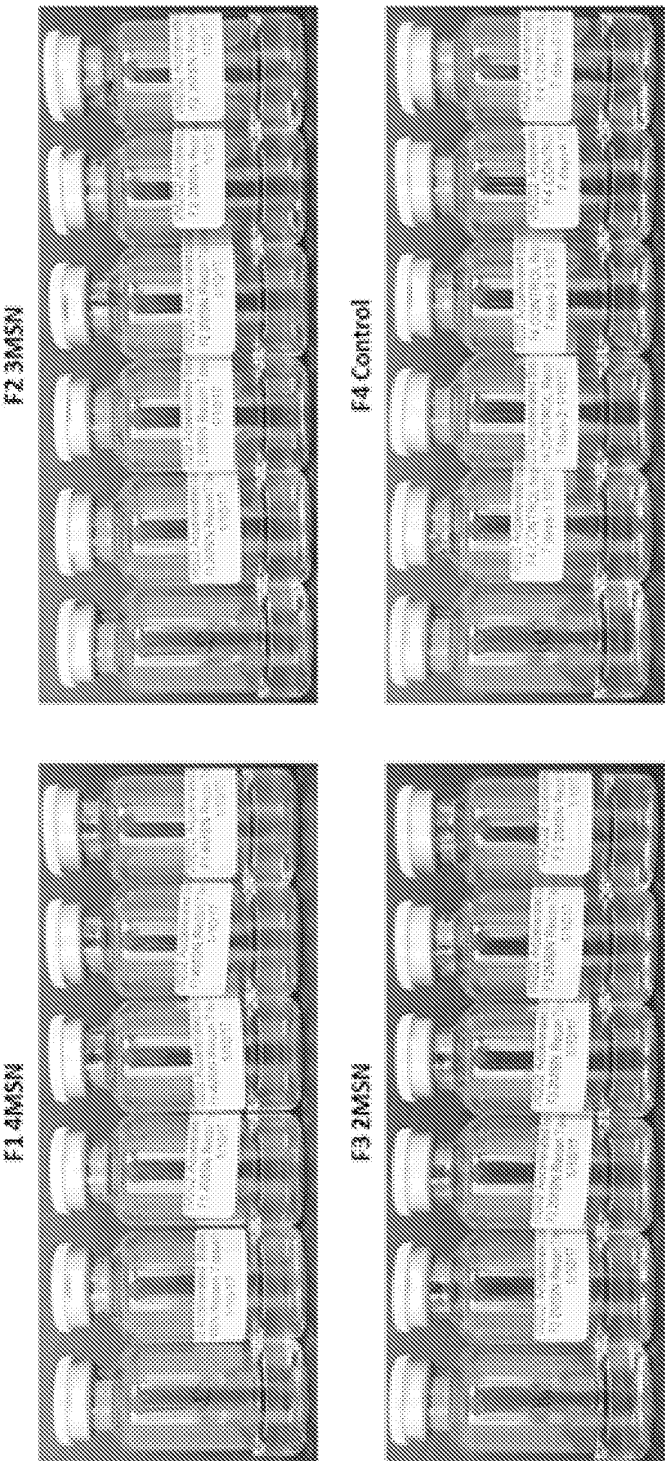

(b) Storage at 25°C for 7 days after Reconstitution
F1 4MSN
F2 3MSN
F3 2MSN
F4 Control

Figure 17A

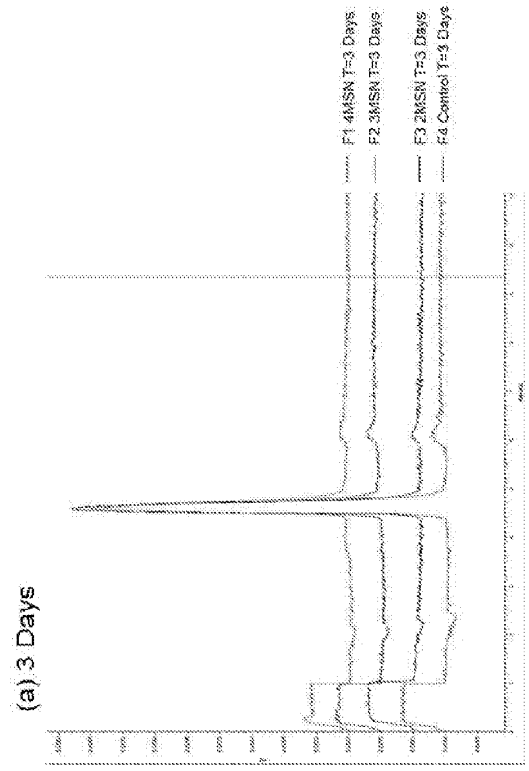
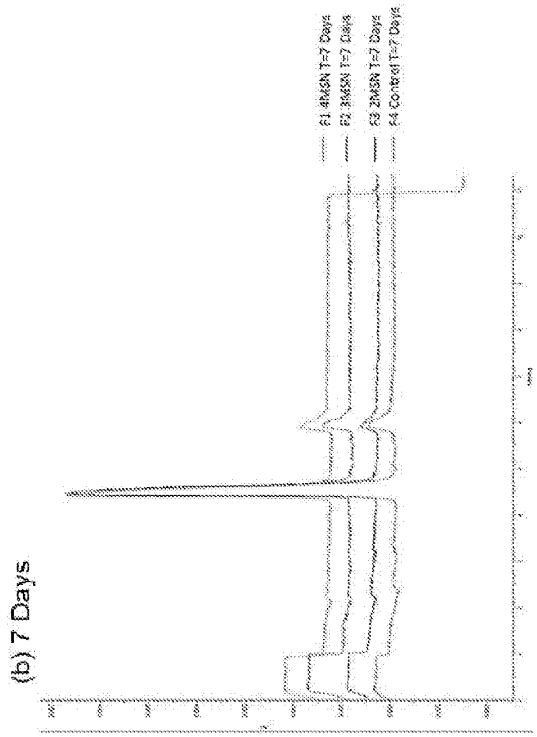


Figure 17B



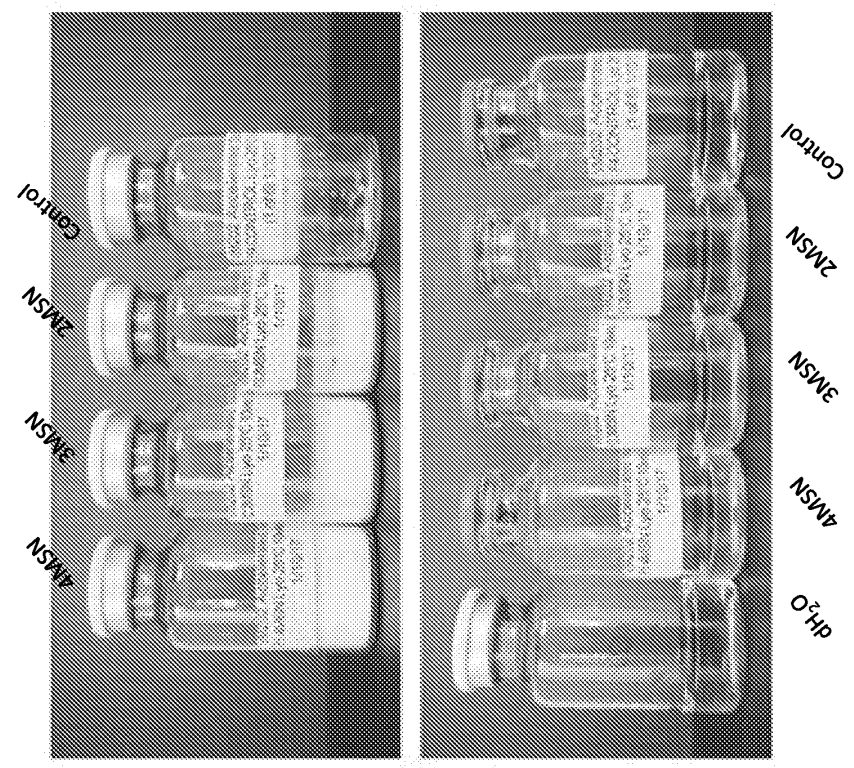

(a) 25°C
Before Reconstitution
After Reconstitution
4MSN
3MSN
2MSN
Control
dH2O
4MSN
3MSN
2MSN
Control

Figure 18A

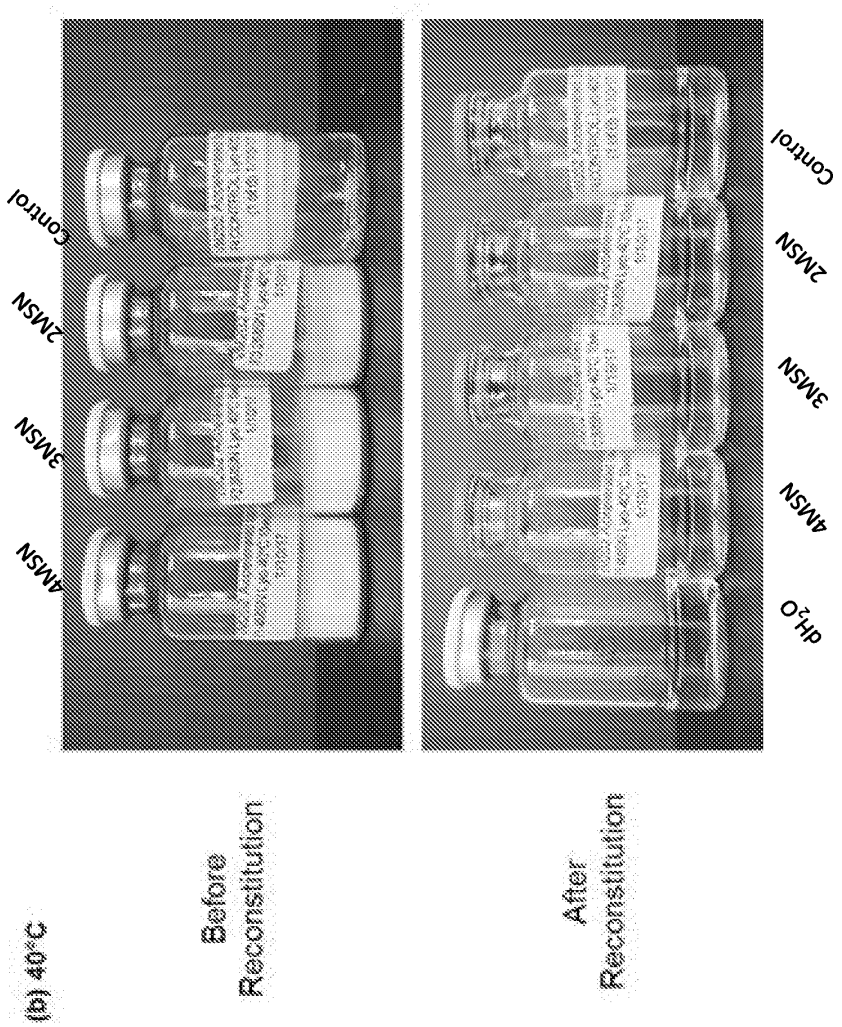

(b) 40°C
Before Reconstitution
After Reconstitution
4MSN
3MSN
2MSN
Control
dH2O
4MSN
3MSN
2MSN
Control

Figure 18B

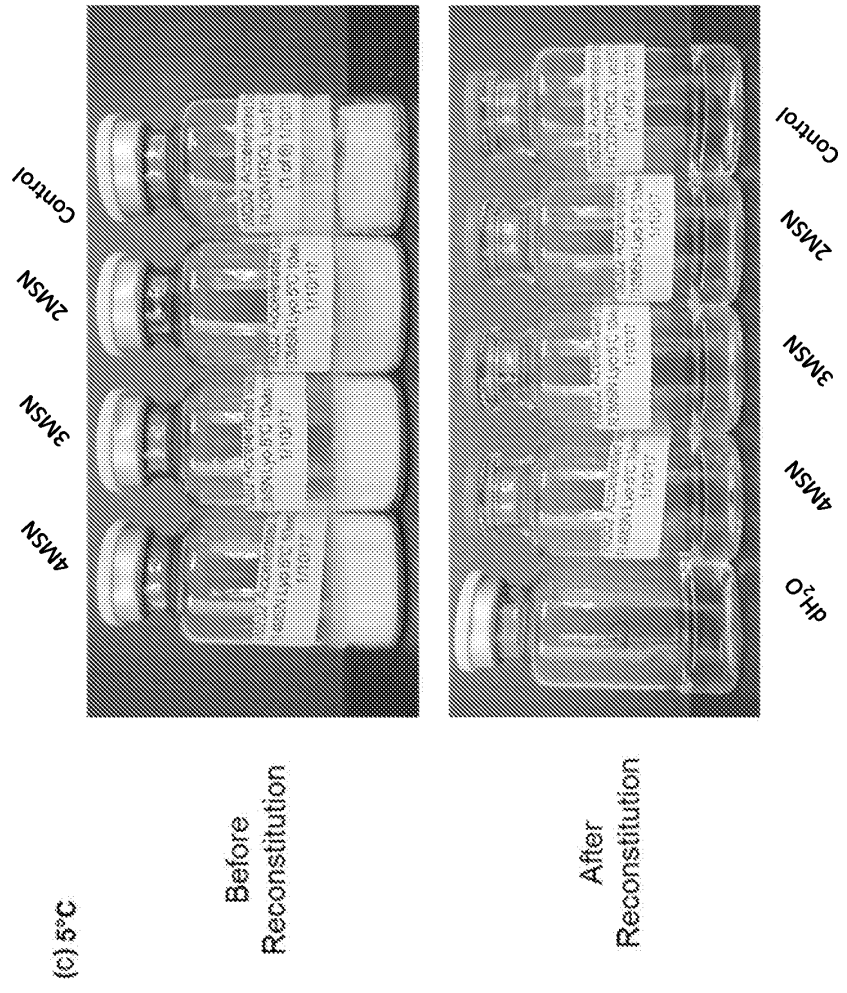
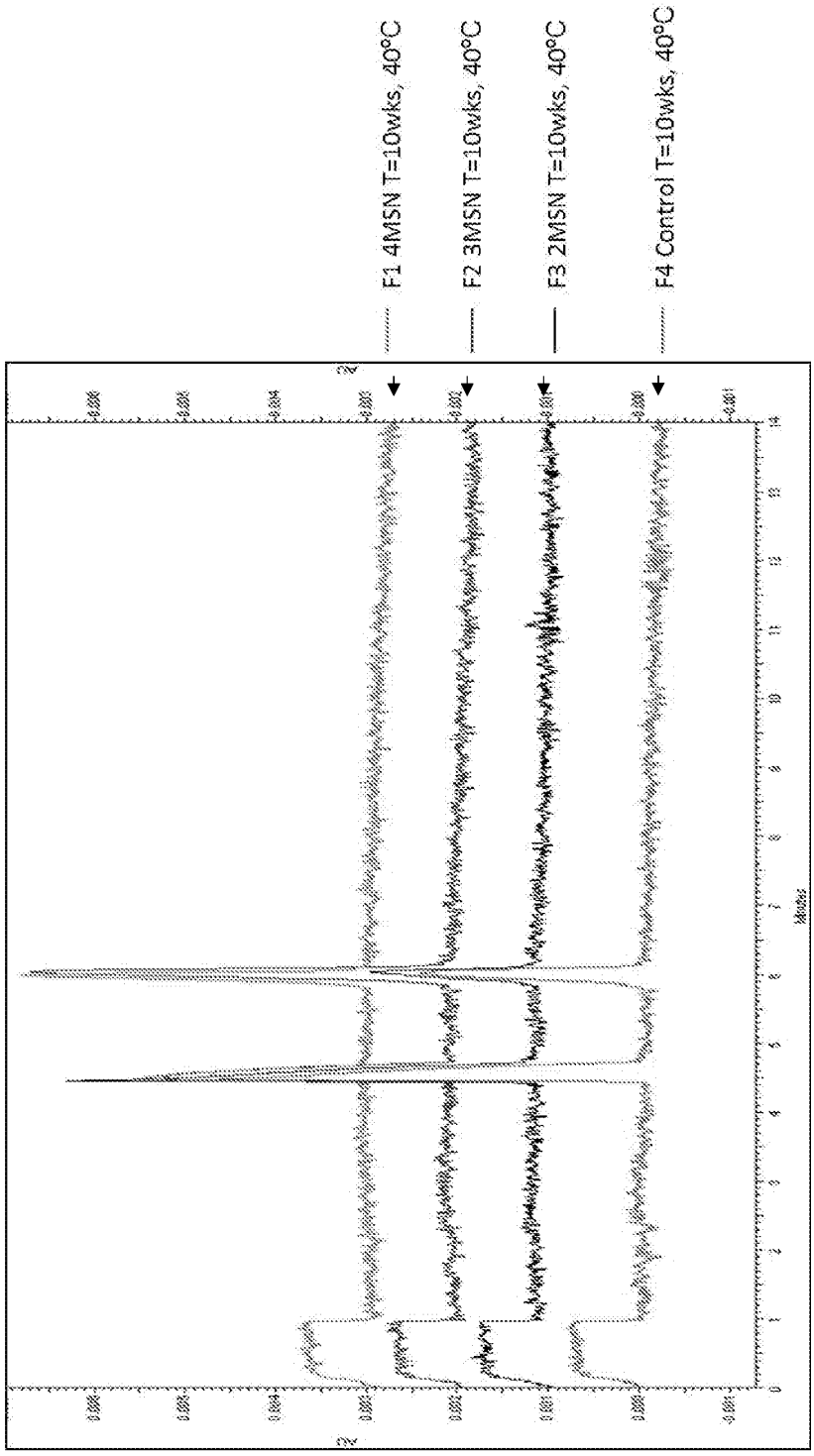

(c) 5°C
Before Reconstitution
After Reconstitution
4MSN
3MSN
2MSN
Control
dH2O
4MSN
3MSN
2MSN
Control

Figure 18C

Figure 19


F1 4MSN T=10wks, 40°C
F2 3MSN T=10wks, 40°C
F3 2MSN T=10wks, 40°C
F4 Control T=10wks, 40°C
W/g
Minutes

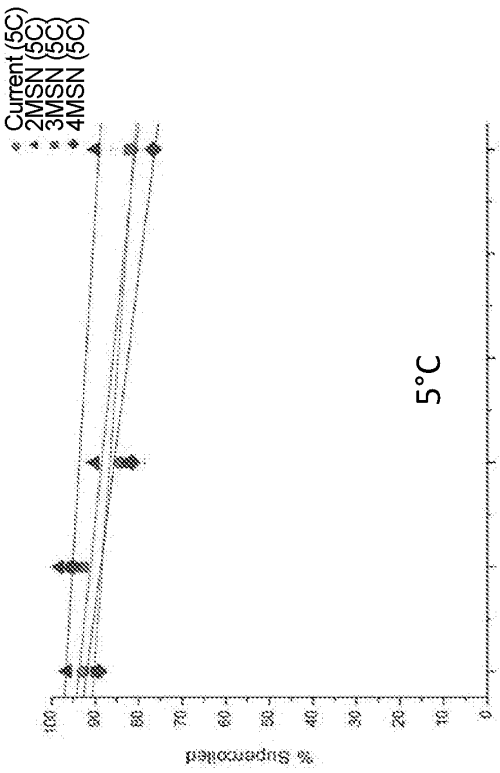


Figure 20A

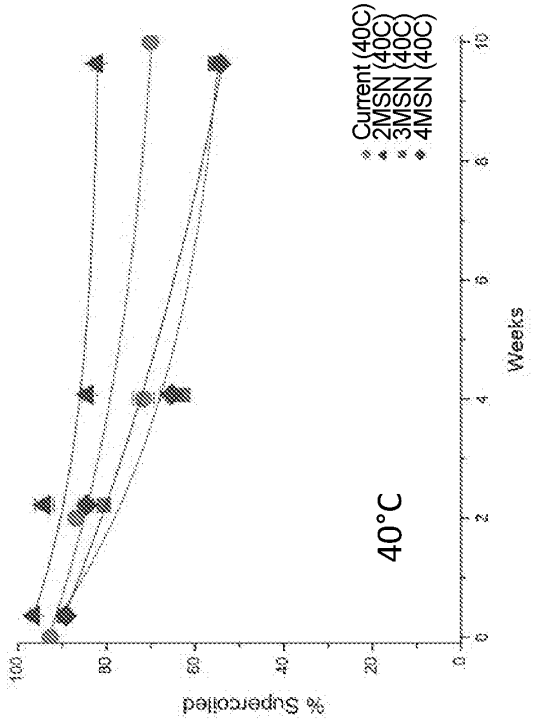


Figure 20C

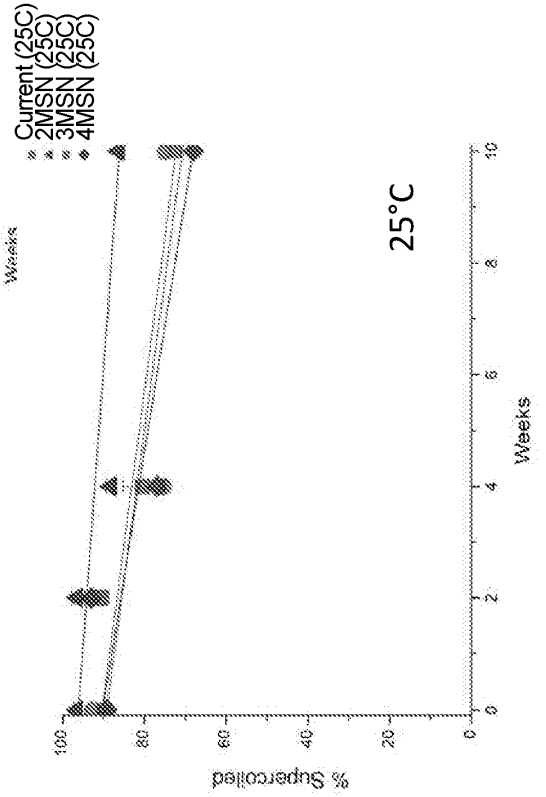


Figure 20B

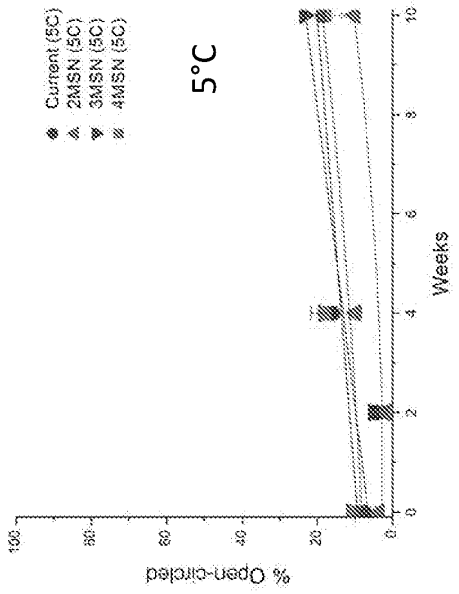


Figure 21A

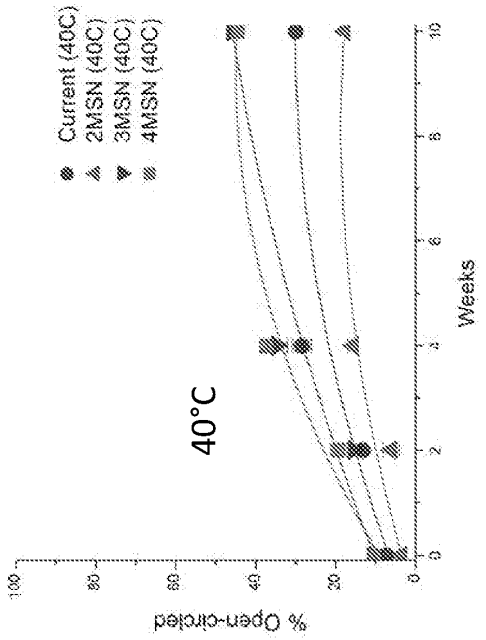


Figure 21C

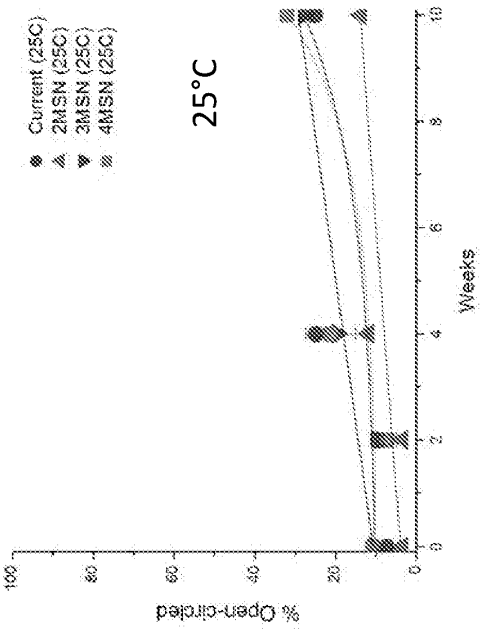


Figure 21B

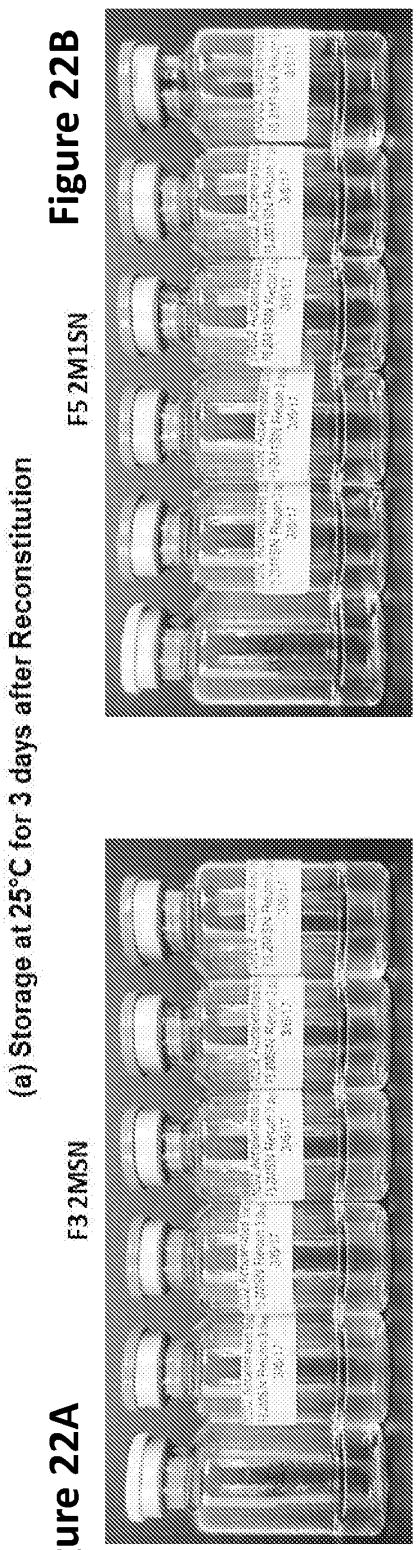


Figure 22A

Figure 22B

Figure 22C

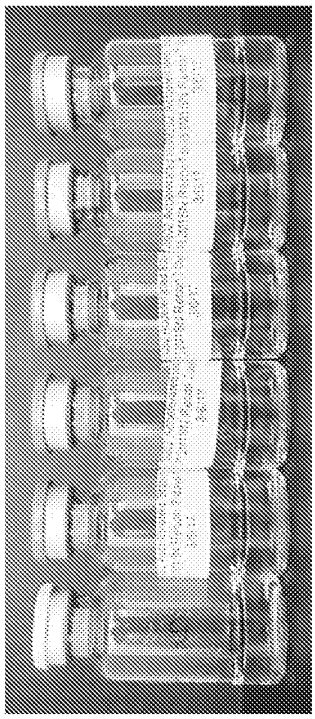


Figure 22D

Figure 23B

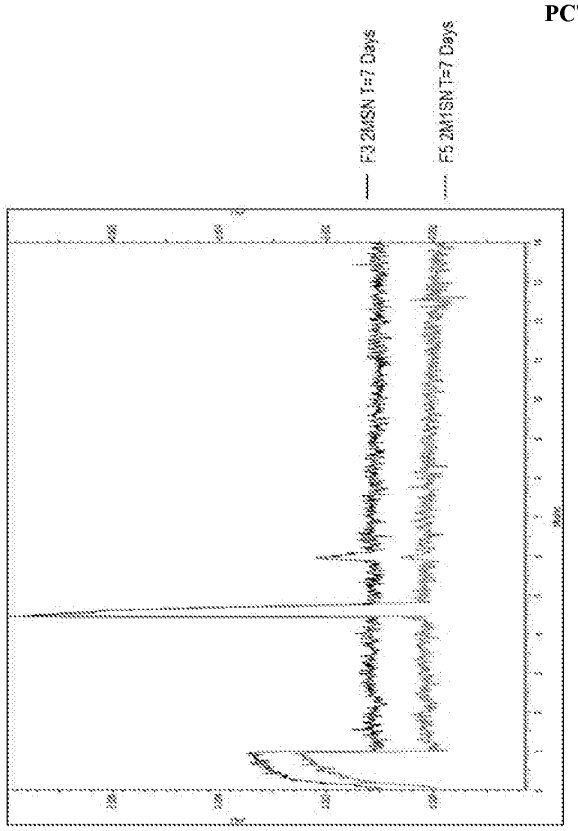


Figure 23A

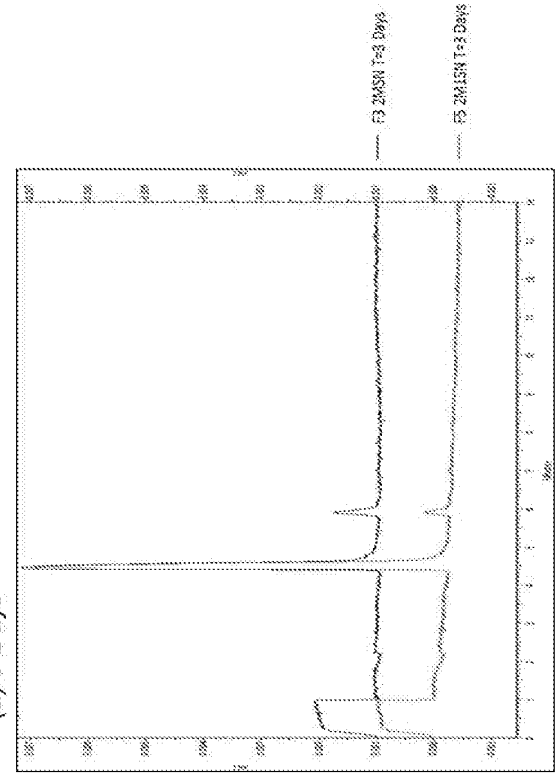
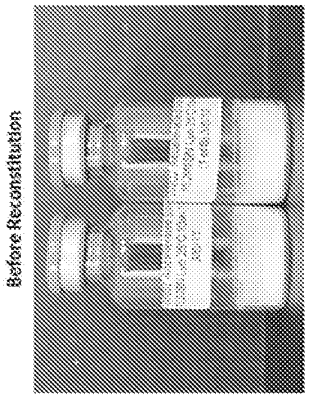


Figure 24A

(a) 25°C



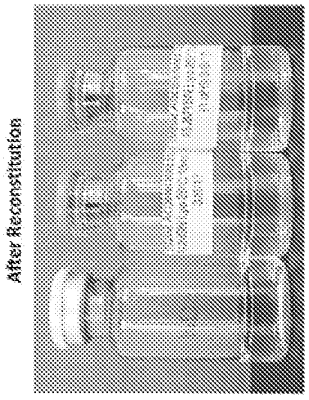


Figure 24B

(b) 40°C

Figure 24C

(c) 5°C

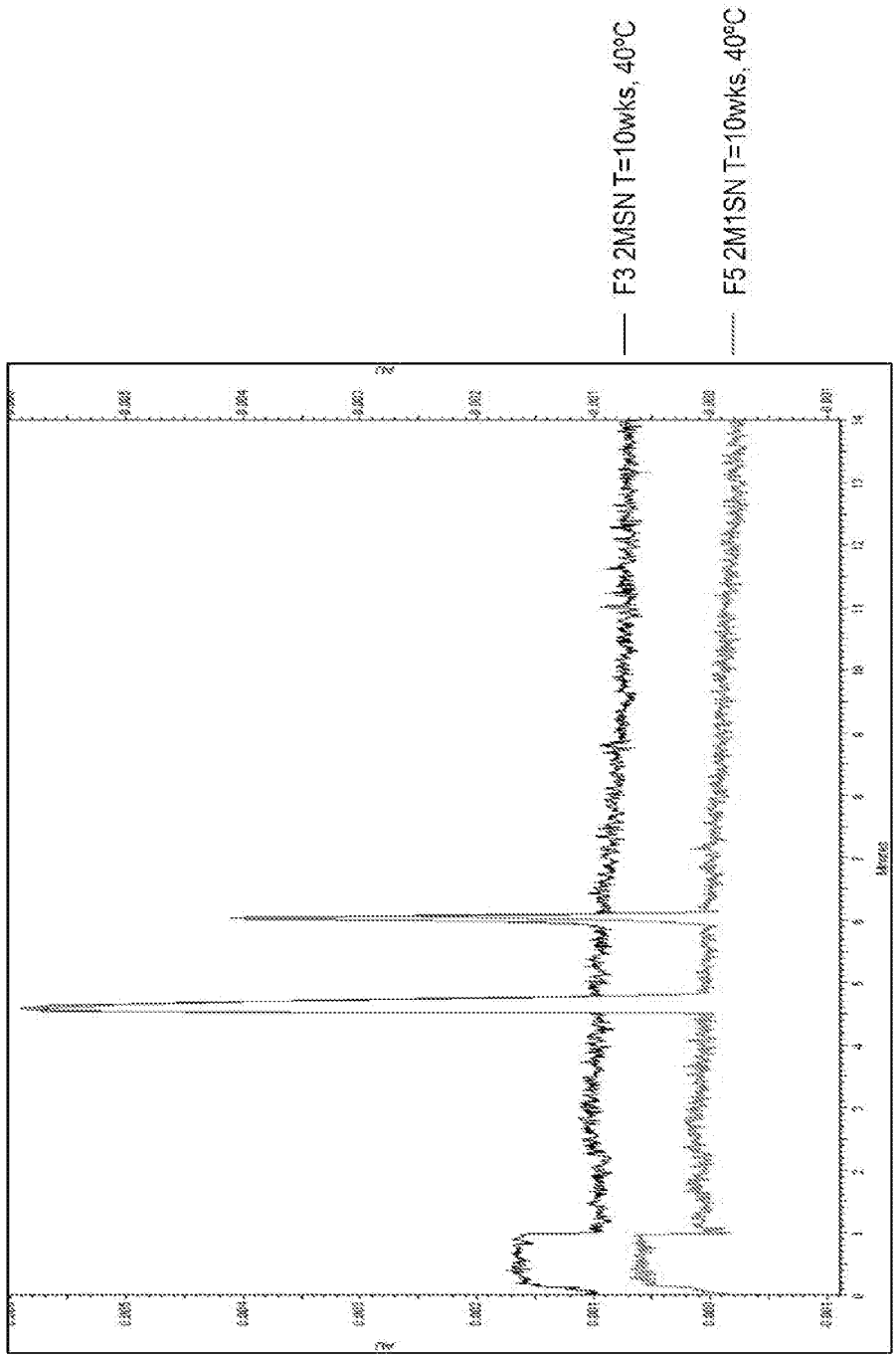


Figure 25

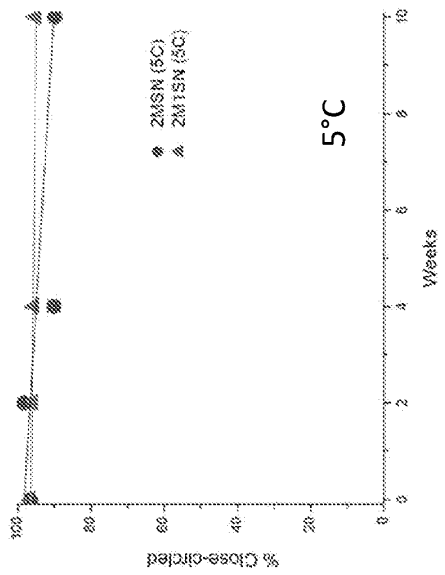


Figure 26A

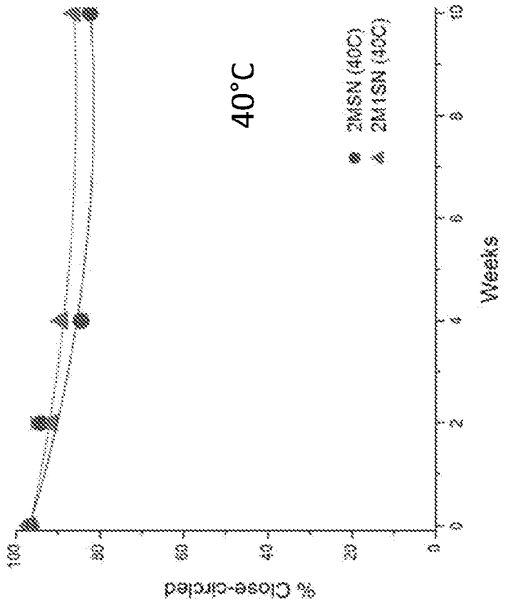


Figure 26C

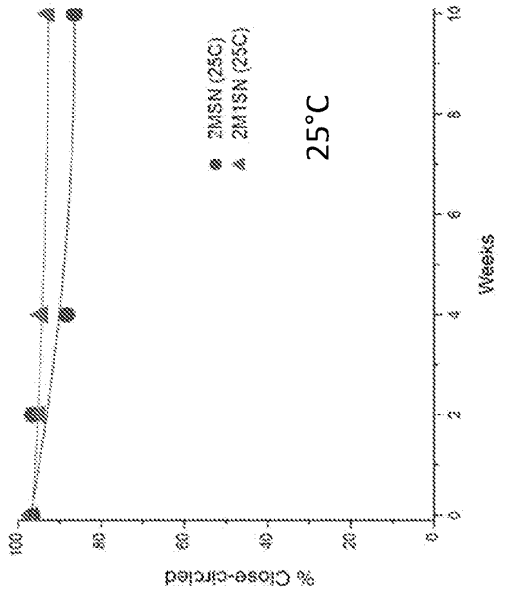


Figure 26B

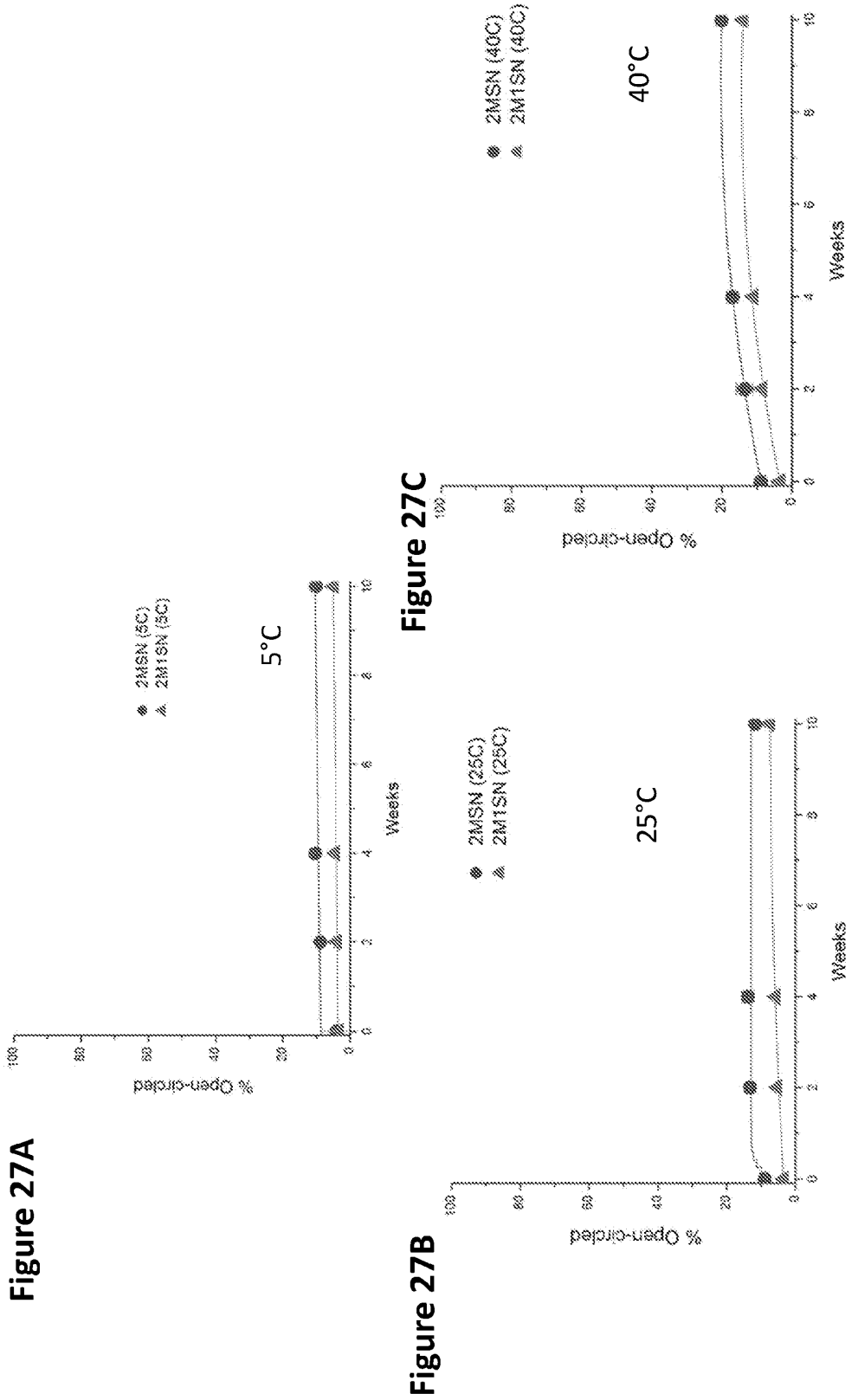


Figure 27A

Figure 27B

Figure 27C

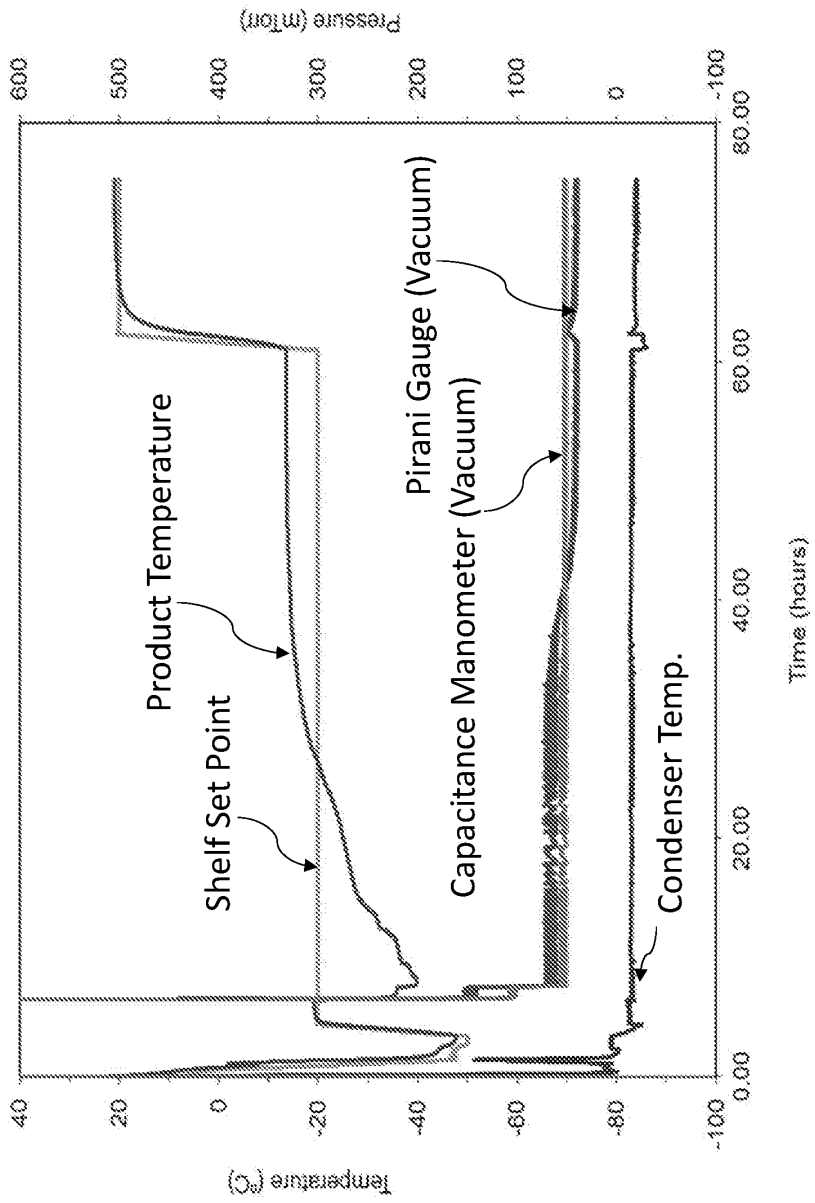

Pressure (mTorr)
600
500
400
300
200
100
0
-100
Temperature (°C)
40
20
0
-20
-40
-60
-80
-100
0.00
20.00
40.00
60.00
80.00
Time (hours)
Product Temperature
Shelf Set Point
Pirani Gauge (Vacuum)
Capacitance Manometer (Vacuum)
Condenser Temp.

Figure 28

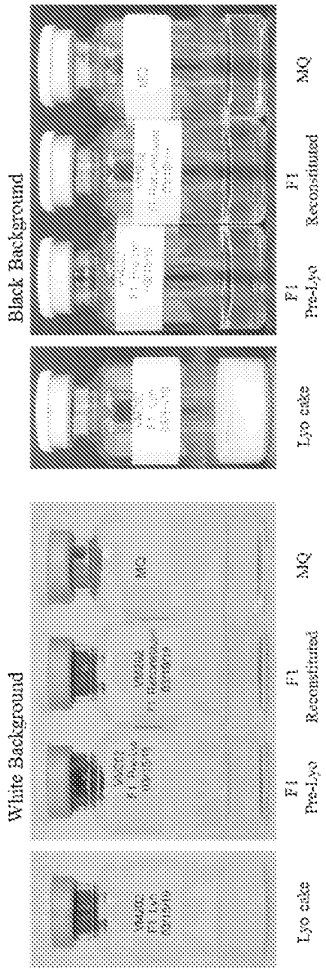


Figure 29

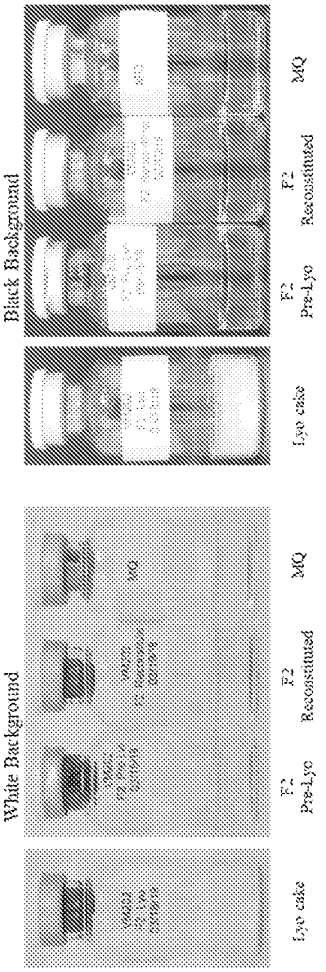


Figure 30

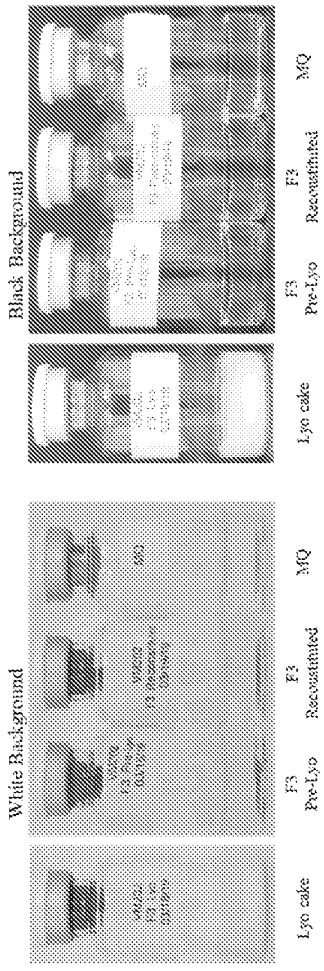


Figure 31

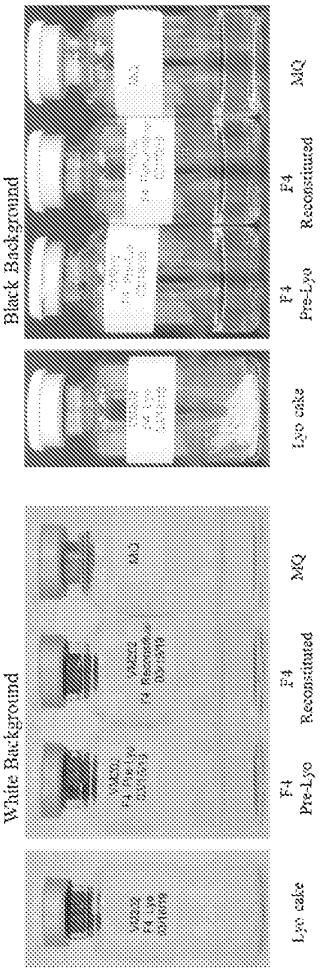


Figure 32

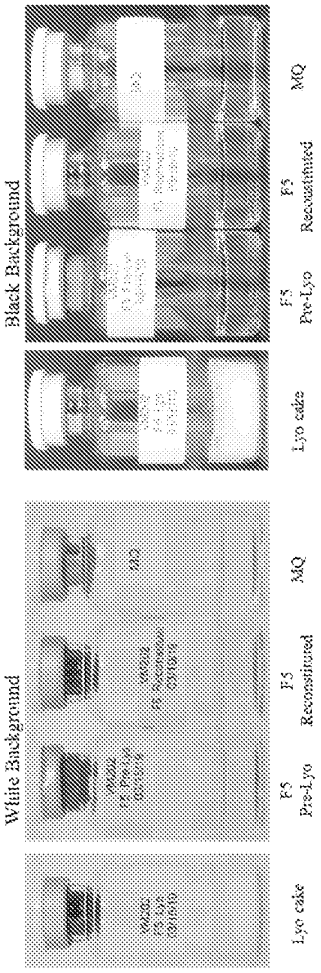


Figure 33

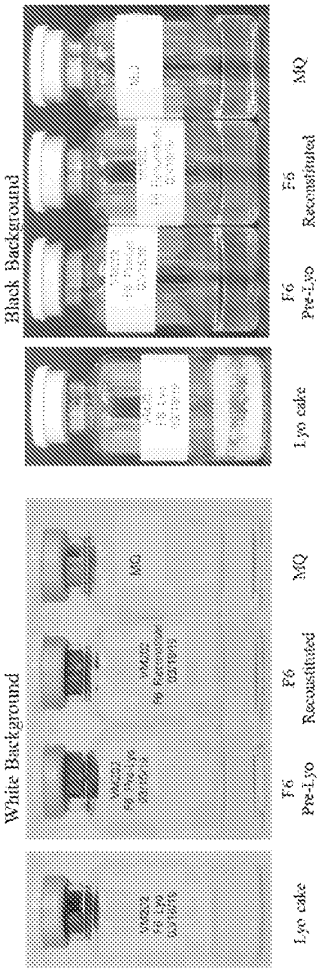


Figure 34

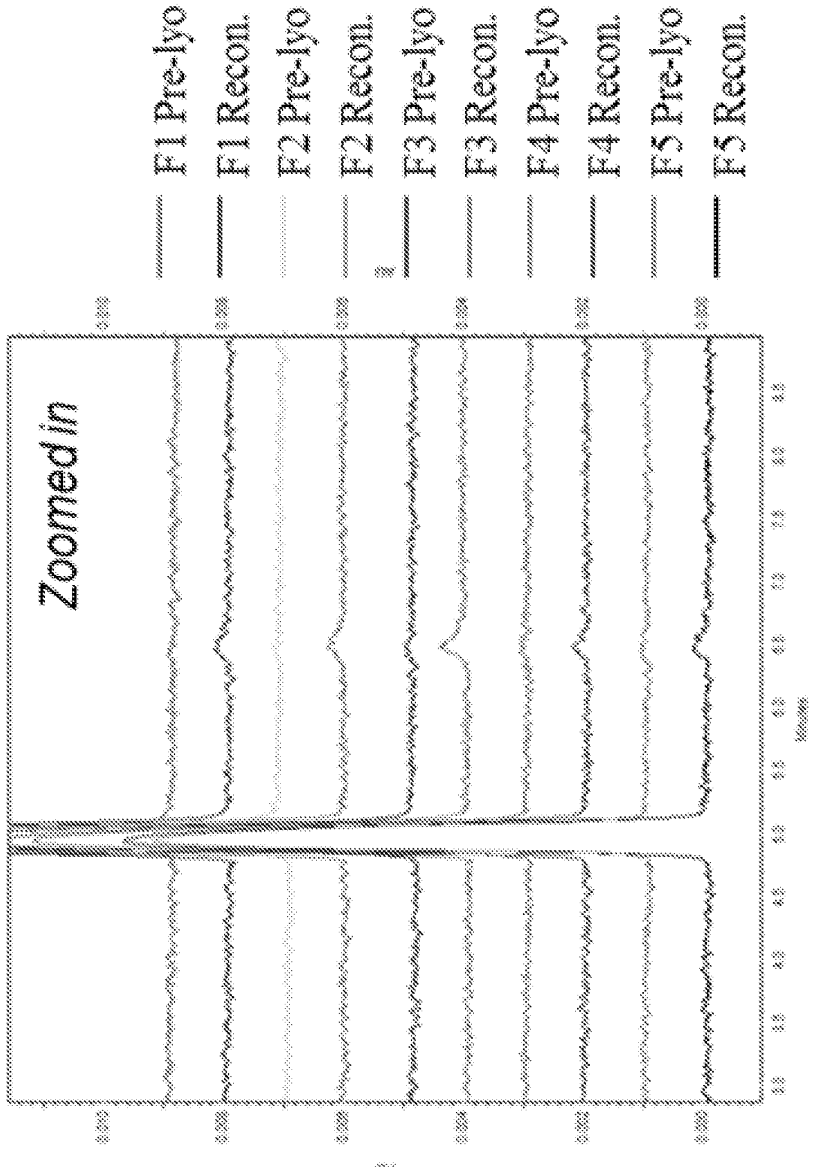

F1 Pre-lyo
F1 Recon.
F2 Pre-lyo
F2 Recon.
F3 Pre-lyo
F3 Recon.
F4 Pre-lyo
F4 Recon.
F5 Pre-lyo
F5 Recon.
Zoomed in

Figure 35

Figure 36

F1

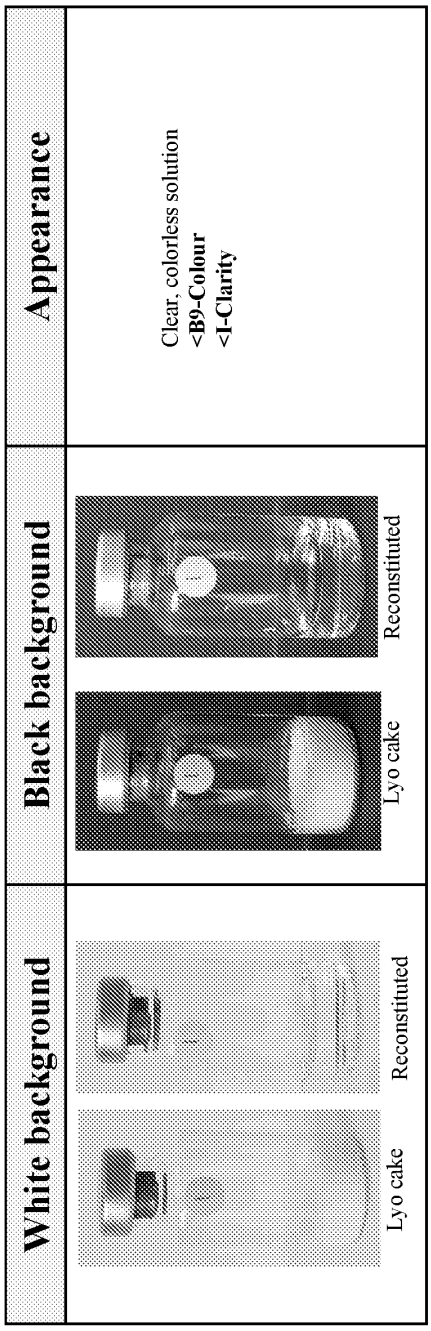


Figure 37

F2

Figure 38

F3

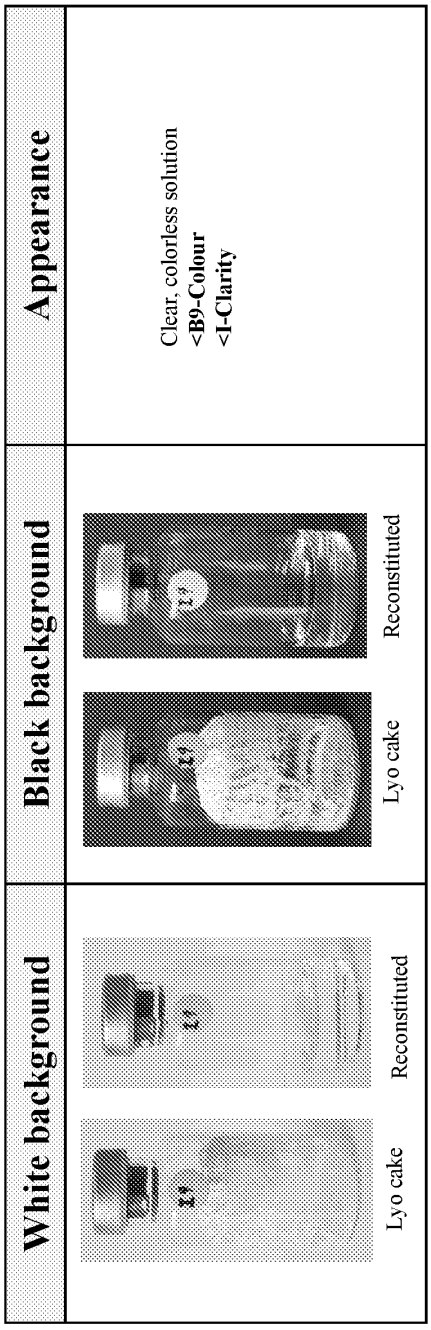


Figure 39

F4

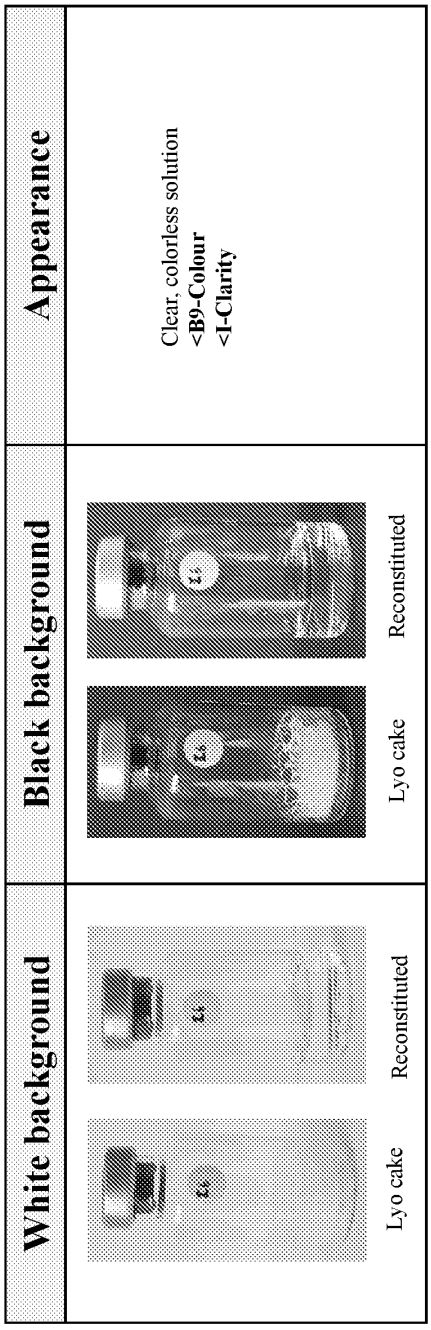


Figure 40

F5

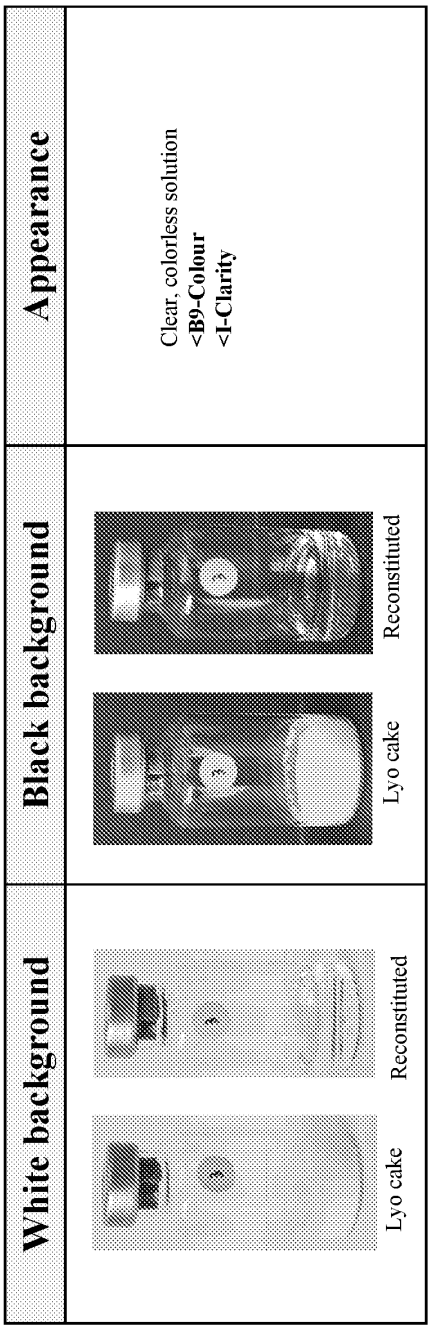


Figure 41

F6

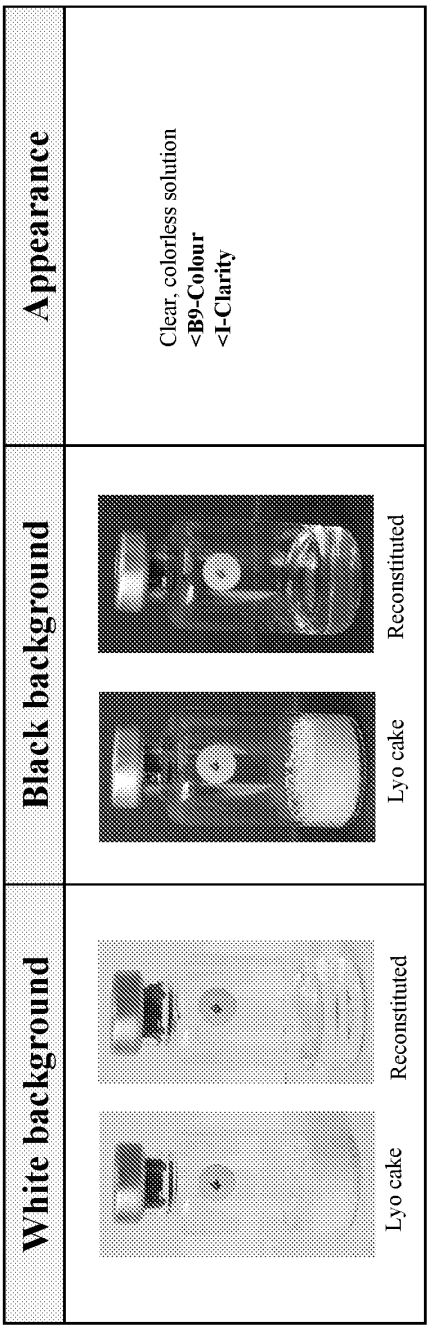


Figure 42

F7

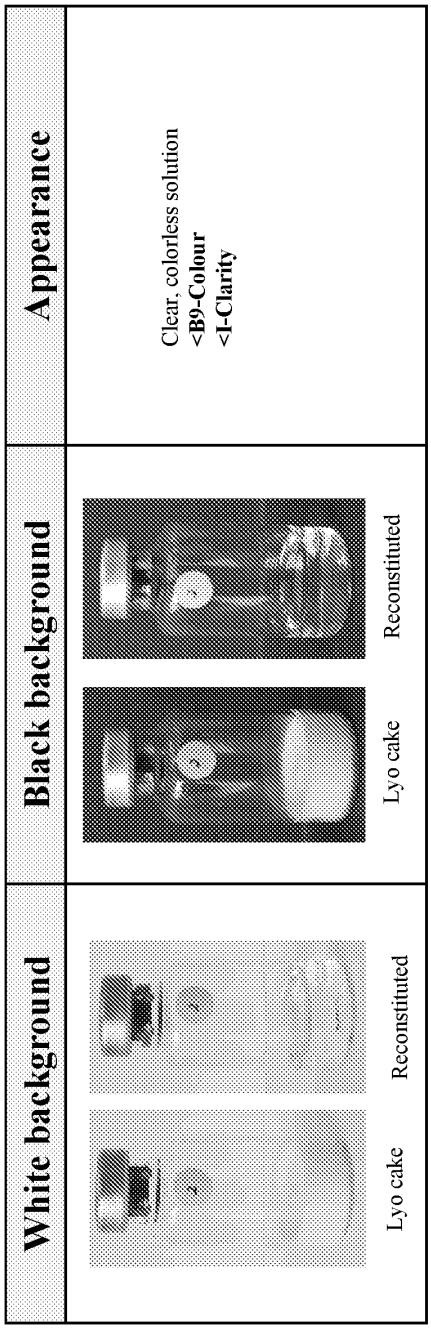
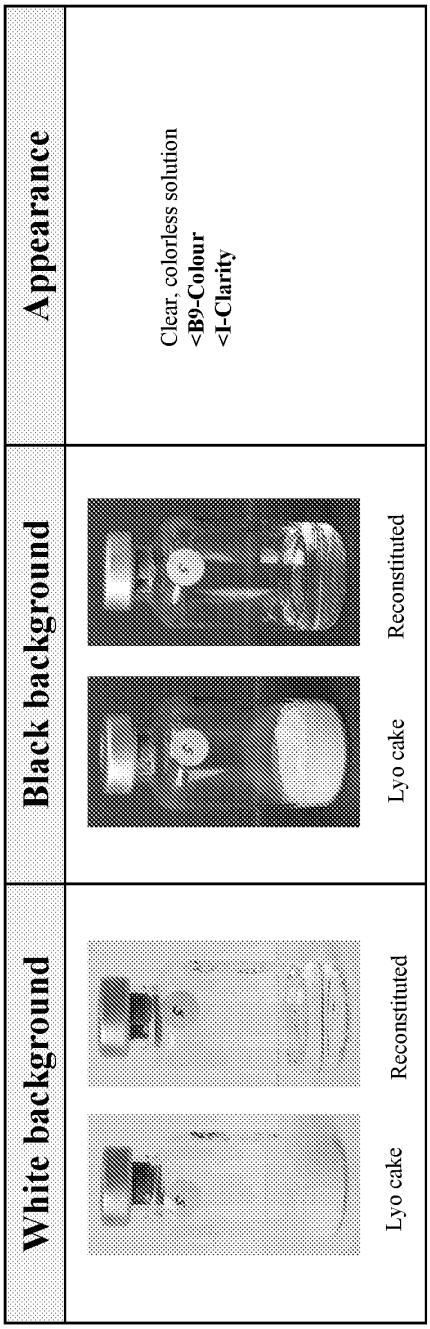


Figure 43

F8



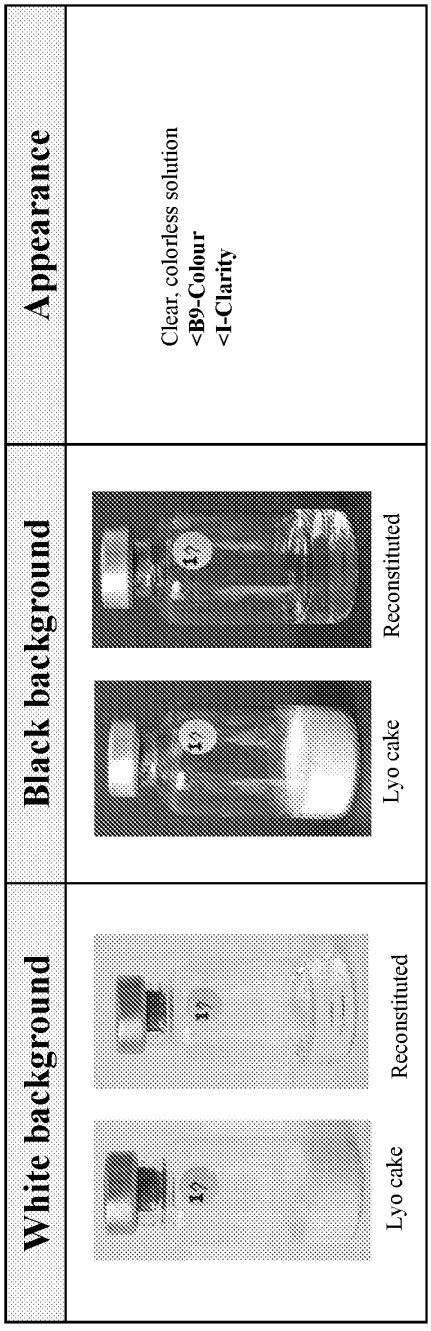

White background
Black background
Appearance
Lyo cake
Reconstituted
Lyo cake
Reconstituted
Clear, colorless solution
<B9-Colour
<1-Clarity
F9

Figure 44

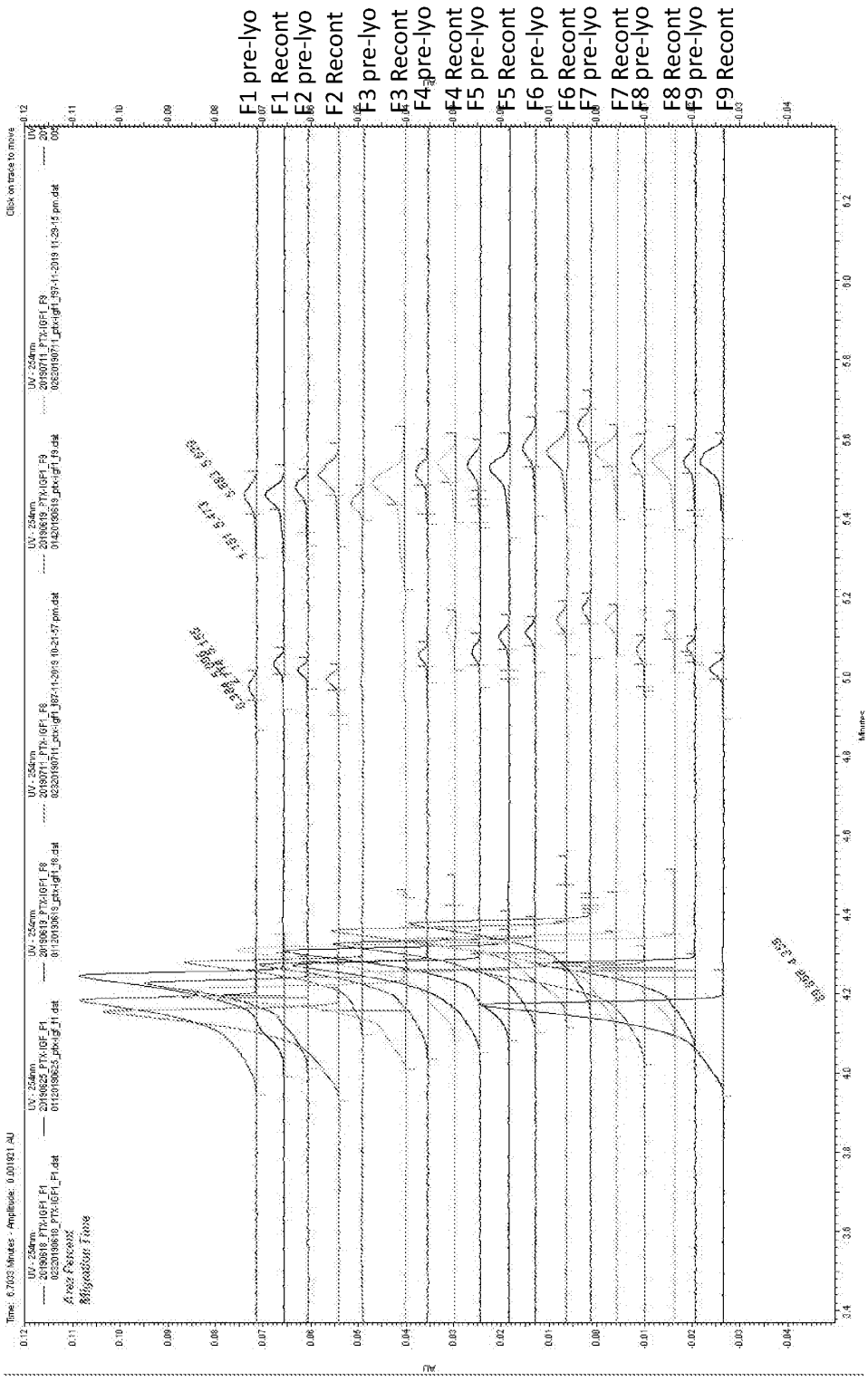

F1 pre-lyo
F1 Recont
F2 pre-lyo
F2 Recont
F3 pre-lyo
F3 Recont
F4 pre-lyo
F4 Recont
F5 pre-lyo
F5 Recont
F6 pre-lyo
F6 Recont
F7 pre-lyo
F7 Recont
F8 pre-lyo
F8 Recont
F9 pre-lyo
F9 Recont

Figure 45

Figure 46

F1

White background	Black background	Appearance
		Clear, colorless solution <**B9-Colour** <**I-Clarity**
Lyo cake Reconstituted	Lyo cake Reconstituted	

Figure 47

F2

White background	Black background	Appearance
		Clear, colorless solution <**B9-Colour** <**I-Clarity**
Lyo cake Reconstituted	Lyo cake Reconstituted	

Figure 48

F3

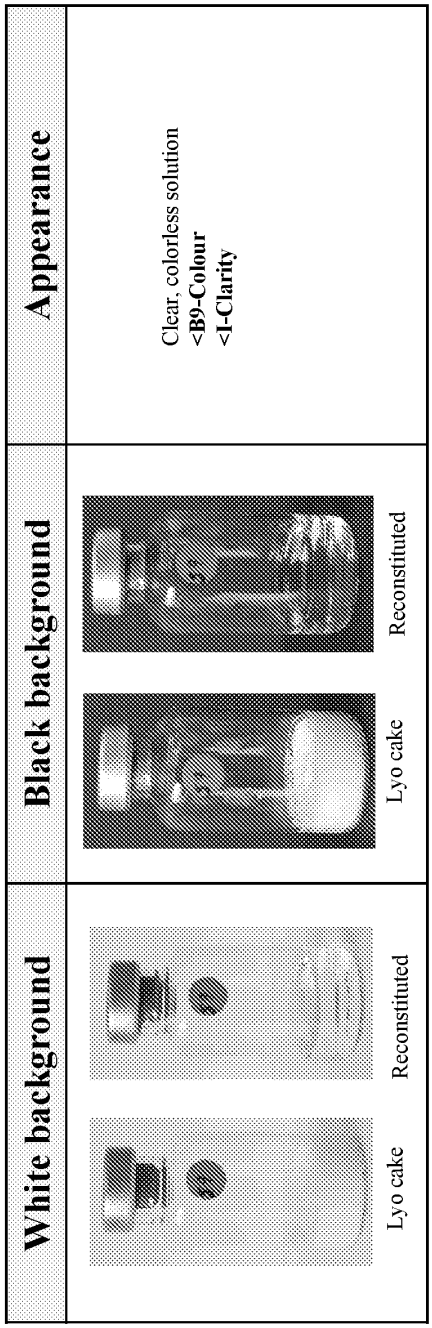


Figure 49

F4

Figure 50

F5

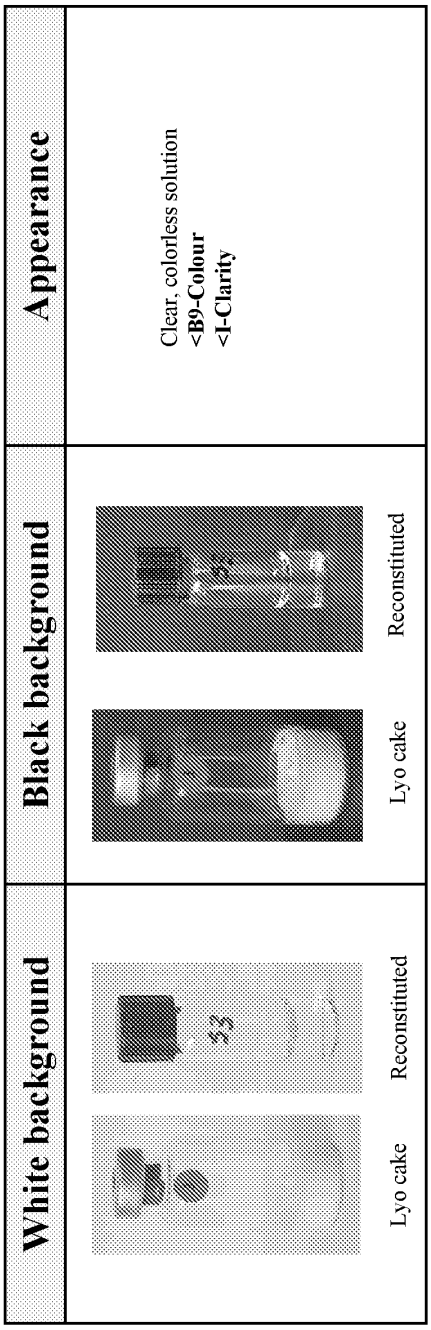


Figure 51

F6

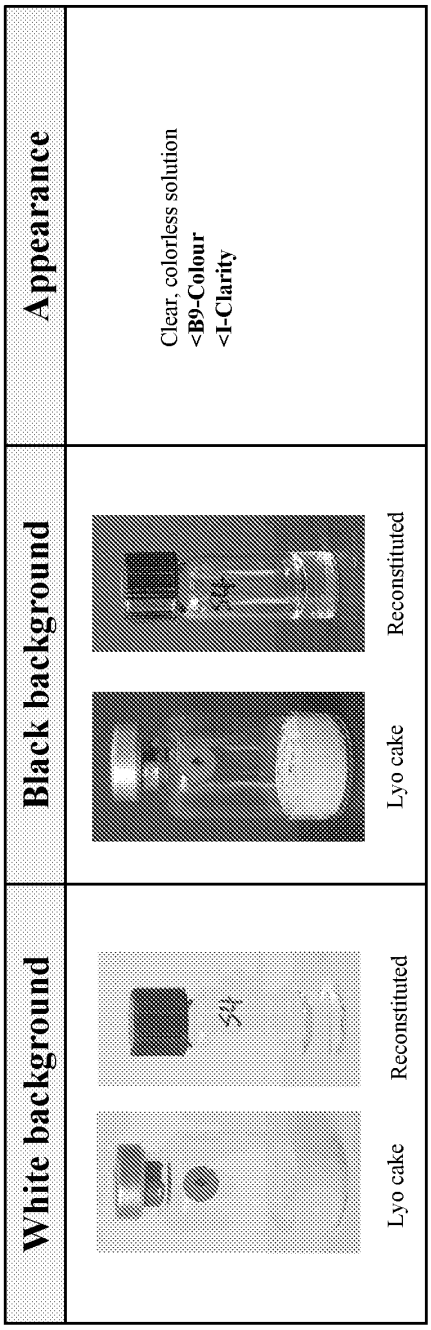


Figure 52

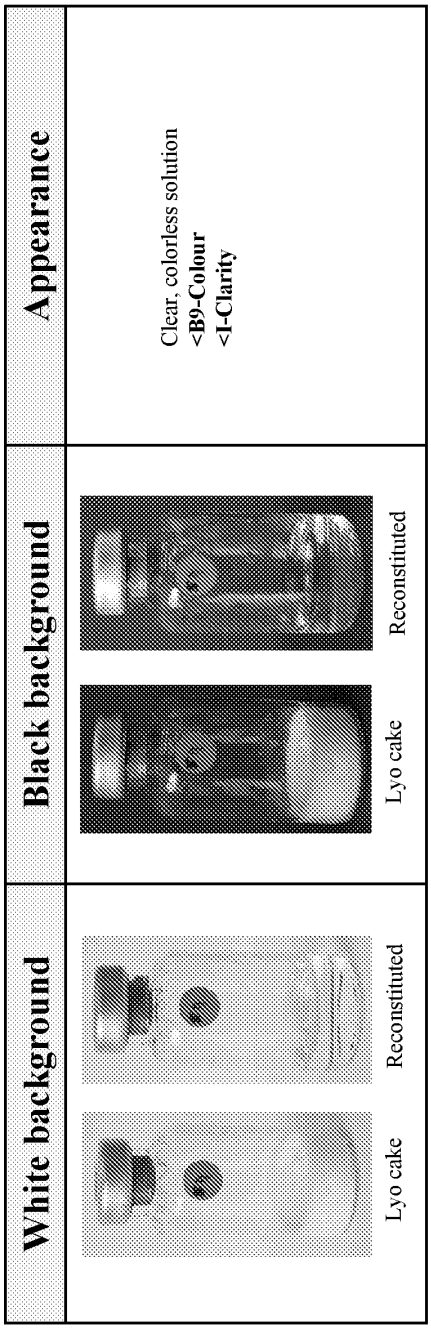
F7

White background		Black background		Appearance
				Clear, colorless solution **<B9-Colour** **<1-Clarity**
Lyo cake	Reconstituted	Lyo cake	Reconstituted	

Figure 53

F8

White background		Black background		Appearance
				Clear, colorless solution **<B9-Colour** **<1-Clarity**
Lyo cake	Reconstituted	Lyo cake	Reconstituted	


White background
Black background
Appearance
Lyo cake
Reconstituted
Lyo cake
Reconstituted
Clear, colorless solution
<B9-Colour
<1-Clarity

F9

Figure 54

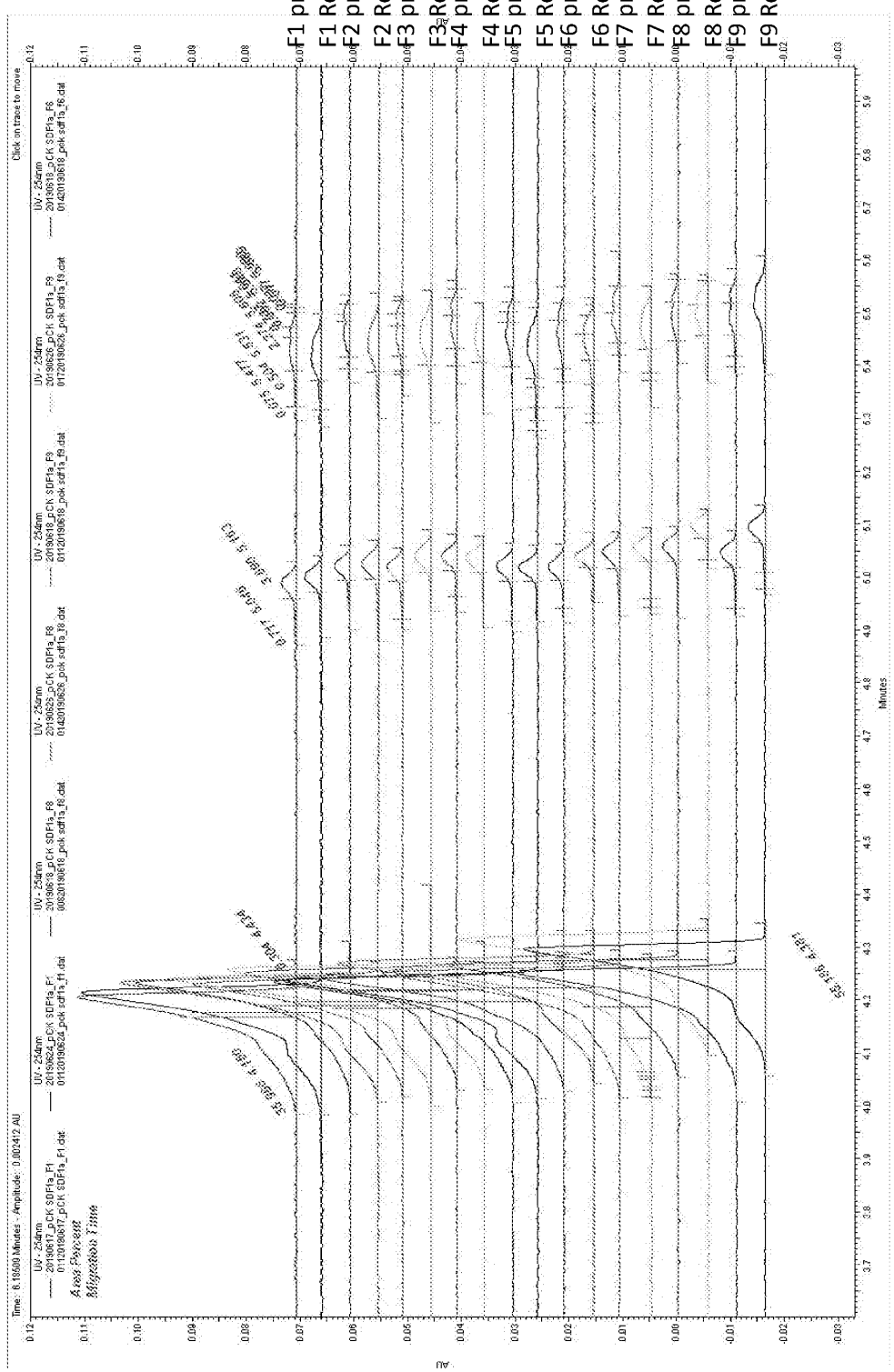

F1 pre-lyo
F1 Recon.
F2 pre-lyo
F2 Recon.
F3 pre-lyo
F3 Recon.
F4 pre-lyo
F4 Recon.
F5 pre-lyo
F5 Recon.
F6 pre-lyo
F6 Recon.
F7 pre-lyo
F7 Recon.
F8 pre-lyo
F8 Recon.
F9 pre-lyo
F9 Recon.
Minutes
AU

Figure 55