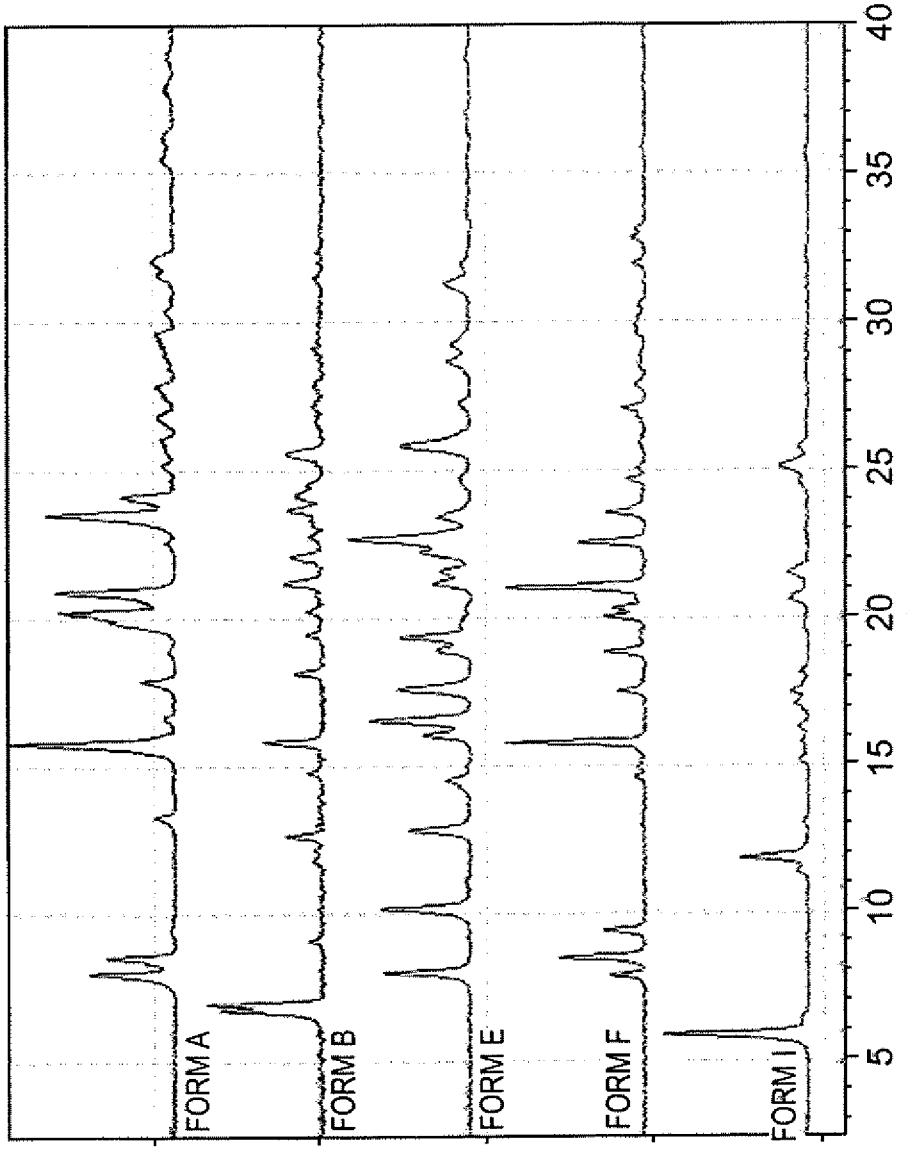

FORM A
FORM B
FORM E
FORM F
FORM I
5
10
15
20
25
30
35
40
2θ (deg)
ARBITRARY Y SCALE

FIG. 1

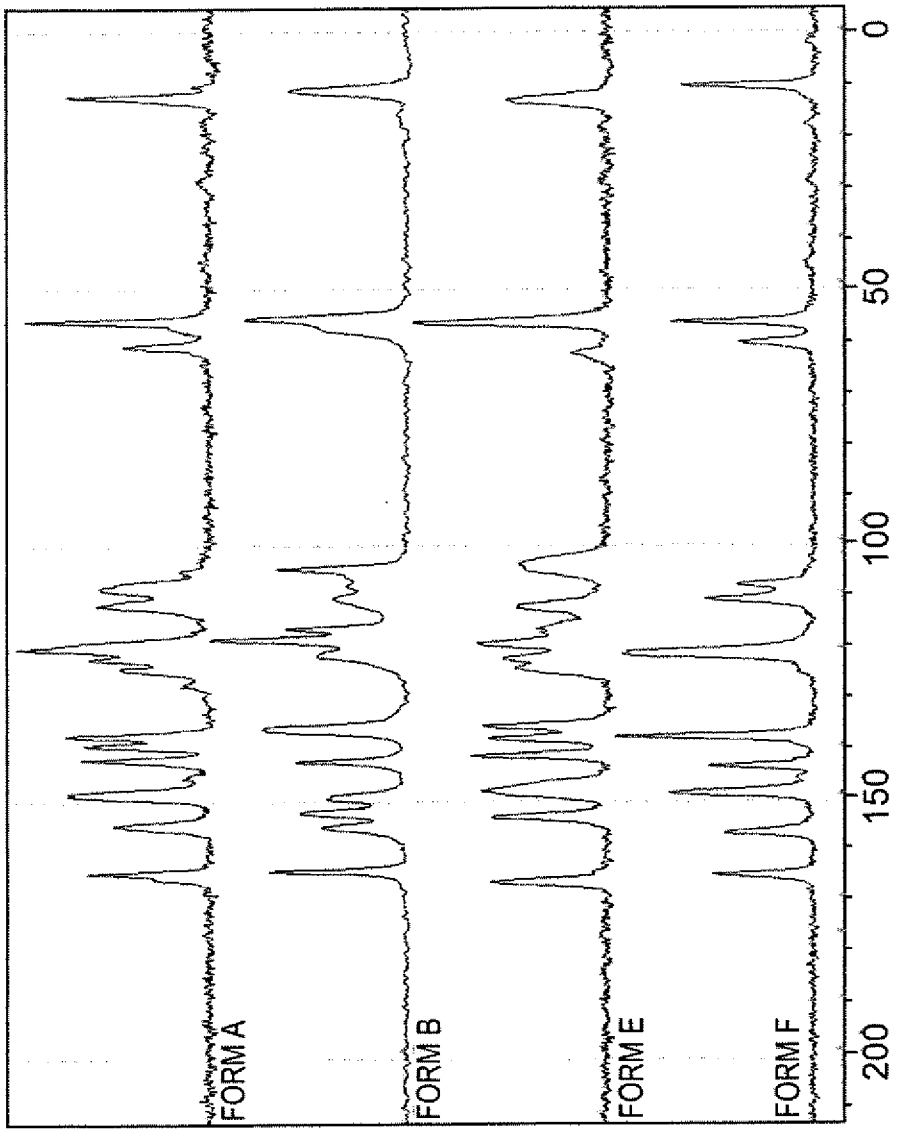


FIG. 2

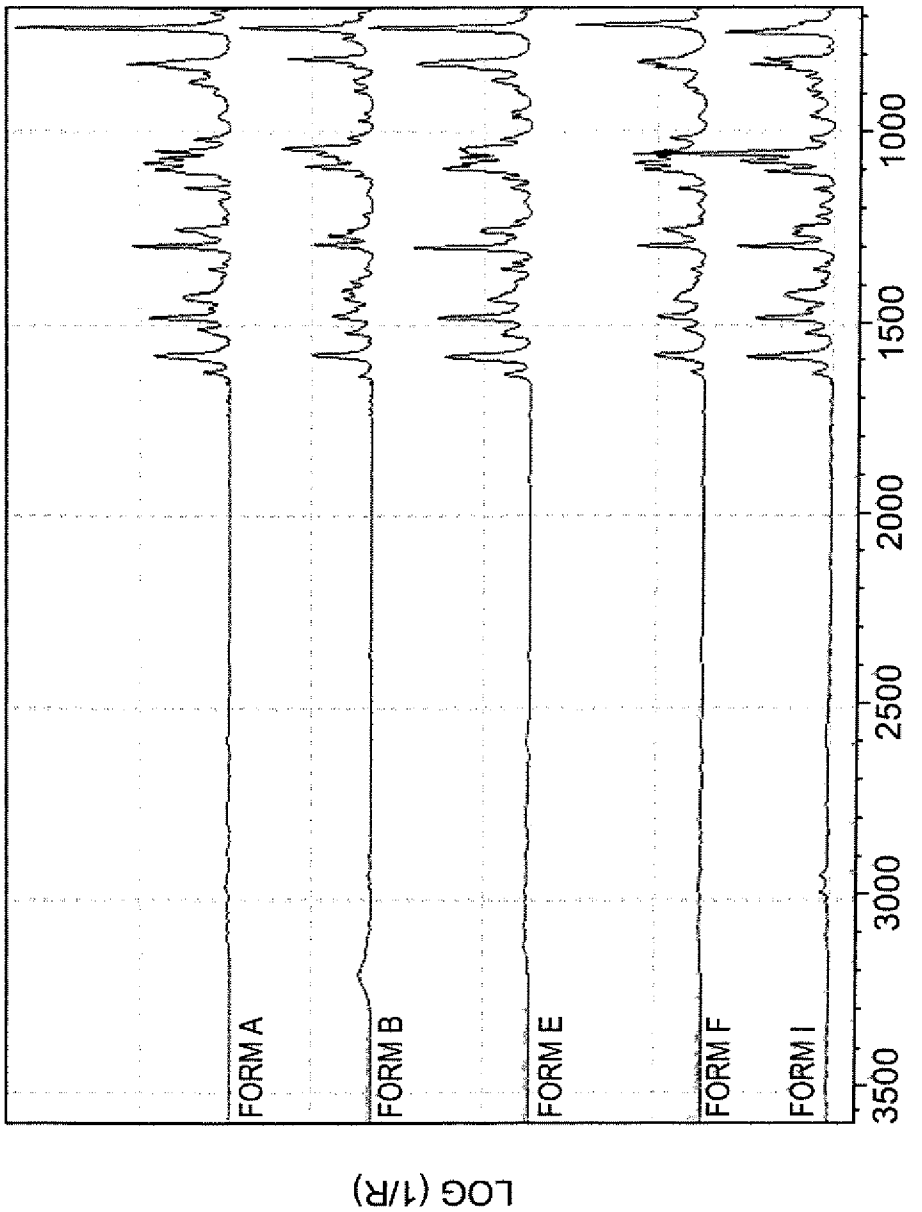

FORM A
FORM B
FORM E
FORM F
FORM I
3500
3000
2500
2000
1500
1000
WAVENUMBERS (1/cm)
LOG (1/R)

FIG. 3

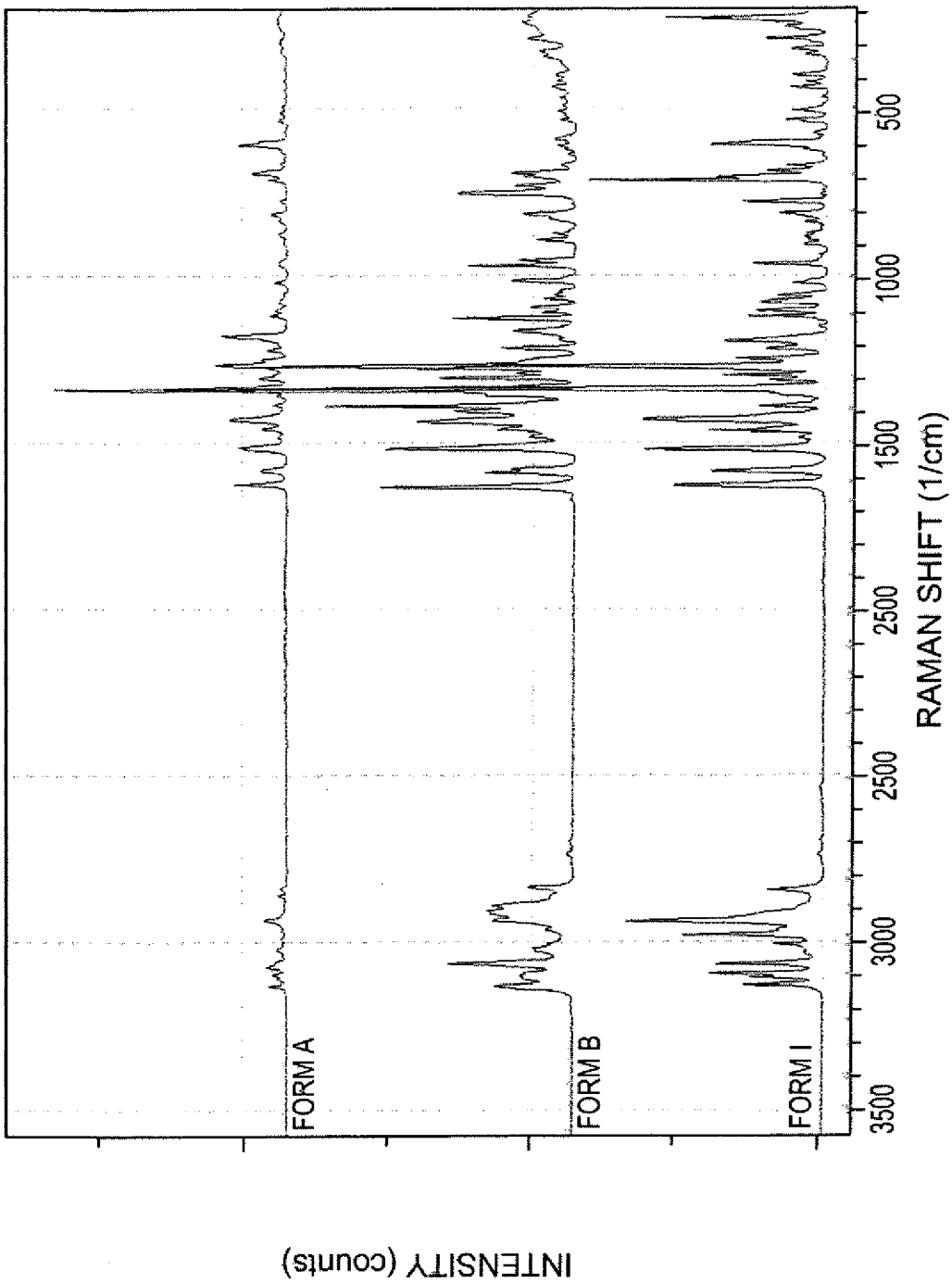

FORM A
FORM B
FORM I
INTENSITY (counts)
RAMAN SHIFT (1/cm)
3500
3000
2500
2000
1500
1000
500

FIG. 4

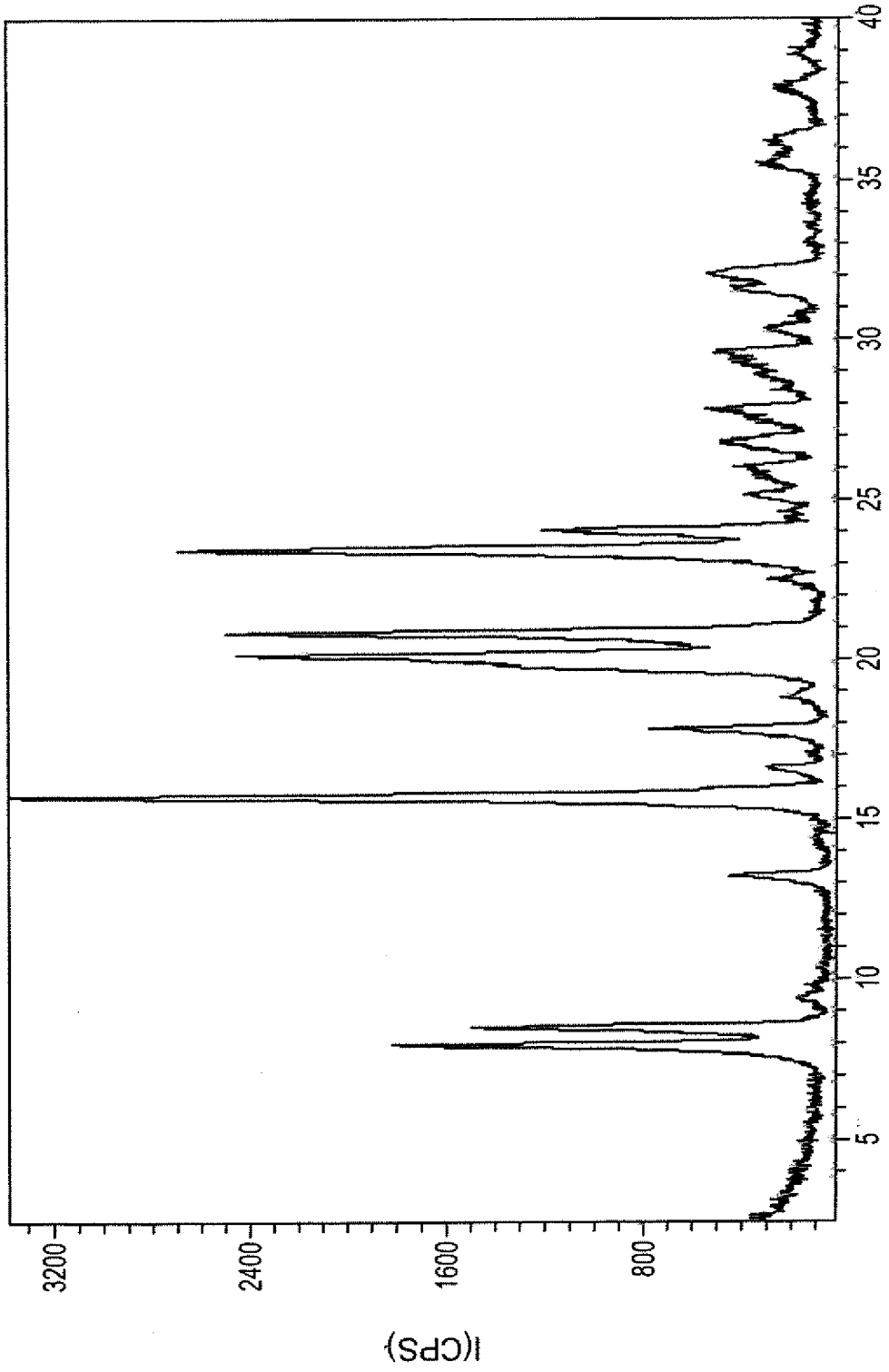


FIG. 5

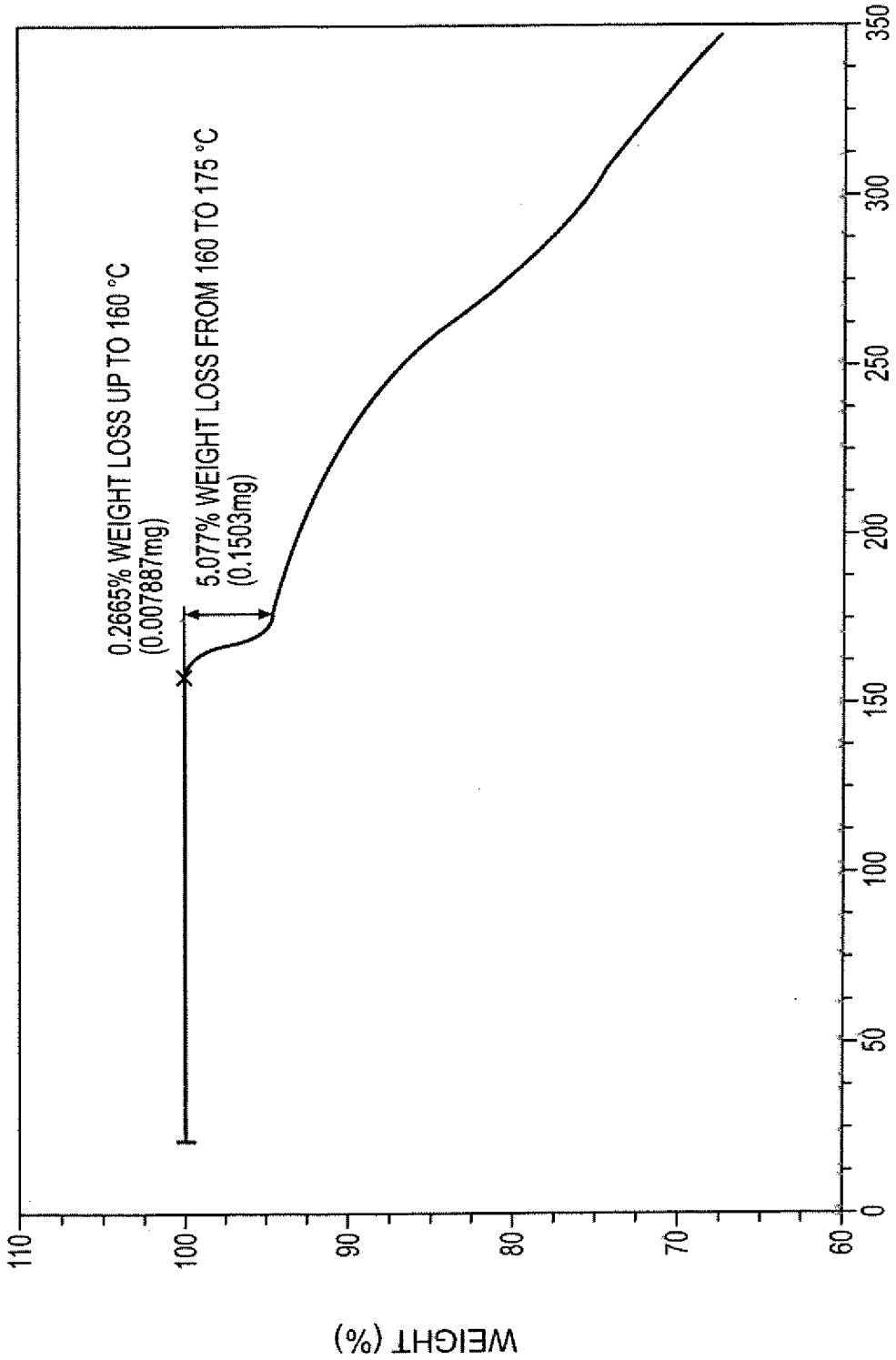

0.2665% WEIGHT LOSS UP TO 160 °C
(0.007887mg)
5.077% WEIGHT LOSS FROM 160 TO 175 °C
(0.1503mg)
WEIGHT (%)
TEMPERATURE (°C)
110
100
90
80
70
60
0
50
100
150
200
250
300
350

FIG. 6

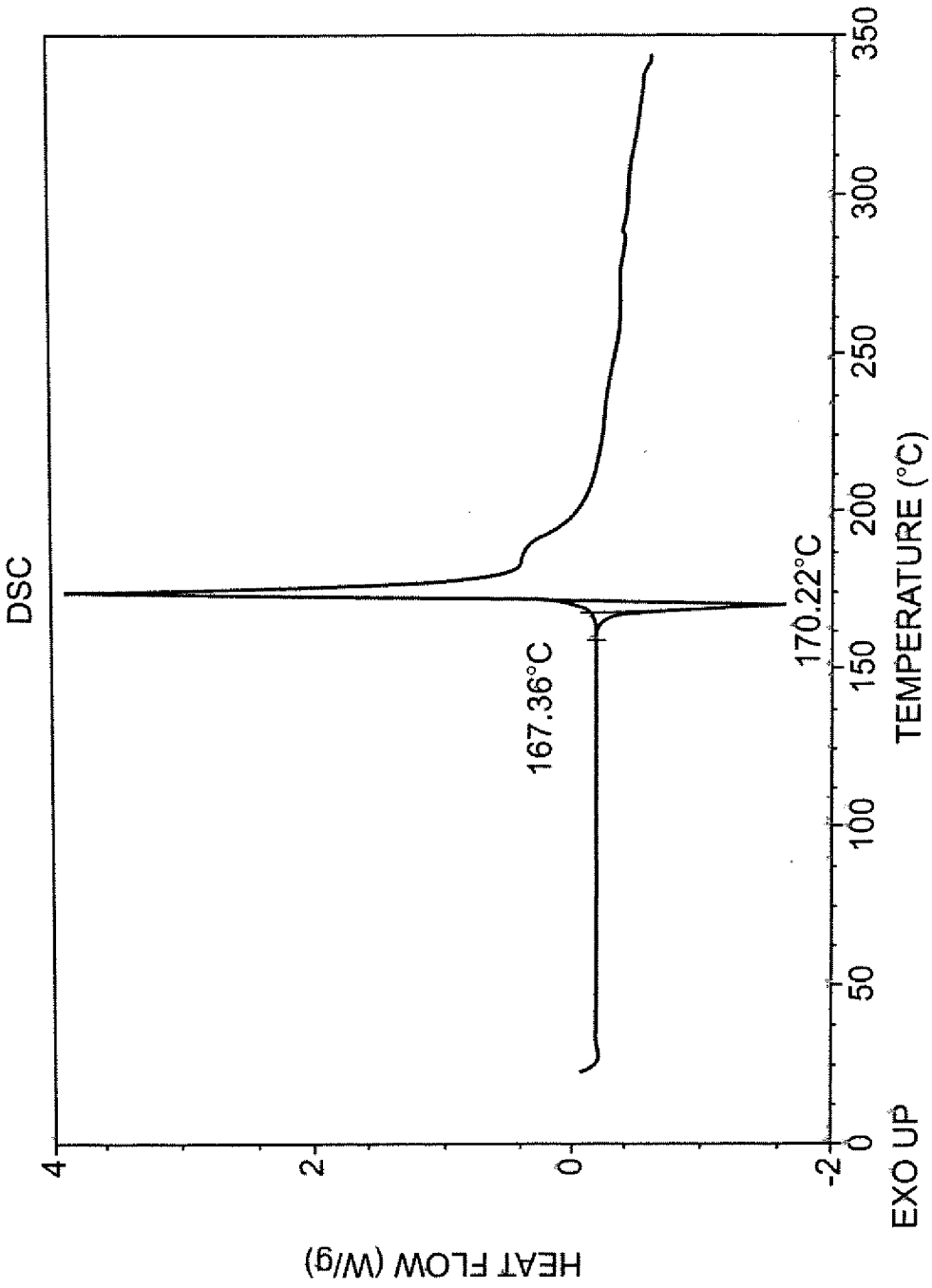

DSC
HEAT FLOW (W/g)
4
2
0
-2
EXO UP
0
50
100
150
200
250
300
350
TEMPERATURE (°C)
167.36°C
170.22°C

FIG. 7

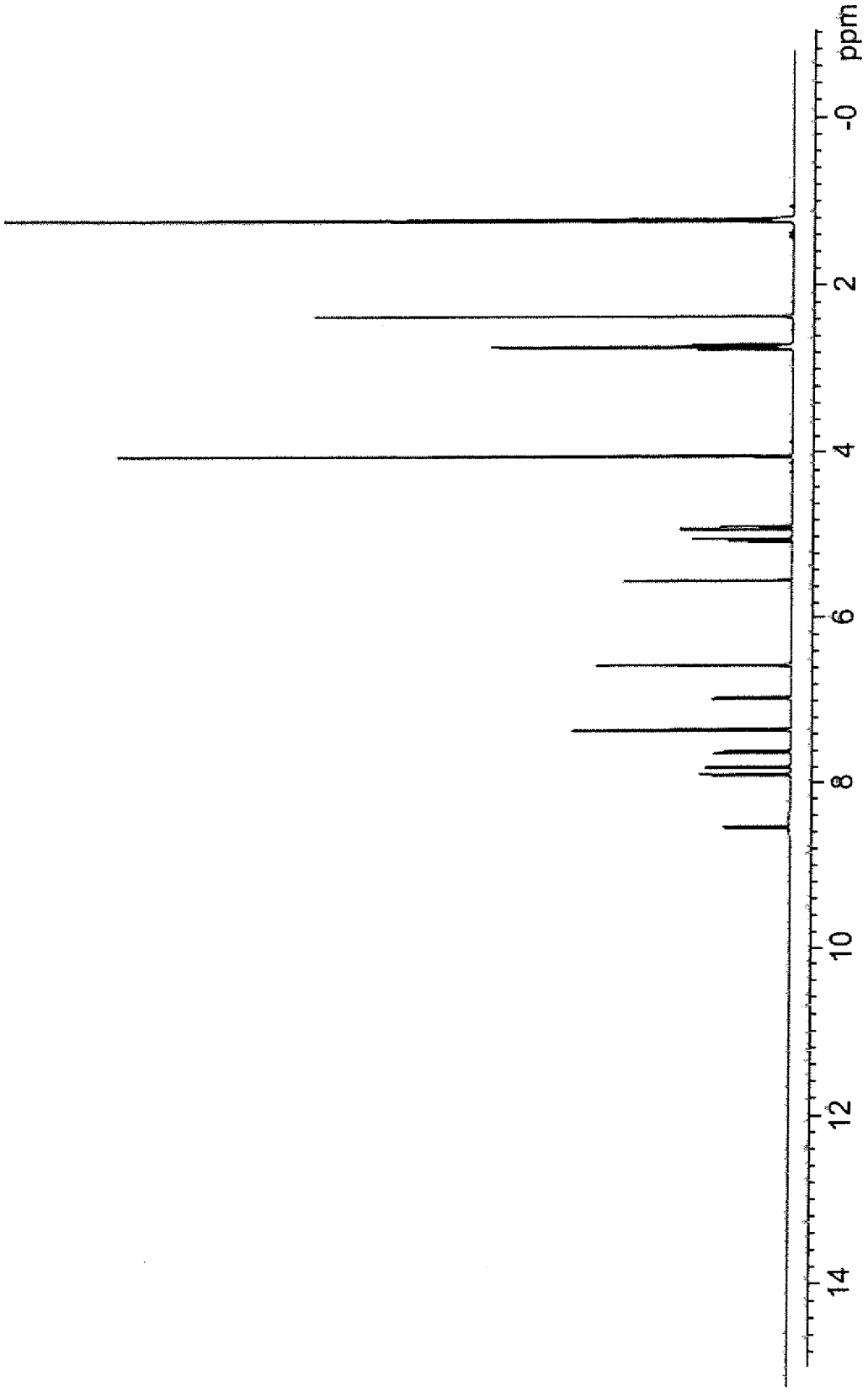


FIG. 8

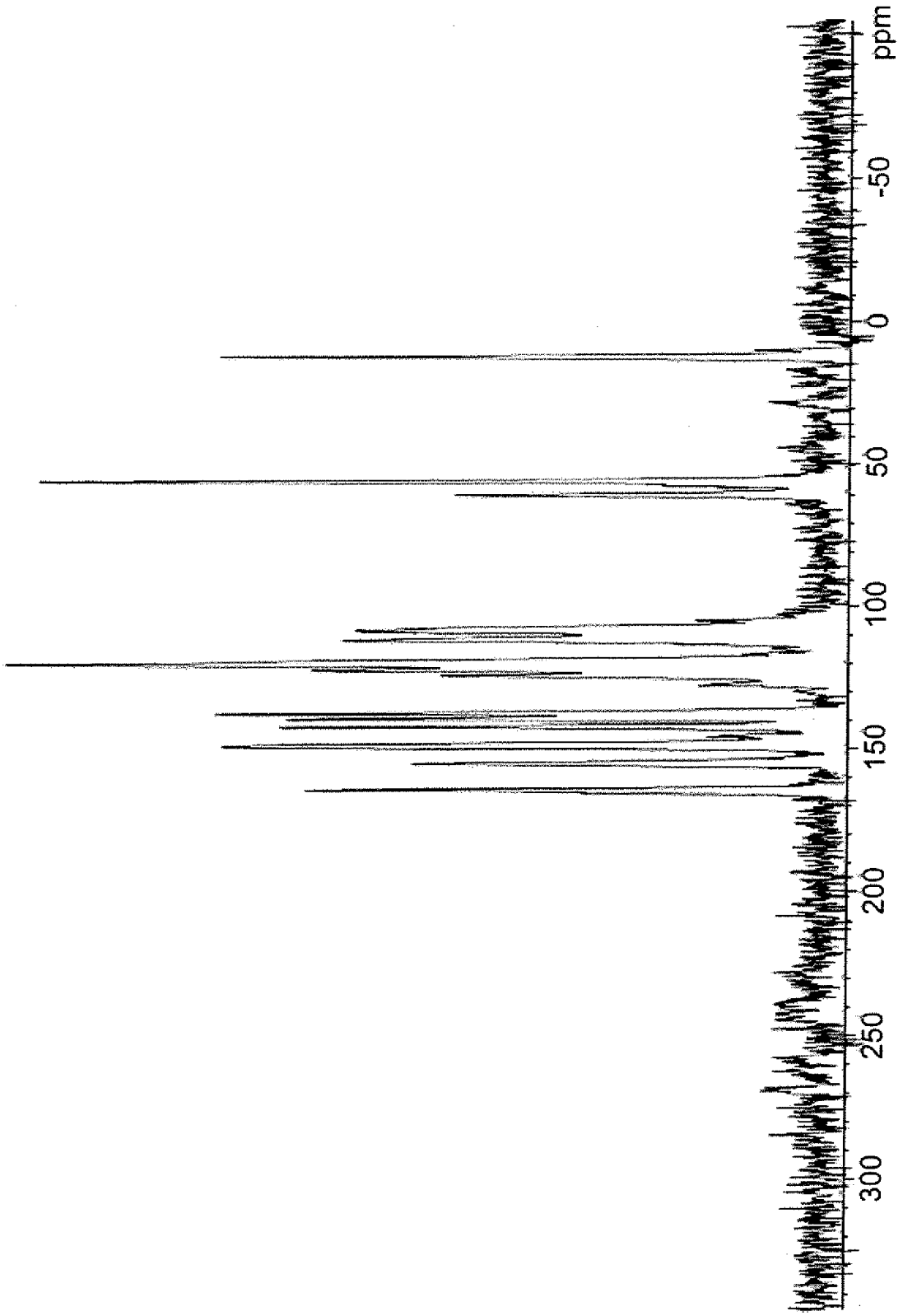


FIG. 9

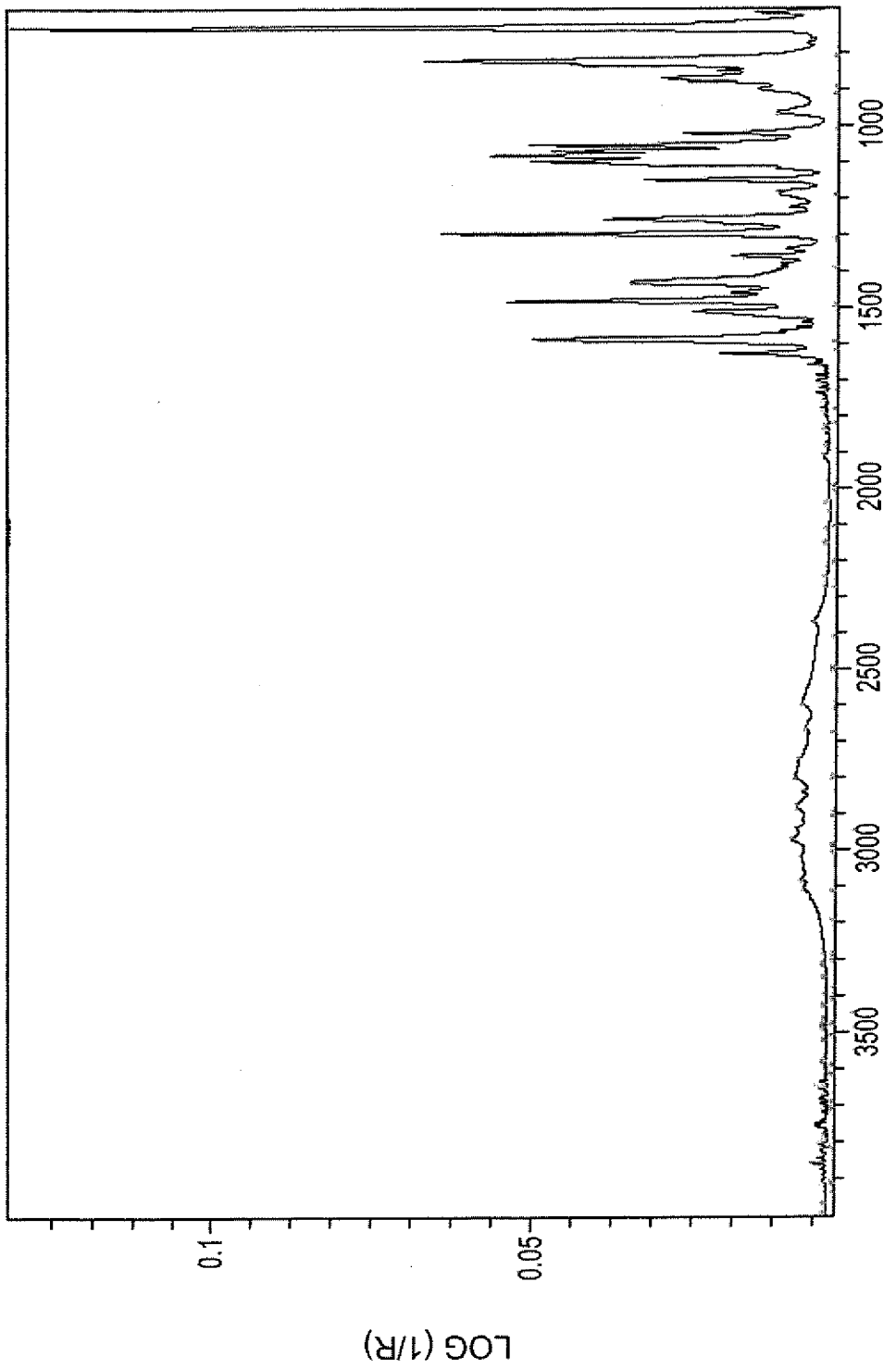


FIG. 10

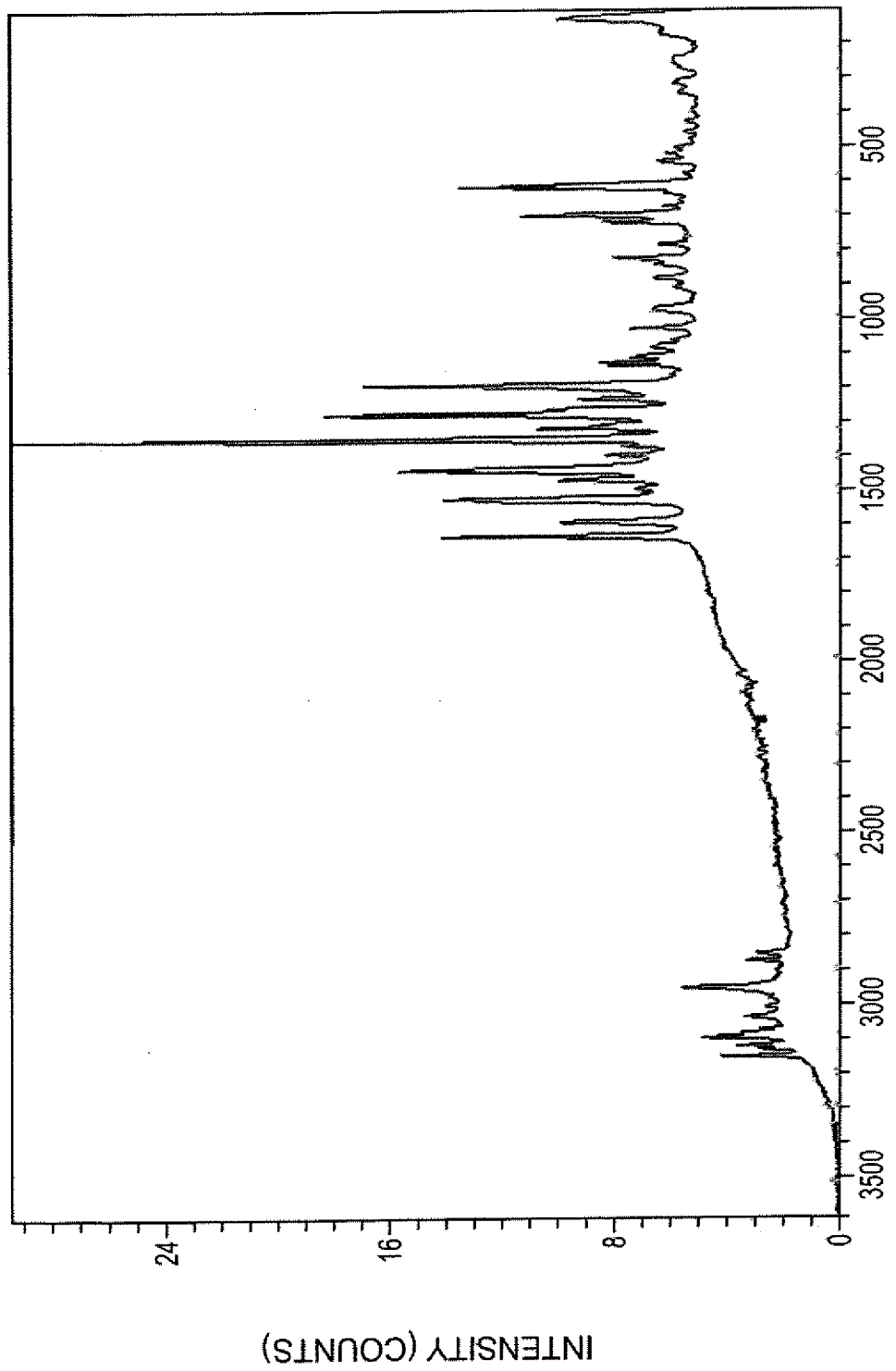

INTENSITY (COUNTS)
0
8
16
24
RAMAN SHIFT (cm-1)
500
1000
1500
2000
2500
3000
3500

FIG. 11

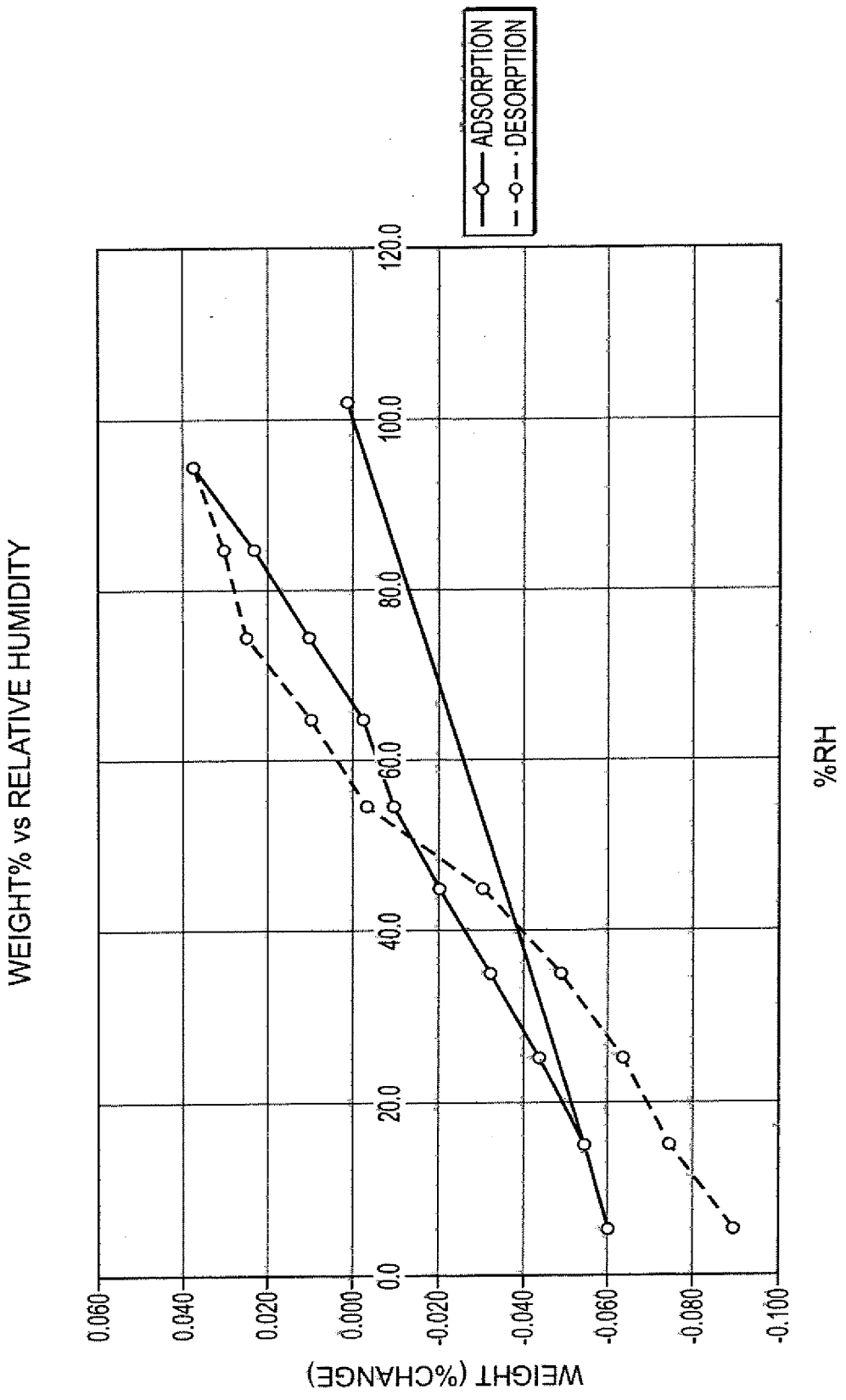

WEIGHT% vs RELATIVE HUMIDITY
ADSORPTION
DESORPTION
WEIGHT (%CHANGE)
0.060
0.040
0.020
0.000
-0.020
-0.040
-0.060
-0.080
-0.100
0.0
20.0
40.0
60.0
80.0
100.0
120.0
%RH

FIG. 12

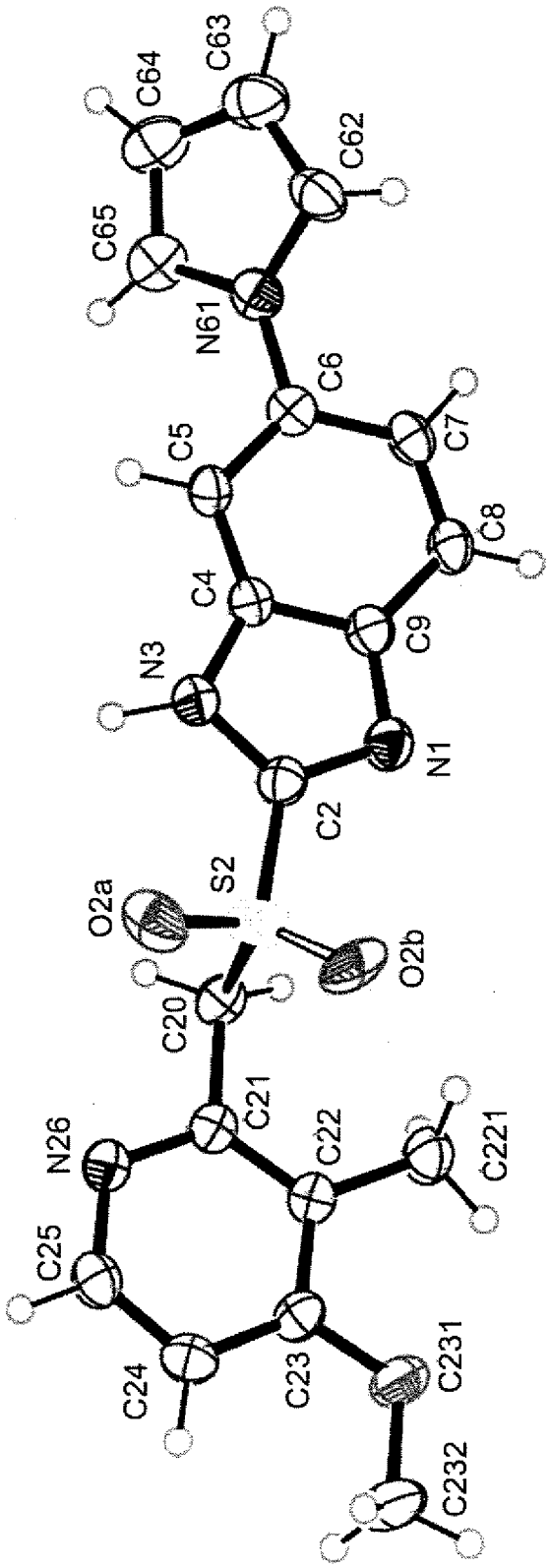
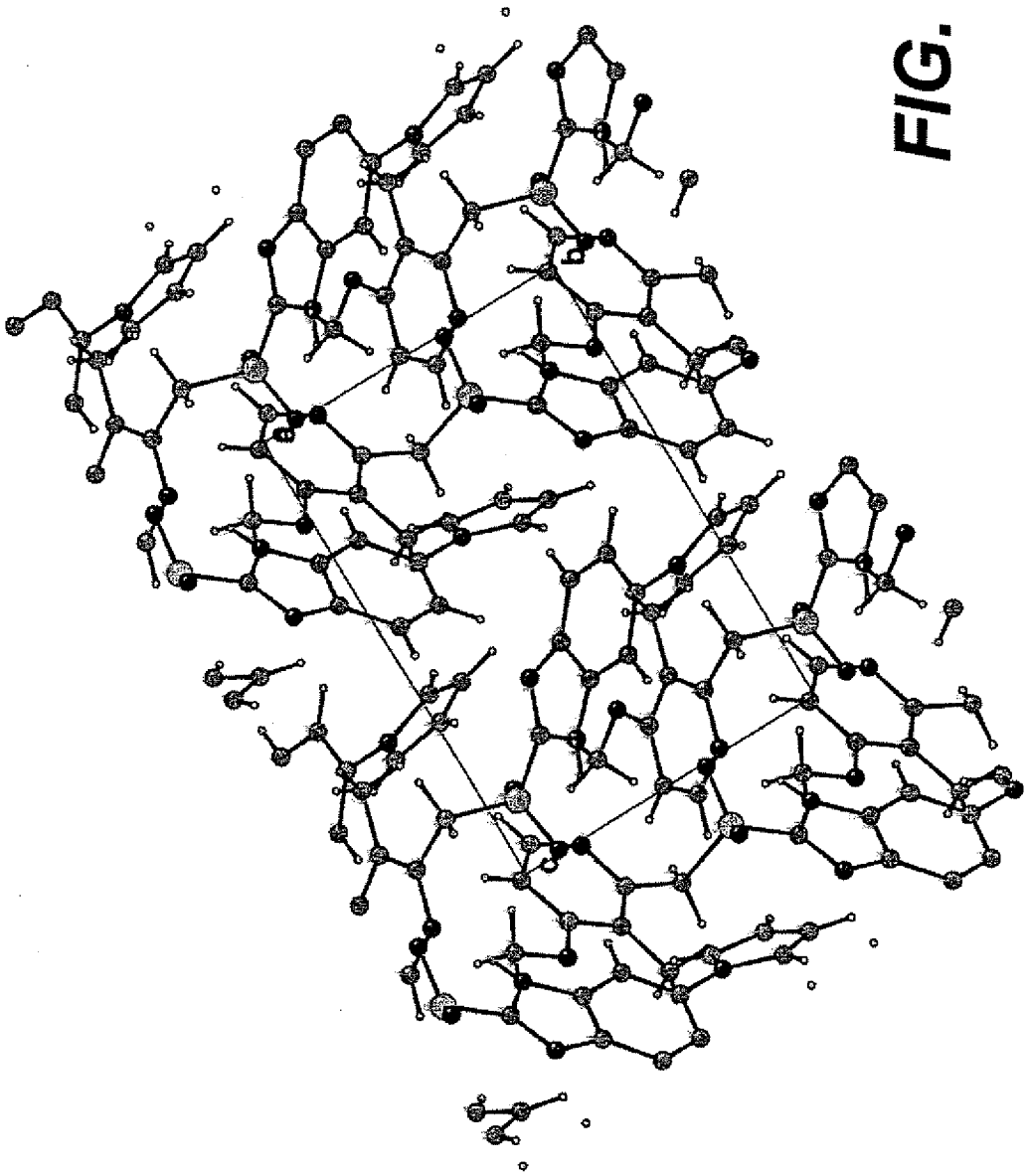

C63
C64
C62
C65
N61
C6
C5
C7
C8
C4
C9
N3
N1
C2
S2
O2a
O2b
C20
C21
C22
C221
N26
C25
C24
C23
C231
C232

FIG. 13

FIG. 14



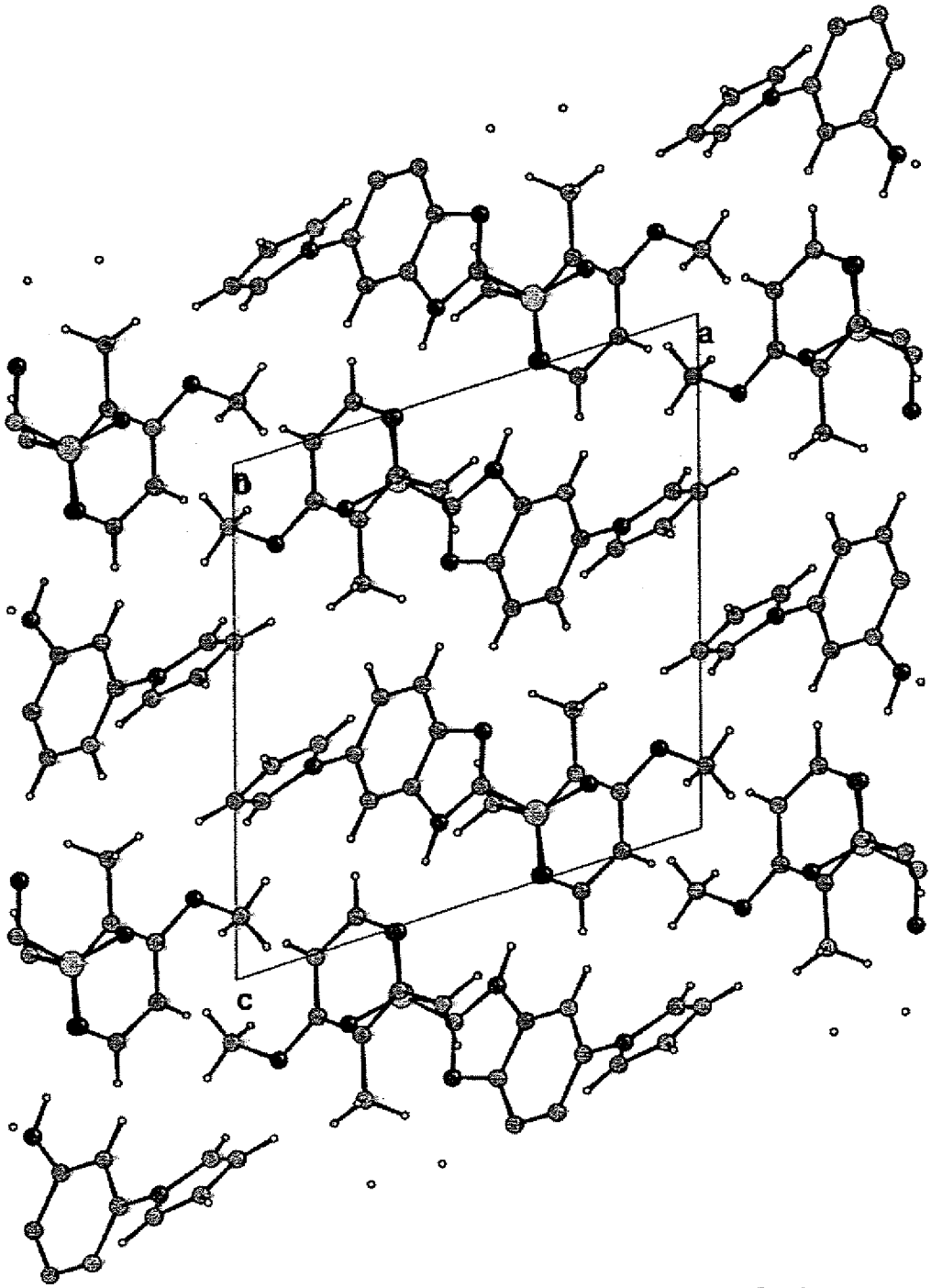


FIG. 15

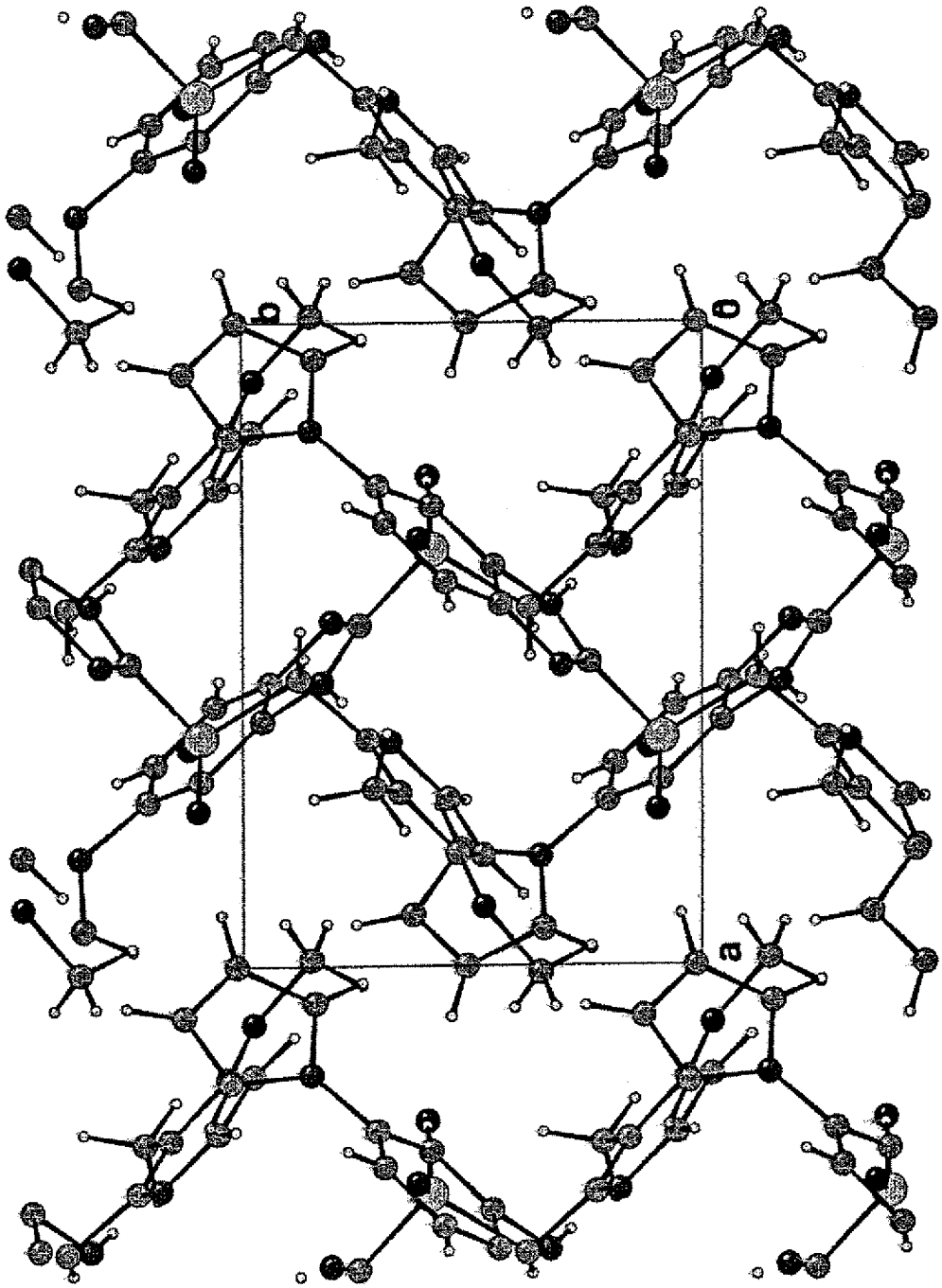


FIG. 16

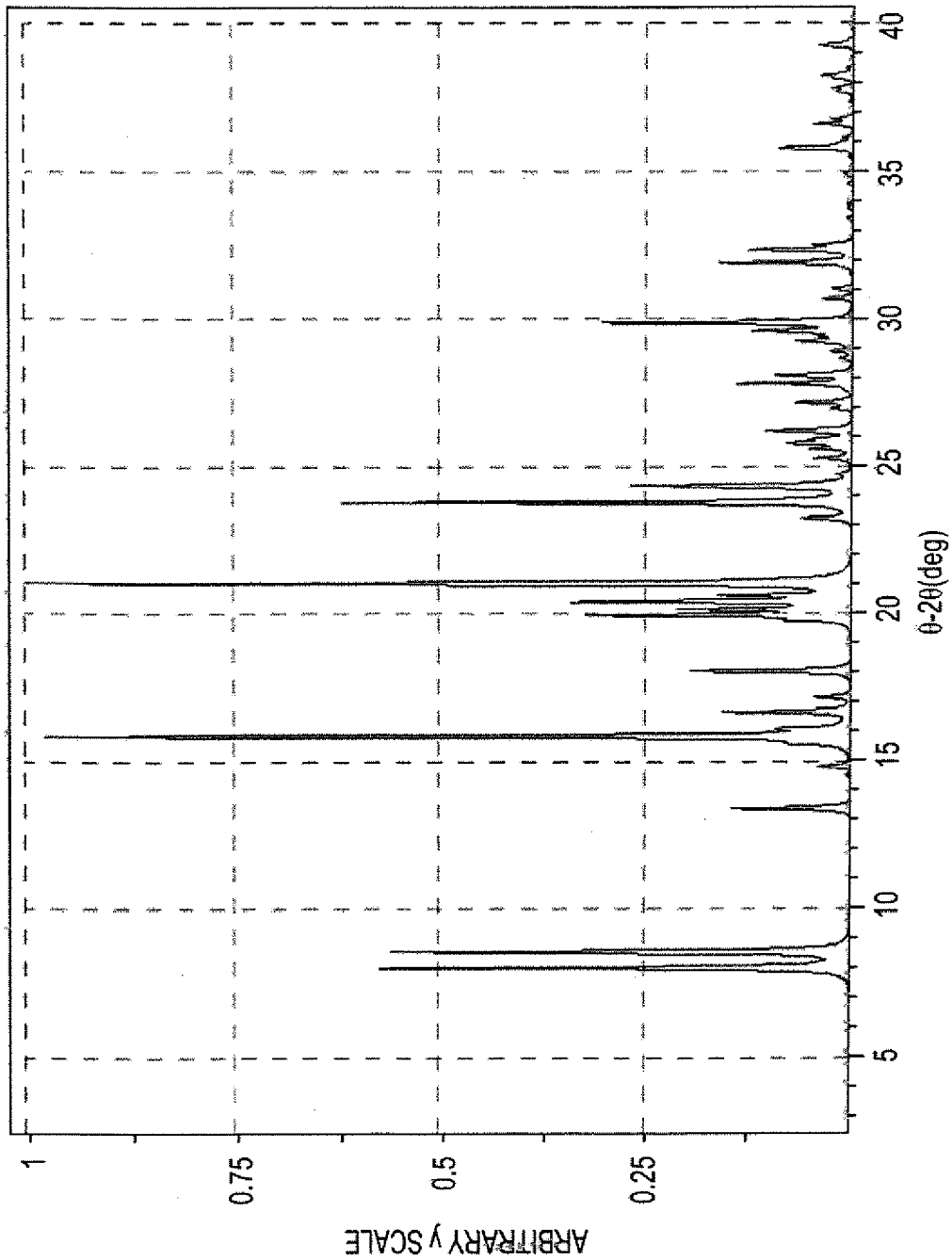


FIG. 17

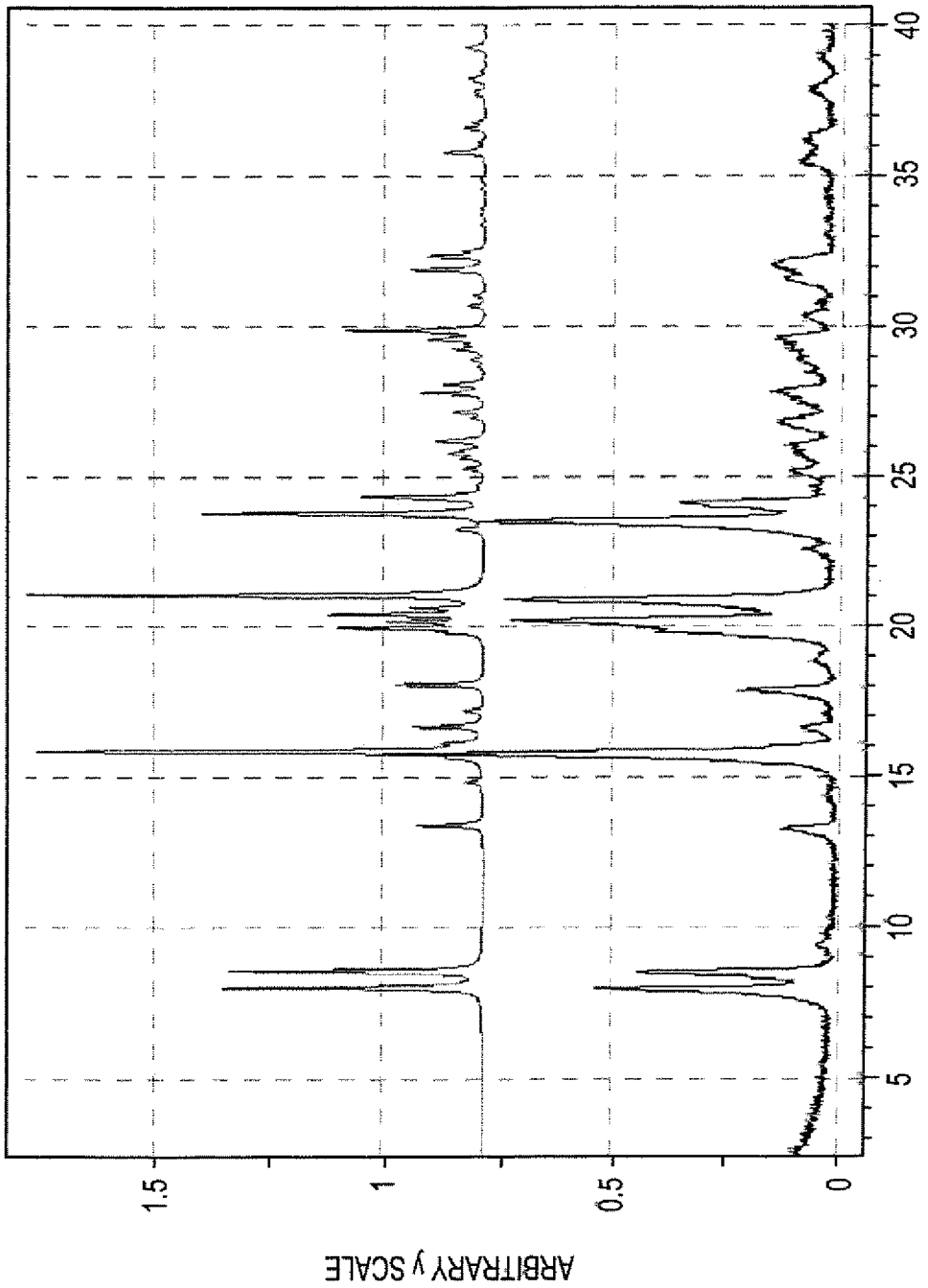


FIG. 18

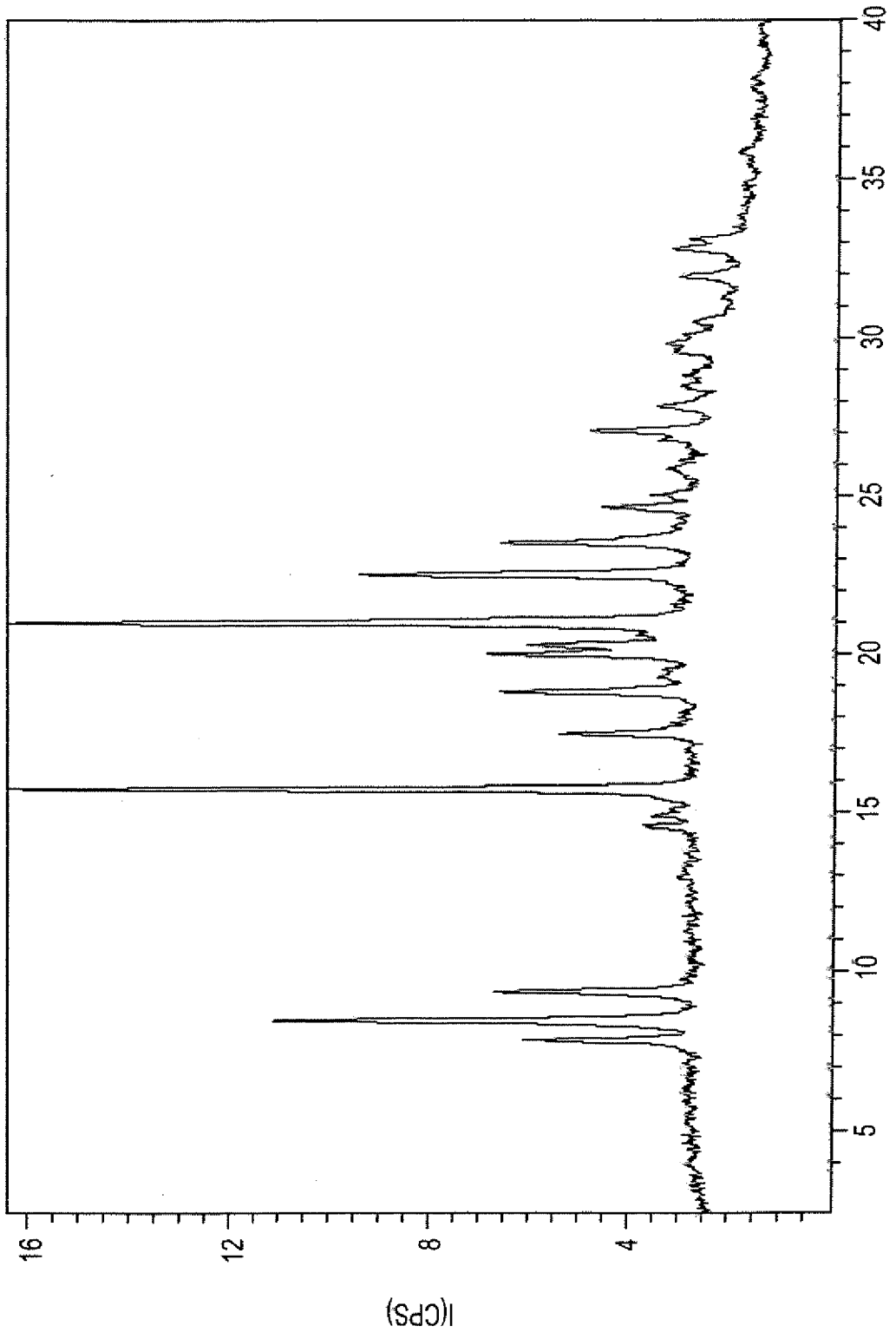


FIG. 19

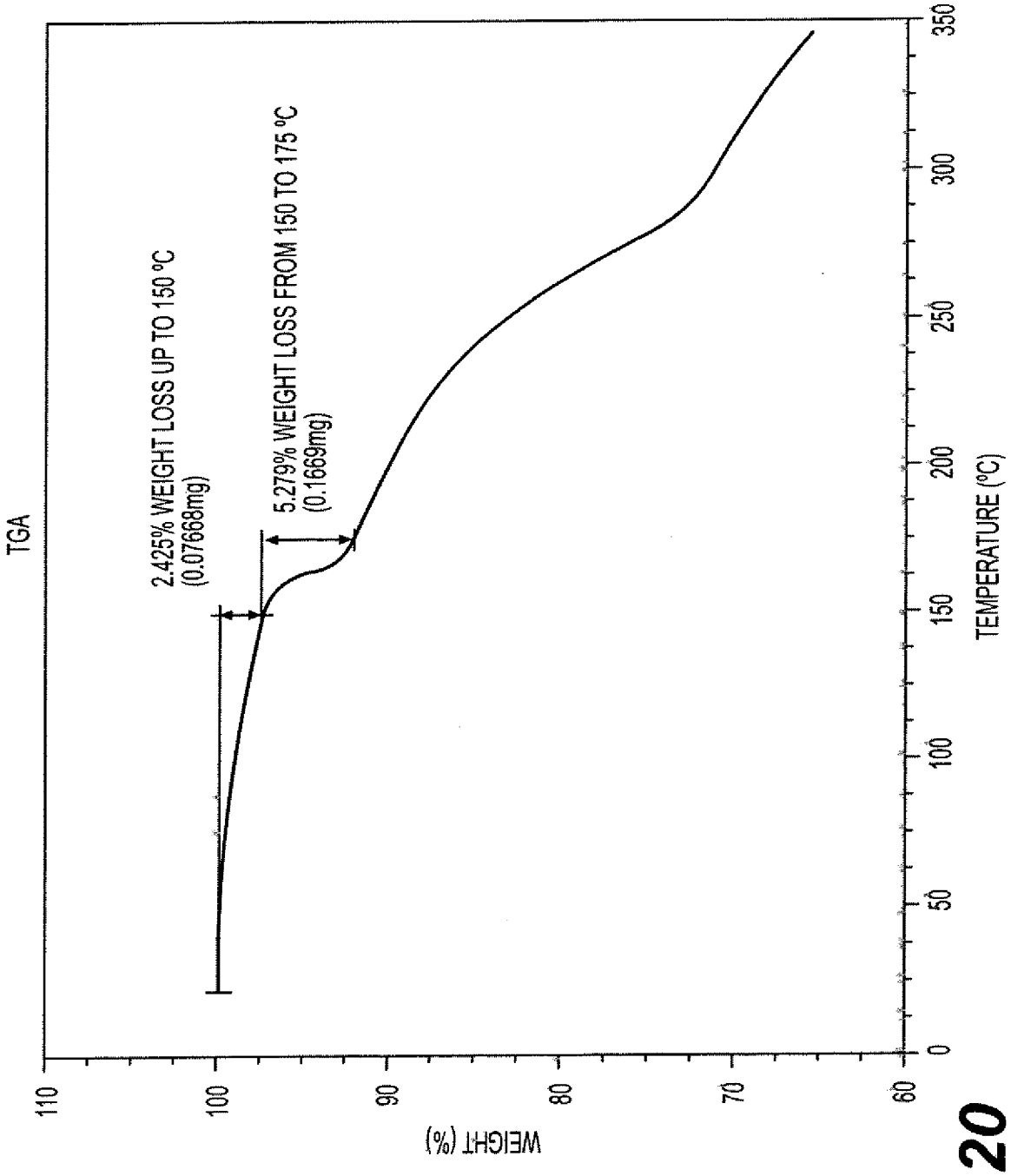

TGA
2.425% WEIGHT LOSS UP TO 150 °C
(0.07668mg)
5.279% WEIGHT LOSS FROM 150 TO 175 °C
(0.1669mg)
WEIGHT (%)
TEMPERATURE (°C)
110
100
90
80
70
60
0
50
100
150
200
250
300
350

FIG. 20

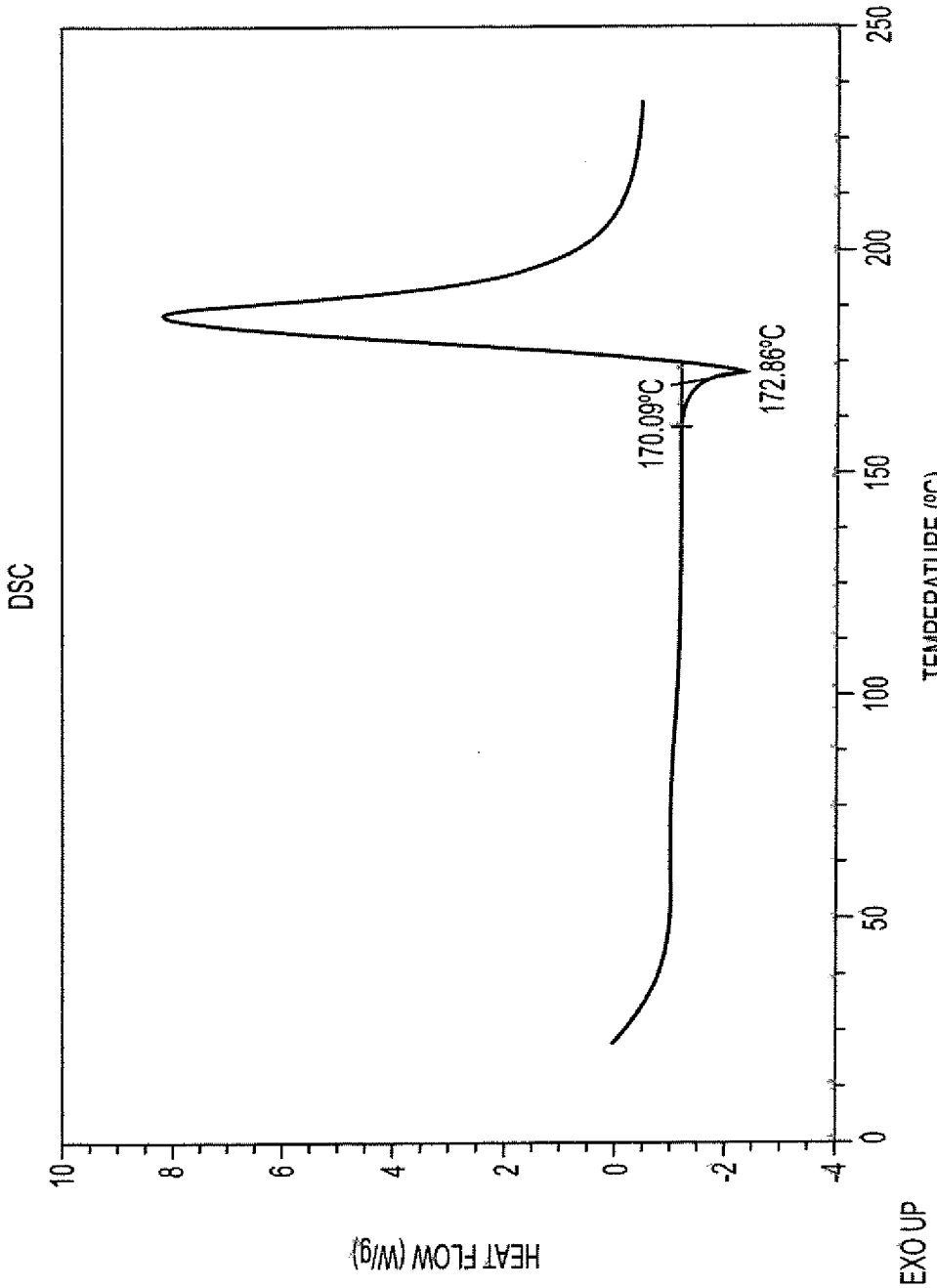

DSC
HEAT FLOW (W/g)
EXO UP
TEMPERATURE (°C)
170.09°C
172.86°C
10
8
6
4
2
0
-2
-4
0
50
100
150
200
250

FIG. 21

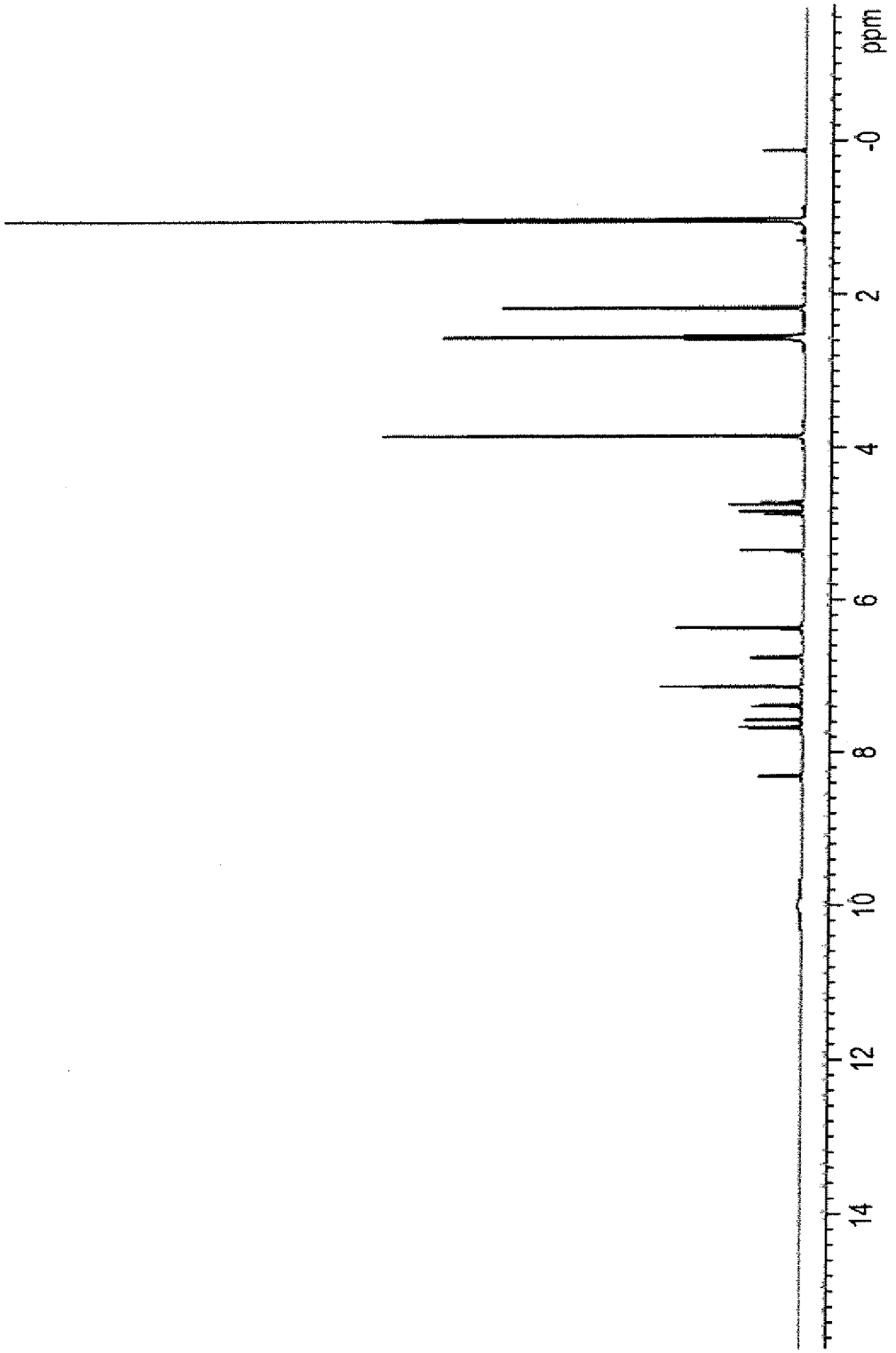


FIG. 22

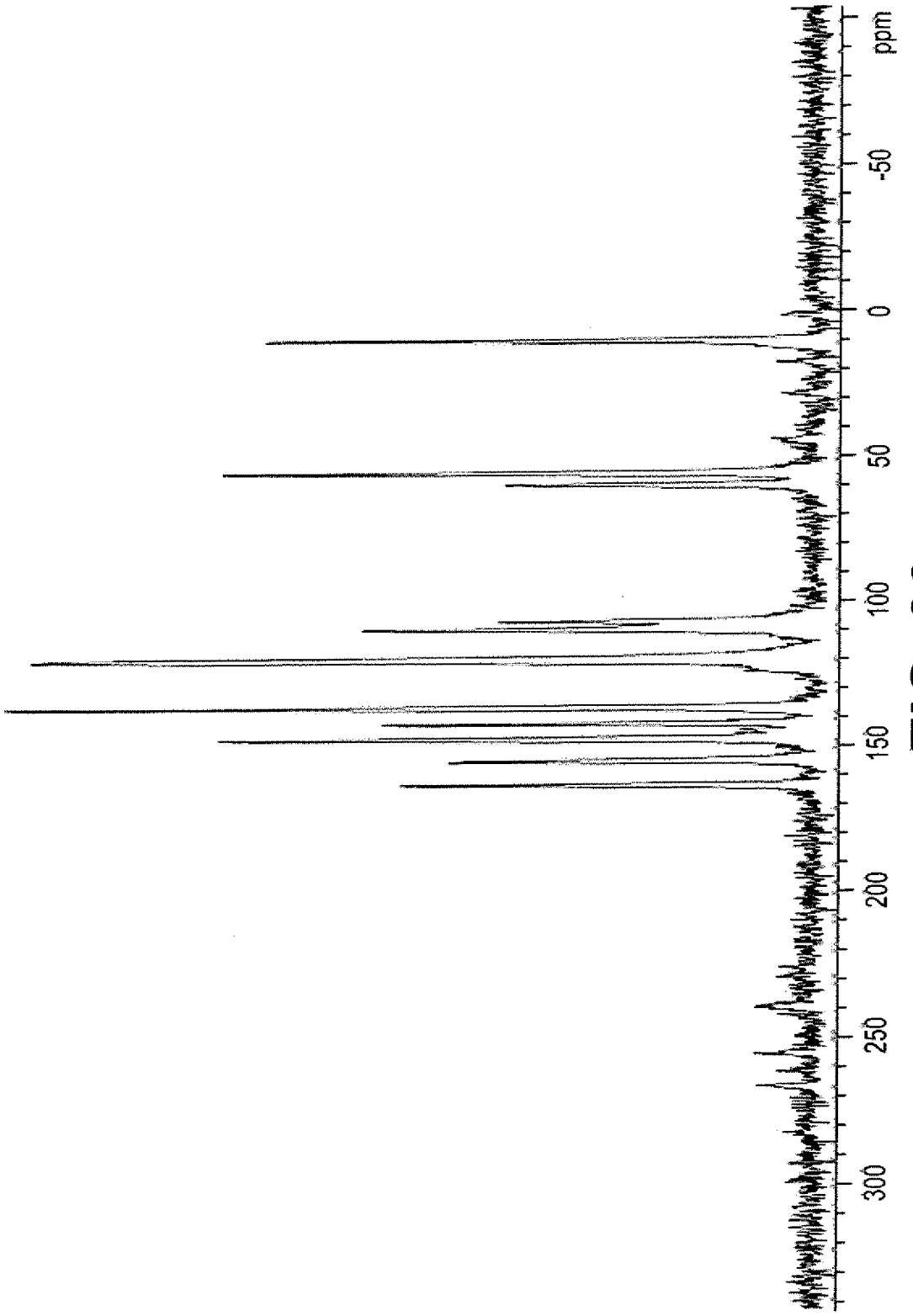


FIG. 23

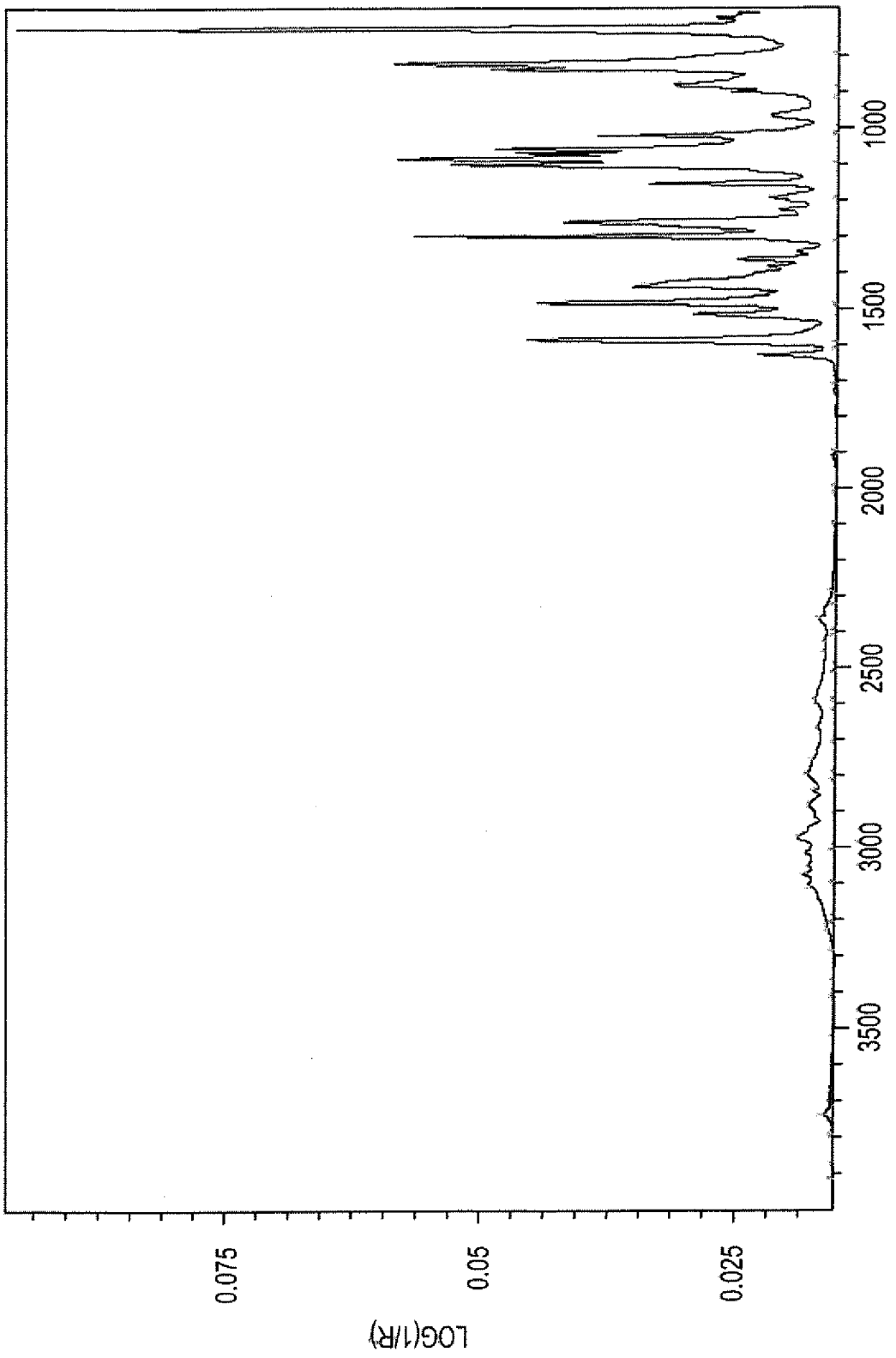

LOG(1/R)
0.075
0.05
0.025
3500
3000
2500
2000
1500
1000
WAVENUMBERS (1/cm)

FIG. 24

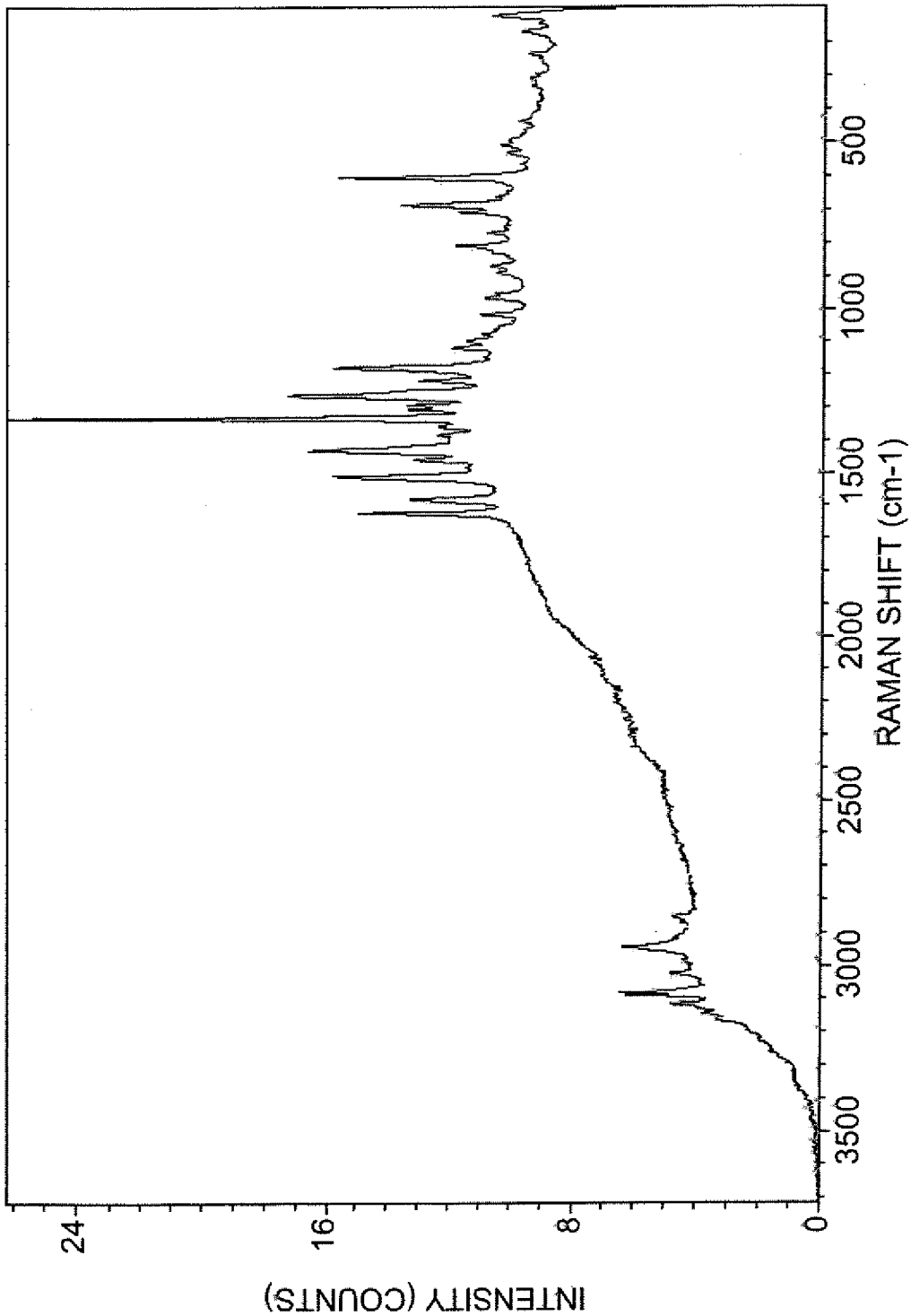

INTENSITY (COUNTS)
0
8
16
24
RAMAN SHIFT (cm-1)
500
1000
1500
2000
2500
3000
3500

FIG. 25

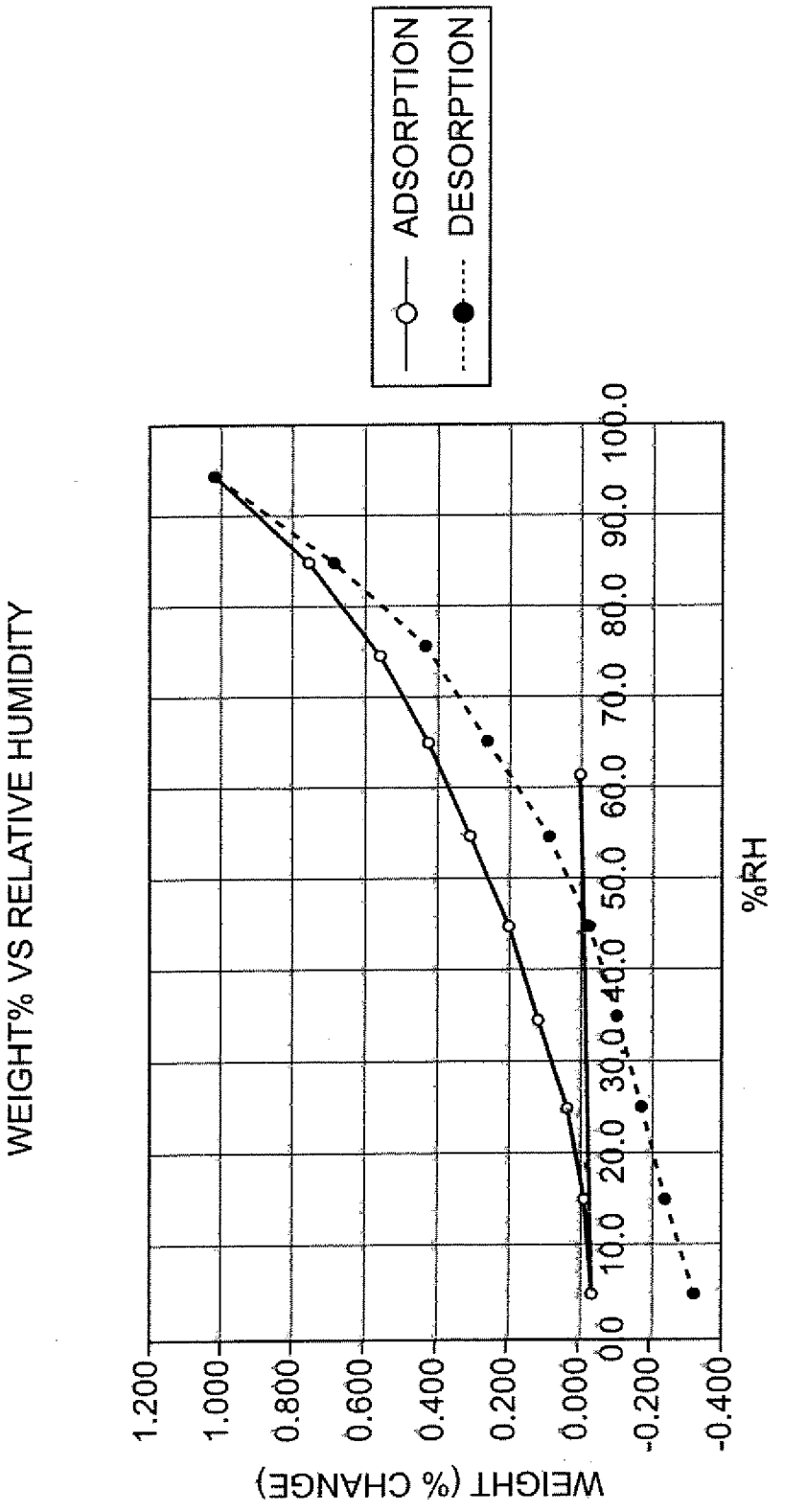

WEIGHT% VS RELATIVE HUMIDITY
ADSORPTION
DESORPTION
WEIGHT (% CHANGE)
1.200
1.000
0.800
0.600
0.400
0.200
0.000
-0.200
-0.400
0
10.0
20.0
30.0
40.0
50.0
60.0
70.0
80.0
90.0
100.0
%RH

FIG. 26

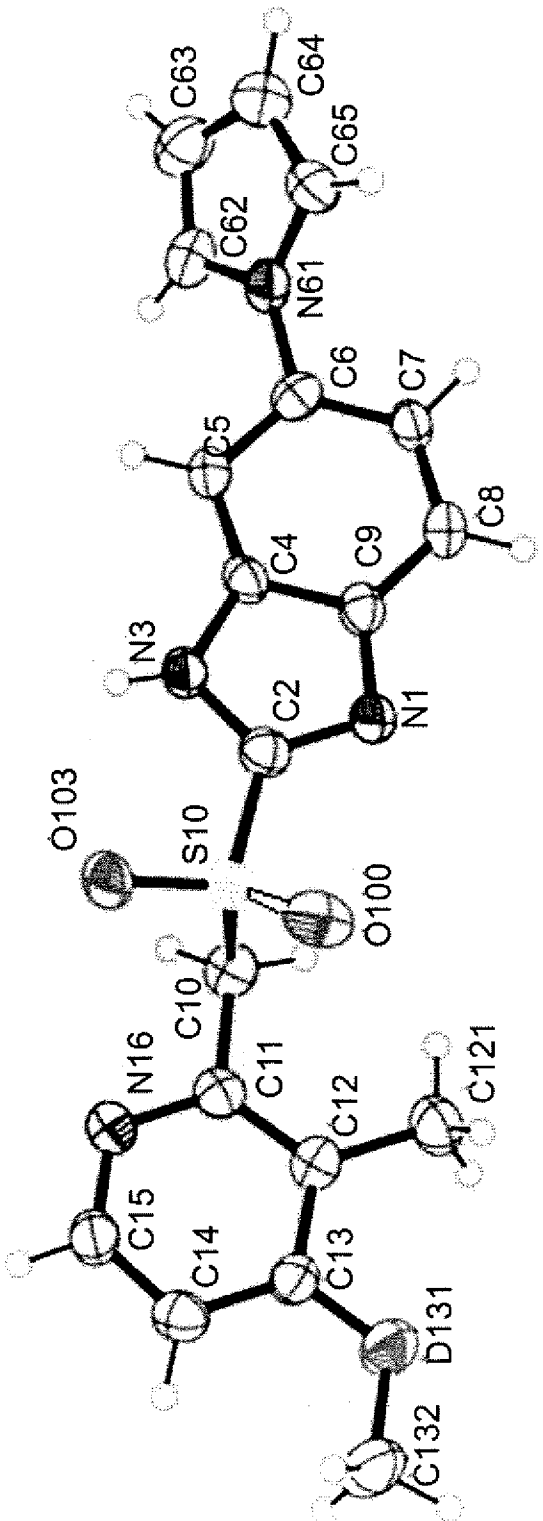

C63
C64
C65
C62
N61
C6
C7
C5
C8
C4
C9
N3
C2
N1
O103
S10
O100
C10
N16
C11
C12
C121
C15
C14
C13
D131
C132

FIG. 27

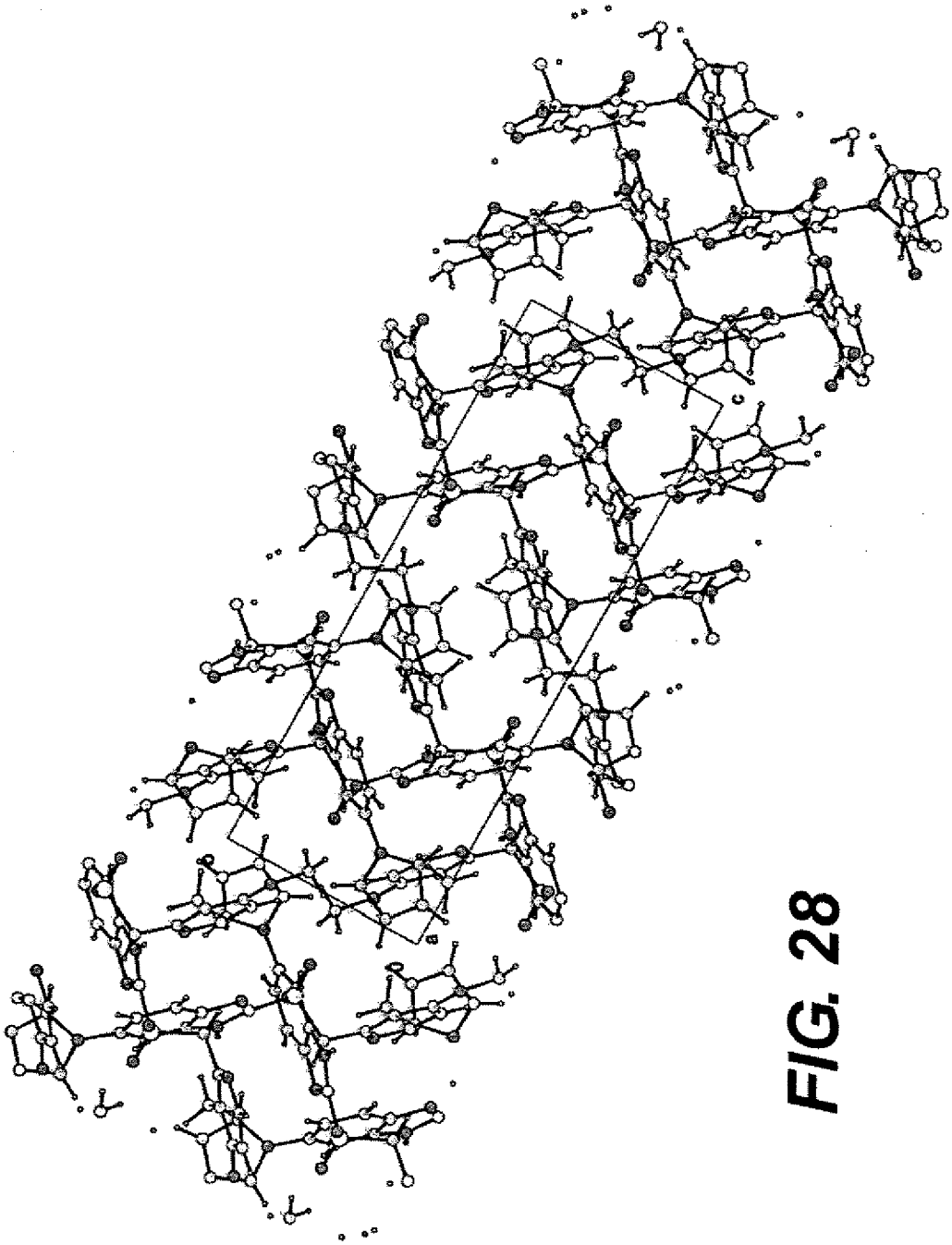


FIG. 28

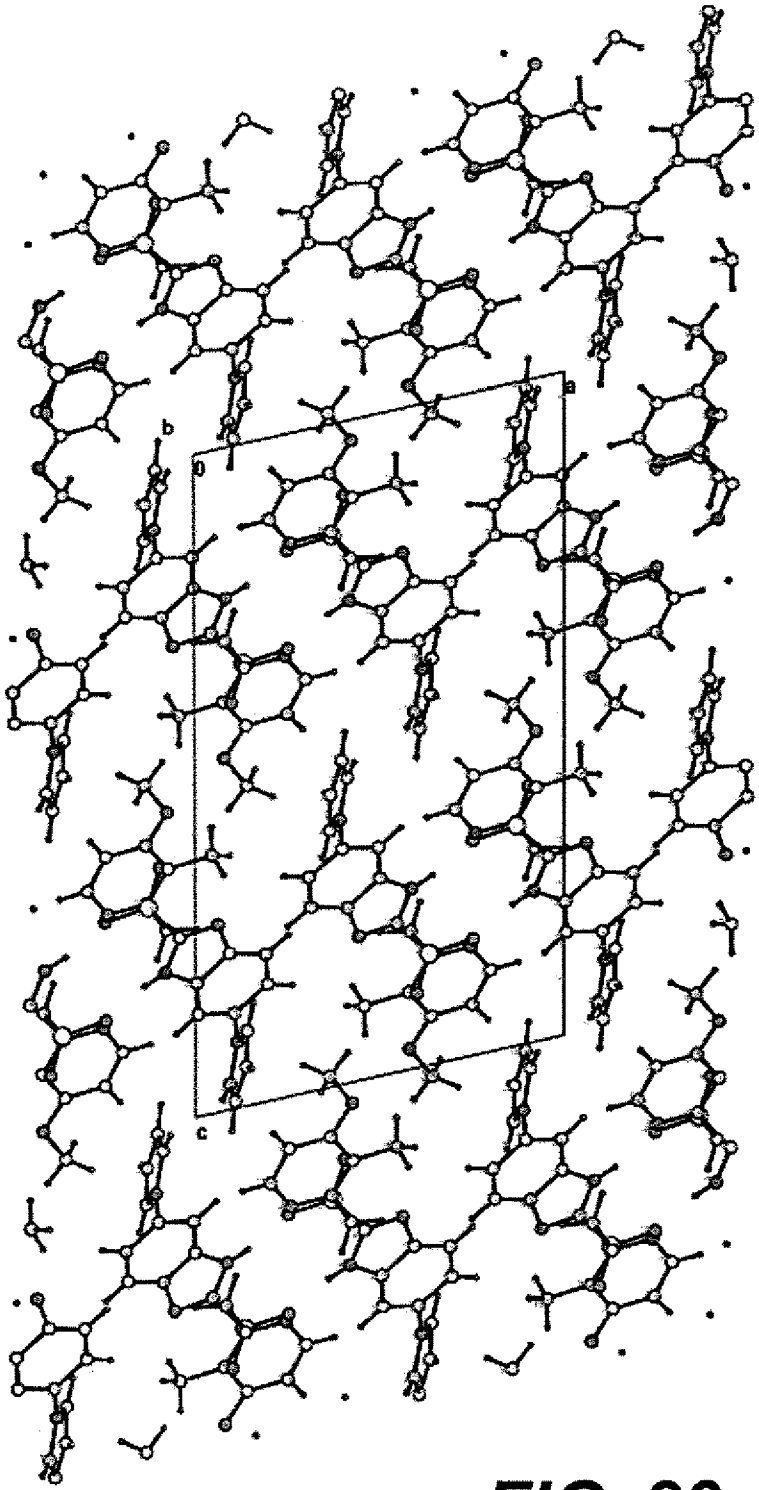


FIG. 29

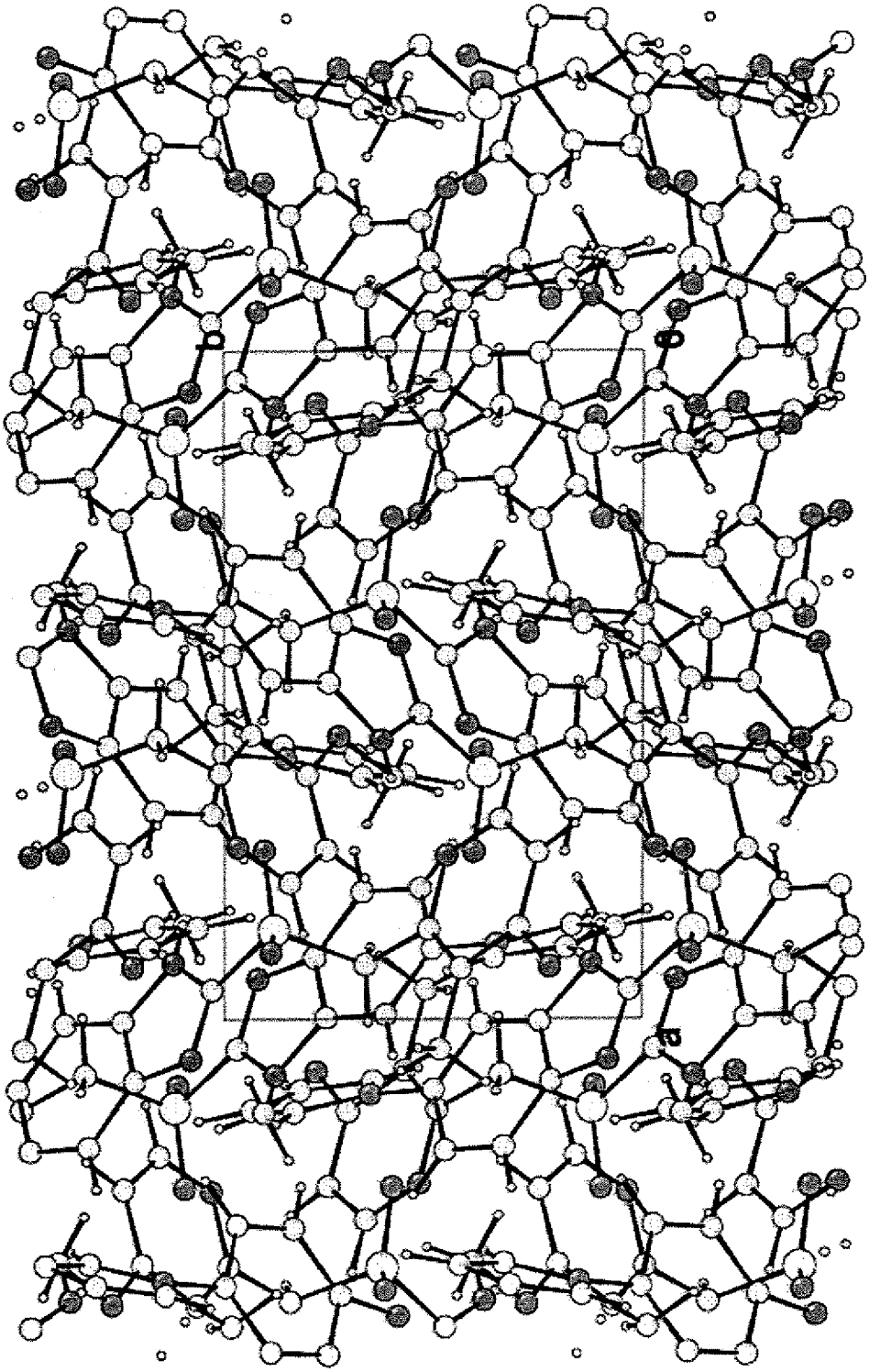


FIG. 30

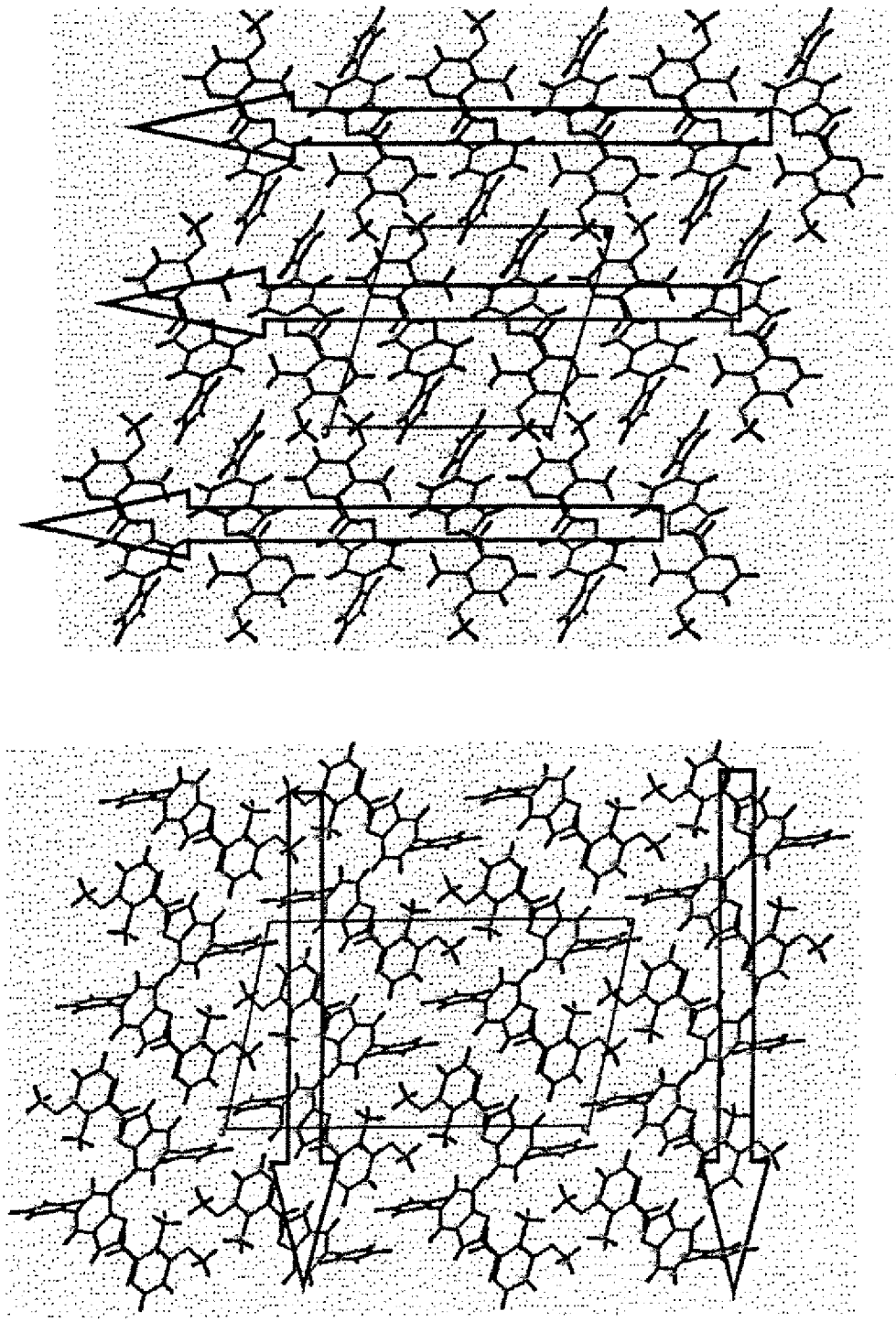


FIG. 31

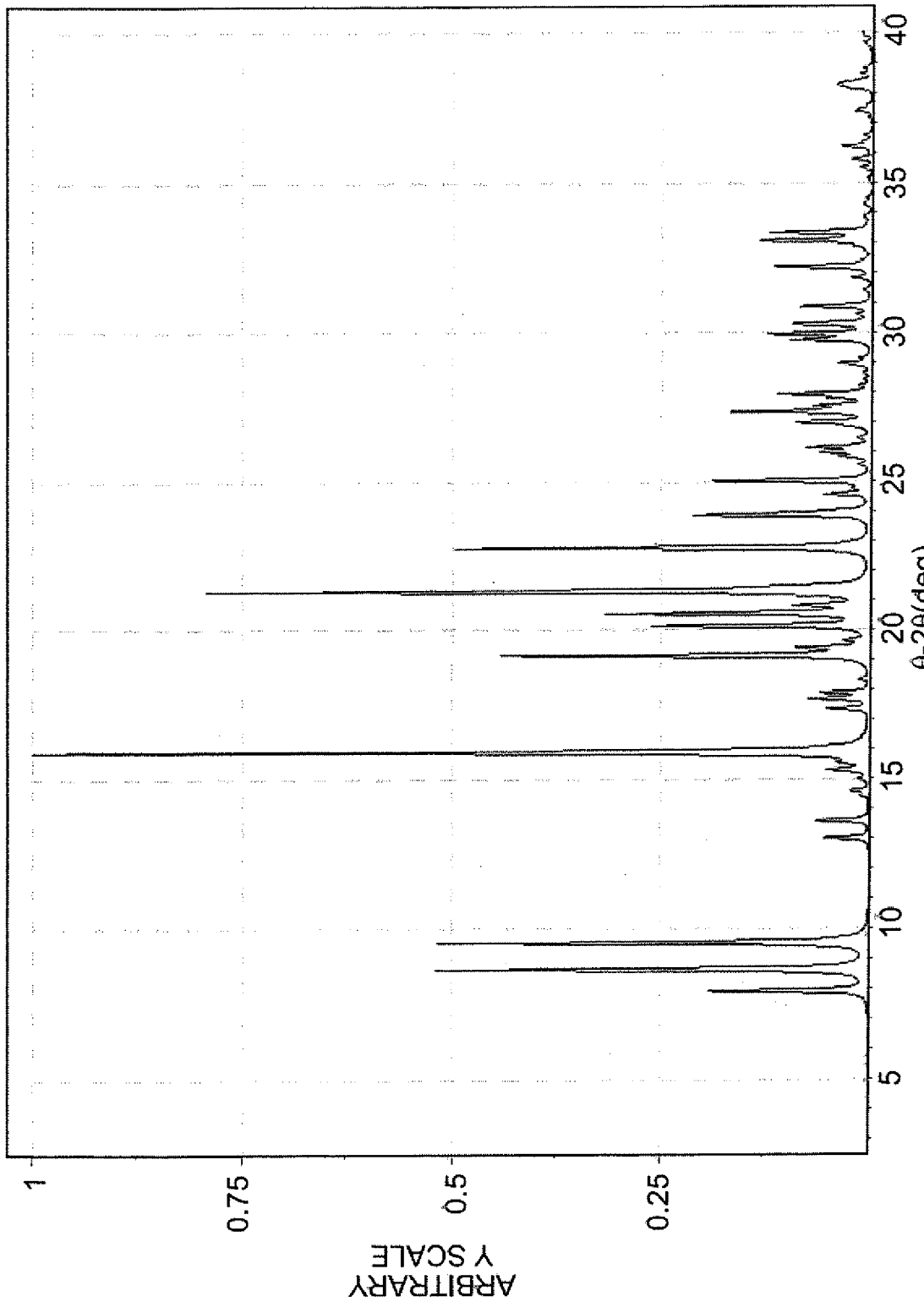


FIG. 32

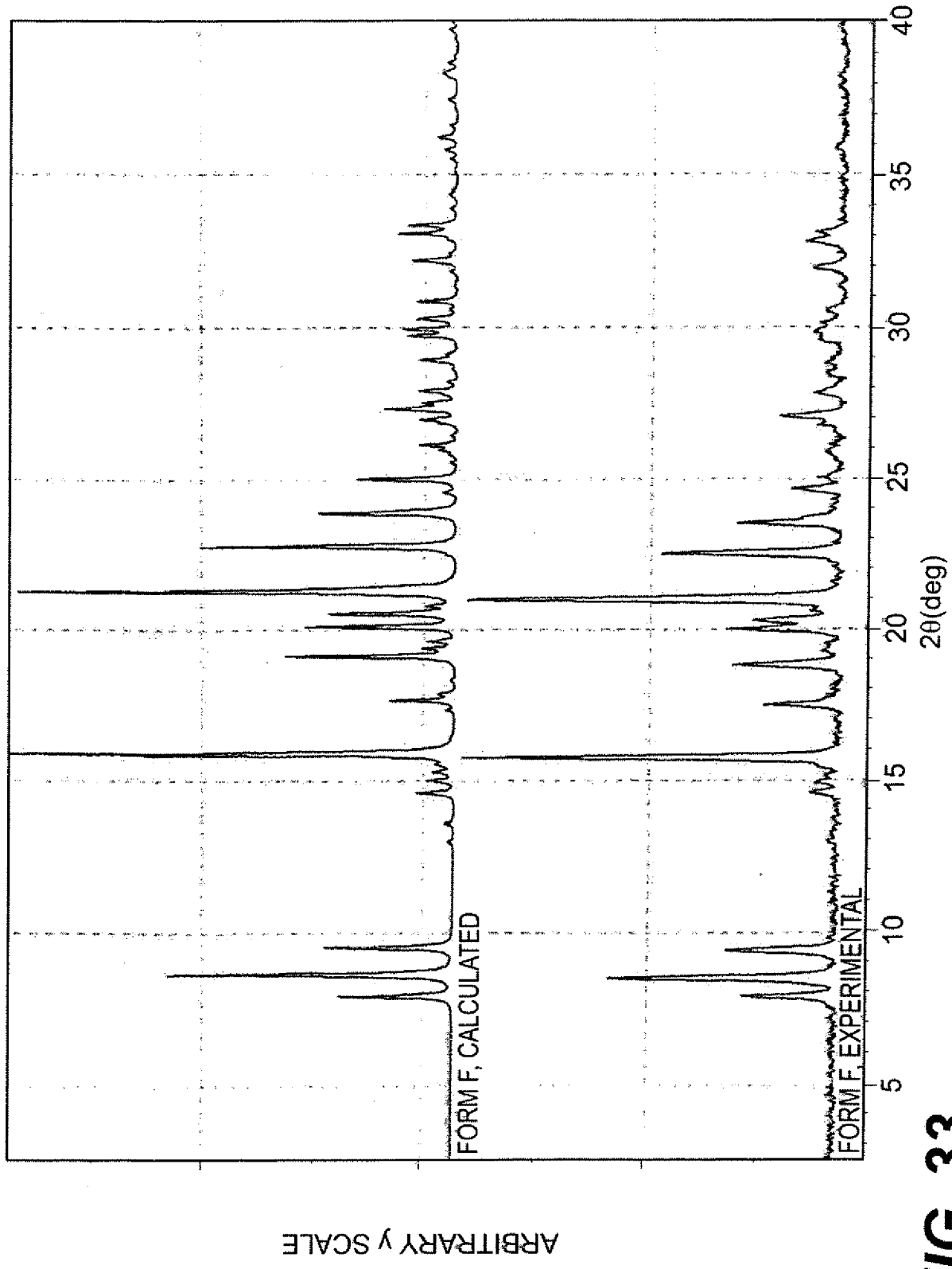

FORM F, CALCULATED
FORM F, EXPERIMENTAL
5
10
15
20
25
30
35
40
2θ(deg)
ARBITRARY y SCALE

FIG. 33

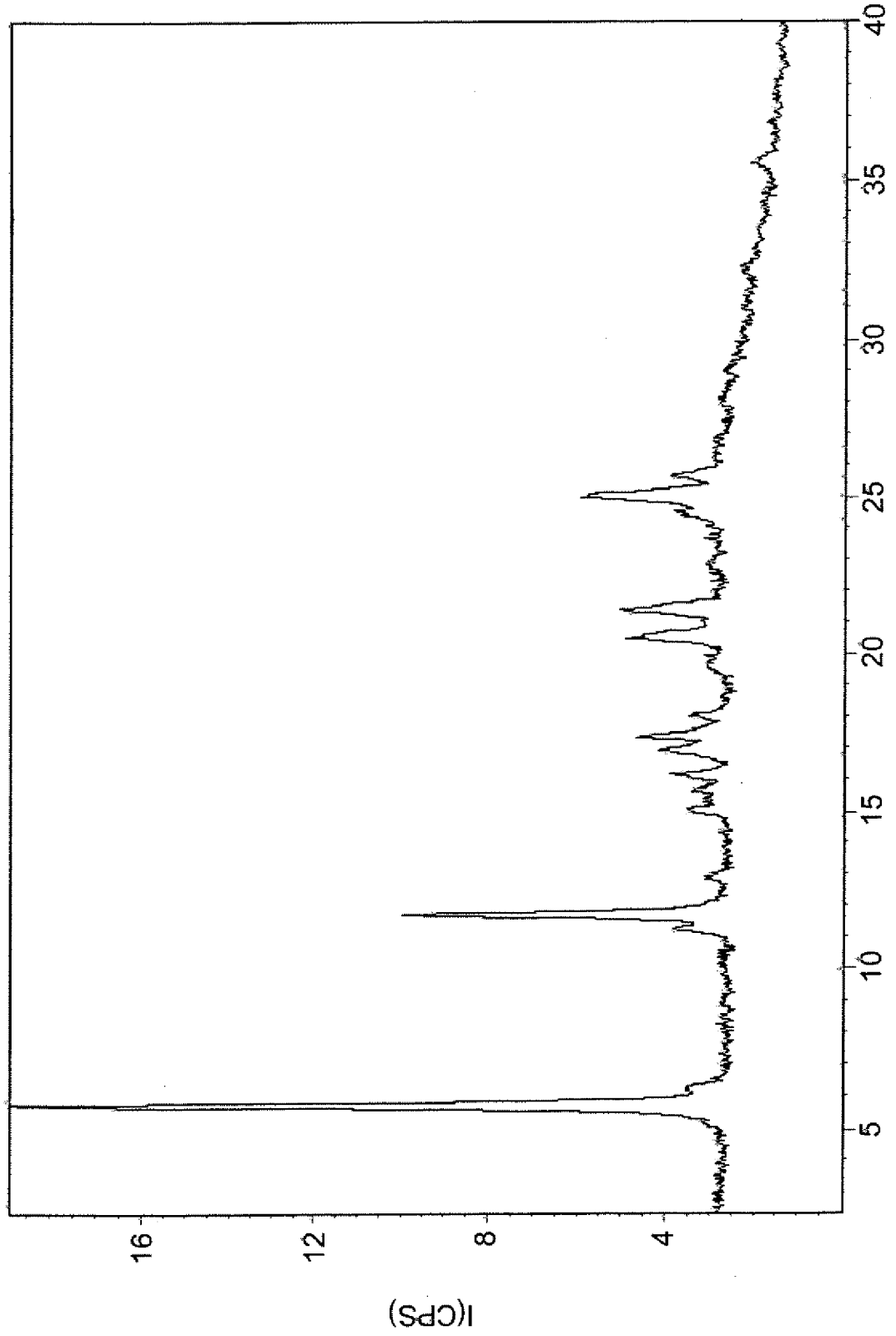


FIG. 34

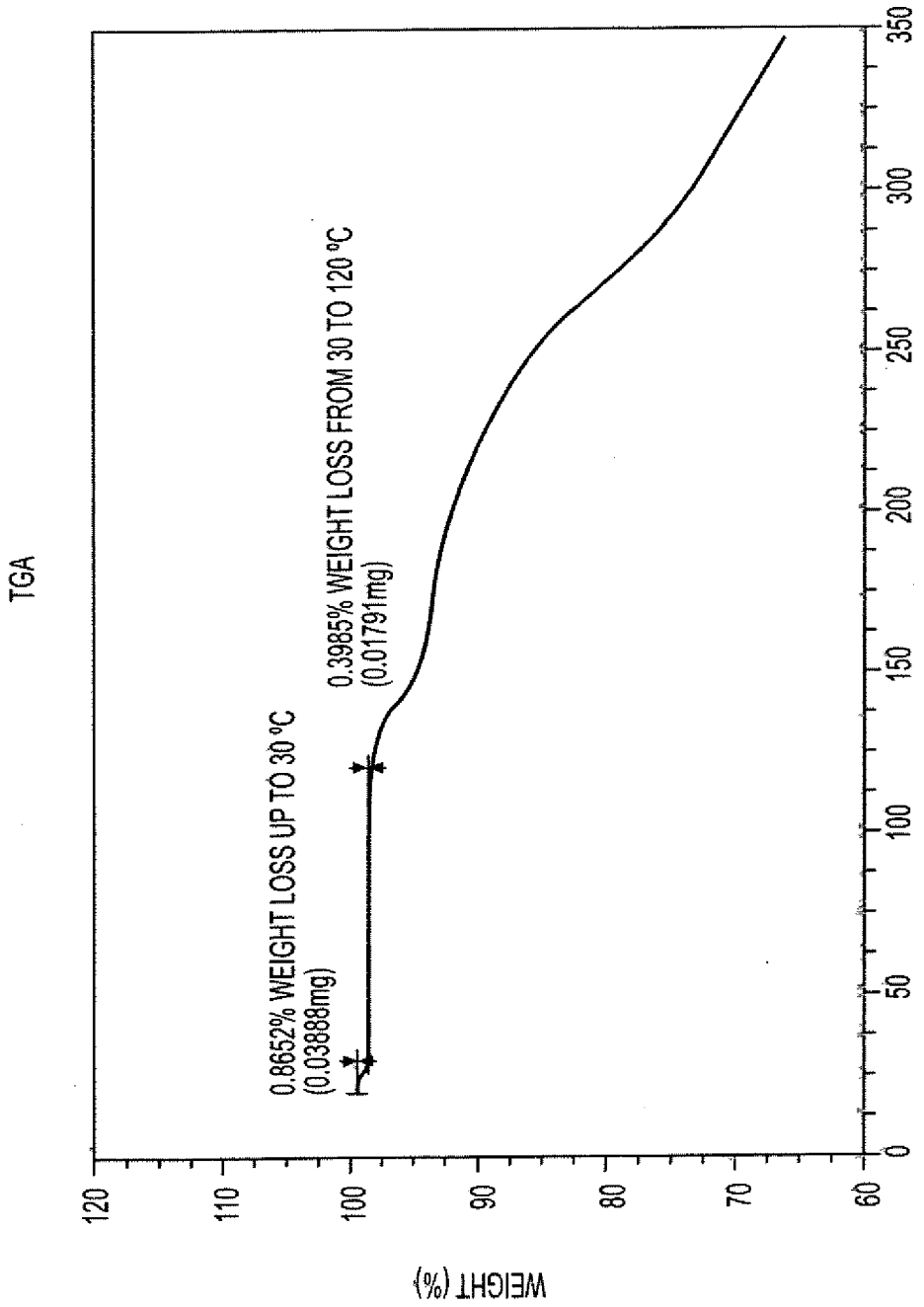

TGA
0.8652% WEIGHT LOSS UP TO 30 °C
(0.03888mg)
0.3985% WEIGHT LOSS FROM 30 TO 120 °C
(0.01791mg)
WEIGHT (%)
TEMPERATURE (°C)
120
110
100
90
80
70
60
0
50
100
150
200
250
300
350

FIG. 35

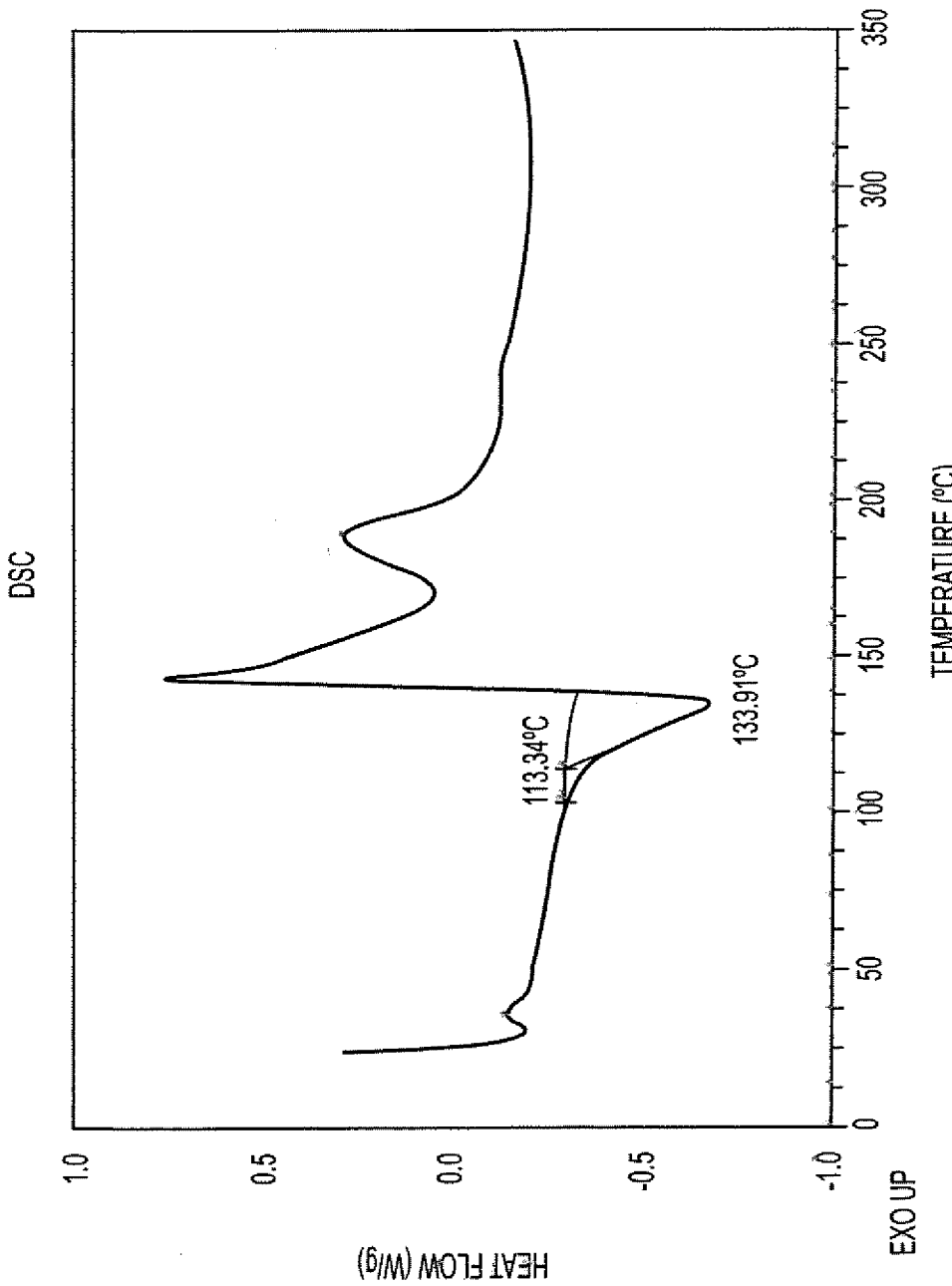

DSC
HEAT FLOW (W/g)
1.0
0.5
0.0
-0.5
-1.0
EXO UP
0
50
100
150
200
250
300
350
TEMPERATURE (°C)
113.34°C
133.91°C

FIG. 36

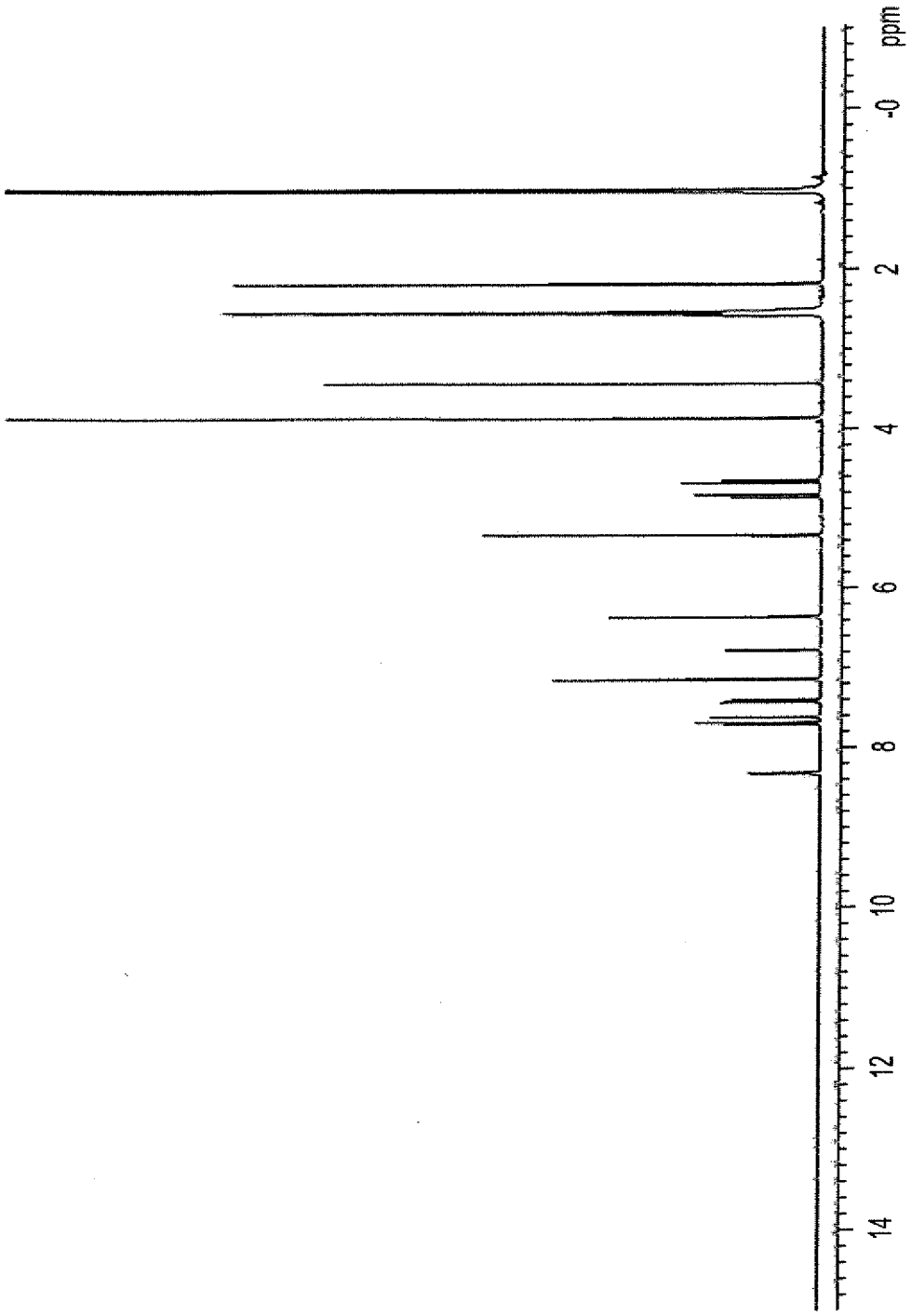


FIG. 37

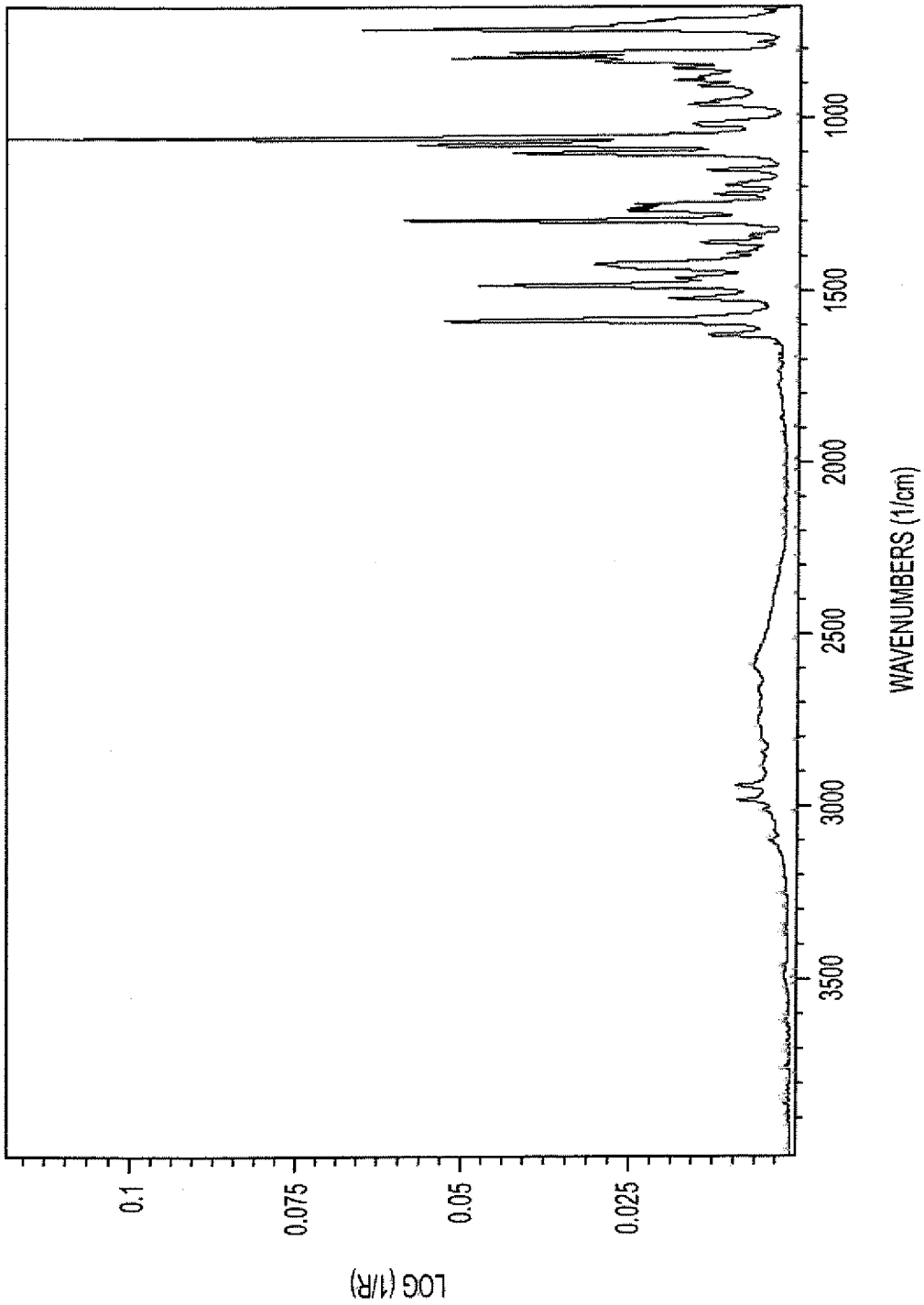

LOG (1/R)
0.1
0.075
0.05
0.025
WAVENUMBERS (1/cm)
3500
3000
2500
2000
1500
1000

FIG. 38

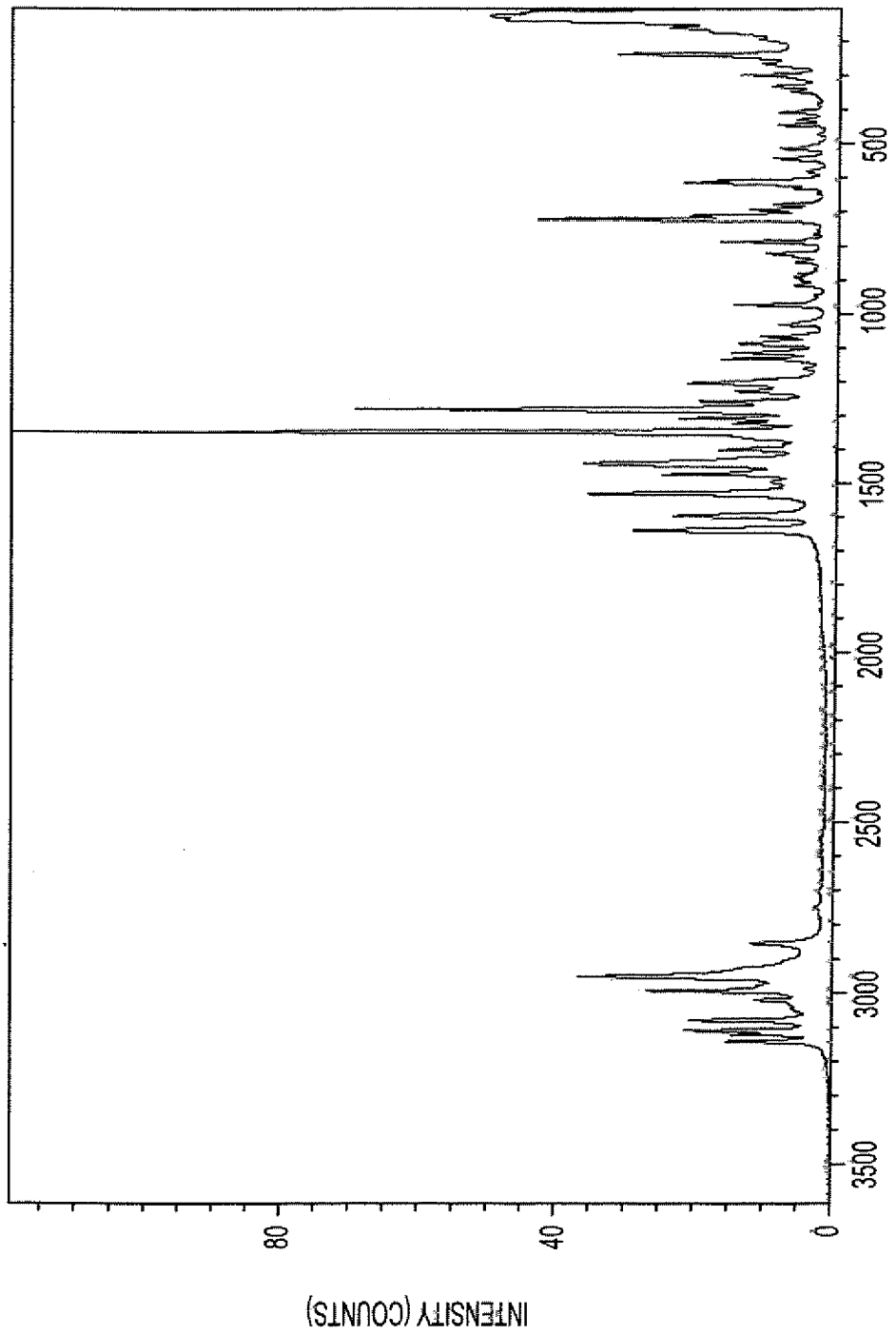

INTENSITY (COUNTS)
0
40
80
3500
3000
2500
2000
1500
1000
500
RAMAN SHIFT (cm-1)

FIG. 39

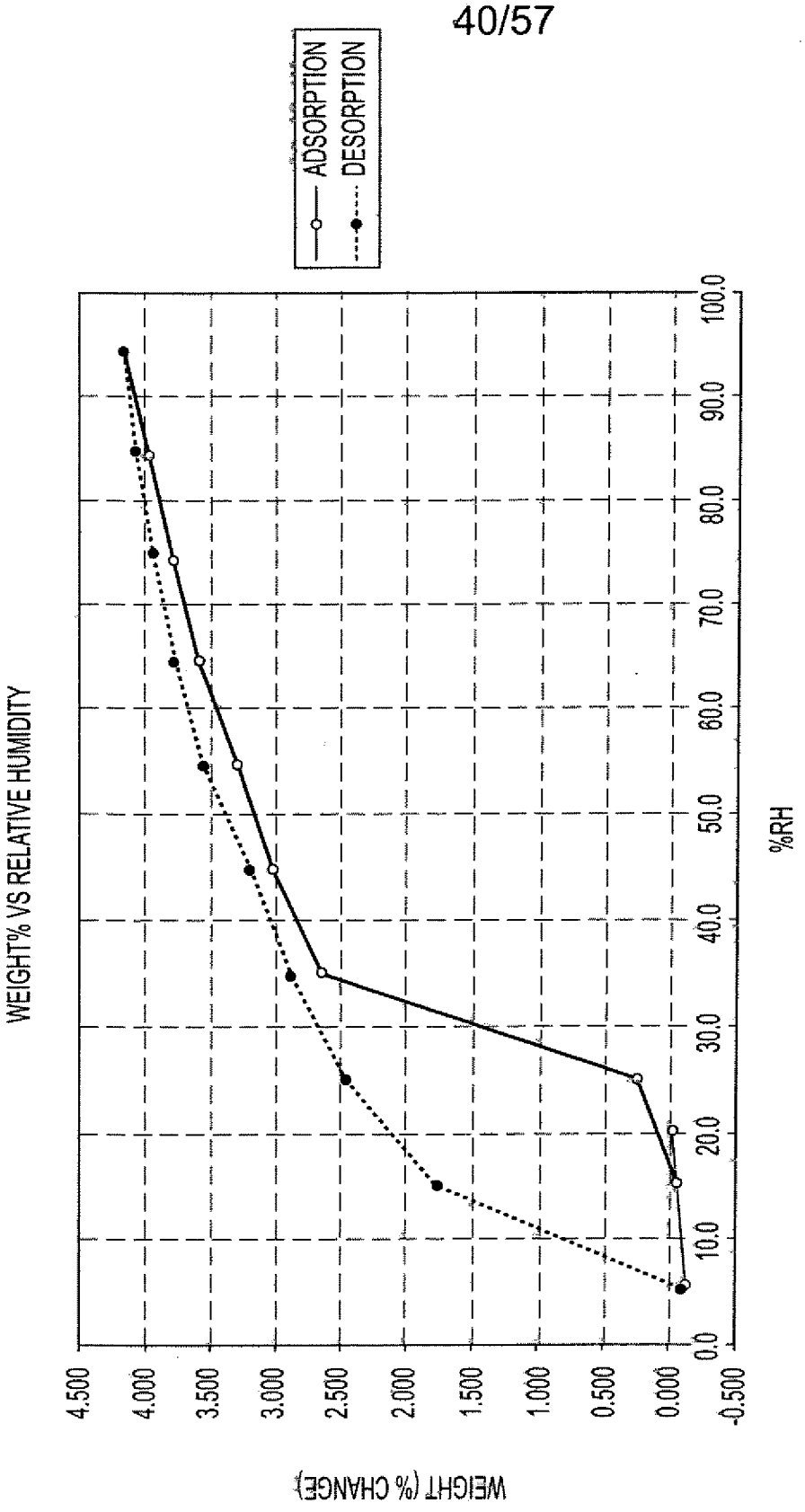

WEIGHT% VS RELATIVE HUMIDITY
ADSORPTION
DESORPTION
WEIGHT (% CHANGE)
%RH
4.500
4.000
3.500
3.000
2.500
2.000
1.500
1.000
0.500
0.000
-0.500
0.0
10.0
20.0
30.0
40.0
50.0
60.0
70.0
80.0
90.0
100.0

FIG. 40

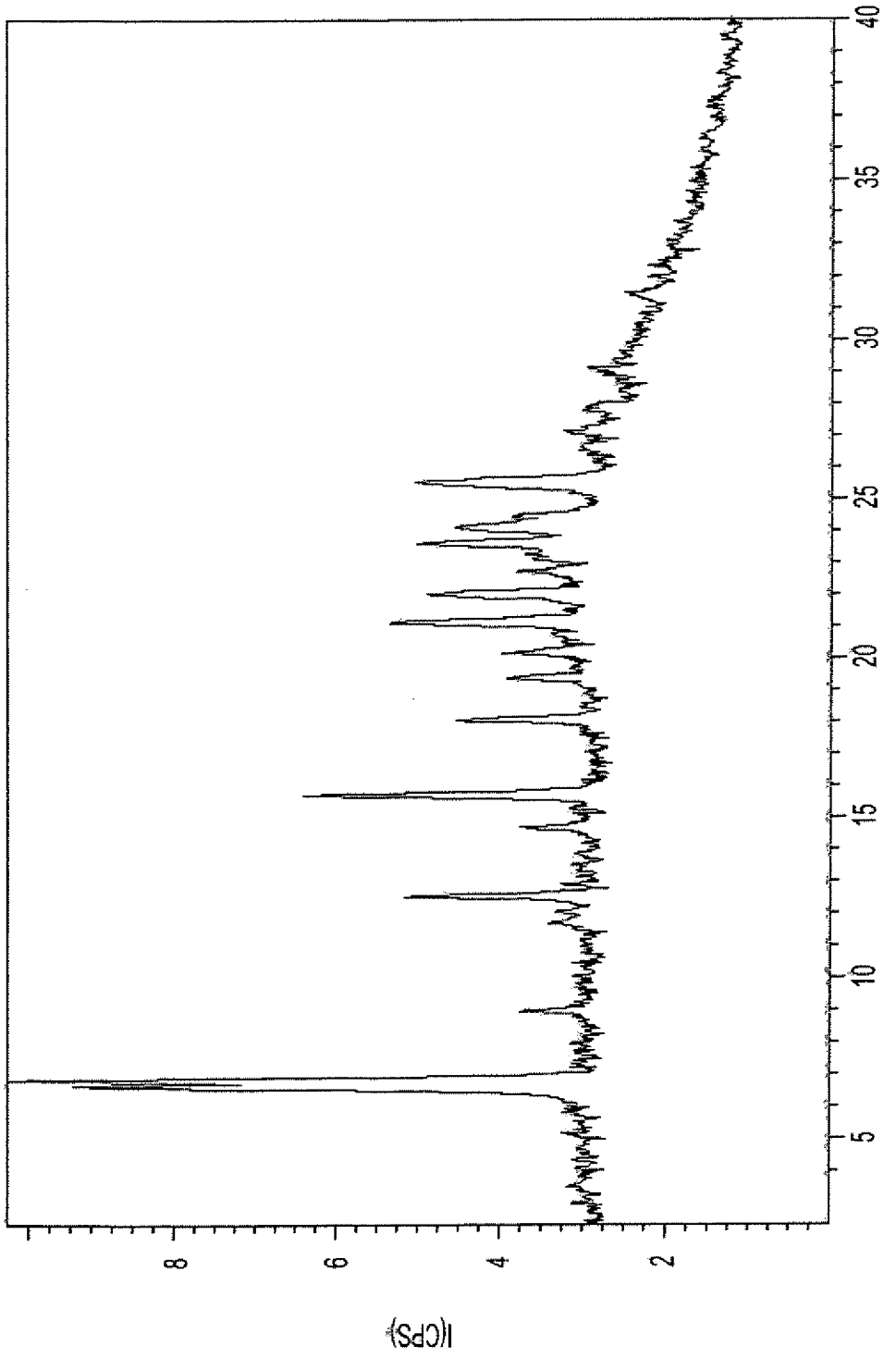


FIG. 41

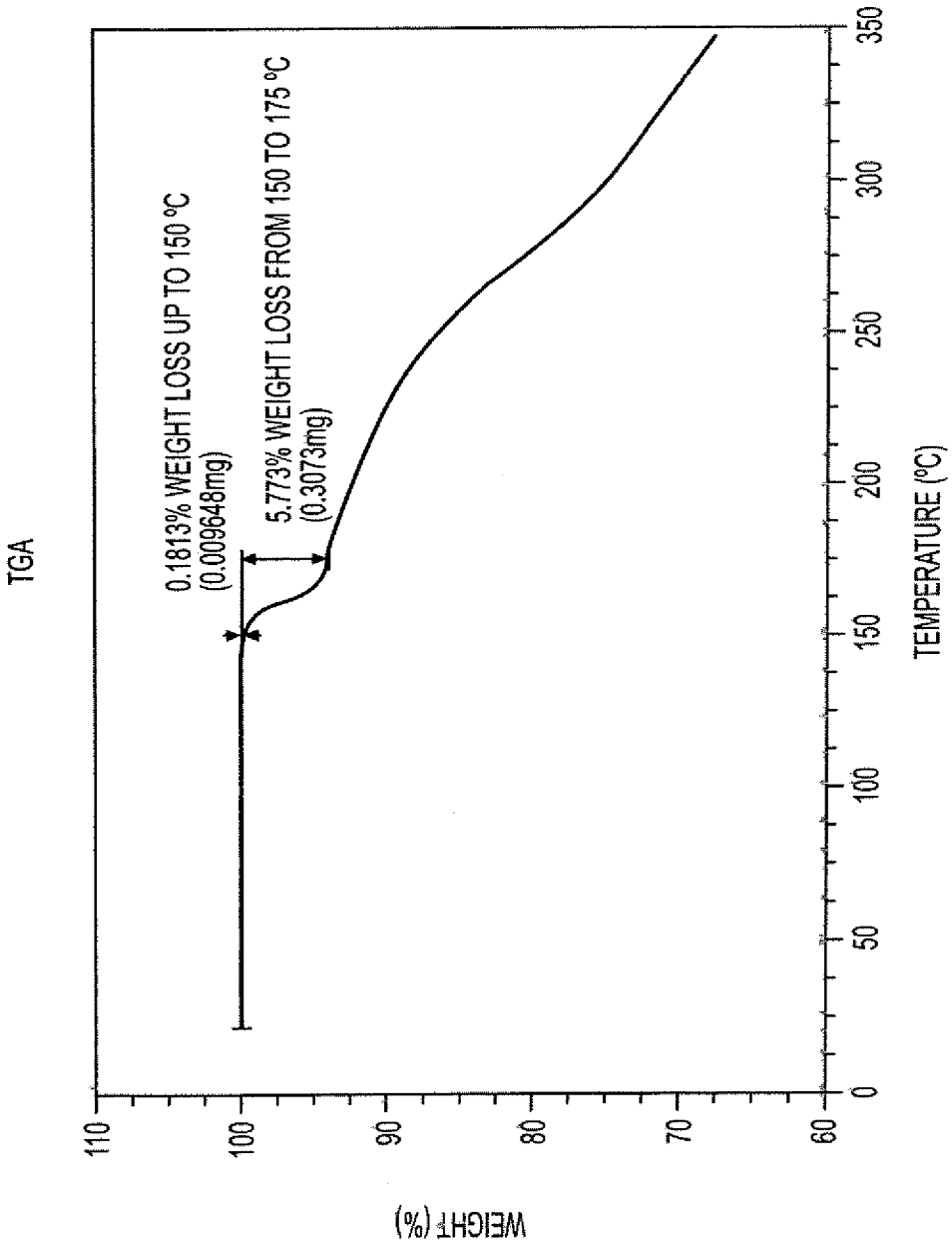

TGA
0.1813% WEIGHT LOSS UP TO 150 °C
(0.009648mg)
5.773% WEIGHT LOSS FROM 150 TO 175 °C
(0.3073mg)
WEIGHT (%)
110
100
90
80
70
60
0
50
100
150
200
250
300
350
TEMPERATURE (°C)

FIG. 42

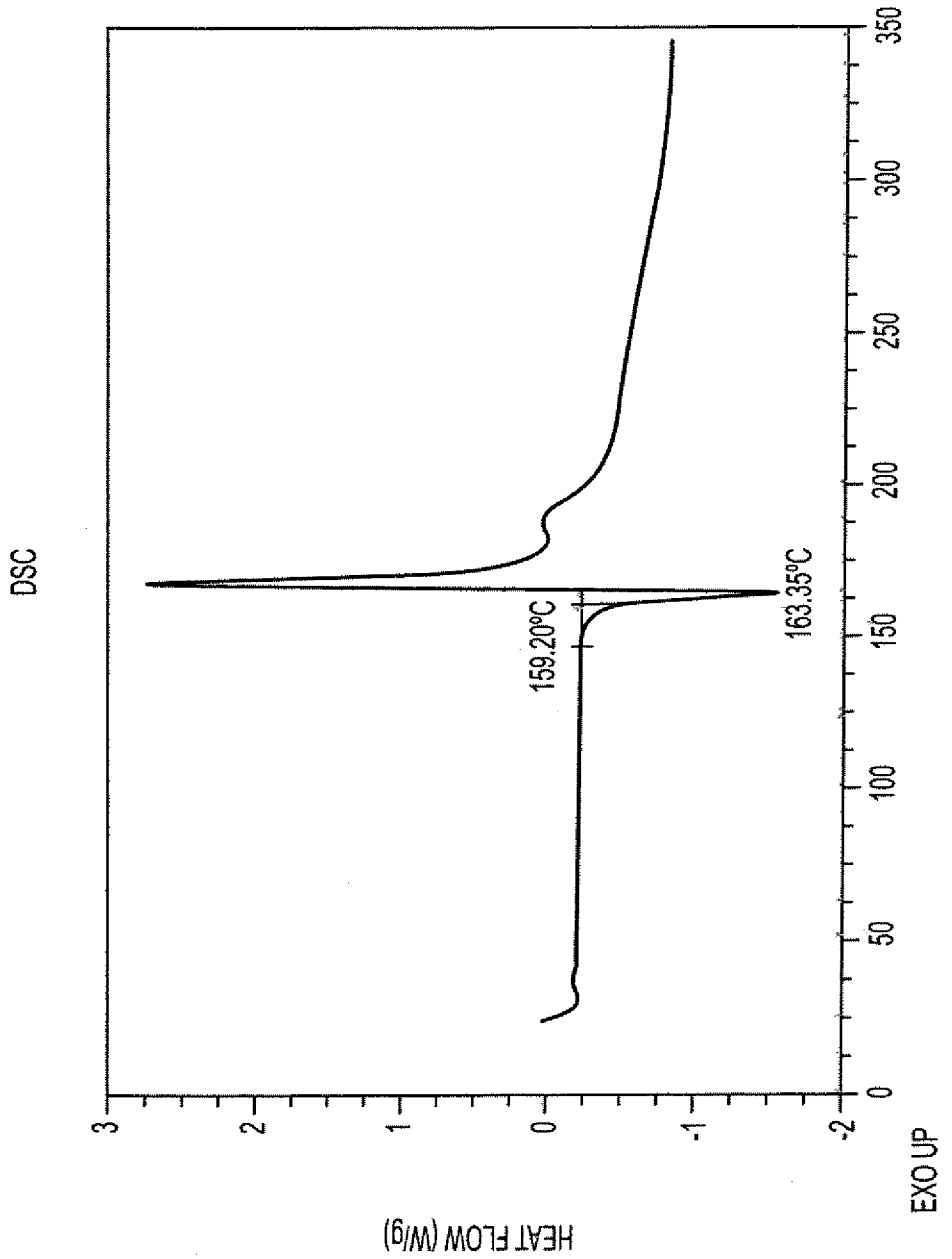

DSC
HEAT FLOW (W/g)
EXO UP
TEMPERATURE (°C)
159.20°C
163.35°C
3
2
1
0
-1
-2
0
50
100
150
200
250
300
350

FIG. 43

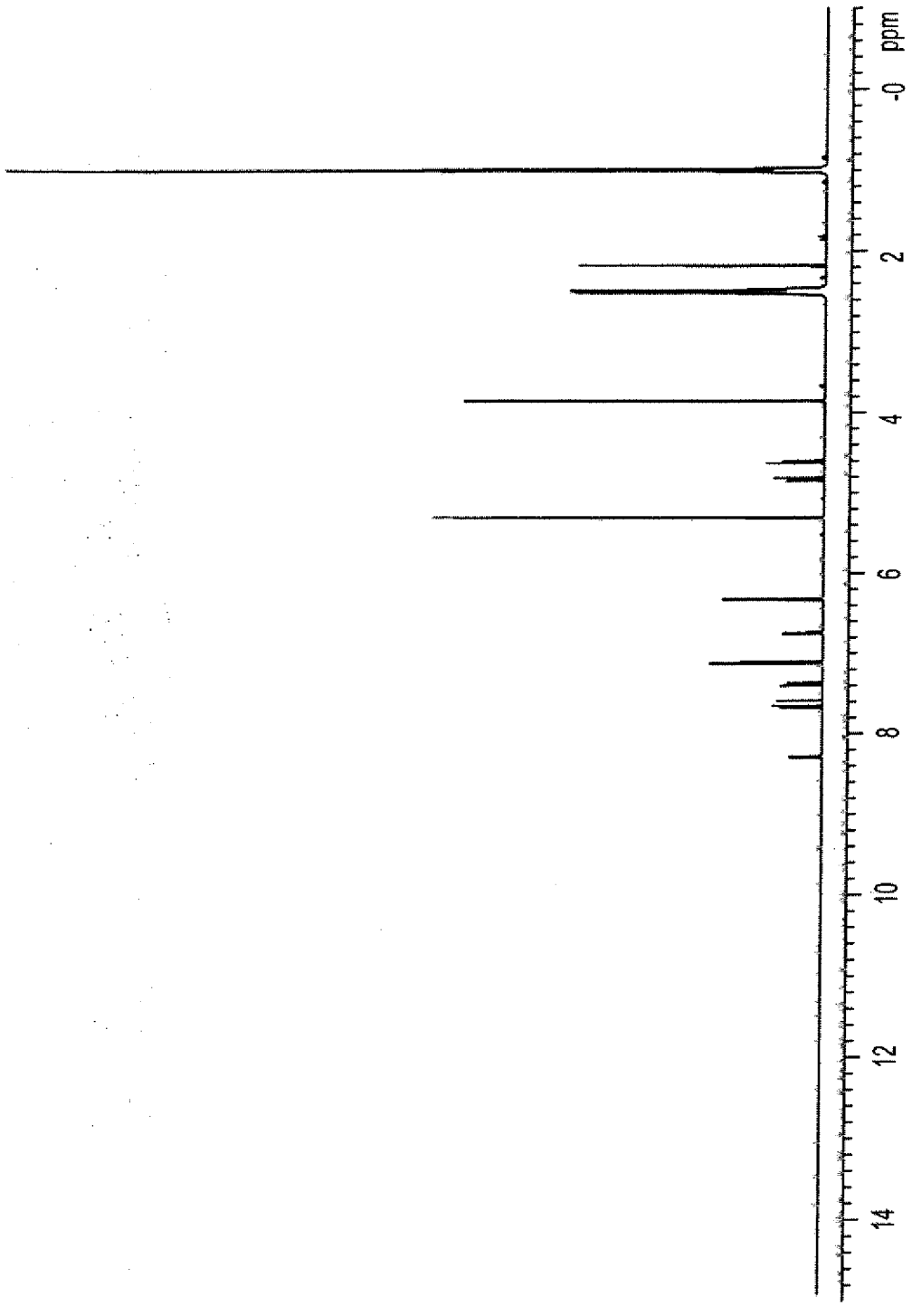


FIG. 44

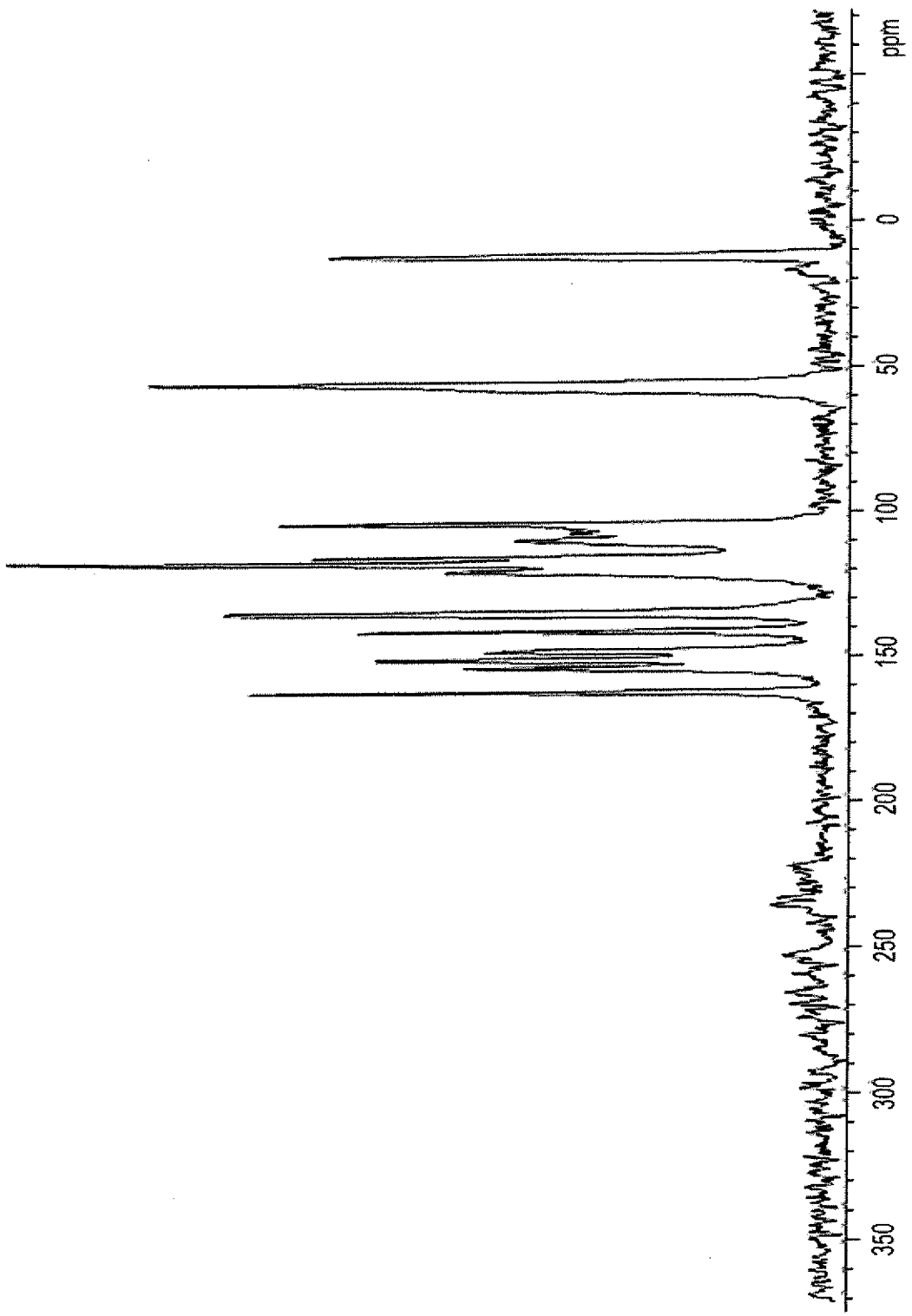


FIG. 45

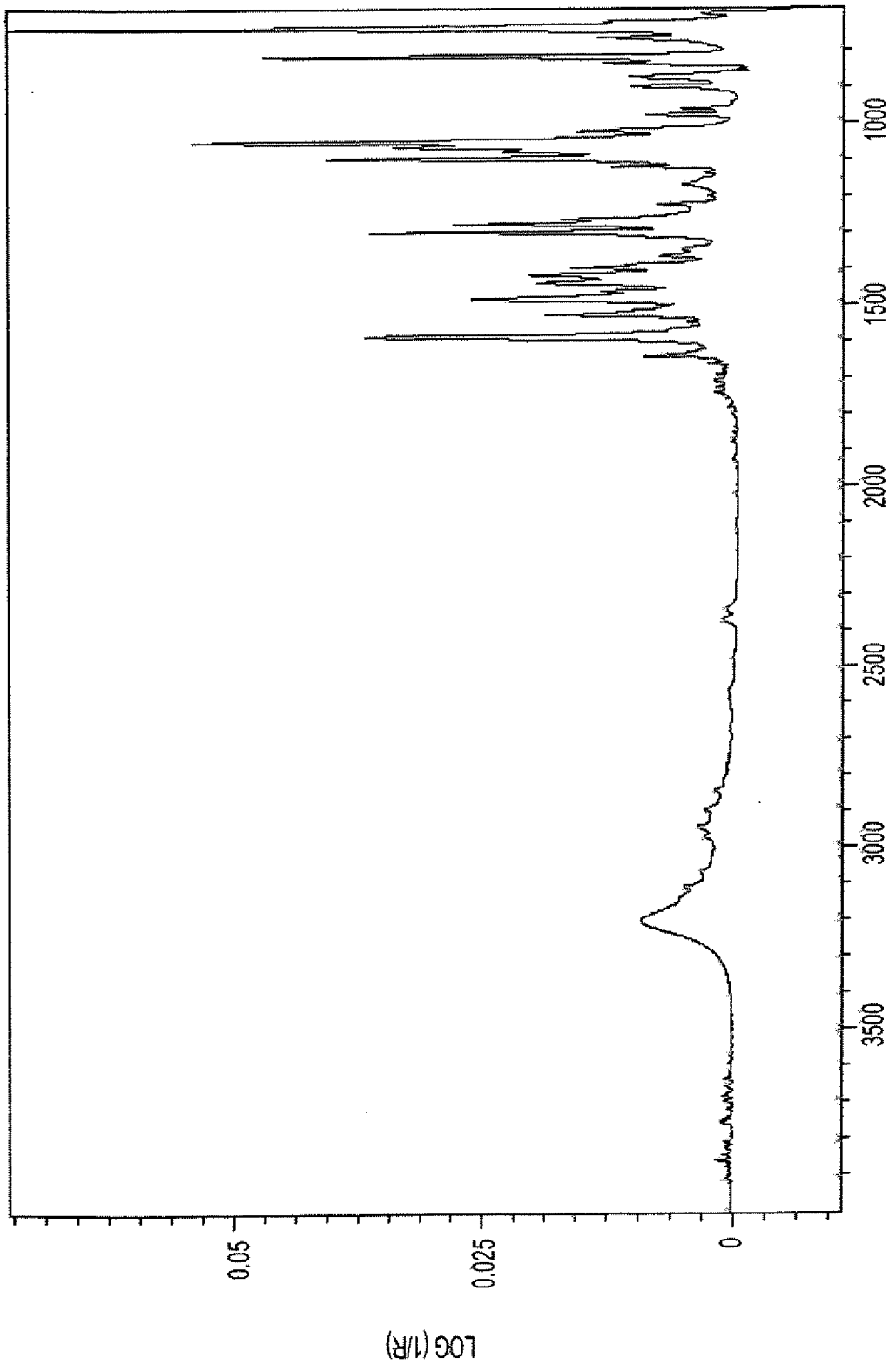

LOG (1/R)
0.05
0.025
0
3500
3000
2500
2000
1500
1000
WAVENUMBERS (1/cm)

FIG. 46

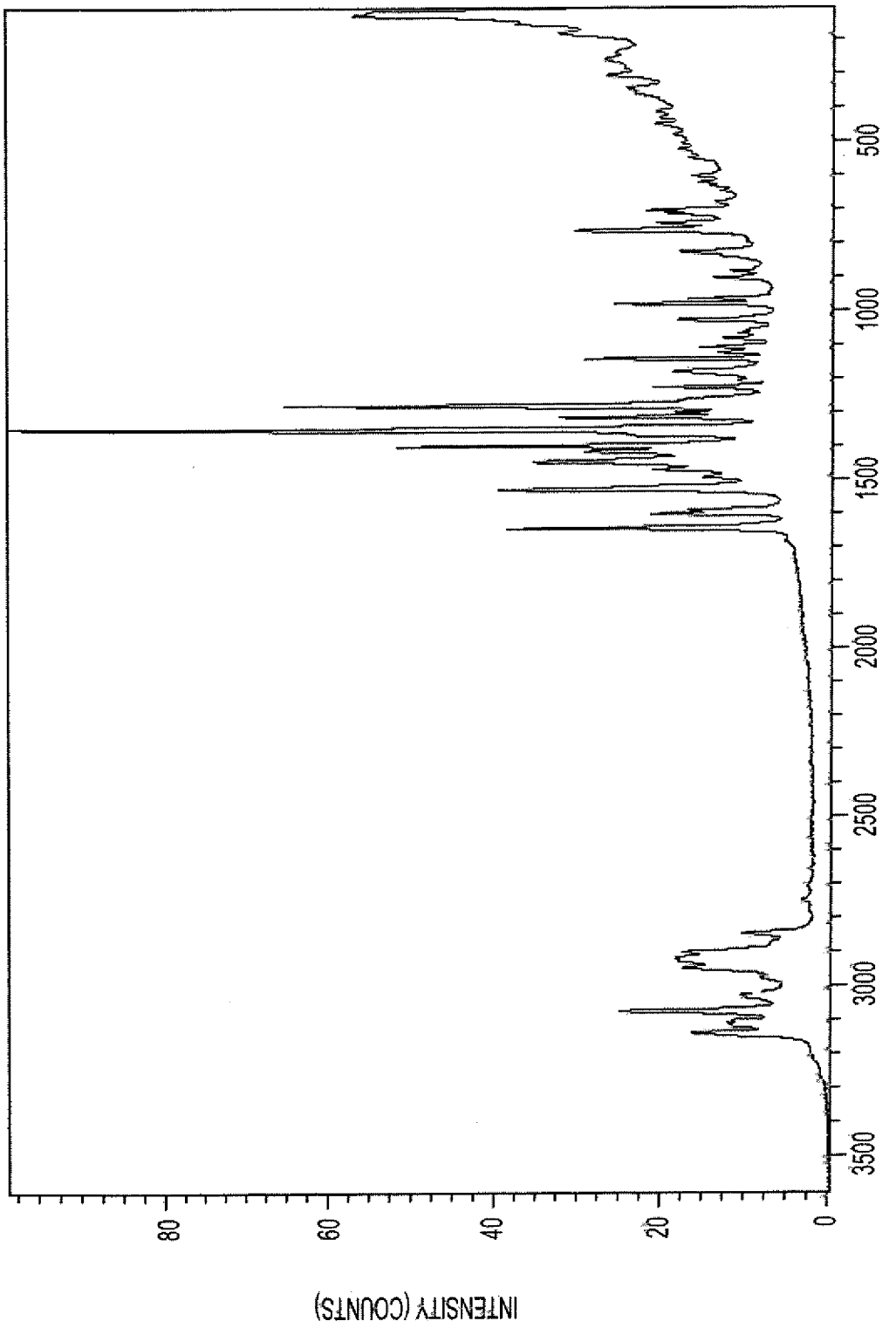

INTENSITY (COUNTS)
0
20
40
60
80
RAMAN SHIFT (cm-1)
500
1000
1500
2000
2500
3000
3500

FIG. 47

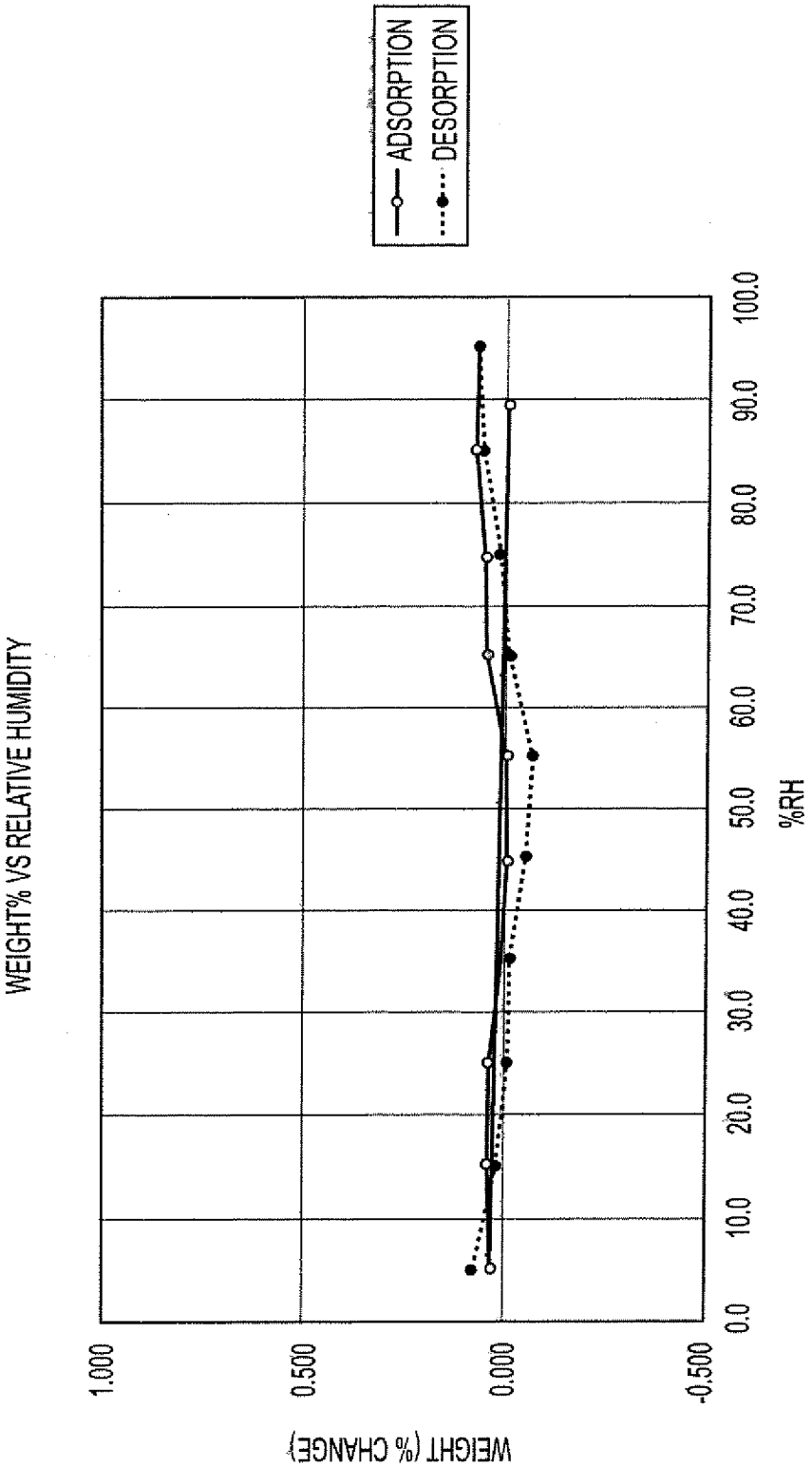

ADSORPTION
DESORPTION
WEIGHT% VS RELATIVE HUMIDITY
WEIGHT (% CHANGE)
1.000
0.500
0.000
-0.500
0.0
10.0
20.0
30.0
40.0
50.0
60.0
70.0
80.0
90.0
100.0
%RH

FIG. 48

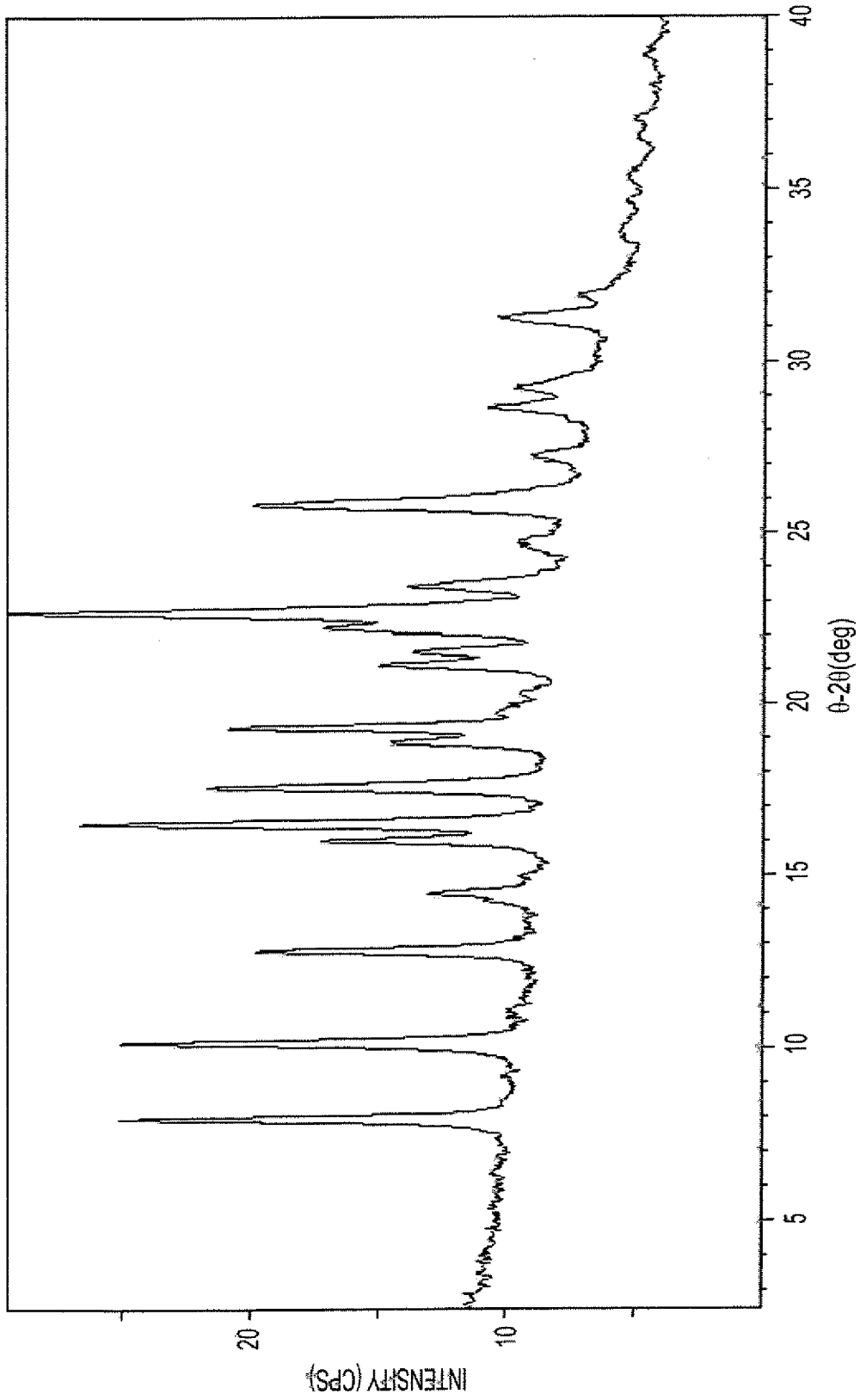


FIG. 49

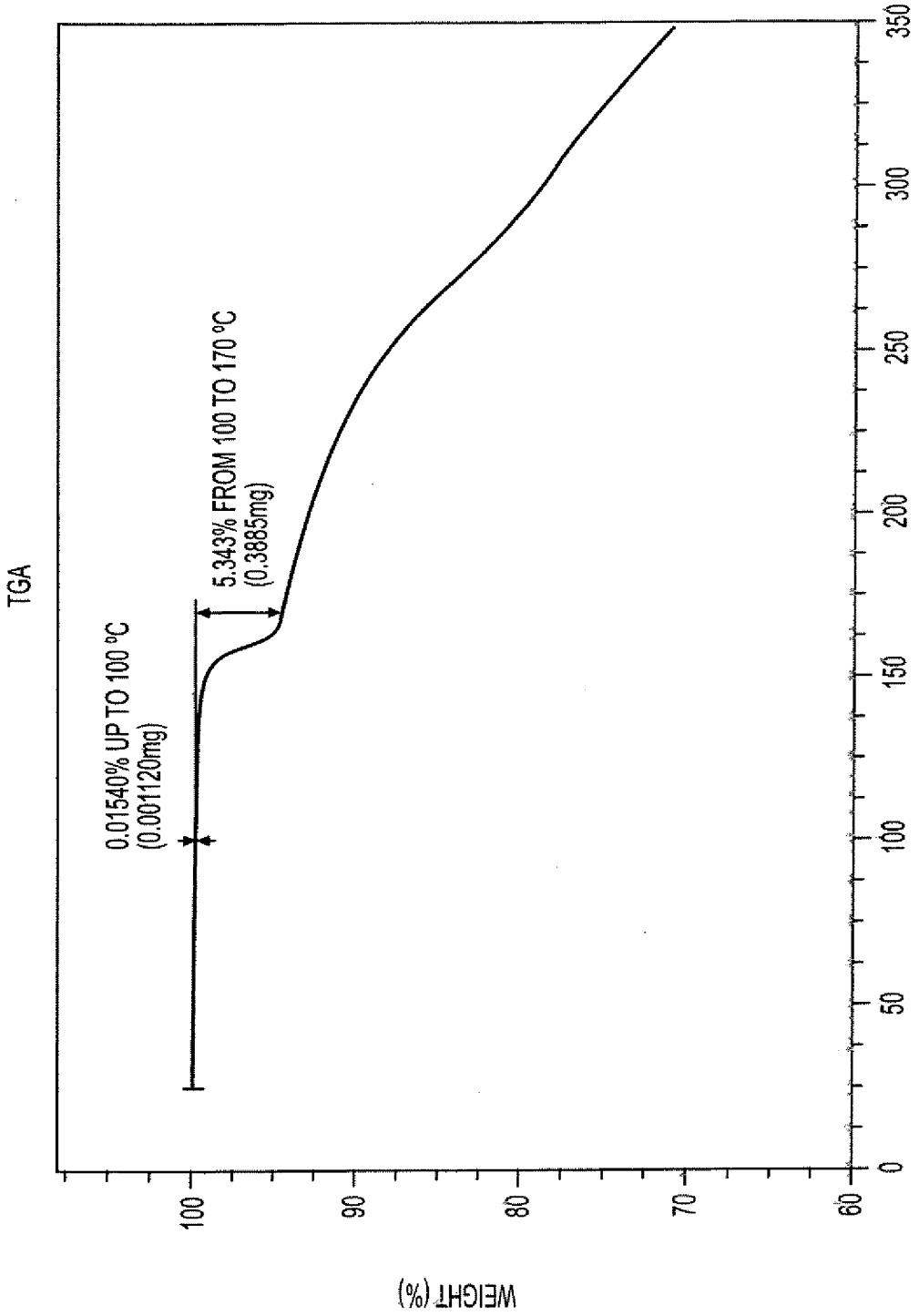

TGA
0.01540% UP TO 100 °C
(0.001120mg)
5.343% FROM 100 TO 170 °C
(0.3885mg)
WEIGHT (%)
100
90
80
70
60
0
50
100
150
200
250
300
350
TEMPERATURE (°C)

FIG. 50

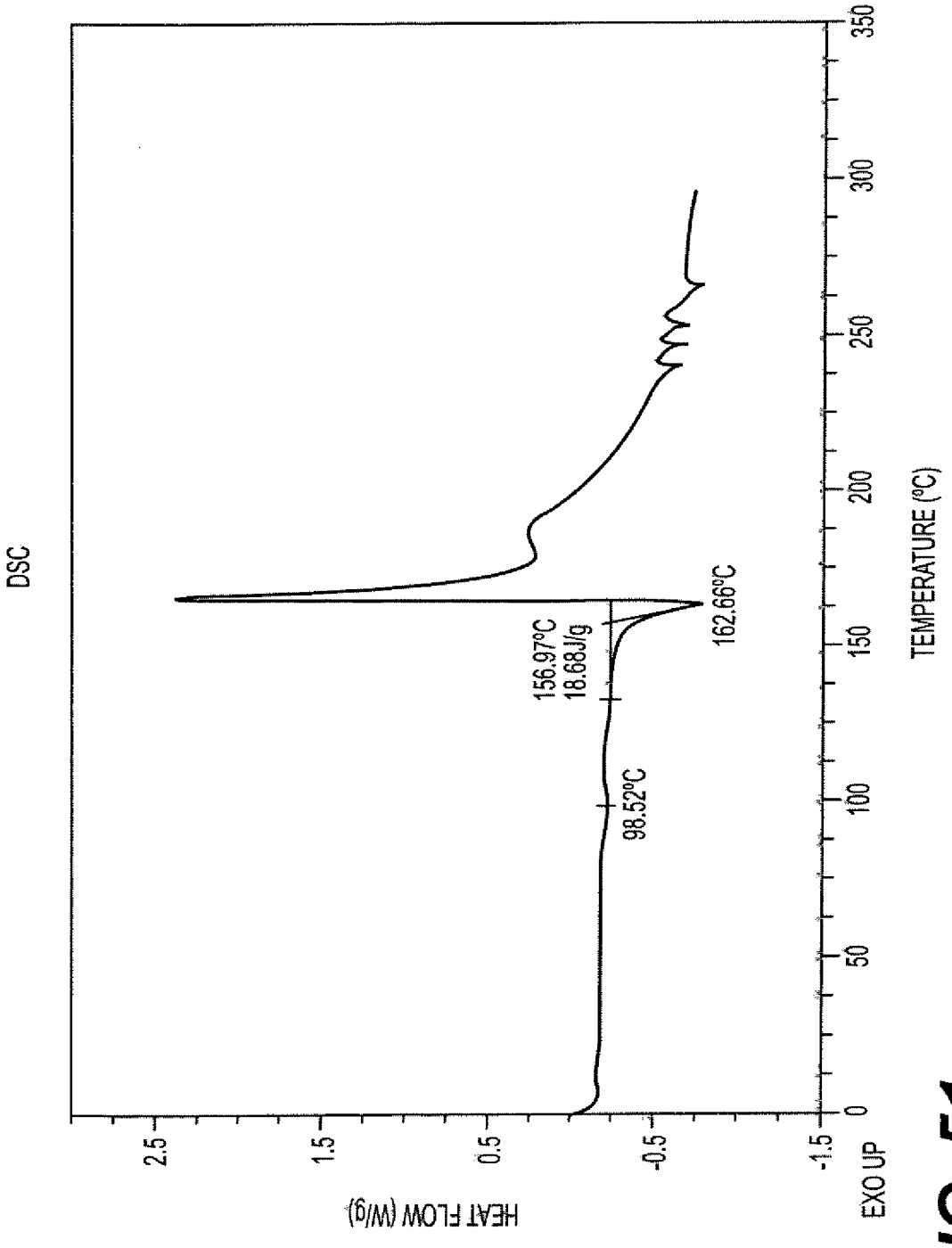

DSC
HEAT FLOW (W/g)
EXO UP
2.5
1.5
0.5
-0.5
-1.5
0
50
100
150
200
250
300
350
TEMPERATURE (°C)
156.97°C
18.68J/g
162.66°C
98.52°C

FIG. 51

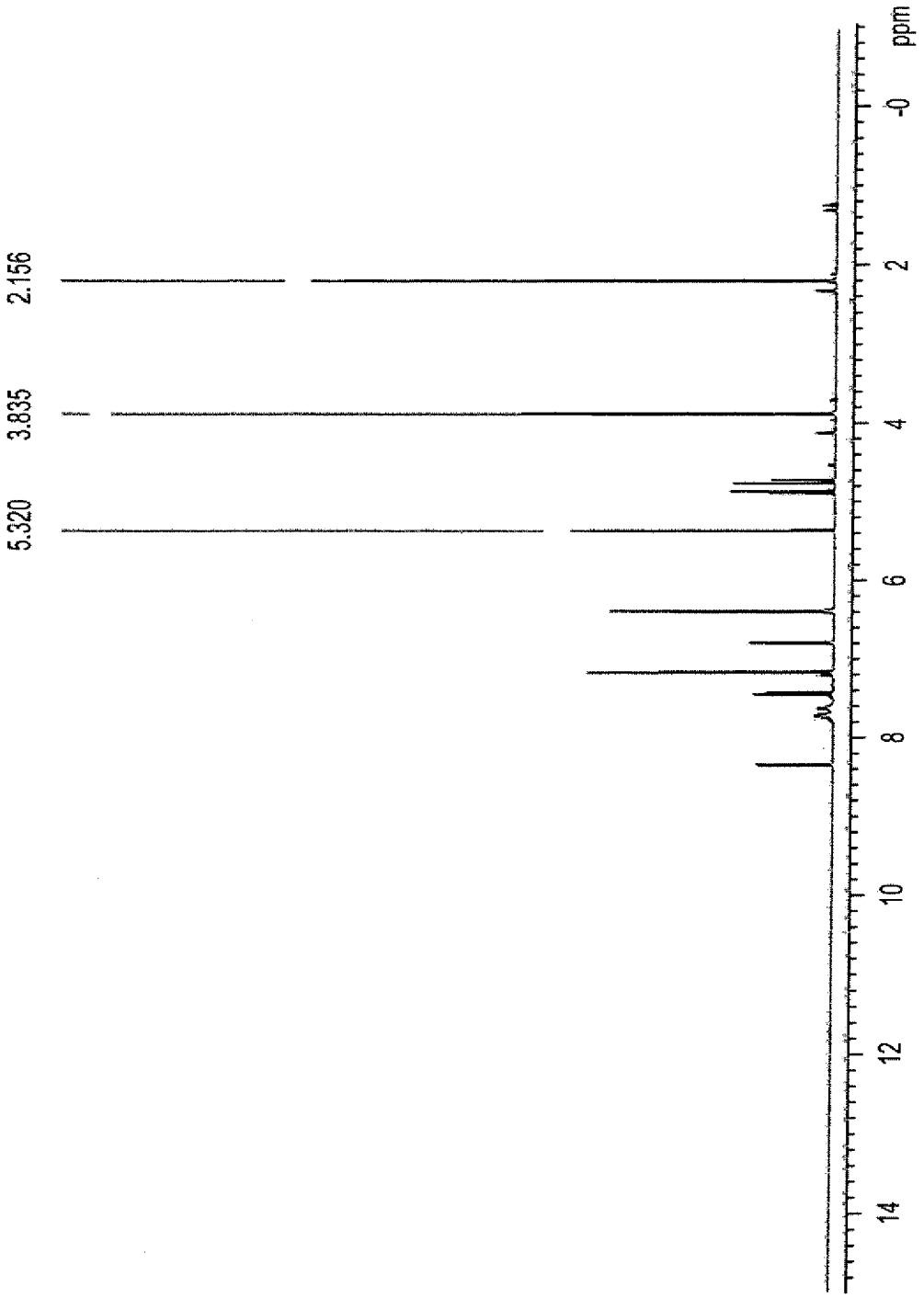


FIG. 52

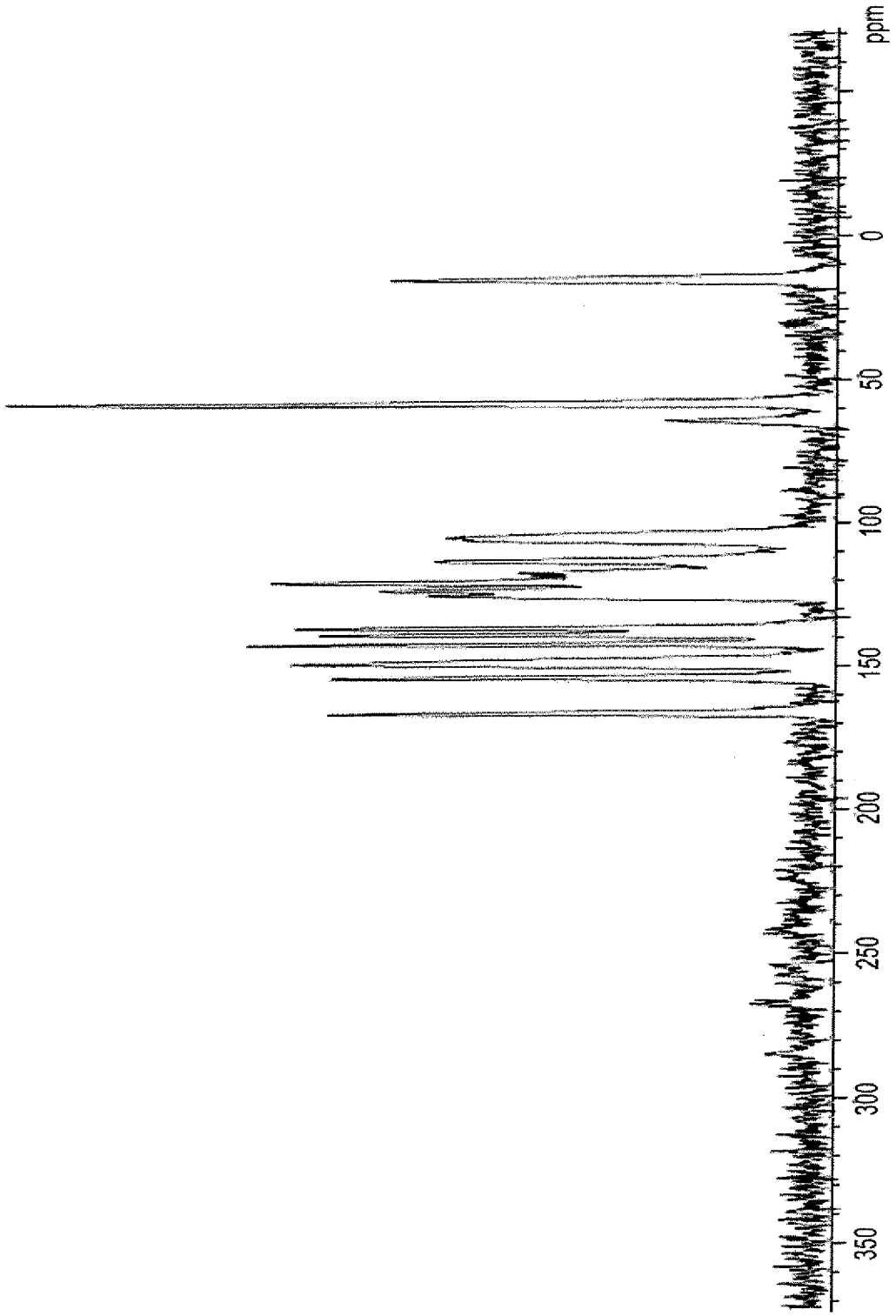


FIG. 53

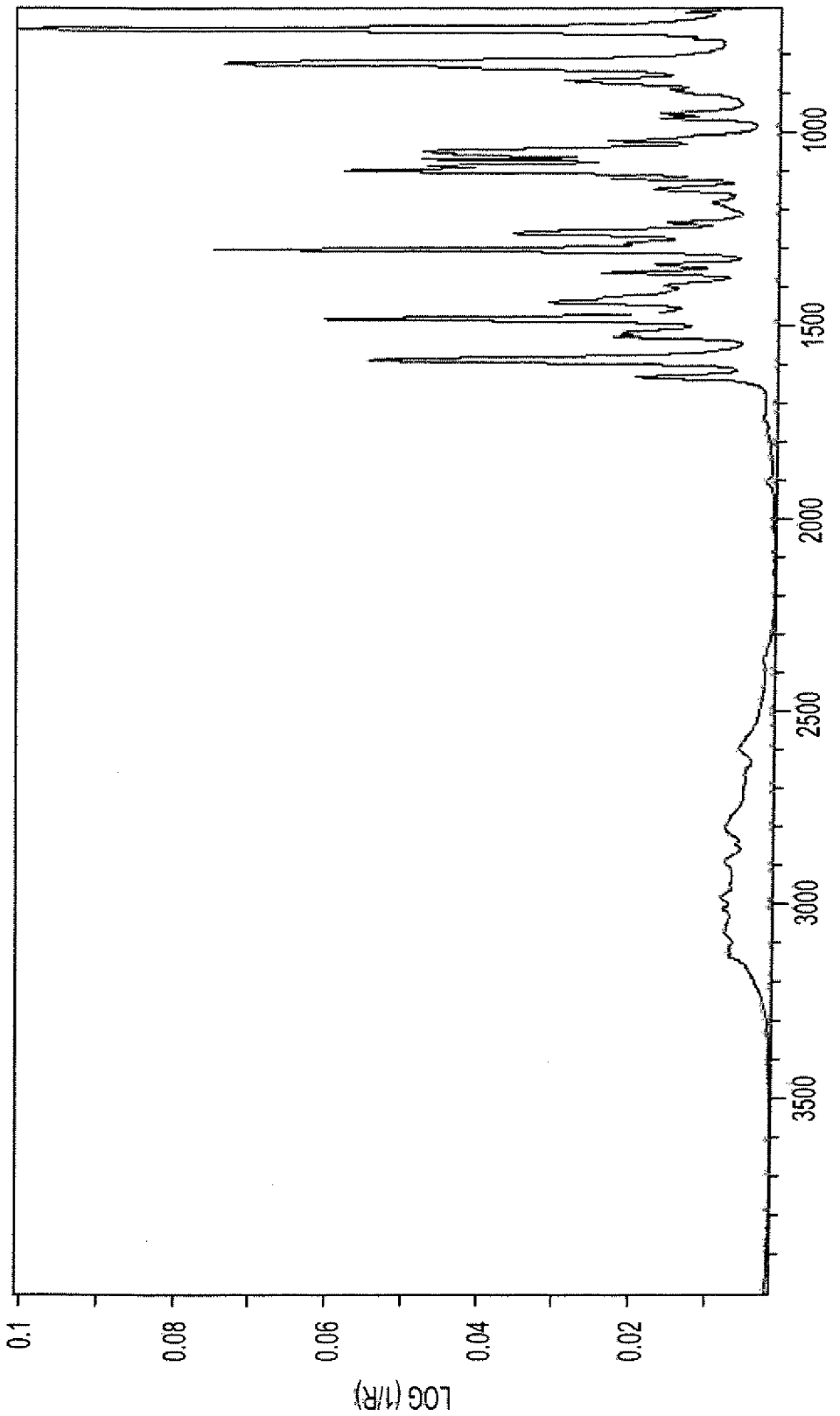

0.1
0.08
0.06
0.04
0.02
LOG (1/R)
3500
3000
2500
2000
1500
1000
WAVENUMBERS (1/cm)

FIG. 54

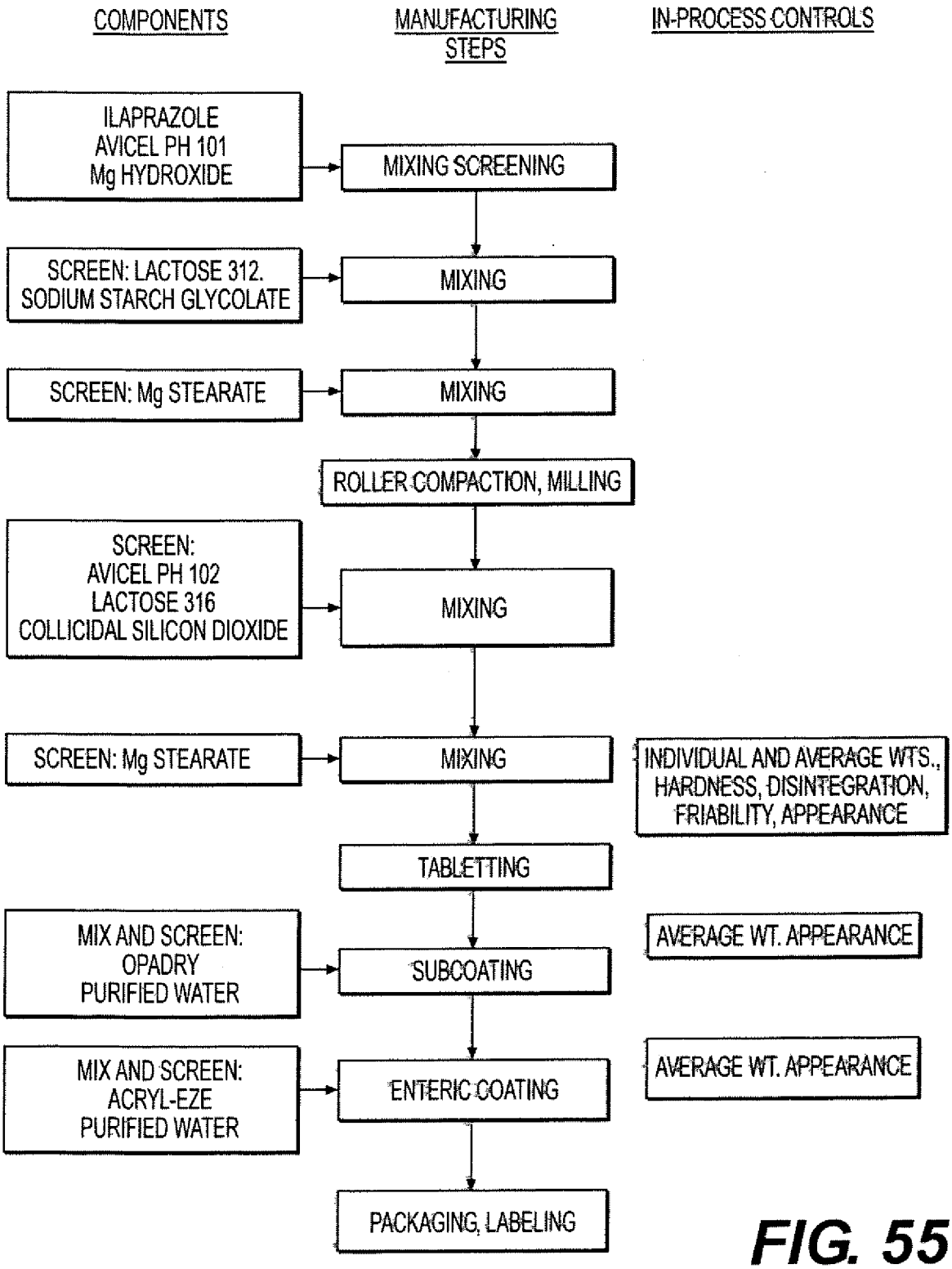

COMPONENTS
MANUFACTURING STEPS
IN-PROCESS CONTROLS
ILAPRAZOLE
AVICEL PH 101
Mg HYDROXIDE
MIXING SCREENING
SCREEN: LACTOSE 312.
SODIUM STARCH GLYCOLATE
MIXING
SCREEN: Mg STEARATE
MIXING
ROLLER COMPACTION, MILLING
SCREEN:
AVICEL PH 102
LACTOSE 316
COLLICIDAL SILICON DIOXIDE
MIXING
SCREEN: Mg STEARATE
MIXING
INDIVIDUAL AND AVERAGE WTS., HARDNESS, DISINTEGRATION, FRIABILITY, APPEARANCE
TABLETTING
MIX AND SCREEN:
OPADRY
PURIFIED WATER
SUBCOATING
AVERAGE WT. APPEARANCE
MIX AND SCREEN:
ACRYL-EZE
PURIFIED WATER
ENTERIC COATING
AVERAGE WT. APPEARANCE
PACKAGING, LABELING

FIG. 55

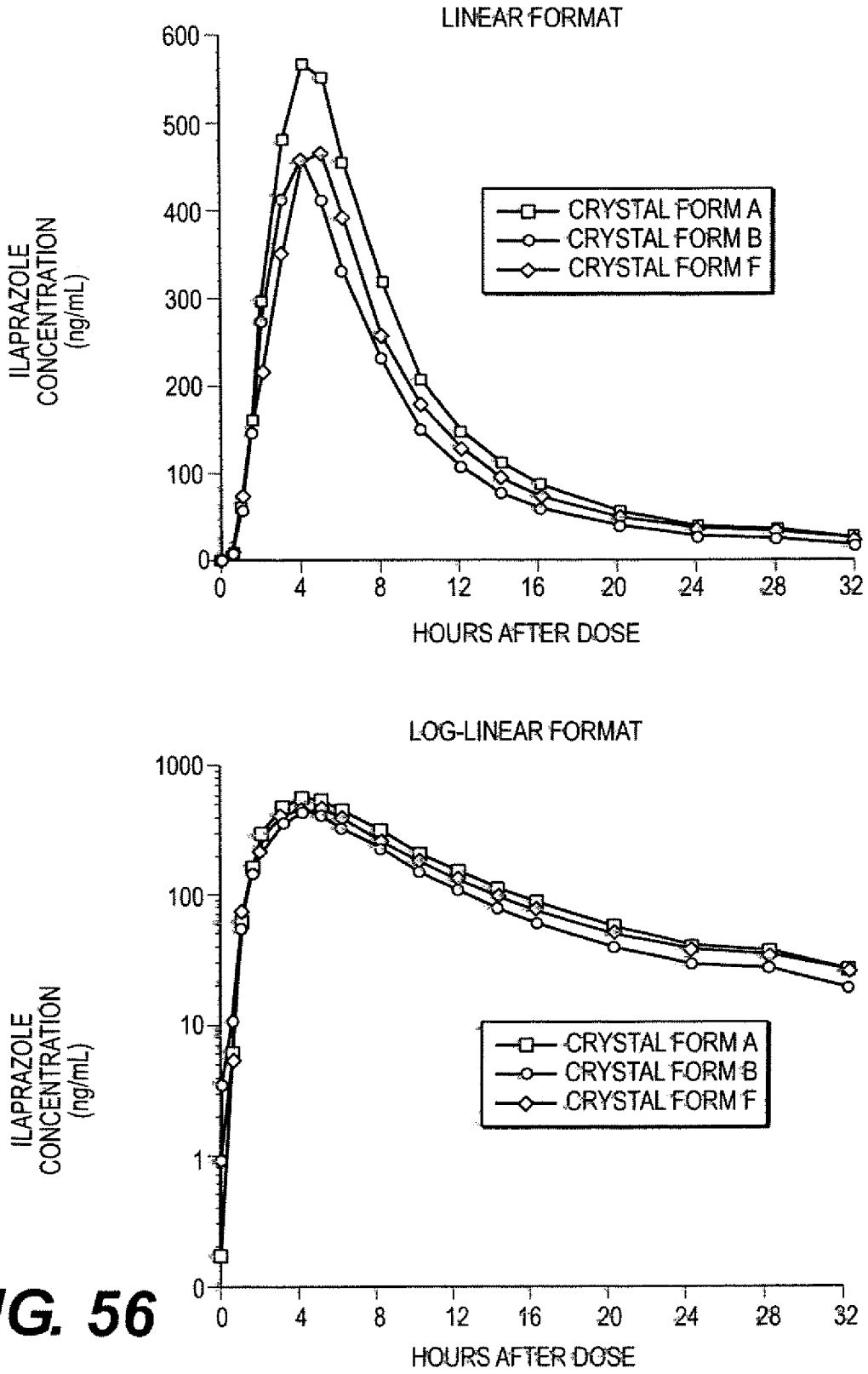

LINEAR FORMAT
ILAPRAZOLE CONCENTRATION (ng/mL)
600
500
400
300
200
100
0
0
4
8
12
16
20
24
28
32
HOURS AFTER DOSE
CRYSTAL FORM A
CRYSTAL FORM B
CRYSTAL FORM F
LOG-LINEAR FORMAT
ILAPRAZOLE CONCENTRATION (ng/mL)
1000
100
10
1
0
0
4
8
12
16
20
24
28
32
HOURS AFTER DOSE
CRYSTAL FORM A
CRYSTAL FORM B
CRYSTAL FORM F

FIG. 56

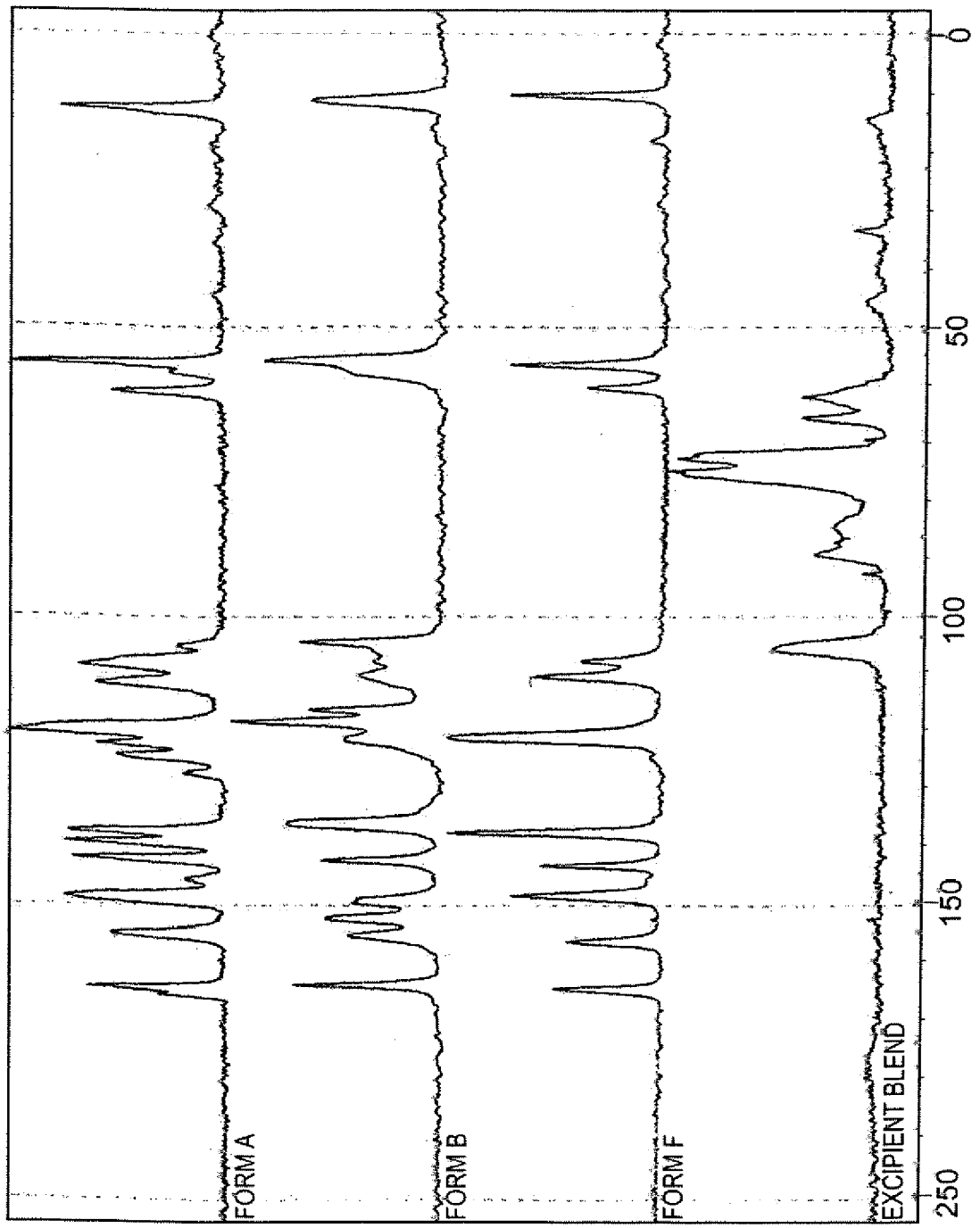


FIG. 57