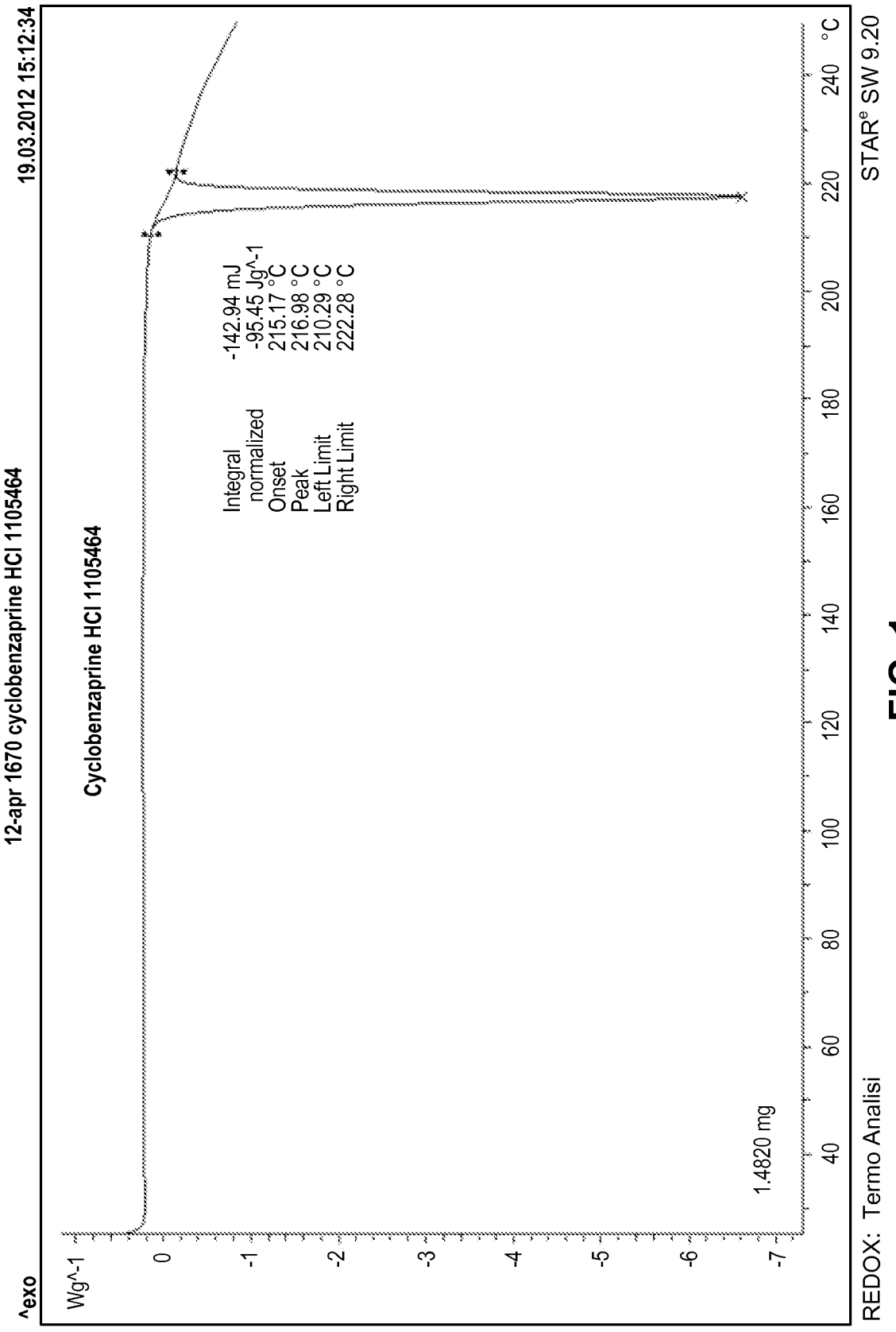

12-apr 1670 cyclobenzaprine HCl 1105464
19.03.2012 15:12:34
Cyclobenzaprine HCl 1105464
Integral -142.94 mJ
normalized -95.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
1.4820 mg
^exo
Wg^-1
0
-1
-2
-3
-4
-5
-6
-7
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 1

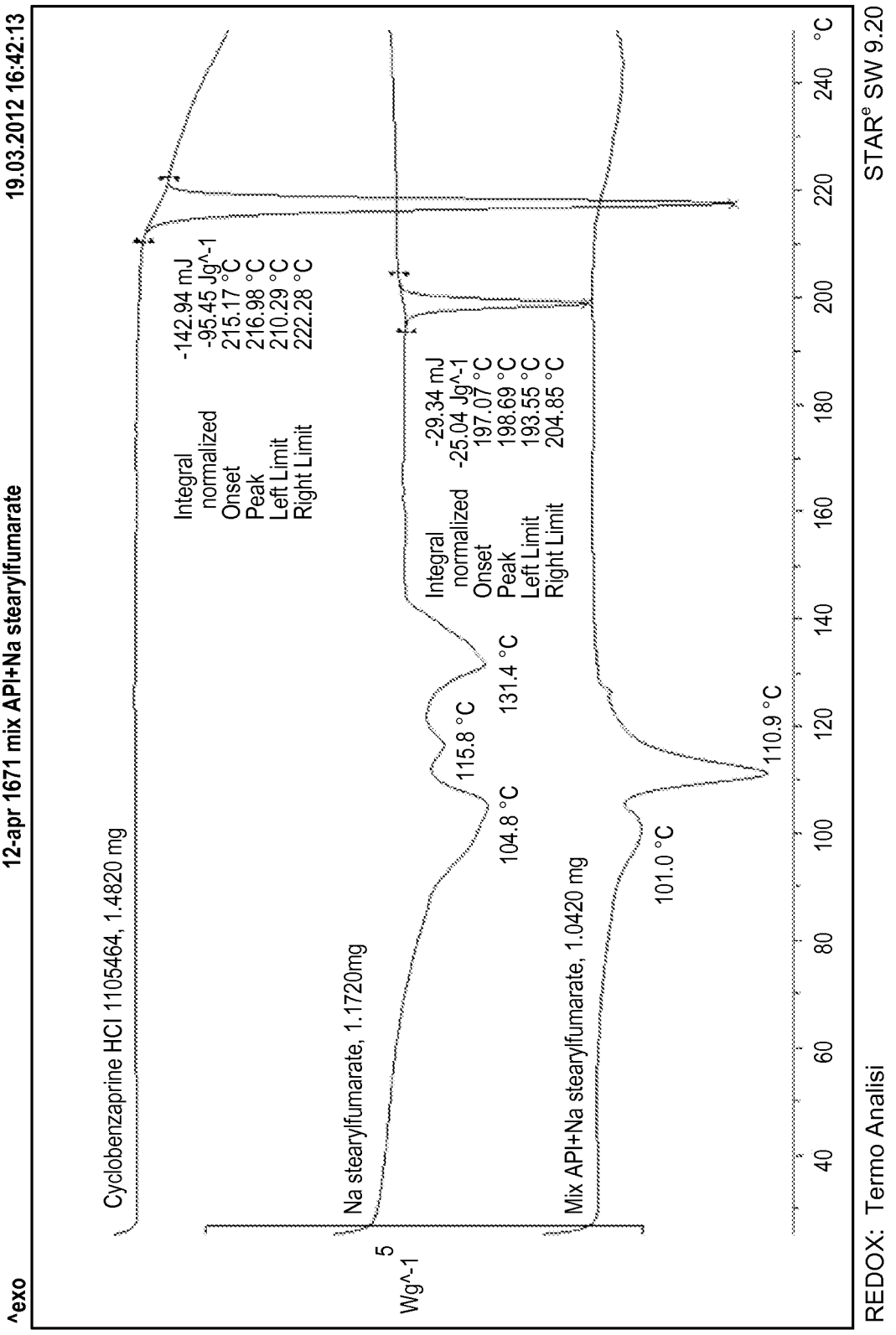

^exo
12-apr 1671 mix API+Na stearylfumarate
19.03.2012 16:42:13
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -95.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Na stearylfumarate, 1.1720mg
Integral -29.34 mJ
normalized -25.04 Jg^-1
Onset 197.07 °C
Peak 198.69 °C
Left Limit 193.55 °C
Right Limit 204.85 °C
115.8 °C
131.4 °C
104.8 °C
110.9 °C
101.0 °C
Mix API+Na stearylfumarate, 1.0420 mg
5
Wg^-1
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 2

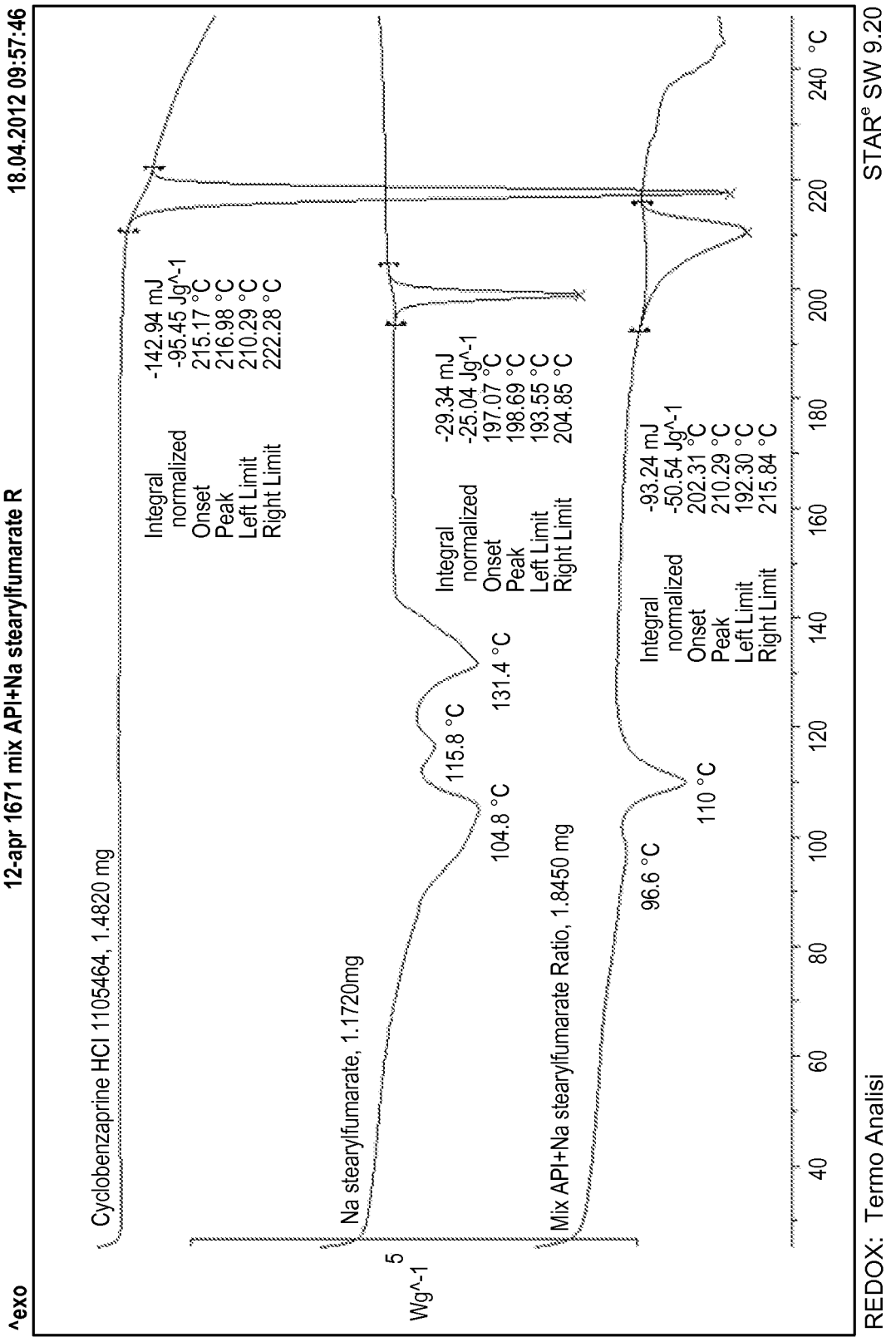

^exo
12-apr 1671 mix API+Na stearylfumarate R
18.04.2012 09:57:46
Cyclobenzaprine HCl 1105464, 1.4820 mg
Na stearylfumarate, 1.1720mg
Mix API+Na stearylfumarate Ratio, 1.8450 mg
Integral -142.94 mJ
normalized -95.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Integral -29.34 mJ
normalized -25.04 Jg^-1
Onset 197.07 °C
Peak 198.69 °C
Left Limit 193.55 °C
Right Limit 204.85 °C
Integral -93.24 mJ
normalized -50.54 Jg^-1
Onset 202.31 °C
Peak 210.29 °C
Left Limit 192.30 °C
Right Limit 215.84 °C
104.8 °C
115.8 °C
131.4 °C
96.6 °C
110 °C
5
Wg^-1
40
60
80
100
120
140
160
180
200
220
240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 3

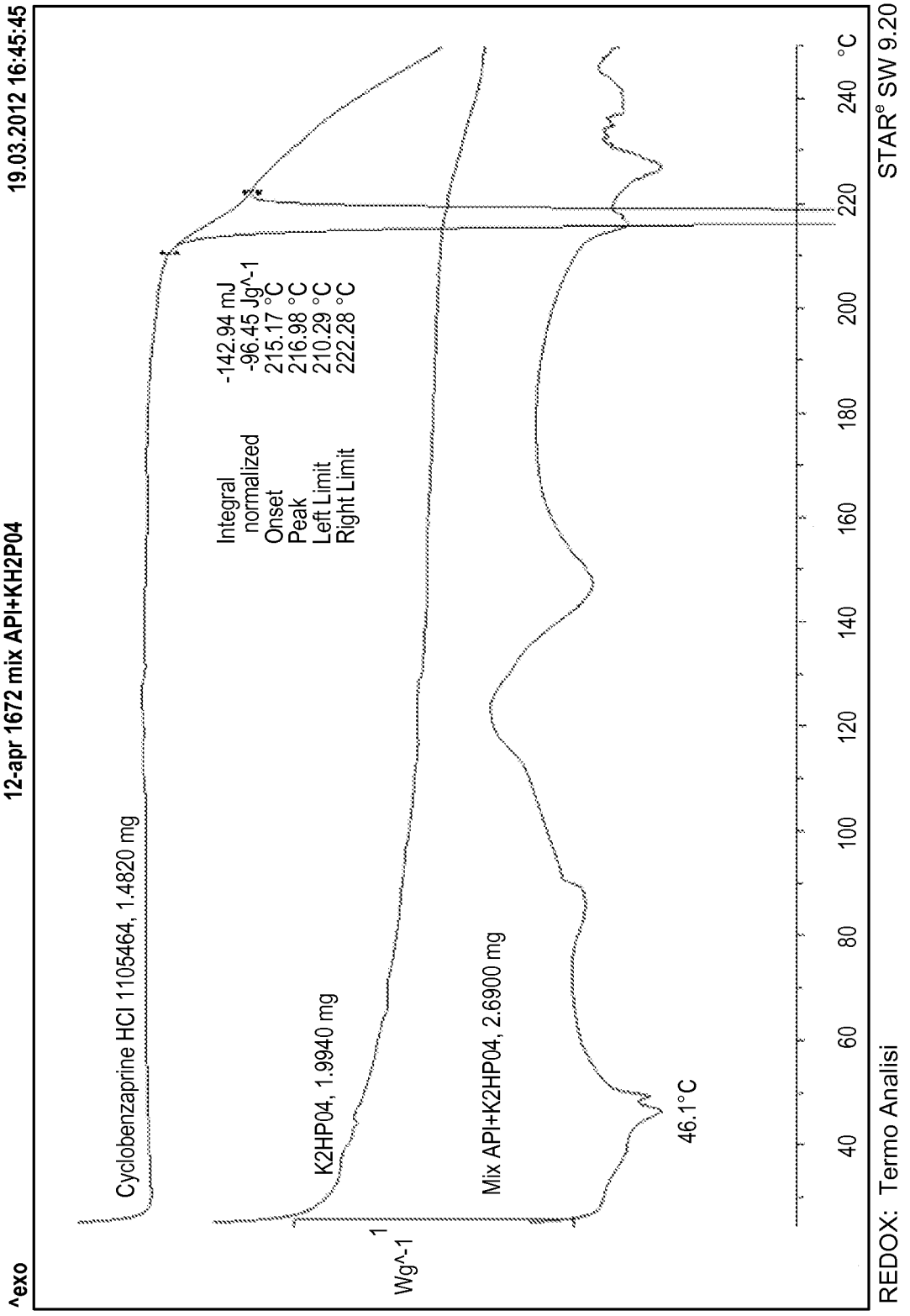

^exo
12-apr 1672 mix API+KH2P04
19.03.2012 16:45:45
Cyclobenzaprine HCl 1105464, 1.4820 mg
K2HP04, 1.9940 mg
Mix API+K2HP04, 2.6900 mg
46.1°C
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
1
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 4

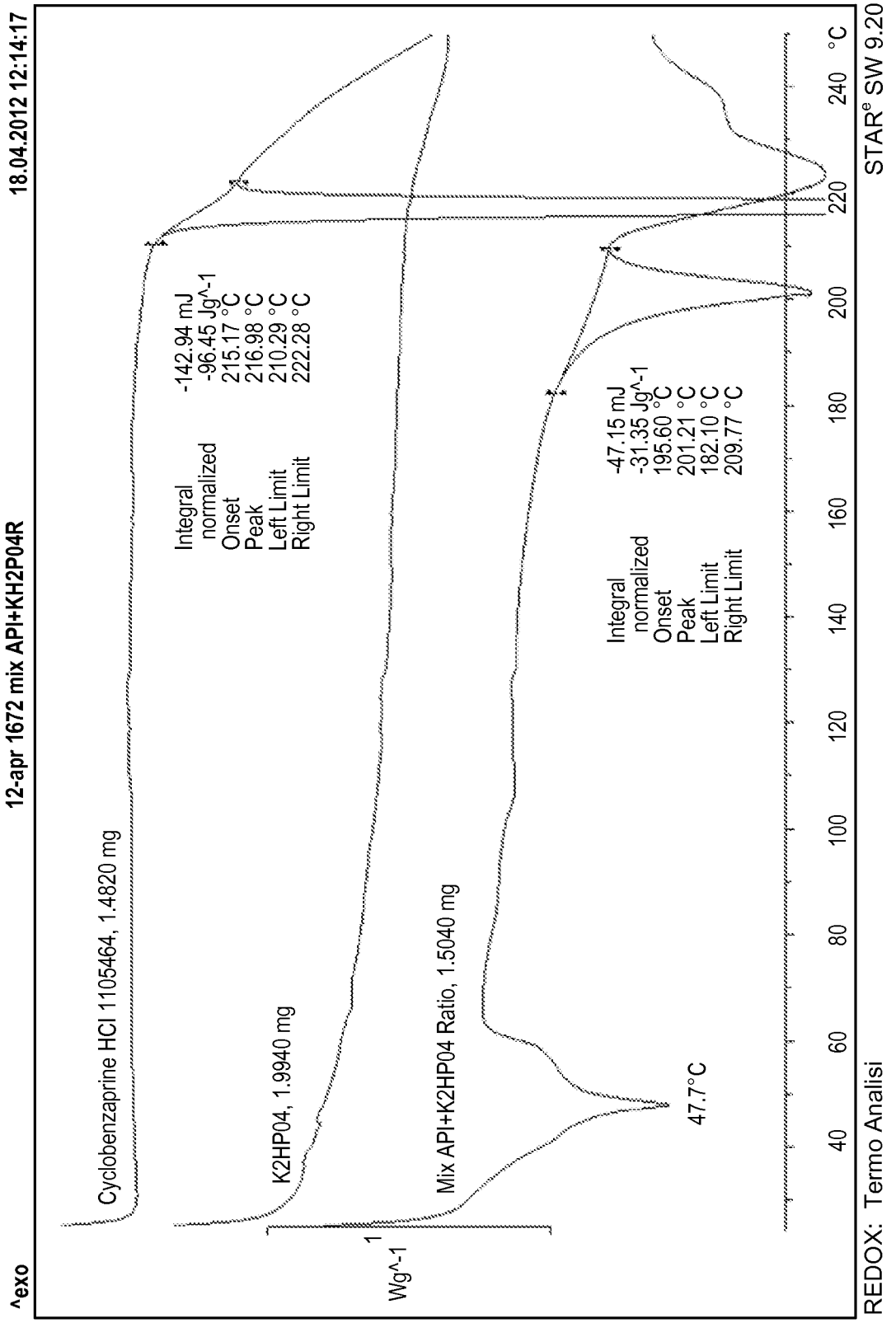

^exo
12-apr 1672 mix API+KH2P04R
18.04.2012 12:14:17
Cyclobenzaprine HCl 1105464, 1.4820 mg
K2HP04, 1.9940 mg
Mix API+K2HP04 Ratio, 1.5040 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Integral -47.15 mJ
normalized -31.35 Jg^-1
Onset 195.60 °C
Peak 201.21 °C
Left Limit 182.10 °C
Right Limit 209.77 °C
47.7°C
1
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 5

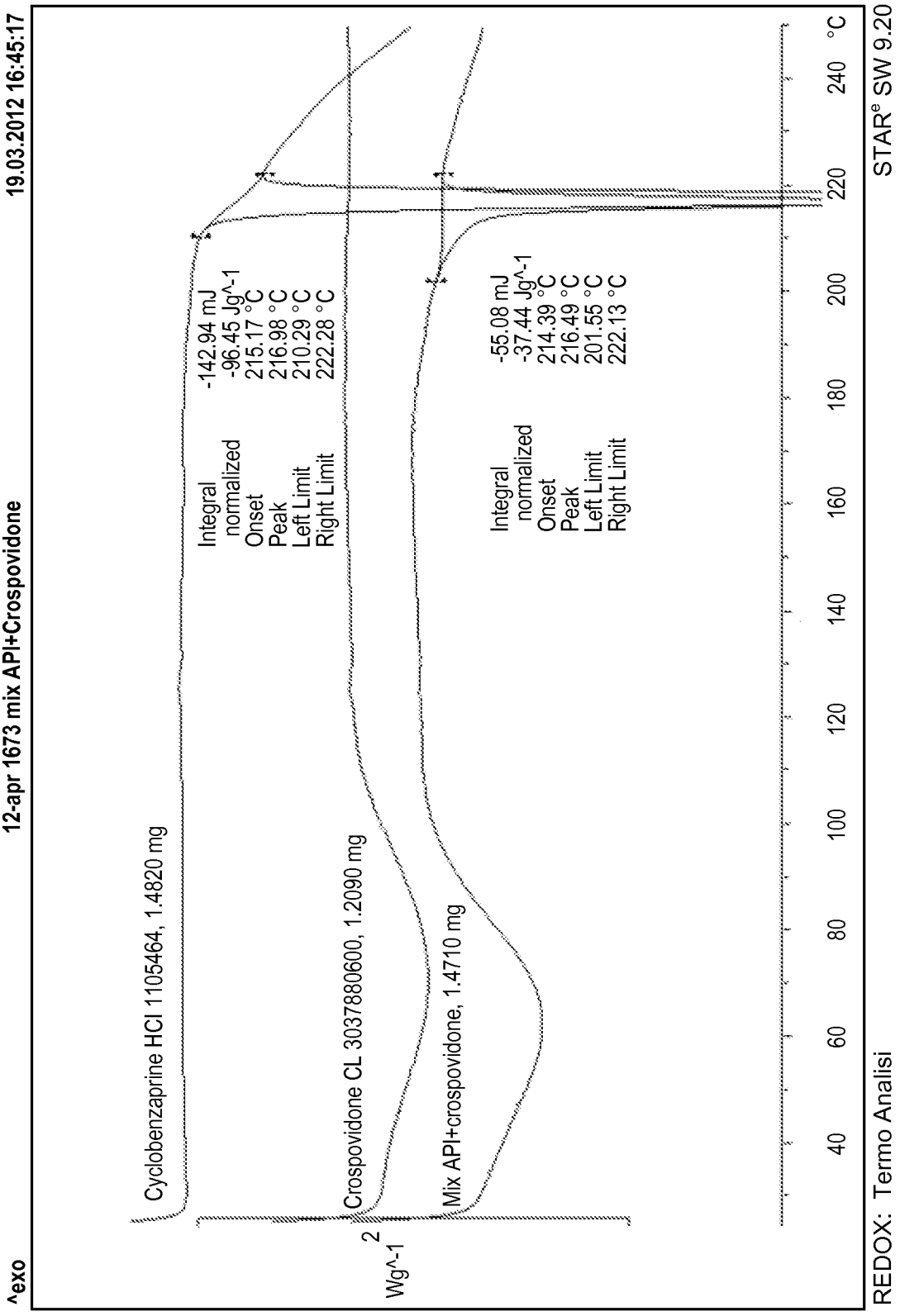

^exo
12-apr 1673 mix API+Crospovidone
19.03.2012 16:45:17
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Crospovidone CL 3037880600, 1.2090 mg
Mix API+crospovidone, 1.4710 mg
Integral -55.08 mJ
normalized -37.44 Jg^-1
Onset 214.39 °C
Peak 216.49 °C
Left Limit 201.55 °C
Right Limit 222.13 °C
2
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 6

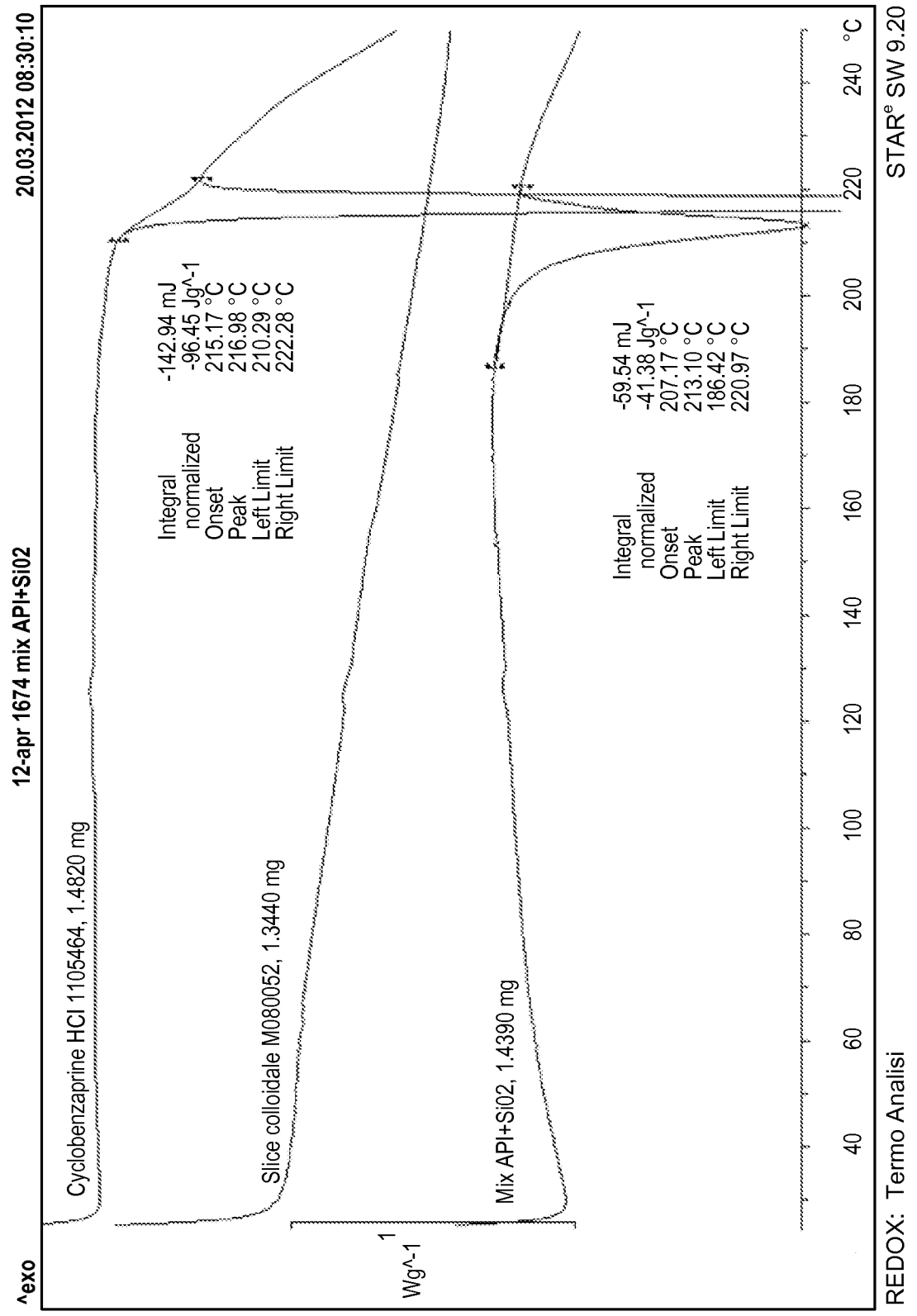

^exo
12-apr 1674 mix API+Si02
20.03.2012 08:30:10
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Slice colloidale M080052, 1.3440 mg
Mix API+Si02, 1.4390 mg
Integral -59.54 mJ
normalized -41.38 Jg^-1
Onset 207.17 °C
Peak 213.10 °C
Left Limit 186.42 °C
Right Limit 220.97 °C
1
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 7

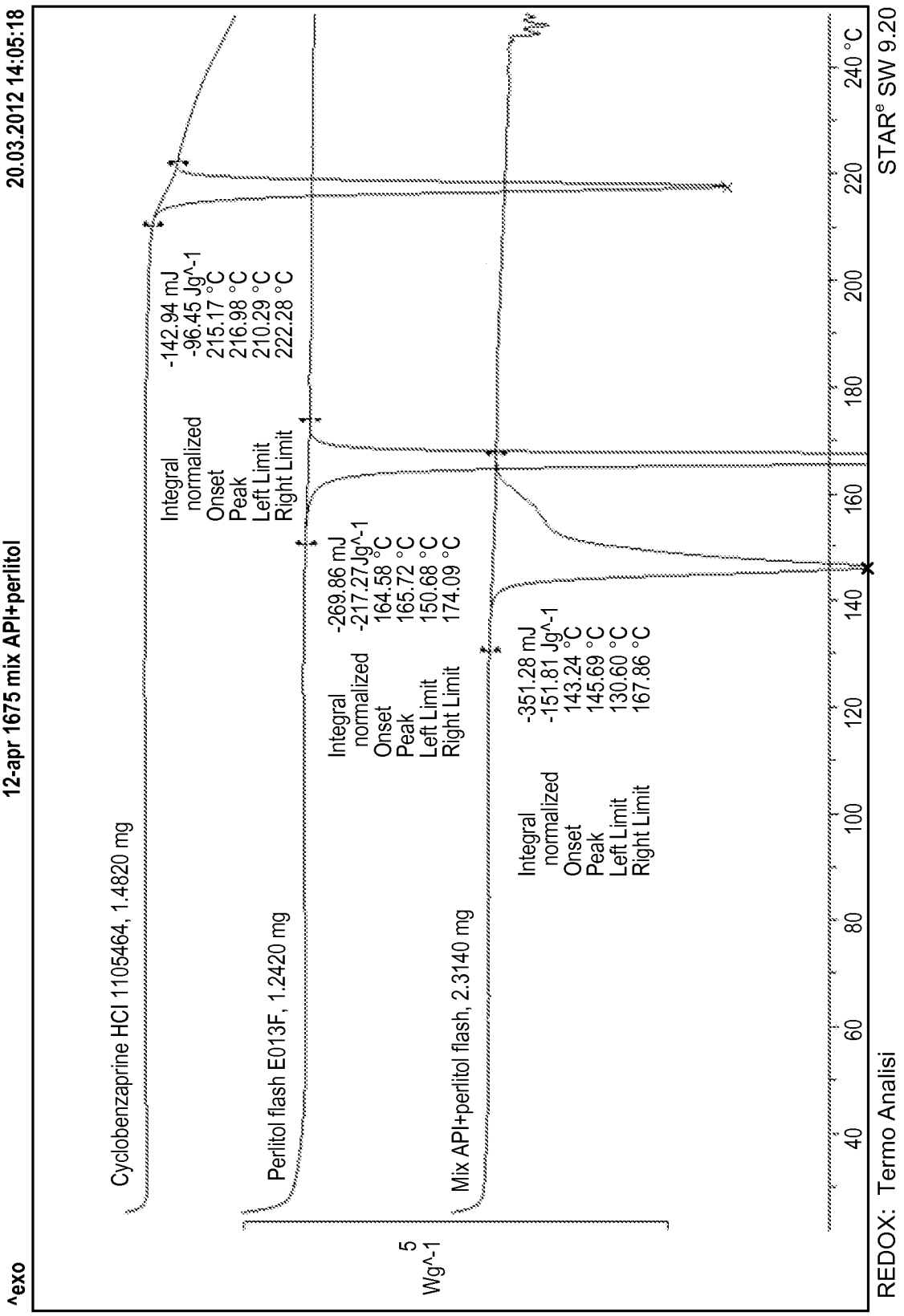

^exo
12-apr 1675 mix API+perlitol
20.03.2012 14:05:18
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Perlitol flash E013F, 1.2420 mg
Integral -269.86 mJ
normalized -217.27Jg^-1
Onset 164.58 °C
Peak 165.72 °C
Left Limit 150.68 °C
Right Limit 174.09 °C
Mix API+perlitol flash, 2.3140 mg
Integral -351.28 mJ
normalized -151.81 Jg^-1
Onset 143.24 °C
Peak 145.69 °C
Left Limit 130.60 °C
Right Limit 167.86 °C
5
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STAR^e SW 9.20

FIG. 8

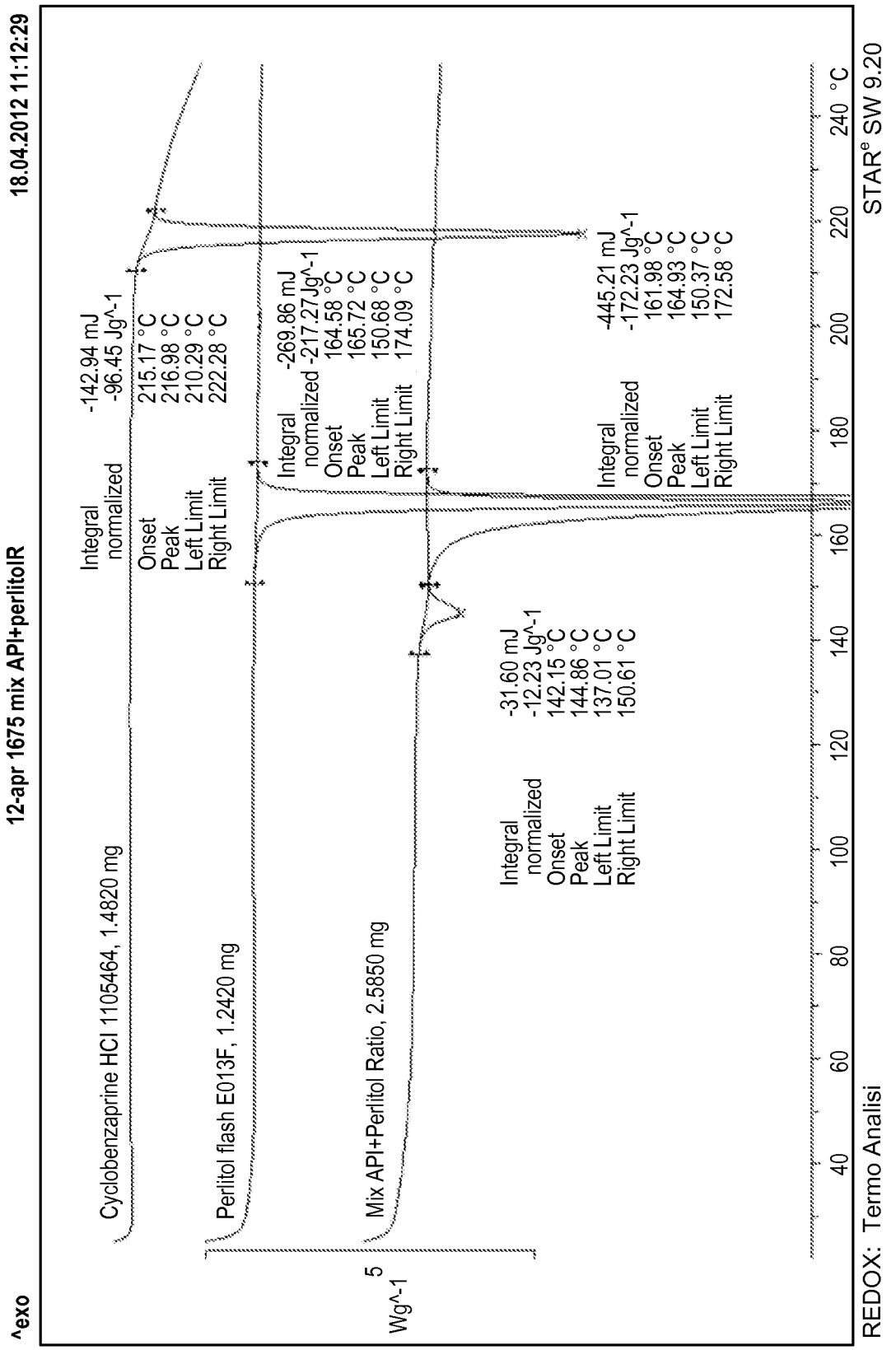

^exo
12-apr 1675 mix API+perlitolR
18.04.2012 11:12:29
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Perlitol flash E013F, 1.2420 mg
Integral -269.86 mJ
normalized -217.27 Jg^-1
Onset 164.58 °C
Peak 165.72 °C
Left Limit 150.68 °C
Right Limit 174.09 °C
Mix API+Perlitol Ratio, 2.5850 mg
Integral -31.60 mJ
normalized -12.23 Jg^-1
Onset 142.15 °C
Peak 144.86 °C
Left Limit 137.01 °C
Right Limit 150.61 °C
Integral -445.21 mJ
normalized -172.23 Jg^-1
Onset 161.98 °C
Peak 164.93 °C
Left Limit 150.37 °C
Right Limit 172.58 °C
5
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 9

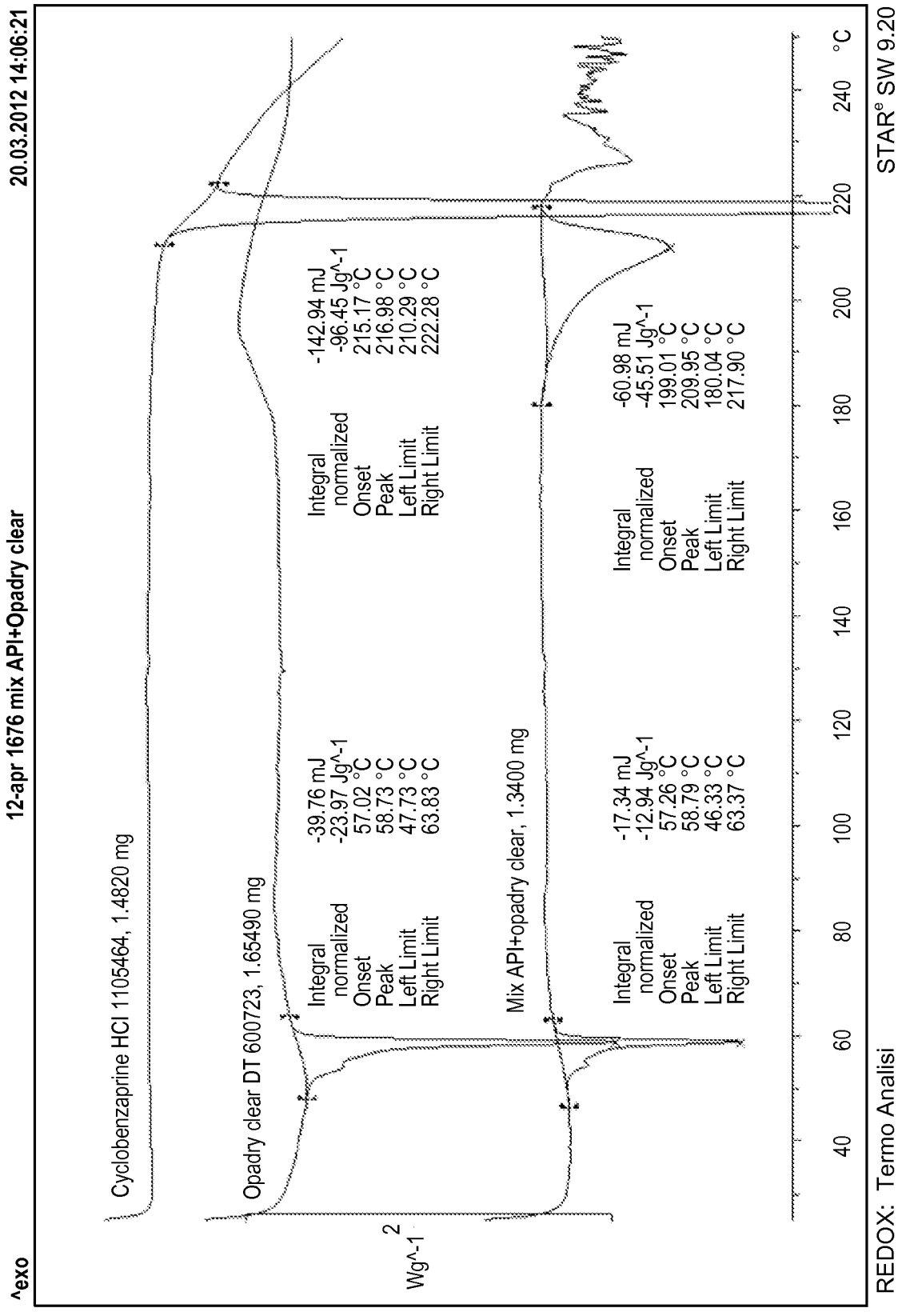

^exo
12-apr 1676 mix API+Opadry clear
20.03.2012 14:06:21
Cyclobenzaprine HCl 1105464, 1.4820 mg
Opadry clear DT 600723, 1.65490 mg
Integral -39.76 mJ
normalized -23.97 Jg^-1
Onset 57.02 °C
Peak 58.73 °C
Left Limit 47.73 °C
Right Limit 63.83 °C
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Mix API+opadry clear, 1.3400 mg
Integral -17.34 mJ
normalized -12.94 Jg^-1
Onset 57.26 °C
Peak 58.79 °C
Left Limit 46.33 °C
Right Limit 63.37 °C
Integral -60.98 mJ
normalized -45.51 Jg^-1
Onset 199.01 °C
Peak 209.95 °C
Left Limit 180.04 °C
Right Limit 217.90 °C
2
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 10

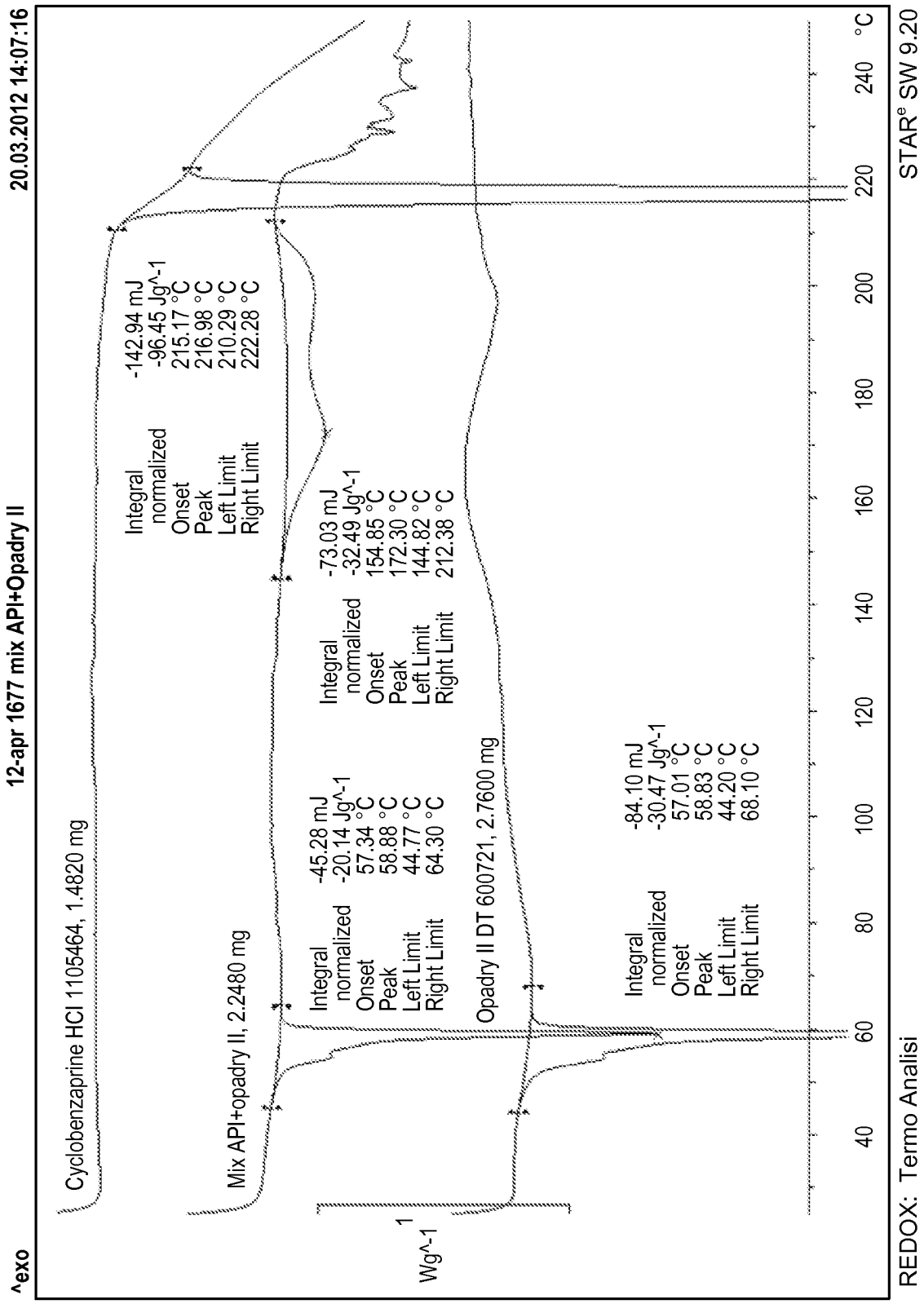

^exo
12-apr 1677 mix API+Opadry II
20.03.2012 14:07:16
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Mix API+opadry II, 2.2480 mg
Integral -73.03 mJ
normalized -32.49 Jg^-1
Onset 154.85 °C
Peak 172.30 °C
Left Limit 144.82 °C
Right Limit 212.38 °C
Integral -45.28 mJ
normalized -20.14 Jg^-1
Onset 57.34 °C
Peak 58.88 °C
Left Limit 44.77 °C
Right Limit 64.30 °C
Opadry II DT 600721, 2.7600 mg
Integral -84.10 mJ
normalized -30.47 Jg^-1
Onset 57.01 °C
Peak 58.83 °C
Left Limit 44.20 °C
Right Limit 68.10 °C
Wg^-1
1
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 11

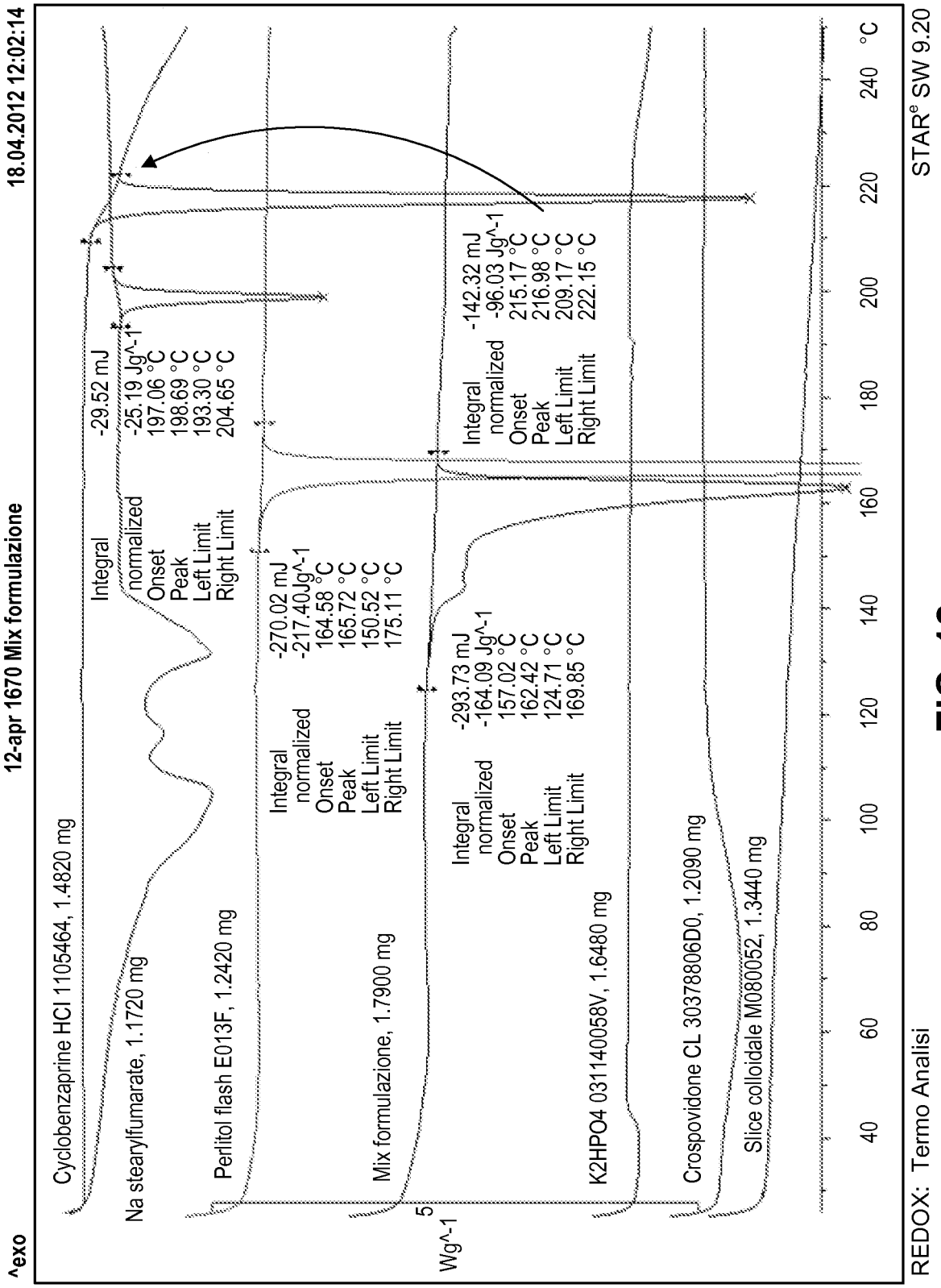

^exo
12-apr 1670 Mix formulazione
18.04.2012 12:02:14
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -29.52 mJ
normalized -25.19 Jg^-1
Onset 197.06 °C
Peak 198.69 °C
Left Limit 193.30 °C
Right Limit 204.65 °C
Na stearylfumarate, 1.1720 mg
Perlitol flash E013F, 1.2420 mg
Integral -270.02 mJ
normalized -217.40Jg^-1
Onset 164.58 °C
Peak 165.72 °C
Left Limit 150.52 °C
Right Limit 175.11 °C
Mix formulazione, 1.7900 mg
Integral -142.32 mJ
normalized -96.03 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 209.17 °C
Right Limit 222.15 °C
Integral -293.73 mJ
normalized -164.09 Jg^-1
Onset 157.02 °C
Peak 162.42 °C
Left Limit 124.71 °C
Right Limit 169.85 °C
K2HPO4 031140058V, 1.6480 mg
Crospovidone CL 30378806D0, 1.2090 mg
Slice colloidale M080052, 1.3440 mg
5
Wg^-1
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 12

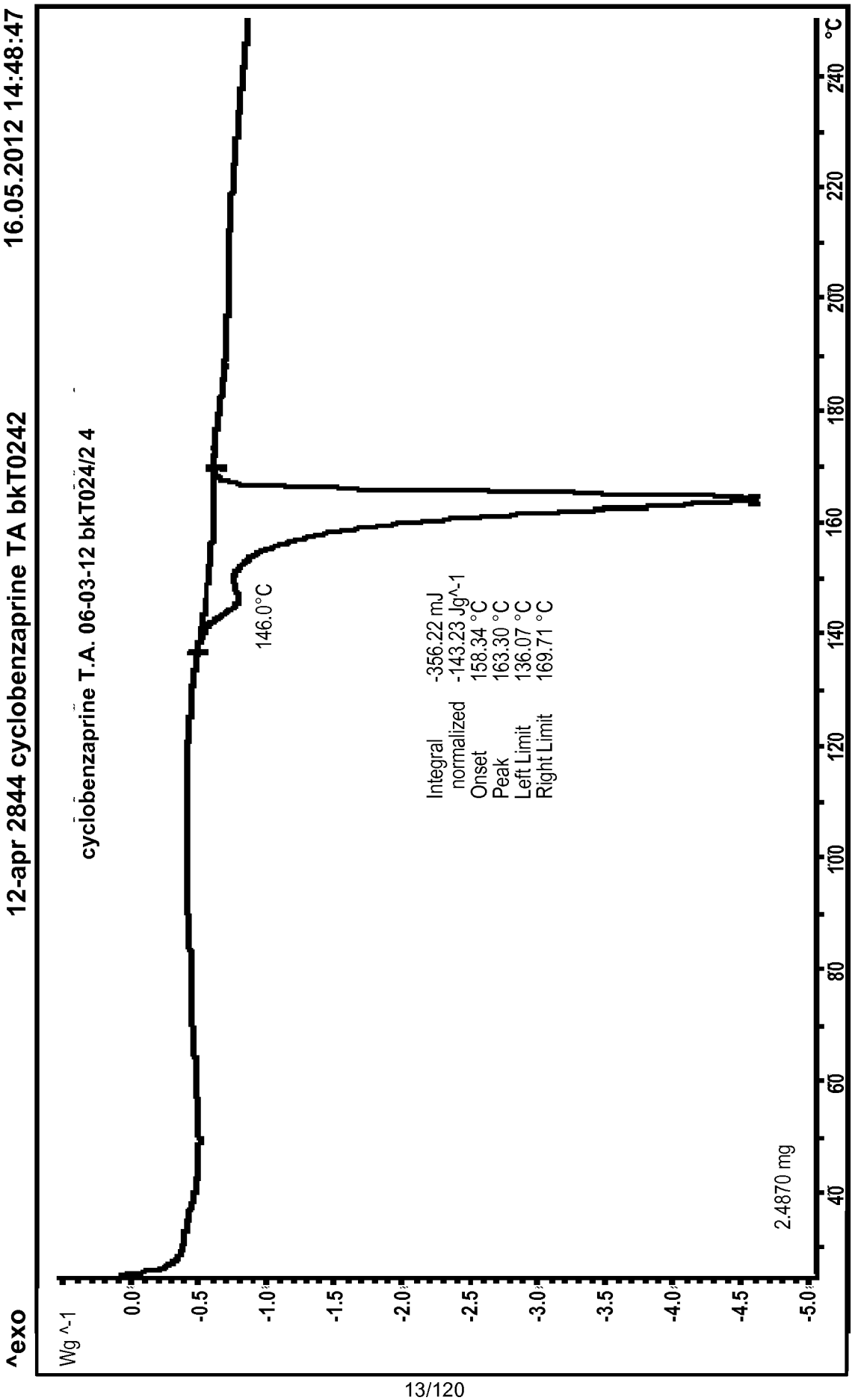

^exo
12-apr 2844 cyclobenzaprine TA bkT0242
16.05.2012 14:48:47
cyclobenzaprine T.A. 06-03-12 bkT024/2 4
146.0°C
Integral -356.22 mJ
normalized -143.23 Jg^-1
Onset 158.34 °C
Peak 163.30 °C
Left Limit 136.07 °C
Right Limit 169.71 °C
2.4870 mg
Wg ^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
-4.5
-5.0
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 13

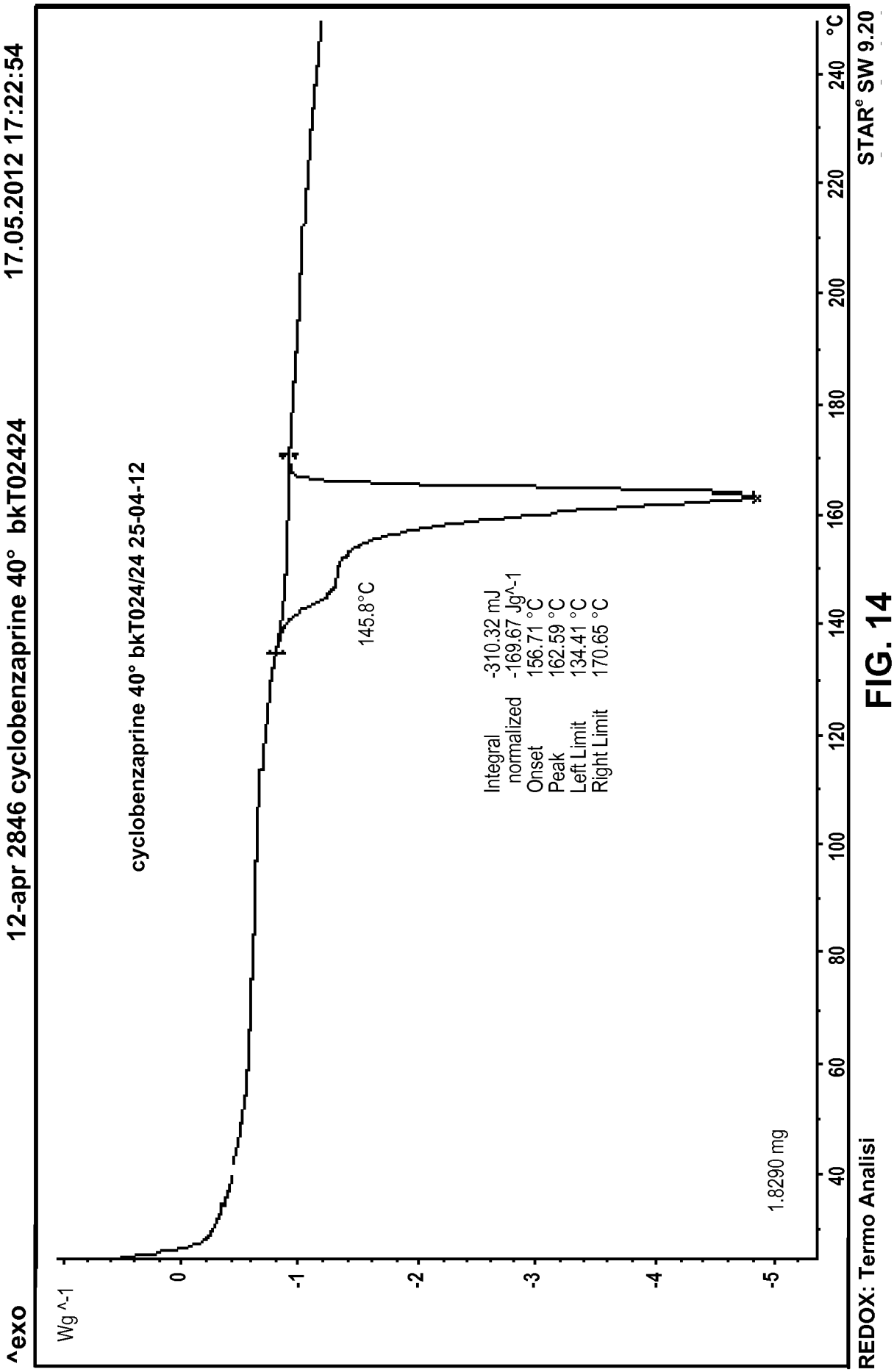

^exo
12-apr 2846 cyclobenzaprine 40° bkT02424 17.05.2012 17:22:54
cyclobenzaprine 40° bkT024/24 25-04-12
Wg ^-1
0
-1
-2
-3
-4
-5
40
60
80
100
120
140
160
180
200
220
240
°C
145.8°C
Integral -310.32 mJ
normalized -169.67 Jg^-1
Onset 156.71 °C
Peak 162.59 °C
Left Limit 134.41 °C
Right Limit 170.65 °C
1.8290 mg
REDOX: Termo Analisi
STARe SW 9.20

FIG. 14

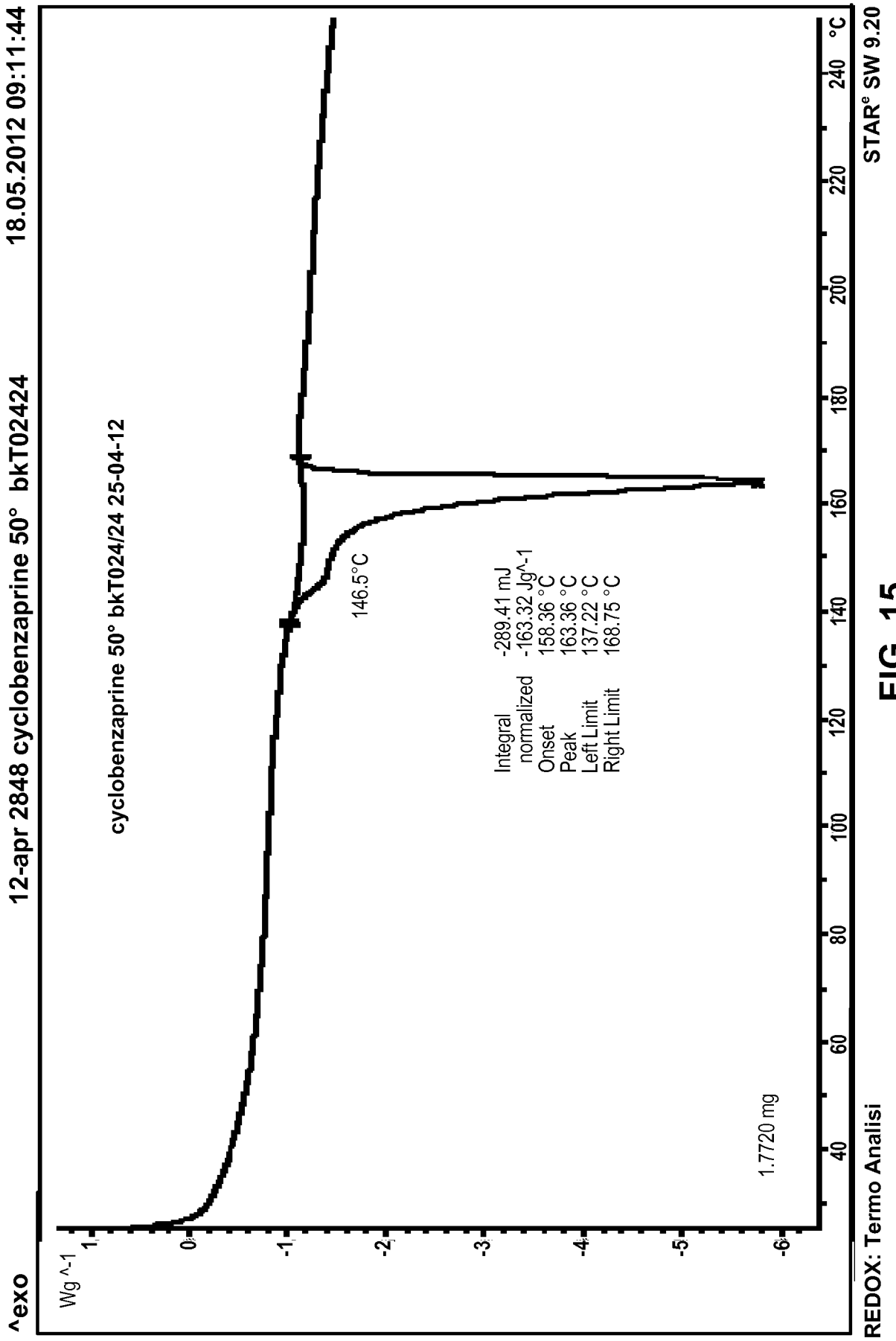

^exo
12-apr 2848 cyclobenzaprine 50° bkT02424
18.05.2012 09:11:44
cyclobenzaprine 50° bkT024/24 25-04-12
146.5°C
Integral -289.41 mJ
normalized -163.32 Jg^-1
Onset 158.36 °C
Peak 163.36 °C
Left Limit 137.22 °C
Right Limit 168.75 °C
1.7720 mg
Wg ^-1
1
0
-1
-2
-3
-4
-5
-6
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 15

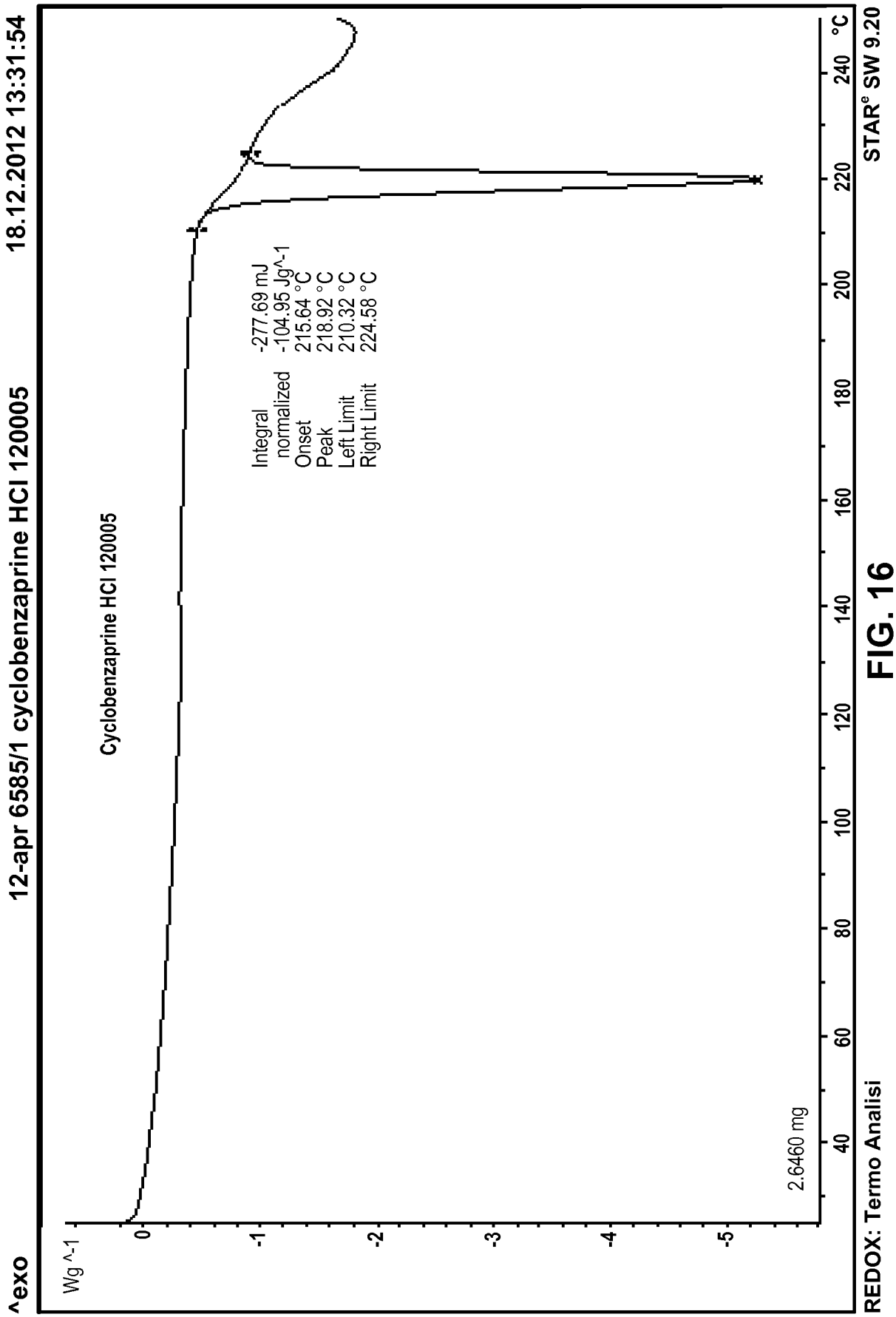

^exo
12-apr 6585/1 cyclobenzaprine HCl 120005
18.12.2012 13:31:54
Cyclobenzaprine HCl 120005
Integral -277.69 mJ
normalized -104.95 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.32 °C
Right Limit 224.58 °C
Wg ^-1
0
-1
-2
-3
-4
-5
2.6460 mg
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 16

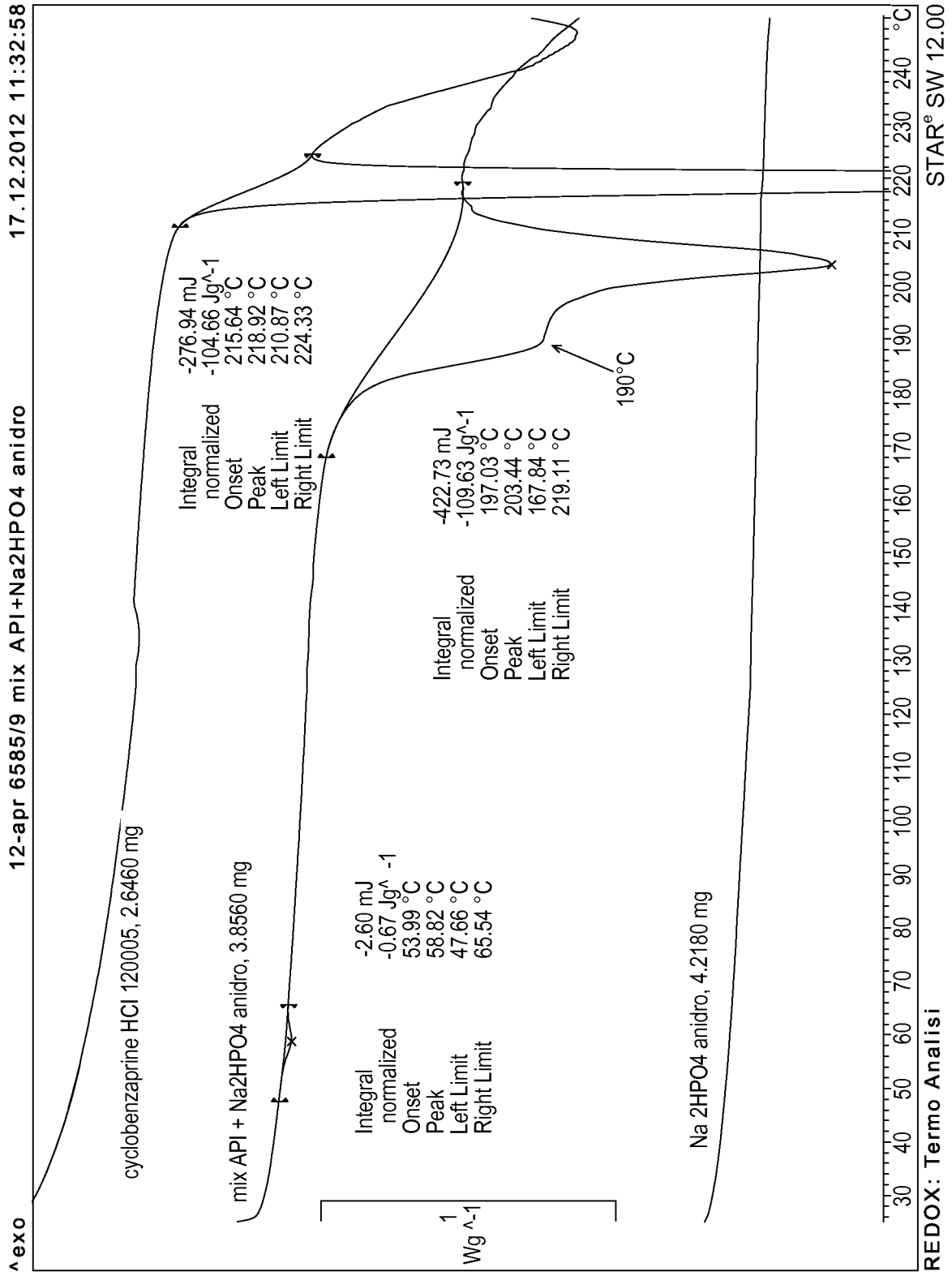

^exo
12-apr 6585/9 mix API+Na2HPO4 anidro
17.12.2012 11:32:58
cyclobenzaprine HCl 120005, 2.6460 mg
mix API + Na2HPO4 anidro, 3.8560 mg
Na 2HPO4 anidro, 4.2180 mg
Integral -276.94 mJ
normalized -104.66 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.87 °C
Right Limit 224.33 °C
Integral -422.73 mJ
normalized -109.63 Jg^-1
Onset 197.03 °C
Peak 203.44 °C
Left Limit 167.84 °C
Right Limit 219.11 °C
Integral -2.60 mJ
normalized -0.67 Jg^ -1
Onset 53.99 °C
Peak 58.82 °C
Left Limit 47.66 °C
Right Limit 65.54 °C
190°C
1
Wg ^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 17

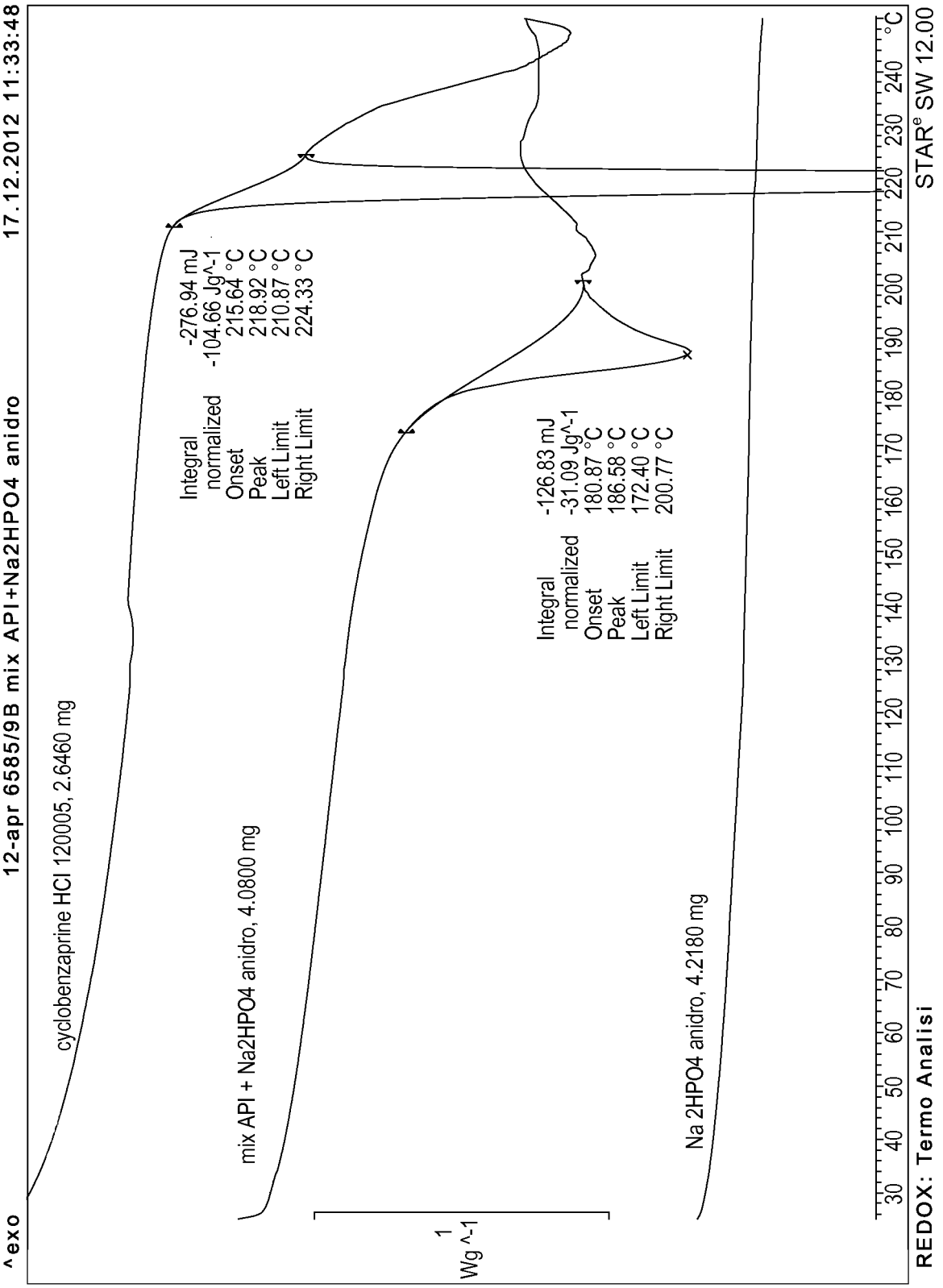

^exo
12-apr 6585/9B mix API+Na2HPO4 anidro
17.12.2012 11:33:48
cyclobenzaprine HCl 120005, 2.6460 mg
mix API + Na2HPO4 anidro, 4.0800 mg
Integral -276.94 mJ
normalized -104.66 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.87 °C
Right Limit 224.33 °C
Integral -126.83 mJ
normalized -31.09 Jg^-1
Onset 180.87 °C
Peak 186.58 °C
Left Limit 172.40 °C
Right Limit 200.77 °C
Na 2HPO4 anidro, 4.2180 mg
1
Wg ^-1
REDOX: Termo Analisi
STARe SW 12.00
°C

FIG. 18

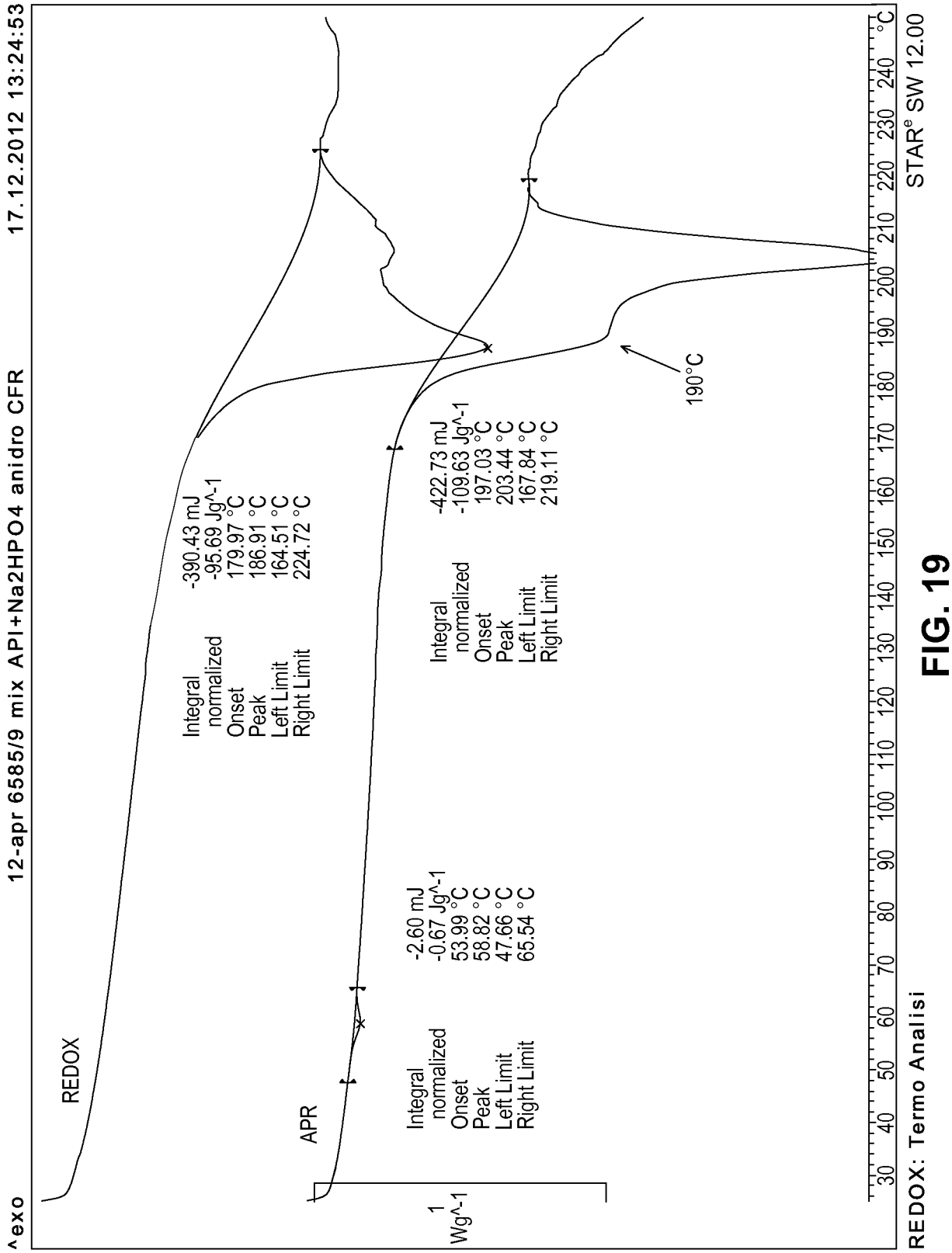

^exo
12-apr 6585/9 mix API+Na2HPO4 anidro CFR
17.12.2012 13:24:53
REDOX
APR
Integral -390.43 mJ
normalized -95.69 Jg^-1
Onset 179.97 °C
Peak 186.91 °C
Left Limit 164.51 °C
Right Limit 224.72 °C
Integral -422.73 mJ
normalized -109.63 Jg^-1
Onset 197.03 °C
Peak 203.44 °C
Left Limit 167.84 °C
Right Limit 219.11 °C
Integral -2.60 mJ
normalized -0.67 Jg^-1
Onset 53.99 °C
Peak 58.82 °C
Left Limit 47.66 °C
Right Limit 65.54 °C
190°C
1
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 19

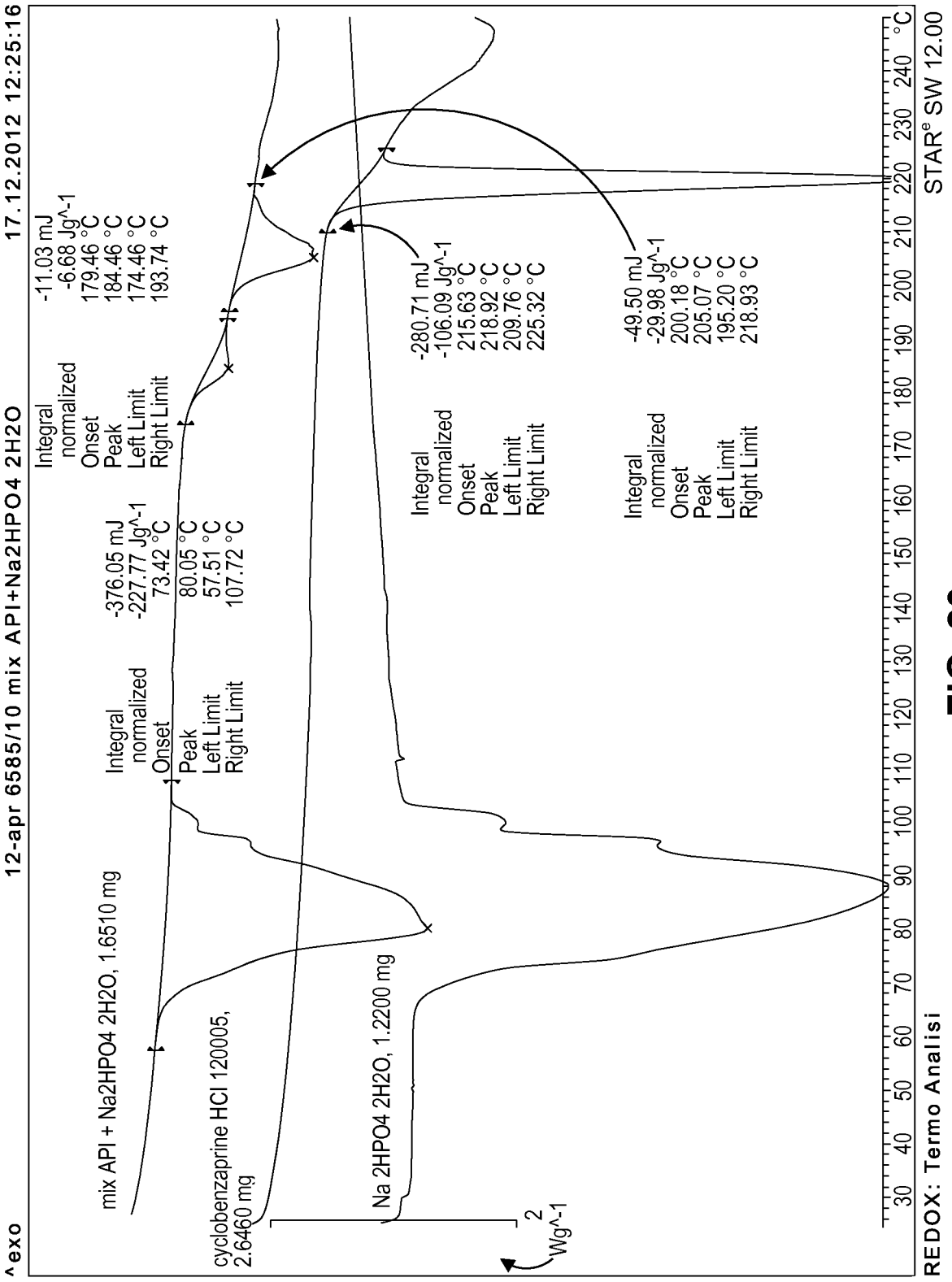

^exo
12-apr 6585/10 mix API+Na2HPO4 2H2O
17.12.2012 12:25:16
mix API + Na2HPO4 2H2O, 1.6510 mg
Integral -376.05 mJ
normalized -227.77 Jg^-1
Onset 73.42 °C
Peak 80.05 °C
Left Limit 57.51 °C
Right Limit 107.72 °C
Integral -11.03 mJ
normalized -6.68 Jg^-1
Onset 179.46 °C
Peak 184.46 °C
Left Limit 174.46 °C
Right Limit 193.74 °C
cyclobenzaprine HCl 120005, 2.6460 mg
Na 2HPO4 2H2O, 1.2200 mg
Integral -280.71 mJ
normalized -106.09 Jg^-1
Onset 215.63 °C
Peak 218.92 °C
Left Limit 209.76 °C
Right Limit 225.32 °C
Integral -49.50 mJ
normalized -29.98 Jg^-1
Onset 200.18 °C
Peak 205.07 °C
Left Limit 195.20 °C
Right Limit 218.93 °C
2 Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 20

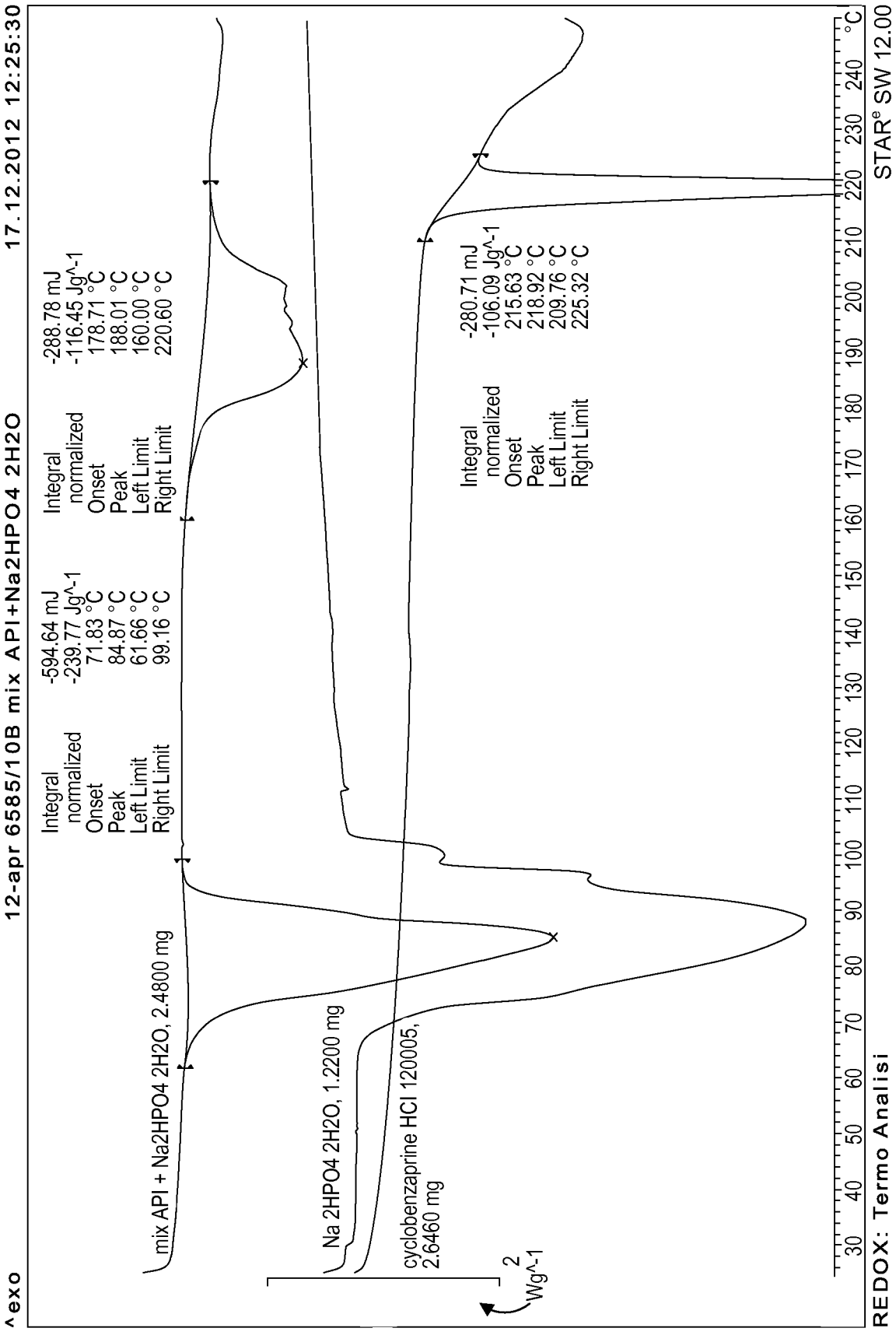

^exo
12-apr 6585/10B mix API+Na2HPO4 2H2O
17.12.2012 12:25:30
Integral -594.64 mJ
normalized -239.77 Jg^-1
Onset 71.83 °C
Peak 84.87 °C
Left Limit 61.66 °C
Right Limit 99.16 °C
Integral -288.78 mJ
normalized -116.45 Jg^-1
Onset 178.71 °C
Peak 188.01 °C
Left Limit 160.00 °C
Right Limit 220.60 °C
Integral -280.71 mJ
normalized -106.09 Jg^-1
Onset 215.63 °C
Peak 218.92 °C
Left Limit 209.76 °C
Right Limit 225.32 °C
mix API + Na2HPO4 2H2O, 2.4800 mg
Na 2HPO4 2H2O, 1.2200 mg
cyclobenzaprine HCl 120005, 2.6460 mg
2 Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 21

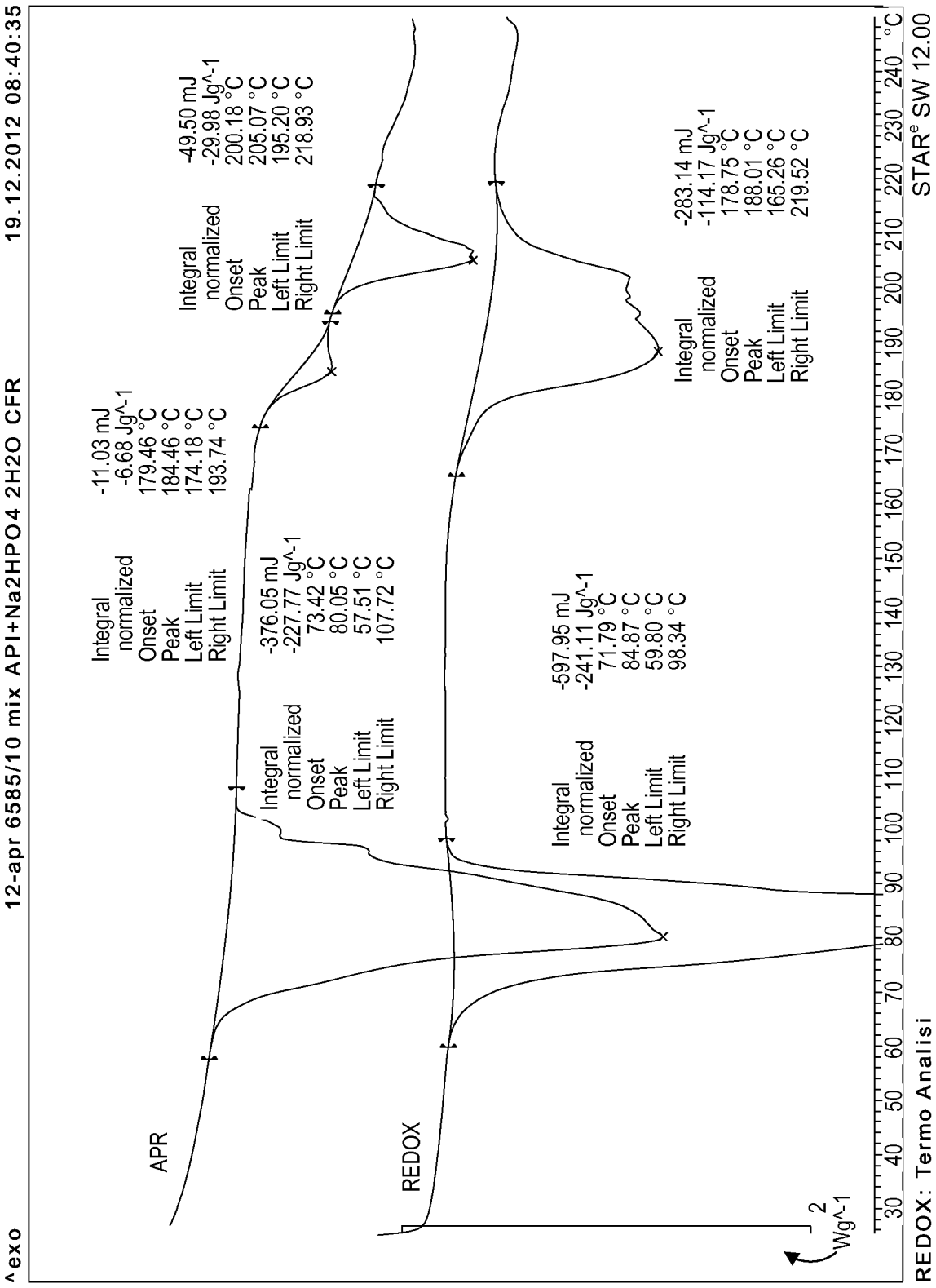

^exo
12-apr 6585/10 mix API+Na2HPO4 2H2O CFR
19.12.2012 08:40:35
APR
Integral -11.03 mJ
normalized -6.68 Jg^-1
Onset 179.46 °C
Peak 184.46 °C
Left Limit 174.18 °C
Right Limit 193.74 °C
Integral -49.50 mJ
normalized -29.98 Jg^-1
Onset 200.18 °C
Peak 205.07 °C
Left Limit 195.20 °C
Right Limit 218.93 °C
REDOX
Integral -376.05 mJ
normalized -227.77 Jg^-1
Onset 73.42 °C
Peak 80.05 °C
Left Limit 57.51 °C
Right Limit 107.72 °C
Integral -597.95 mJ
normalized -241.11 Jg^-1
Onset 71.79 °C
Peak 84.87 °C
Left Limit 59.80 °C
Right Limit 98.34 °C
Integral -283.14 mJ
normalized -114.17 Jg^-1
Onset 178.75 °C
Peak 188.01 °C
Left Limit 165.26 °C
Right Limit 219.52 °C
2
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 22

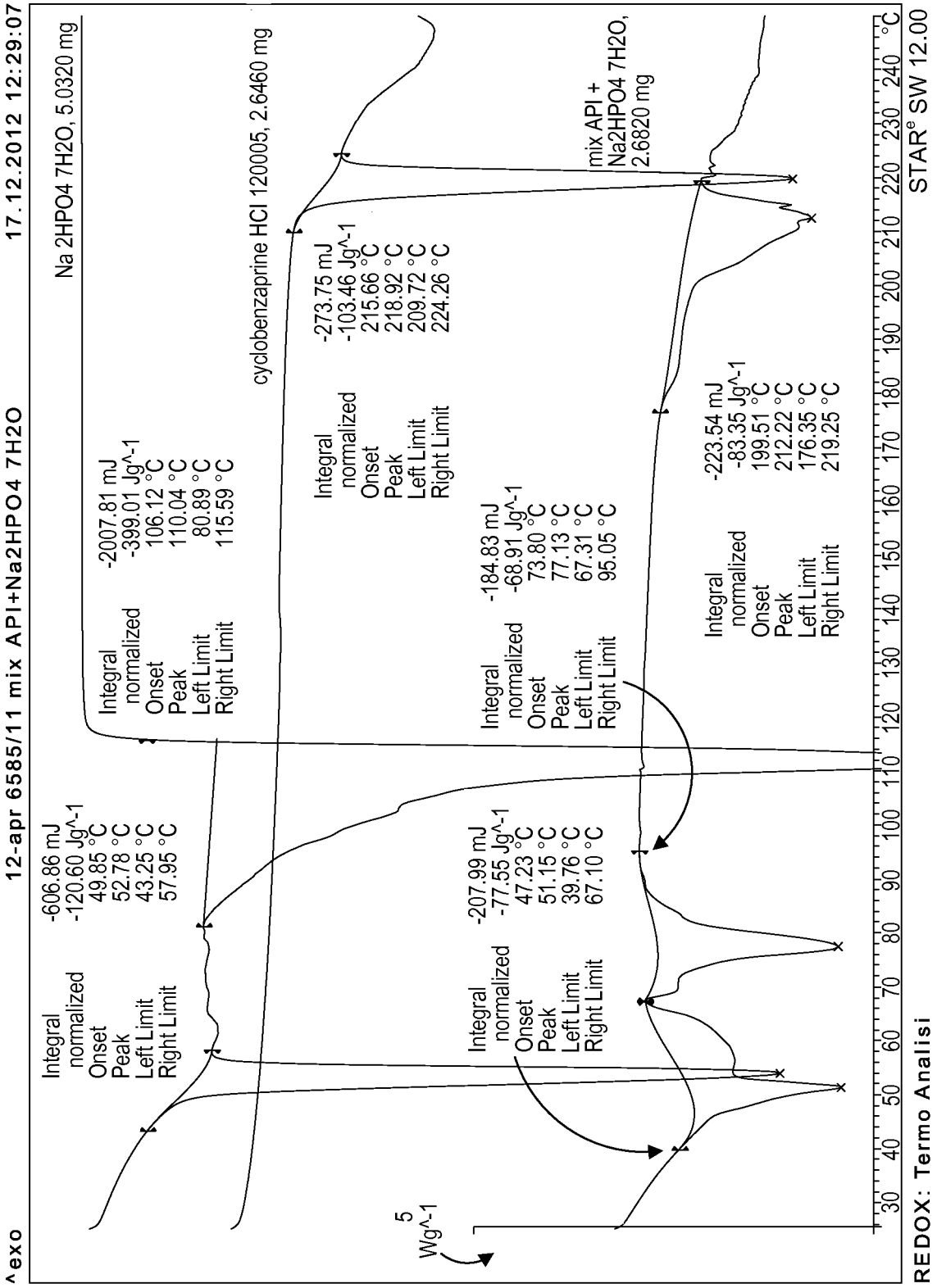

^exo
12-apr 6585/11 mix API+Na2HPO4 7H2O
17.12.2012 12:29:07
Na 2HPO4 7H2O, 5.0320 mg
Integral -606.86 mJ
normalized -120.60 Jg^-1
Onset 49.85 °C
Peak 52.78 °C
Left Limit 43.25 °C
Right Limit 57.95 °C
Integral -2007.81 mJ
normalized -399.01 Jg^-1
Onset 106.12 °C
Peak 110.04 °C
Left Limit 80.89 °C
Right Limit 115.59 °C
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -273.75 mJ
normalized -103.46 Jg^-1
Onset 215.66 °C
Peak 218.92 °C
Left Limit 209.72 °C
Right Limit 224.26 °C
mix API + Na2HPO4 7H2O, 2.6820 mg
Integral -207.99 mJ
normalized -77.55 Jg^-1
Onset 47.23 °C
Peak 51.15 °C
Left Limit 39.76 °C
Right Limit 67.10 °C
Integral -184.83 mJ
normalized -68.91 Jg^-1
Onset 73.80 °C
Peak 77.13 °C
Left Limit 67.31 °C
Right Limit 95.05 °C
Integral -223.54 mJ
normalized -83.35 Jg^-1
Onset 199.51 °C
Peak 212.22 °C
Left Limit 176.35 °C
Right Limit 219.25 °C
5
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 23

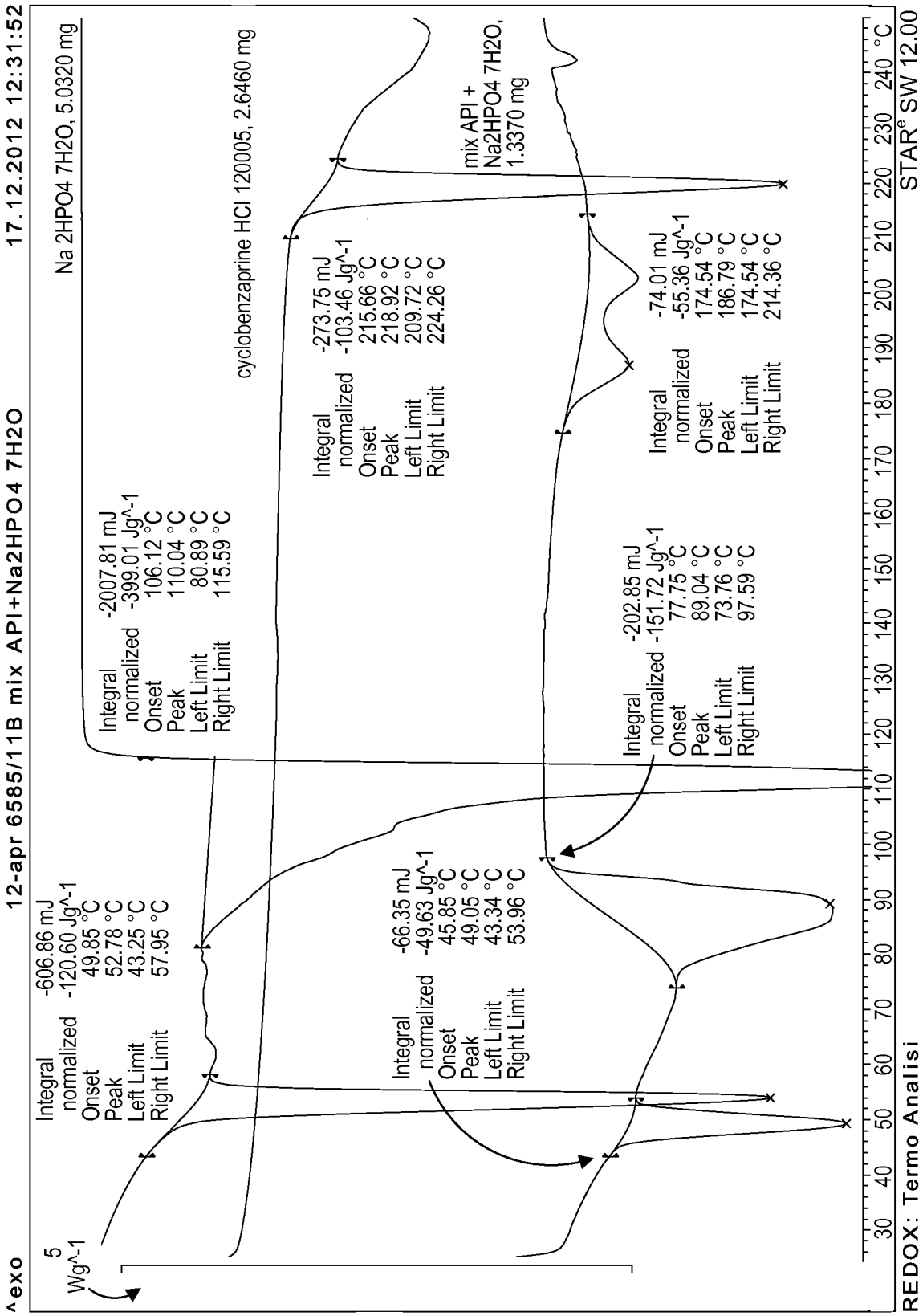

^exo
5
Wg^-1
12-apr 6585/11B mix API+Na2HPO4 7H2O
17.12.2012 12:31:52
Na 2HPO4 7H2O, 5.0320 mg
cyclobenzaprine HCl 120005, 2.6460 mg
mix API + Na2HPO4 7H2O, 1.3370 mg
Integral -606.86 mJ
normalized -120.60 Jg^-1
Onset 49.85 °C
Peak 52.78 °C
Left Limit 43.25 °C
Right Limit 57.95 °C
Integral -2007.81 mJ
normalized -399.01 Jg^-1
Onset 106.12 °C
Peak 110.04 °C
Left Limit 80.89 °C
Right Limit 115.59 °C
Integral -66.35 mJ
normalized -49.63 Jg^-1
Onset 45.85 °C
Peak 49.05 °C
Left Limit 43.34 °C
Right Limit 53.96 °C
Integral -273.75 mJ
normalized -103.46 Jg^-1
Onset 215.66 °C
Peak 218.92 °C
Left Limit 209.72 °C
Right Limit 224.26 °C
Integral -202.85 mJ
normalized -151.72 Jg^-1
Onset 77.75 °C
Peak 89.04 °C
Left Limit 73.76 °C
Right Limit 97.59 °C
Integral -74.01 mJ
normalized -55.36 Jg^-1
Onset 174.54 °C
Peak 186.79 °C
Left Limit 174.54 °C
Right Limit 214.36 °C
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 24

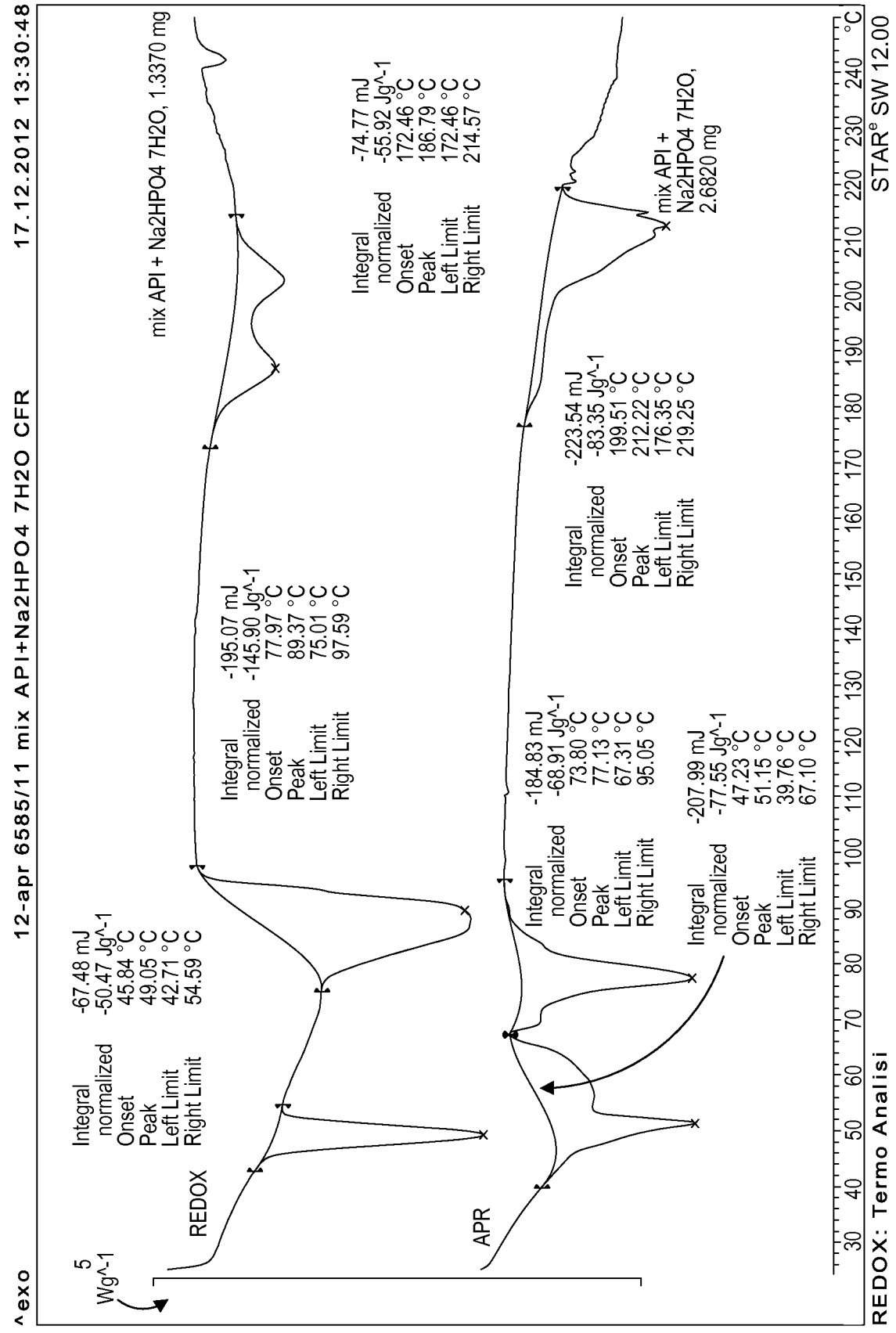

^exo
12-apr 6585/11 mix API+Na2HPO4 7H2O CFR
17.12.2012 13:30:48
5
Wg^-1
REDOX
Integral -67.48 mJ
normalized -50.47 Jg^-1
Onset 45.84 °C
Peak 49.05 °C
Left Limit 42.71 °C
Right Limit 54.59 °C
mix API + Na2HPO4 7H2O, 1.3370 mg
Integral -195.07 mJ
normalized -145.90 Jg^-1
Onset 77.97 °C
Peak 89.37 °C
Left Limit 75.01 °C
Right Limit 97.59 °C
Integral -74.77 mJ
normalized -55.92 Jg^-1
Onset 172.46 °C
Peak 186.79 °C
Left Limit 172.46 °C
Right Limit 214.57 °C
APR
Integral -184.83 mJ
normalized -68.91 Jg^-1
Onset 73.80 °C
Peak 77.13 °C
Left Limit 67.31 °C
Right Limit 95.05 °C
Integral -223.54 mJ
normalized -83.35 Jg^-1
Onset 199.51 °C
Peak 212.22 °C
Left Limit 176.35 °C
Right Limit 219.25 °C
Integral -207.99 mJ
normalized -77.55 Jg^-1
Onset 47.23 °C
Peak 51.15 °C
Left Limit 39.76 °C
Right Limit 67.10 °C
mix API + Na2HPO4 7H2O, 2.6820 mg
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 25

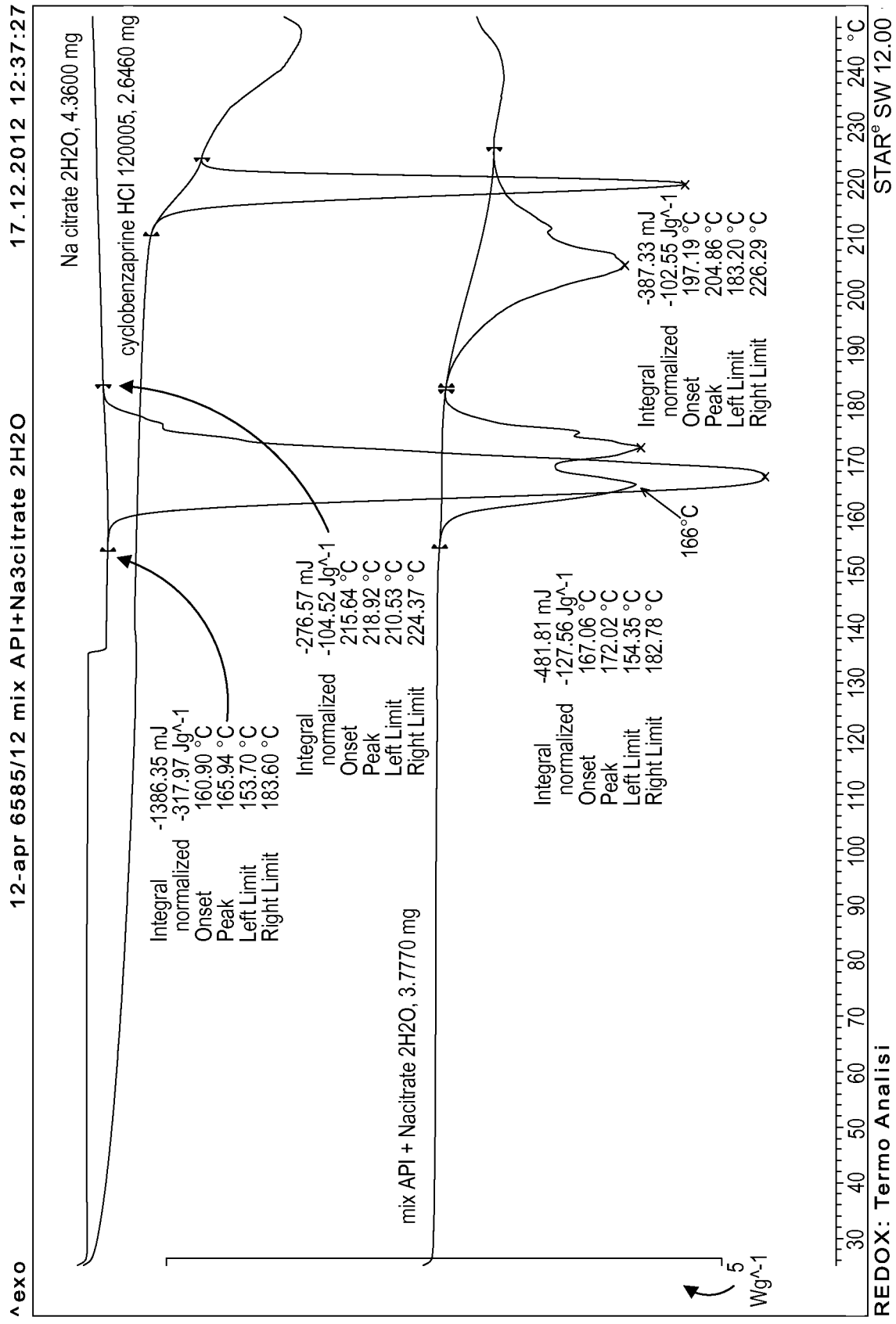

^exo
12-apr 6585/12 mix API+Na3citrate 2H2O
17.12.2012 12:37:27
Na citrate 2H2O, 4.3600 mg
cyclobenzaprine HCl 120005, 2.6460 mg
mix API + Nacitrate 2H2O, 3.7770 mg
Integral -1386.35 mJ
normalized -317.97 Jg^-1
Onset 160.90 °C
Peak 165.94 °C
Left Limit 153.70 °C
Right Limit 183.60 °C
Integral -276.57 mJ
normalized -104.52 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.53 °C
Right Limit 224.37 °C
Integral -481.81 mJ
normalized -127.56 Jg^-1
Onset 167.06 °C
Peak 172.02 °C
Left Limit 154.35 °C
Right Limit 182.78 °C
166°C
Integral -387.33 mJ
normalized -102.55 Jg^-1
Onset 197.19 °C
Peak 204.86 °C
Left Limit 183.20 °C
Right Limit 226.29 °C
5
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 26

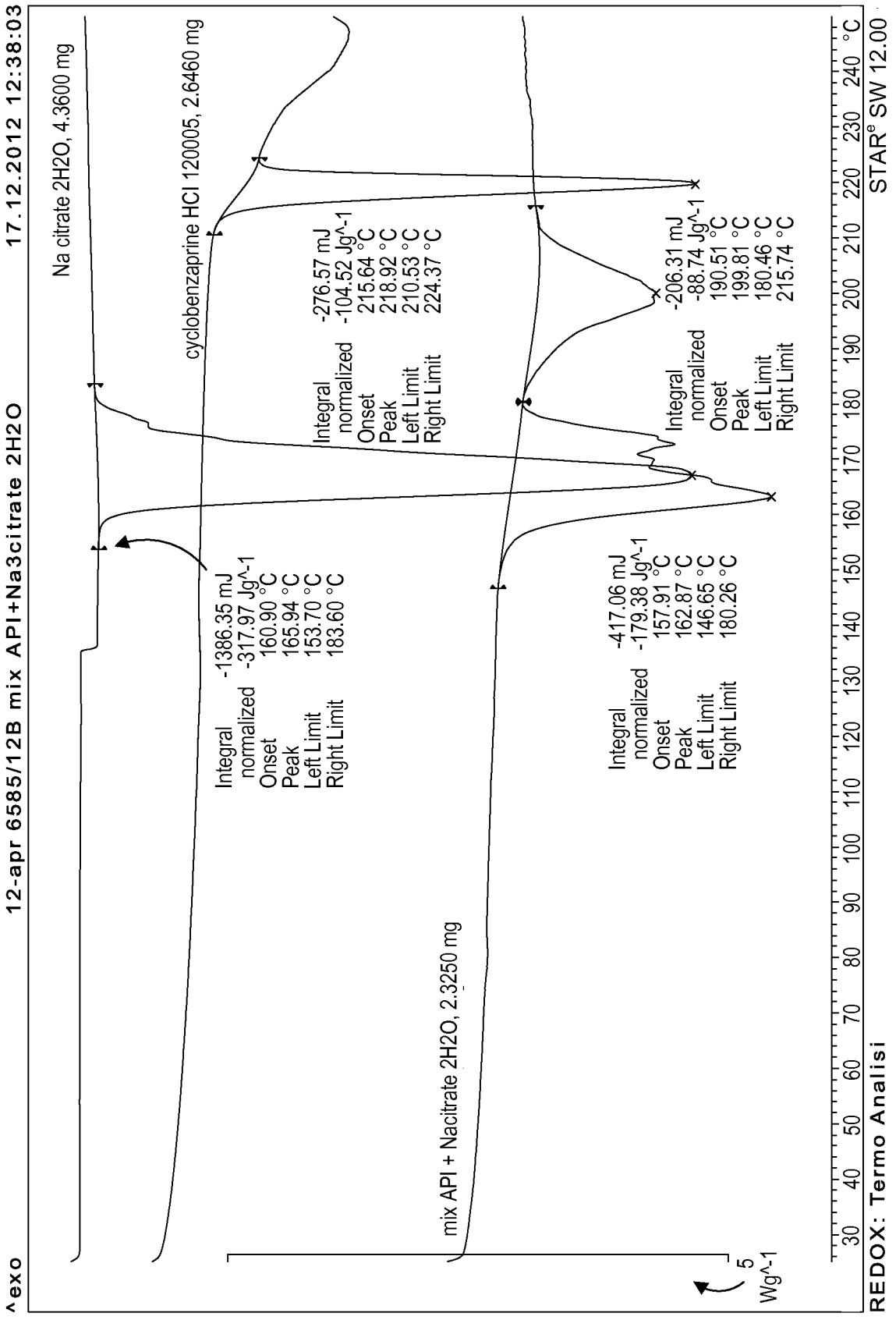

^exo
12-apr 6585/12B mix API+Na3citrate 2H2O
17.12.2012 12:38:03
Na citrate 2H2O, 4.3600 mg
cyclobenzaprine HCl 120005, 2.6460 mg
mix API + Nacitrate 2H2O, 2.3250 mg
Integral -1386.35 mJ
normalized -317.97 Jg^-1
Onset 160.90 °C
Peak 165.94 °C
Left Limit 153.70 °C
Right Limit 183.60 °C
Integral -276.57 mJ
normalized -104.52 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.53 °C
Right Limit 224.37 °C
Integral -417.06 mJ
normalized -179.38 Jg^-1
Onset 157.91 °C
Peak 162.87 °C
Left Limit 146.65 °C
Right Limit 180.26 °C
Integral -206.31 mJ
normalized -88.74 Jg^-1
Onset 190.51 °C
Peak 199.81 °C
Left Limit 180.46 °C
Right Limit 215.74 °C
5
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 27

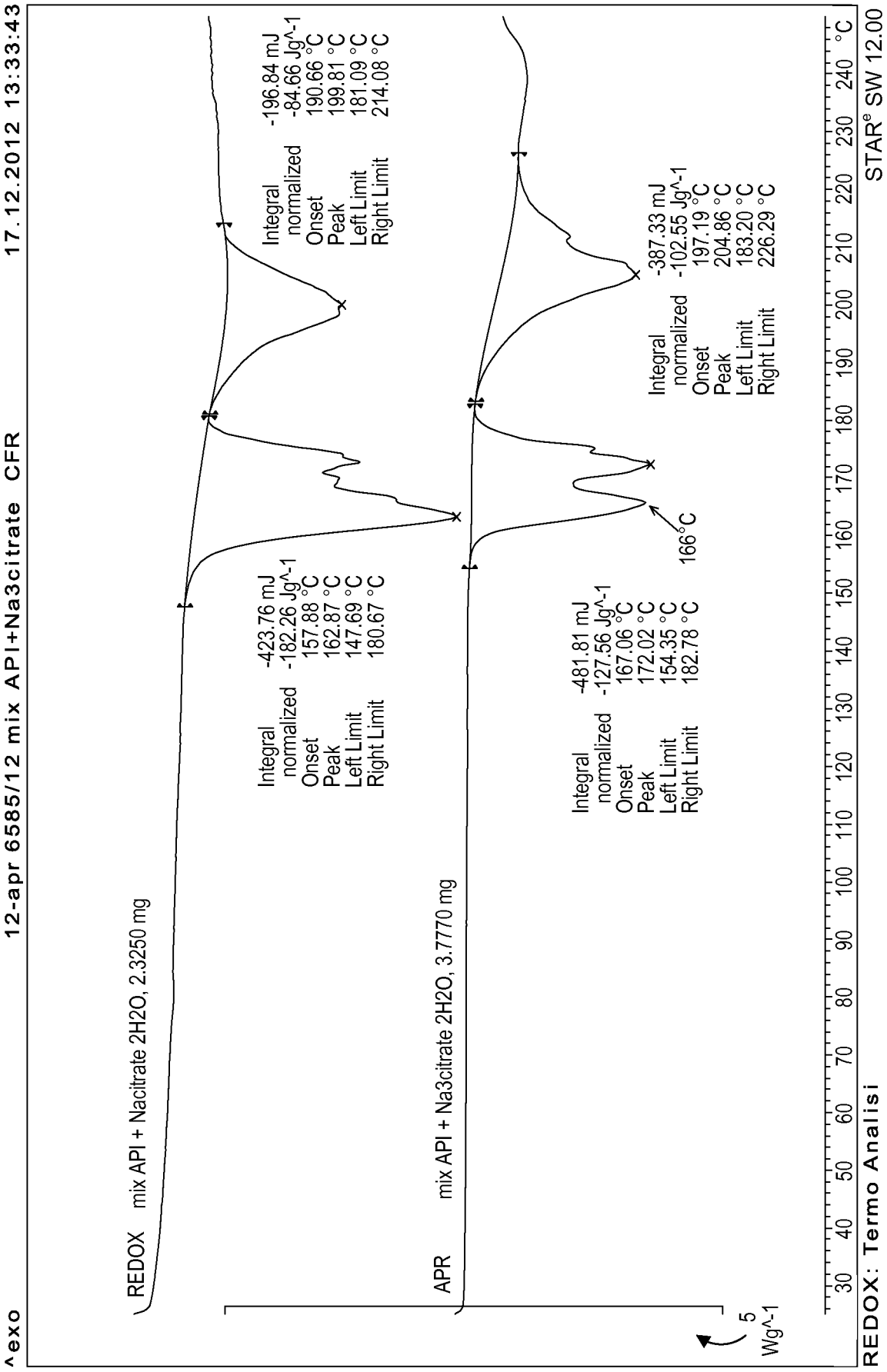

^exo
12-apr 6585/12 mix API+Na3citrate CFR
17.12.2012 13:33:43
REDOX mix API + Nacitrate 2H2O, 2.3250 mg
Integral -423.76 mJ
normalized -182.26 Jg^-1
Onset 157.88 °C
Peak 162.87 °C
Left Limit 147.69 °C
Right Limit 180.67 °C
Integral -196.84 mJ
normalized -84.66 Jg^-1
Onset 190.66 °C
Peak 199.81 °C
Left Limit 181.09 °C
Right Limit 214.08 °C
APR mix API + Na3citrate 2H2O, 3.7770 mg
Integral -481.81 mJ
normalized -127.56 Jg^-1
Onset 167.06 °C
Peak 172.02 °C
Left Limit 154.35 °C
Right Limit 182.78 °C
166°C
Integral -387.33 mJ
normalized -102.55 Jg^-1
Onset 197.19 °C
Peak 204.86 °C
Left Limit 183.20 °C
Right Limit 226.29 °C
5
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 28

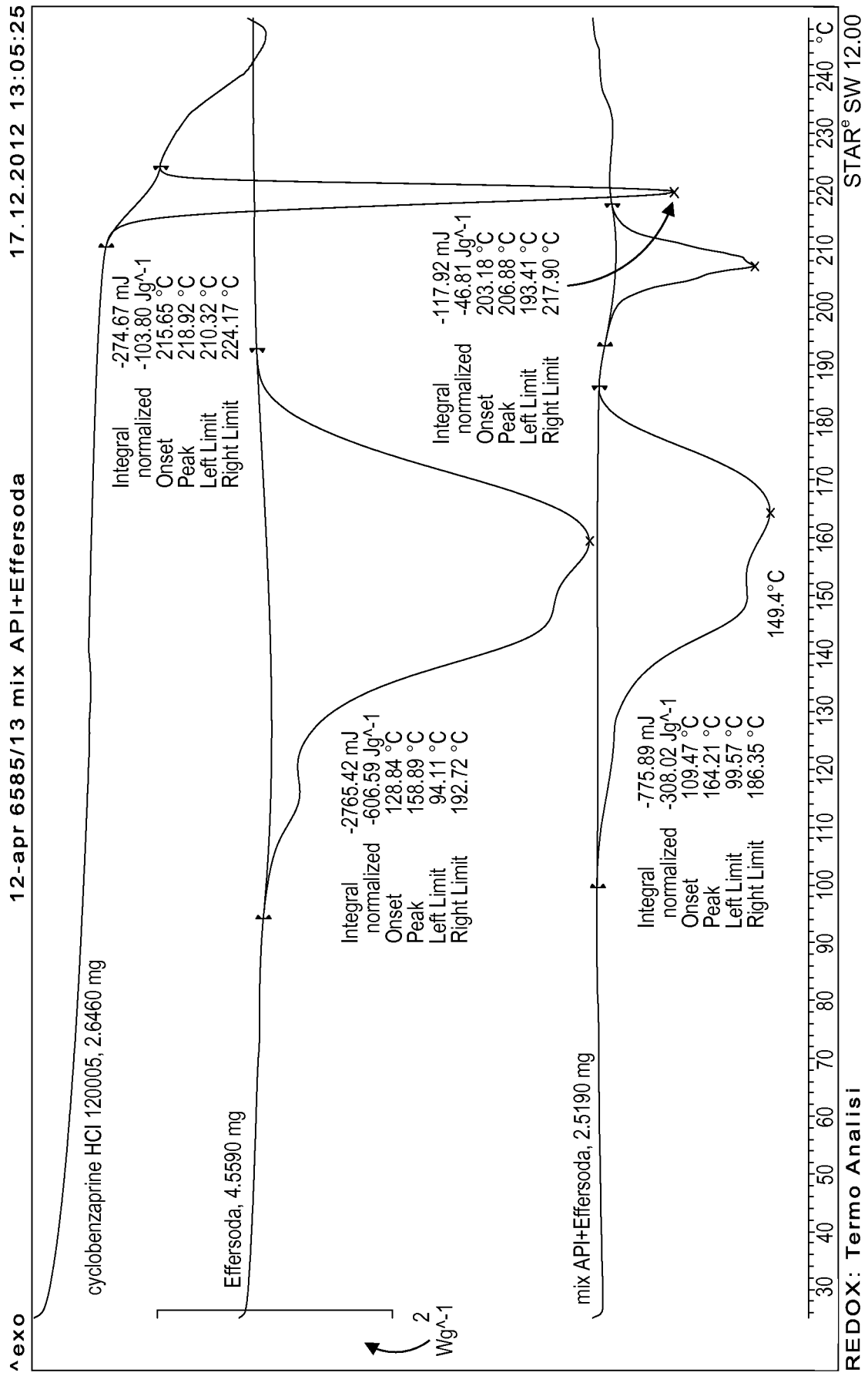

^exo
12-apr 6585/13 mix API+Effersoda
17.12.2012 13:05:25
cyclobenzaprine HCl 120005, 2.6460 mg
Effersoda, 4.5590 mg
mix API+Effersoda, 2.5190 mg
Integral -274.67 mJ
normalized -103.80 Jg^-1
Onset 215.65 °C
Peak 218.92 °C
Left Limit 210.32 °C
Right Limit 224.17 °C
Integral -2765.42 mJ
normalized -606.59 Jg^-1
Onset 128.84 °C
Peak 158.89 °C
Left Limit 94.11 °C
Right Limit 192.72 °C
Integral -117.92 mJ
normalized -46.81 Jg^-1
Onset 203.18 °C
Peak 206.88 °C
Left Limit 193.41 °C
Right Limit 217.90 °C
Integral -775.89 mJ
normalized -308.02 Jg^-1
Onset 109.47 °C
Peak 164.21 °C
Left Limit 99.57 °C
Right Limit 186.35 °C
149.4°C
2
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 29

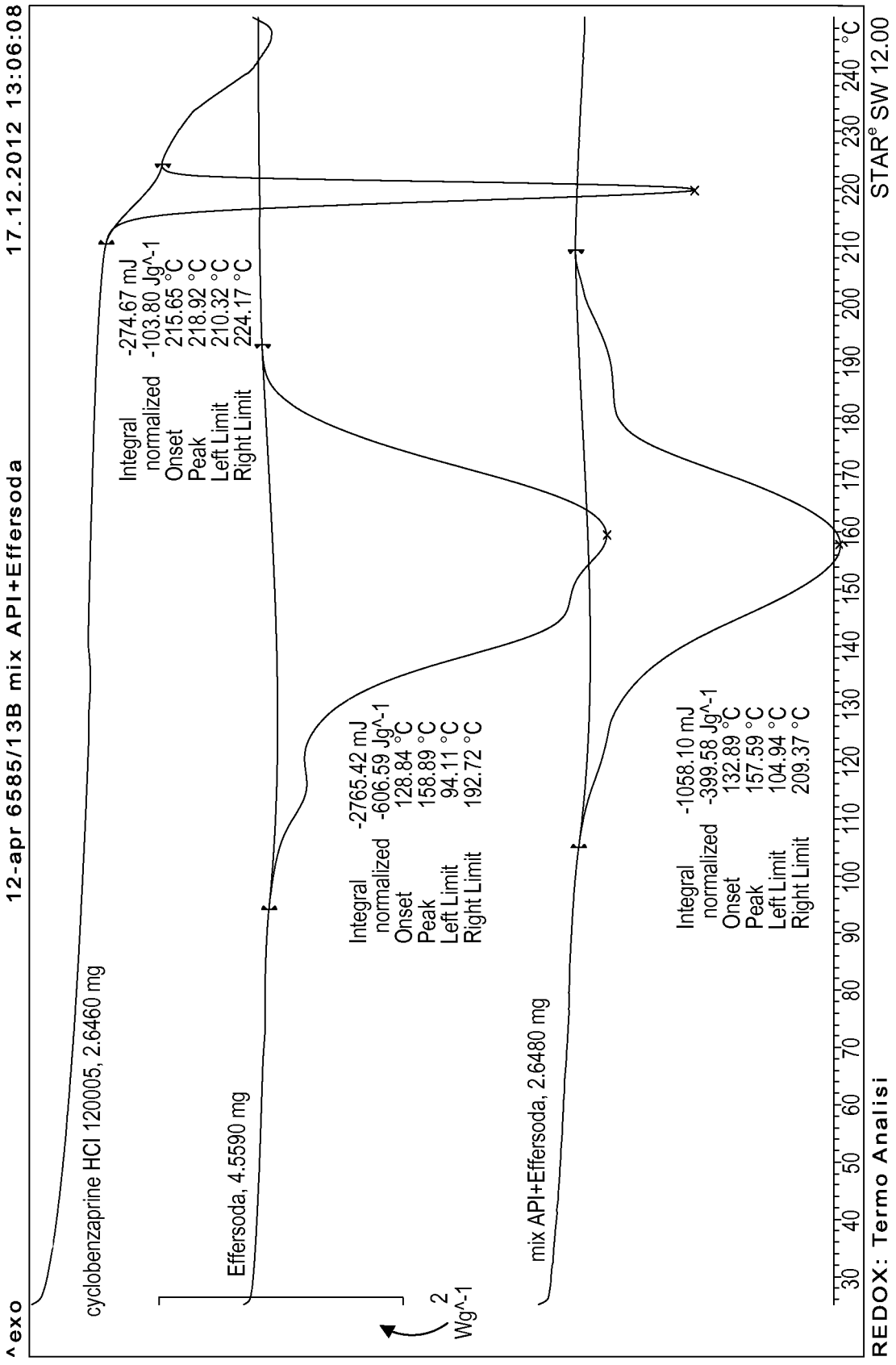

^exo
12-apr 6585/13B mix API+Effersoda
17.12.2012 13:06:08
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -274.67 mJ
normalized -103.80 Jg^-1
Onset 215.65 °C
Peak 218.92 °C
Left Limit 210.32 °C
Right Limit 224.17 °C
Effersoda, 4.5590 mg
Integral -2765.42 mJ
normalized -606.59 Jg^-1
Onset 128.84 °C
Peak 158.89 °C
Left Limit 94.11 °C
Right Limit 192.72 °C
2
Wg^-1
mix API+Effersoda, 2.6480 mg
Integral -1058.10 mJ
normalized -399.58 Jg^-1
Onset 132.89 °C
Peak 157.59 °C
Left Limit 104.94 °C
Right Limit 209.37 °C
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 30

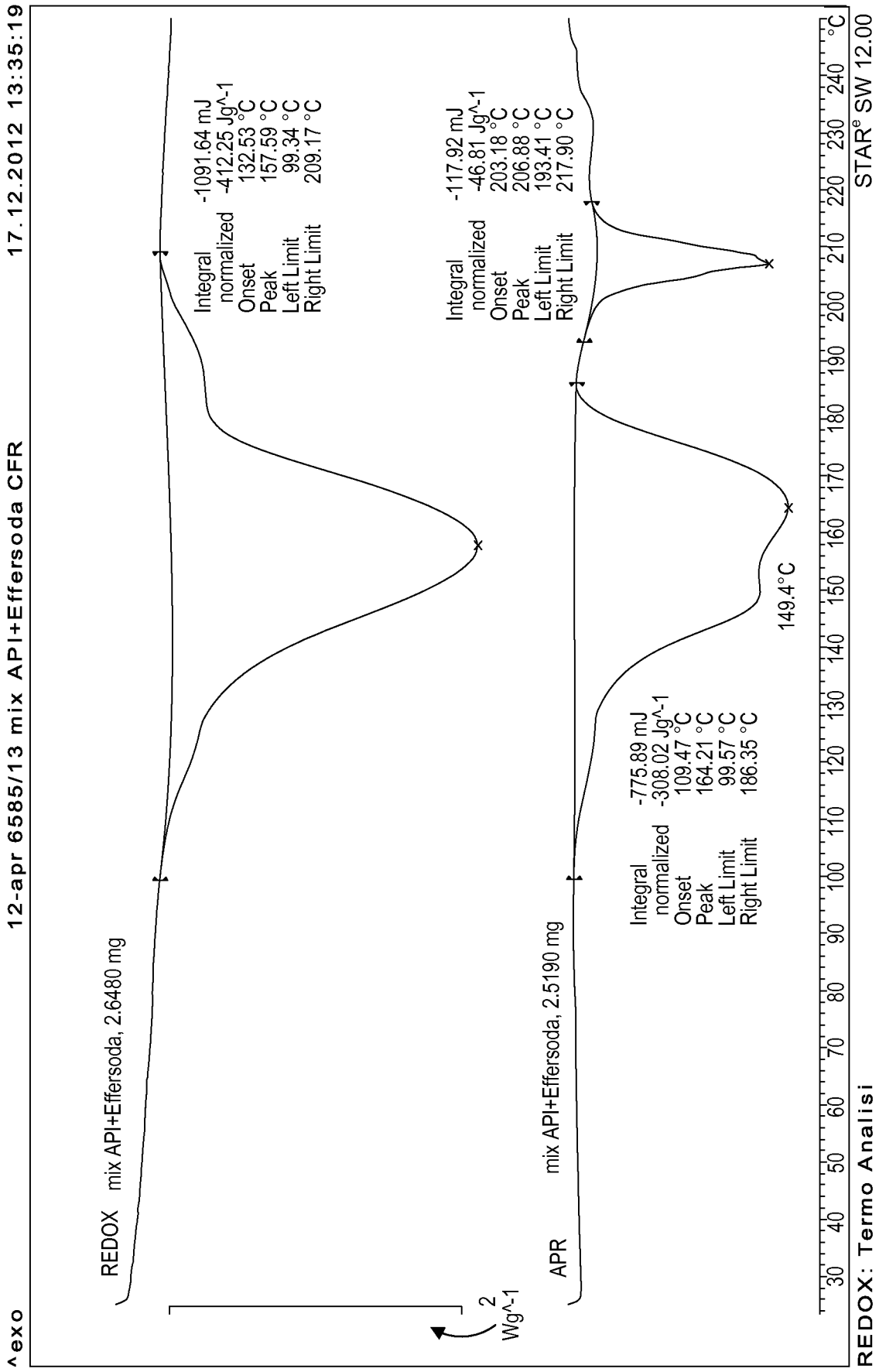

^exo
12-apr 6585/13 mix API+Effersoda CFR
17.12.2012 13:35:19
REDOX mix API+Effersoda, 2.6480 mg
Integral -1091.64 mJ
normalized -412.25 Jg^-1
Onset 132.53 °C
Peak 157.59 °C
Left Limit 99.34 °C
Right Limit 209.17 °C
2
Wg^-1
APR mix API+Effersoda, 2.5190 mg
Integral -117.92 mJ
normalized -46.81 Jg^-1
Onset 203.18 °C
Peak 206.88 °C
Left Limit 193.41 °C
Right Limit 217.90 °C
Integral -775.89 mJ
normalized -308.02 Jg^-1
Onset 109.47 °C
Peak 164.21 °C
Left Limit 99.57 °C
Right Limit 186.35 °C
149.4°C
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 31

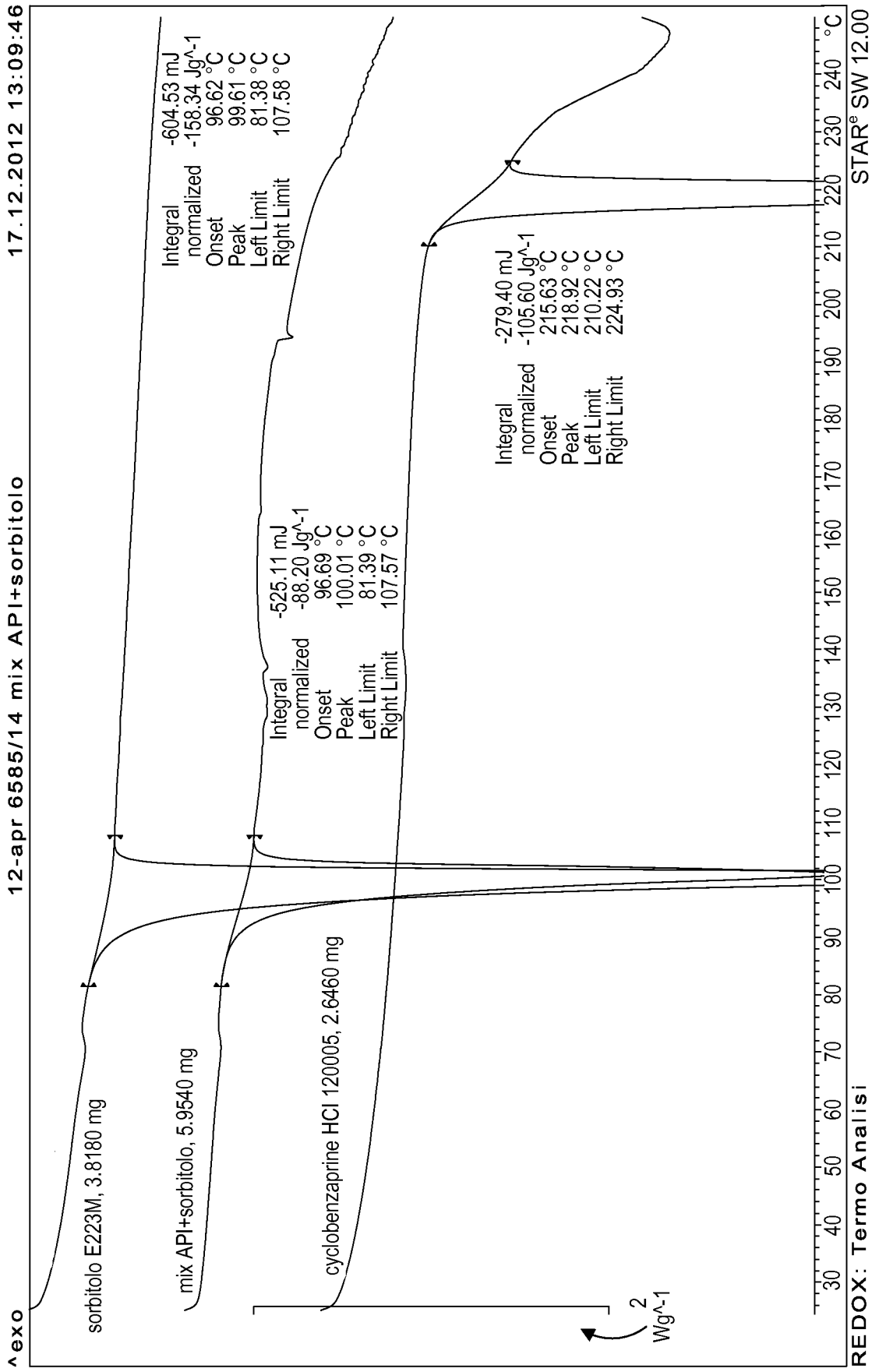

^exo
12-apr 6585/14 mix API+sorbitolo 17.12.2012 13:09:46
sorbitolo E223M, 3.8180 mg
mix API+sorbitolo, 5.9540 mg
cyclobenzaprine HCl 120005, 2.6460 mg
2
Wg^-1
Integral -604.53 mJ
normalized -158.34 Jg^-1
Onset 96.62 °C
Peak 99.61 °C
Left Limit 81.38 °C
Right Limit 107.58 °C
Integral -525.11 mJ
normalized -88.20 Jg^-1
Onset 96.69 °C
Peak 100.01 °C
Left Limit 81.39 °C
Right Limit 107.57 °C
Integral -279.40 mJ
normalized -105.60 Jg^-1
Onset 215.63 °C
Peak 218.92 °C
Left Limit 210.22 °C
Right Limit 224.93 °C
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 32

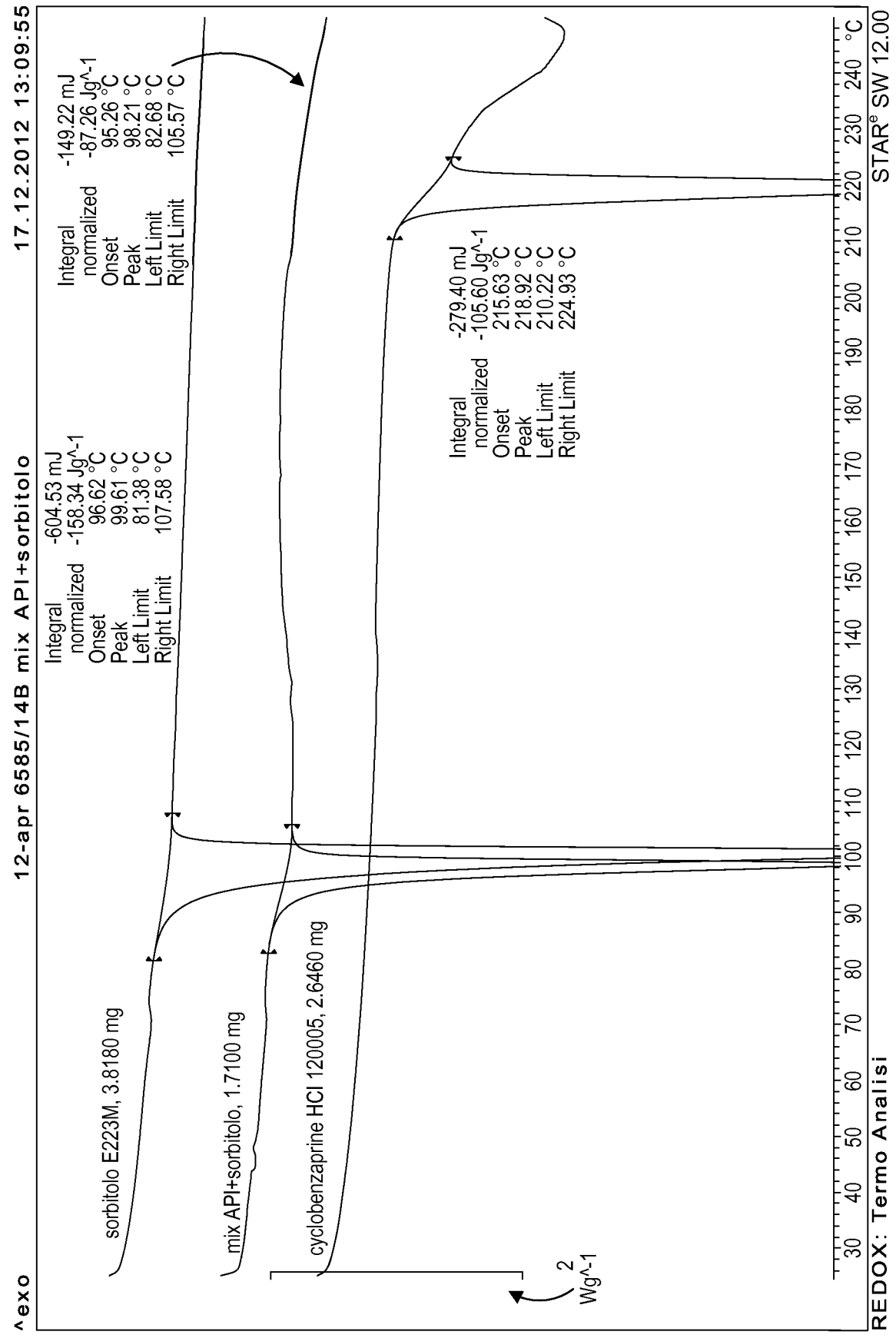

^exo
12-apr 6585/14B mix API+sorbitolo
17.12.2012 13:09:55
sorbitolo E223M, 3.8180 mg
Integral -604.53 mJ
normalized -158.34 Jg^-1
Onset 96.62 °C
Peak 99.61 °C
Left Limit 81.38 °C
Right Limit 107.58 °C
mix API+sorbitolo, 1.7100 mg
Integral -149.22 mJ
normalized -87.26 Jg^-1
Onset 95.26 °C
Peak 98.21 °C
Left Limit 82.68 °C
Right Limit 105.57 °C
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -279.40 mJ
normalized -105.60 Jg^-1
Onset 215.63 °C
Peak 218.92 °C
Left Limit 210.22 °C
Right Limit 224.93 °C
2
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 33

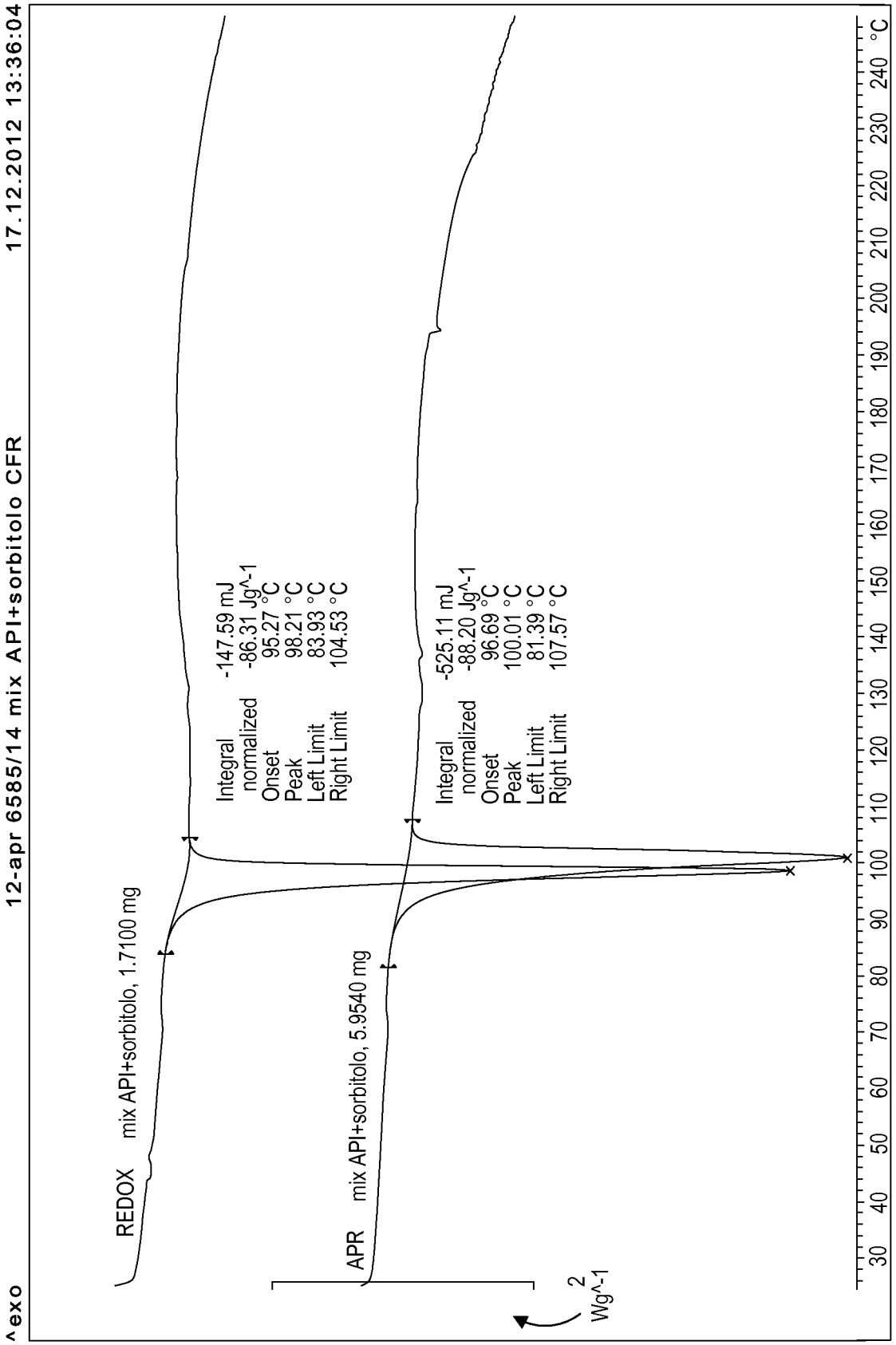

^exo
12-apr 6585/14 mix API+sorbitolo CFR
17.12.2012 13:36:04
REDOX mix API+sorbitolo, 1.7100 mg
Integral -147.59 mJ
normalized -86.31 Jg^-1
Onset 95.27 °C
Peak 98.21 °C
Left Limit 83.93 °C
Right Limit 104.53 °C
APR mix API+sorbitolo, 5.9540 mg
Integral -525.11 mJ
normalized -88.20 Jg^-1
Onset 96.69 °C
Peak 100.01 °C
Left Limit 81.39 °C
Right Limit 107.57 °C
2
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 34

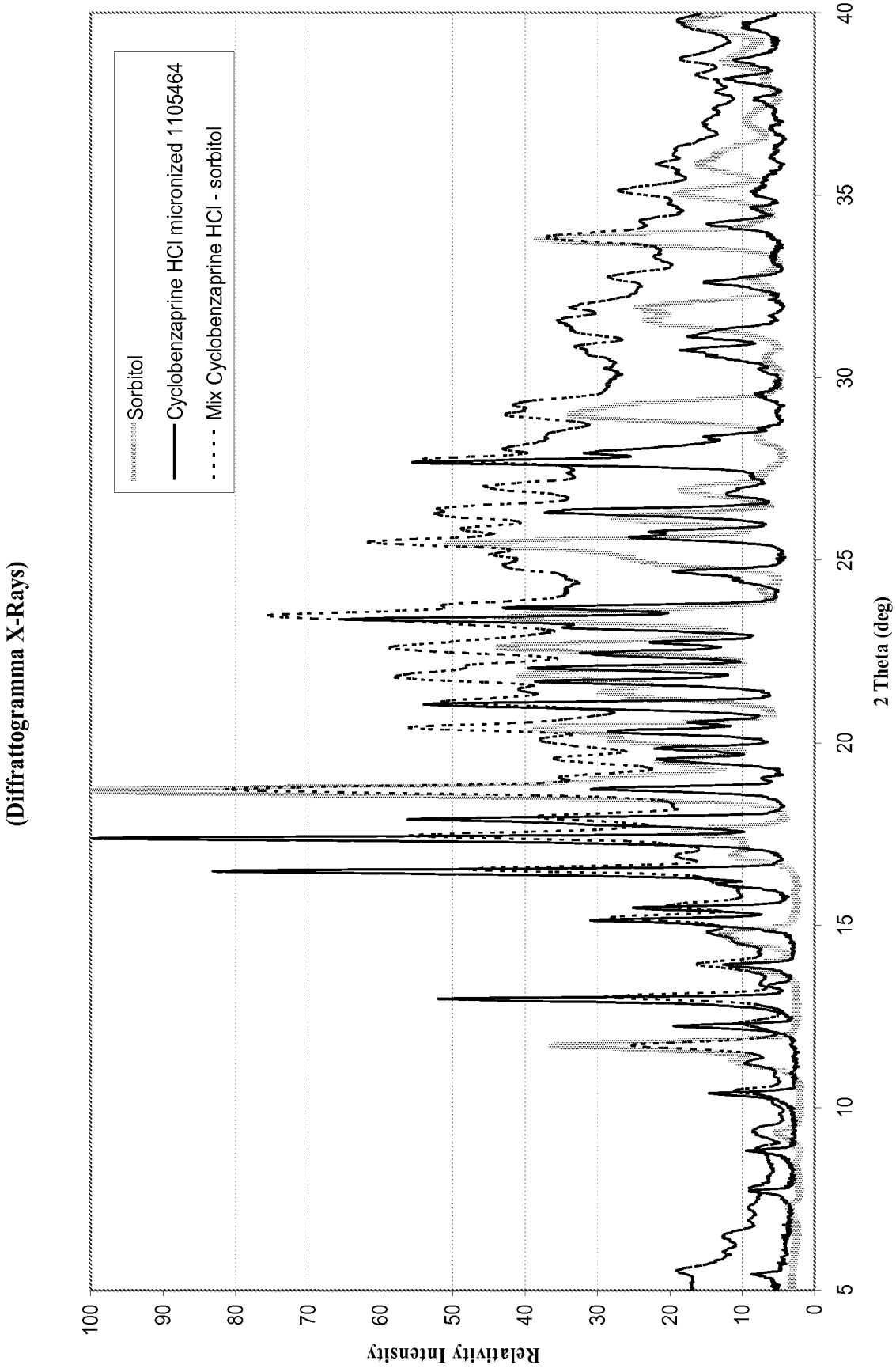

(Diffrattogramma X-Rays)
Sorbitol
Cyclobenzaprine HCl micronized 1105464
Mix Cyclobenzaprine HCl - sorbitol
Relativity Intensity
2 Theta (deg)
0
10
20
30
40
50
60
70
80
90
100
5
10
15
20
25
30
35
40

FIG. 35

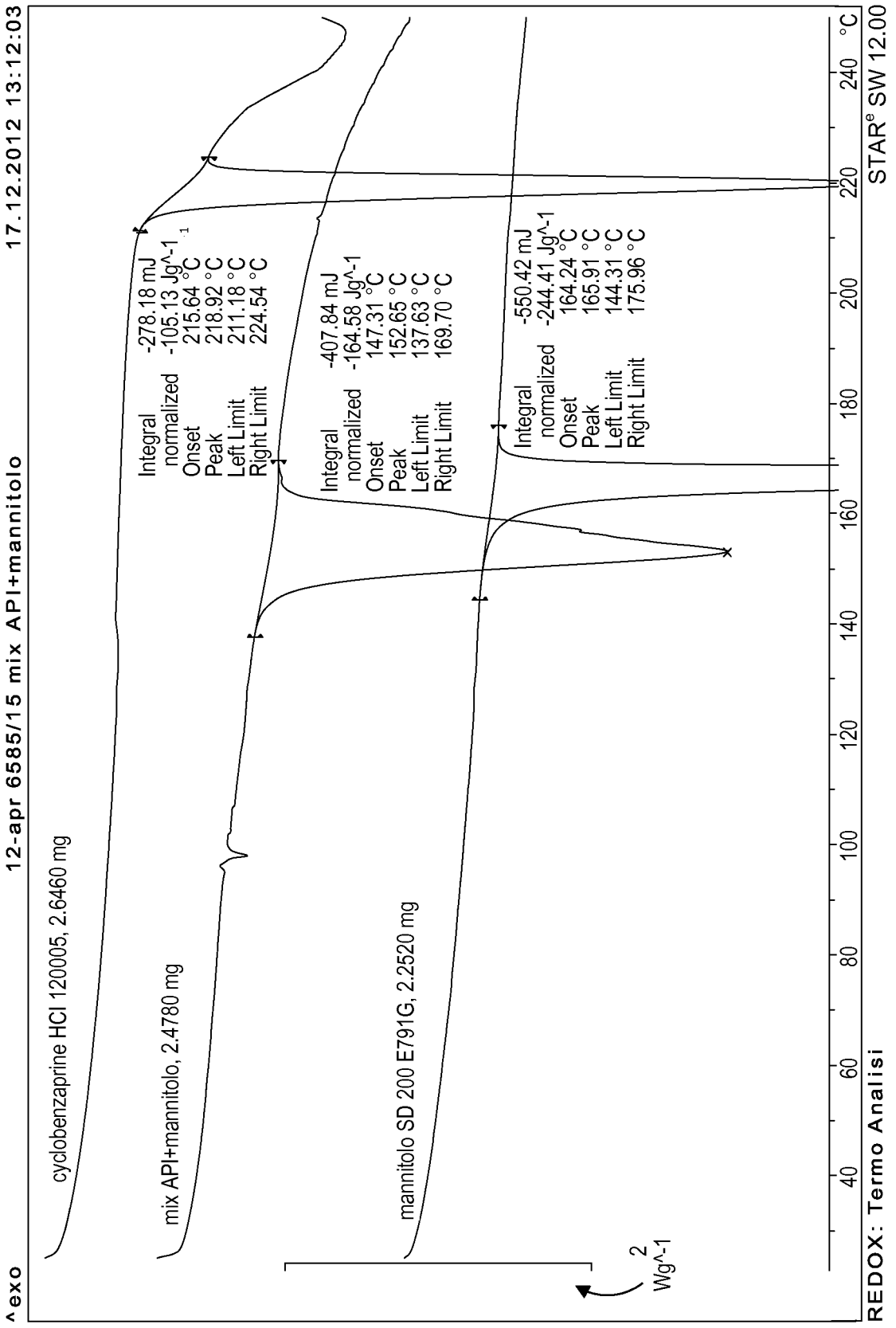

^exo
12-apr 6585/15 mix API+mannitolo
17.12.2012 13:12:03
cyclobenzaprine HCl 120005, 2.6460 mg
mix API+mannitolo, 2.4780 mg
mannitolo SD 200 E791G, 2.2520 mg
Integral -278.18 mJ
normalized -105.13 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 211.18 °C
Right Limit 224.54 °C
Integral -407.84 mJ
normalized -164.58 Jg^-1
Onset 147.31 °C
Peak 152.65 °C
Left Limit 137.63 °C
Right Limit 169.70 °C
Integral -550.42 mJ
normalized -244.41 Jg^-1
Onset 164.24 °C
Peak 165.91 °C
Left Limit 144.31 °C
Right Limit 175.96 °C
2 Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 36

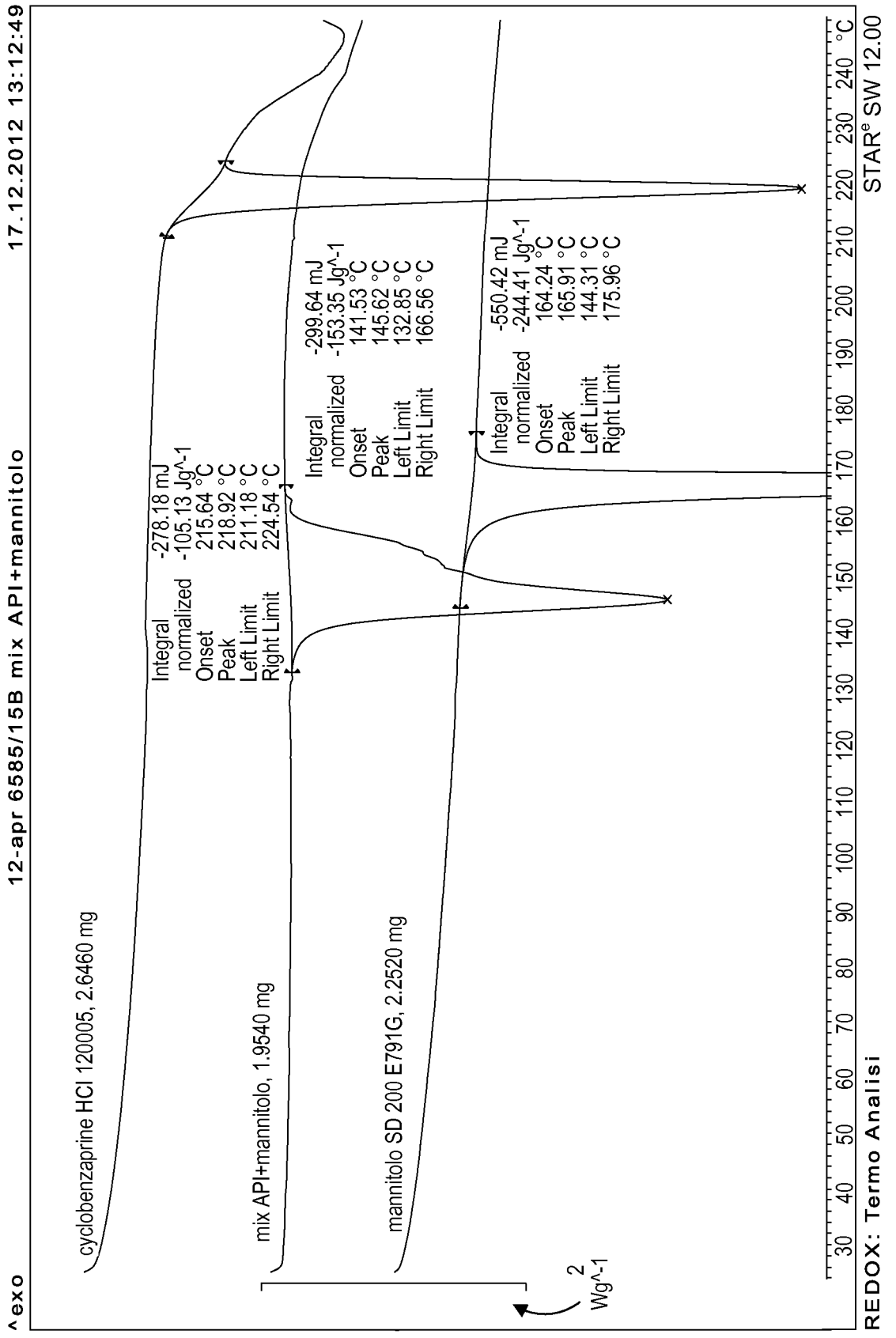

^exo
12-apr 6585/15B mix API+mannitolo
17.12.2012 13:12:49
cyclobenzaprine HCl 120005, 2.6460 mg
mix API+mannitolo, 1.9540 mg
mannitolo SD 200 E791G, 2.2520 mg
Integral -278.18 mJ
normalized -105.13 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 211.18 °C
Right Limit 224.54 °C
Integral -299.64 mJ
normalized -153.35 Jg^-1
Onset 141.53 °C
Peak 145.62 °C
Left Limit 132.85 °C
Right Limit 166.56 °C
Integral -550.42 mJ
normalized -244.41 Jg^-1
Onset 164.24 °C
Peak 165.91 °C
Left Limit 144.31 °C
Right Limit 175.96 °C
2
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 37

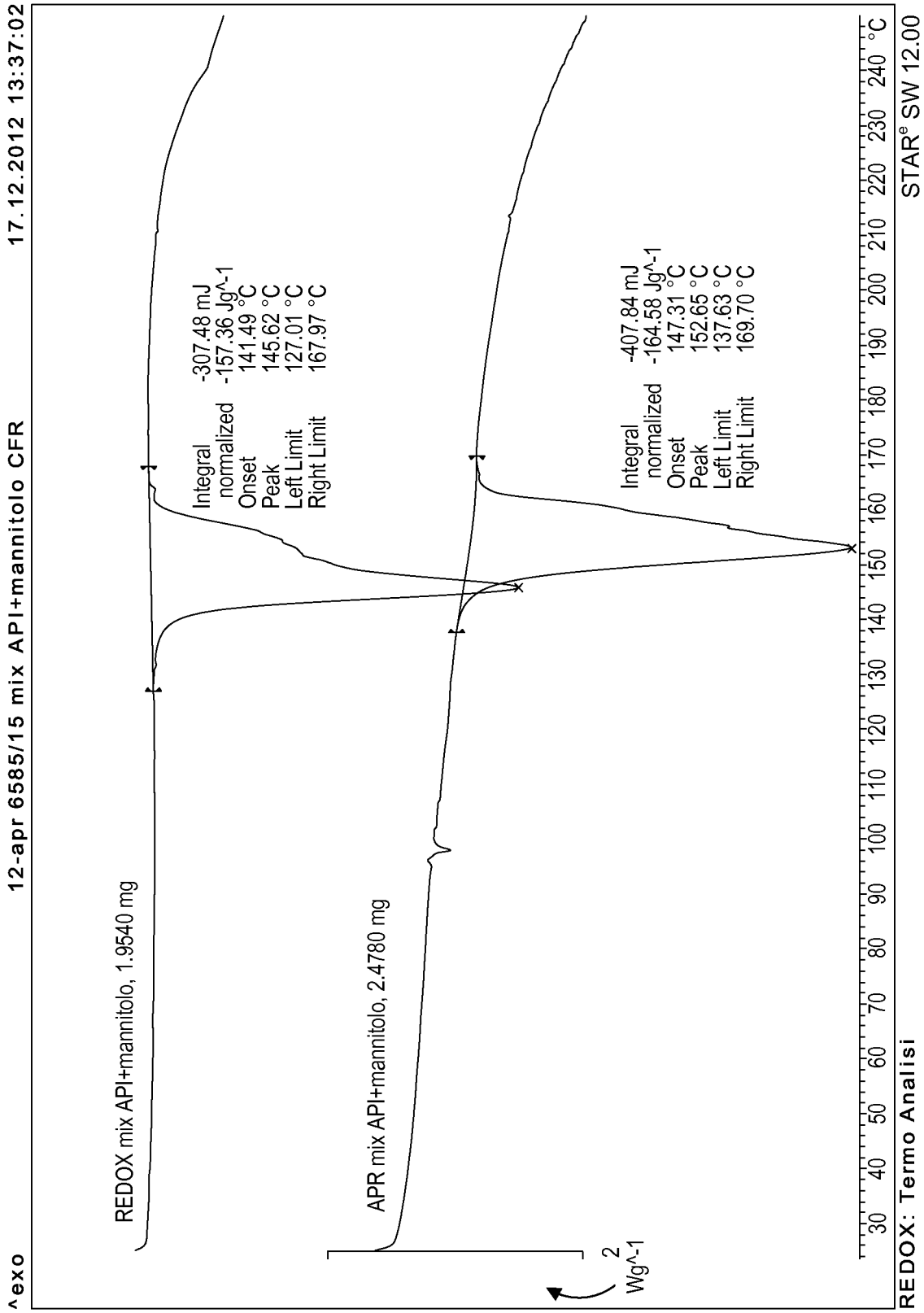

^exo
12-apr 6585/15 mix API+mannitolo CFR
17.12.2012 13:37:02
REDOX mix API+mannitolo, 1.9540 mg
APR mix API+mannitolo, 2.4780 mg
Integral -307.48 mJ
normalized -157.36 Jg^-1
Onset 141.49 °C
Peak 145.62 °C
Left Limit 127.01 °C
Right Limit 167.97 °C
Integral -407.84 mJ
normalized -164.58 Jg^-1
Onset 147.31 °C
Peak 152.65 °C
Left Limit 137.63 °C
Right Limit 169.70 °C
2
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 38

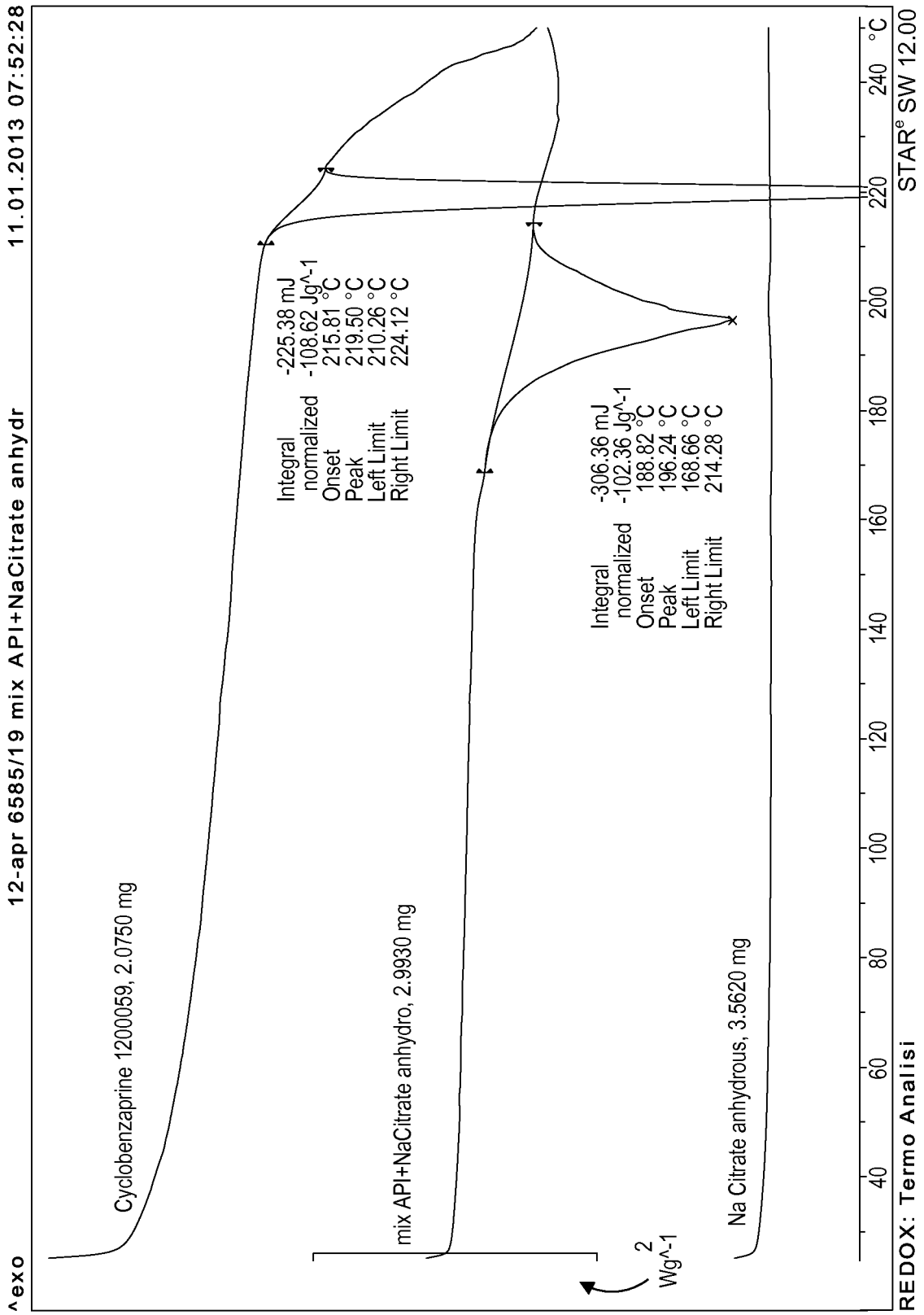

^exo
12-apr 6585/19 mix API+NaCitrate anhydr
11.01.2013 07:52:28
Cyclobenzaprine 1200059, 2.0750 mg
Integral -225.38 mJ
normalized -108.62 Jg^-1
Onset 215.81 °C
Peak 219.50 °C
Left Limit 210.26 °C
Right Limit 224.12 °C
mix API+NaCitrate anhydro, 2.9930 mg
Integral -306.36 mJ
normalized -102.36 Jg^-1
Onset 188.82 °C
Peak 196.24 °C
Left Limit 168.66 °C
Right Limit 214.28 °C
2
Wg^-1
Na Citrate anhydrous, 3.5620 mg
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 39

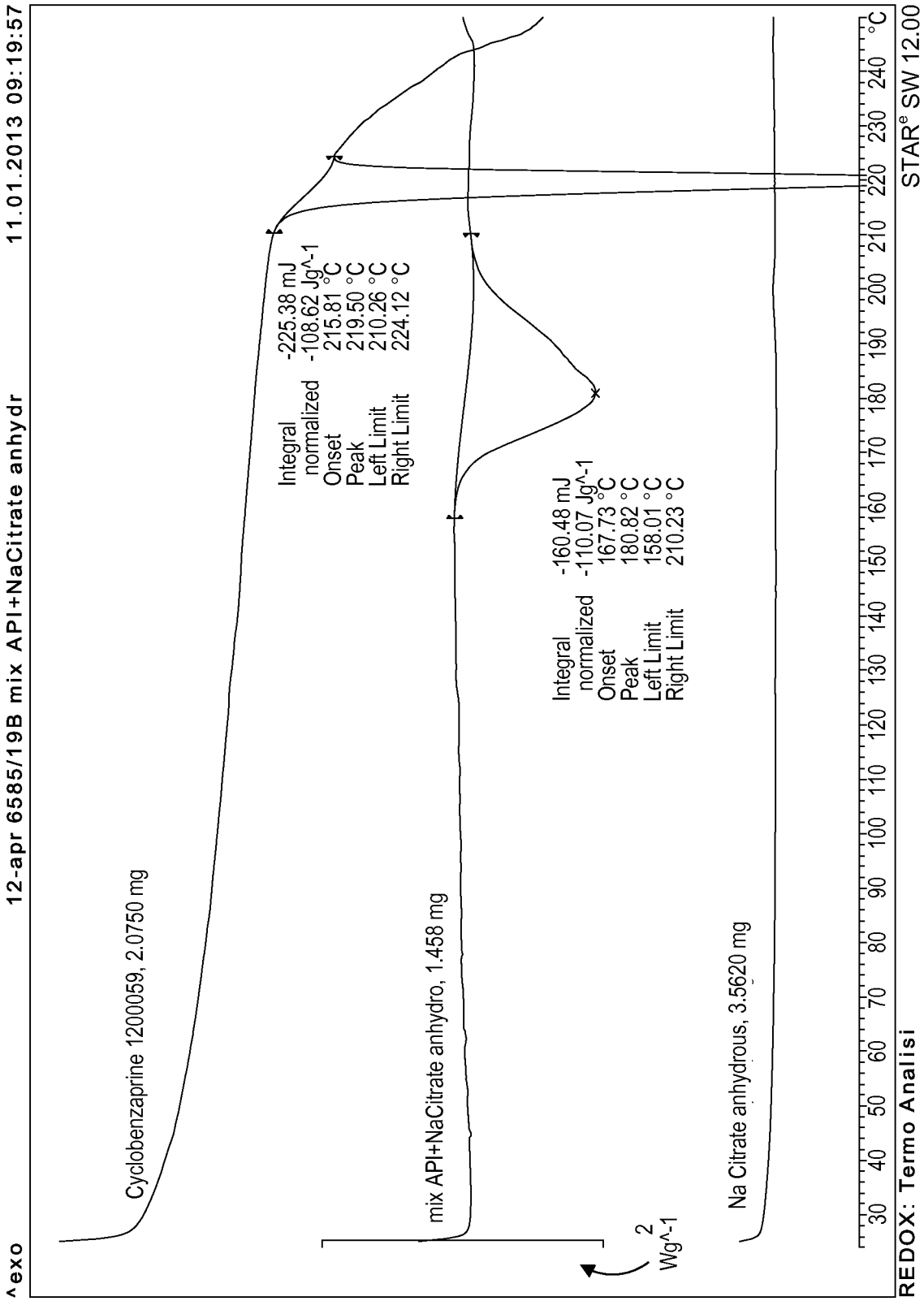

^exo
12-apr 6585/19B mix API+NaCitrate anhydr
11.01.2013 09:19:57
Cyclobenzaprine 1200059, 2.0750 mg
mix API+NaCitrate anhydro, 1.458 mg
Na Citrate anhydrous, 3.5620 mg
Integral -225.38 mJ
normalized -108.62 Jg^-1
Onset 215.81 °C
Peak 219.50 °C
Left Limit 210.26 °C
Right Limit 224.12 °C
Integral -160.48 mJ
normalized -110.07 Jg^-1
Onset 167.73 °C
Peak 180.82 °C
Left Limit 158.01 °C
Right Limit 210.23 °C
2
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 40

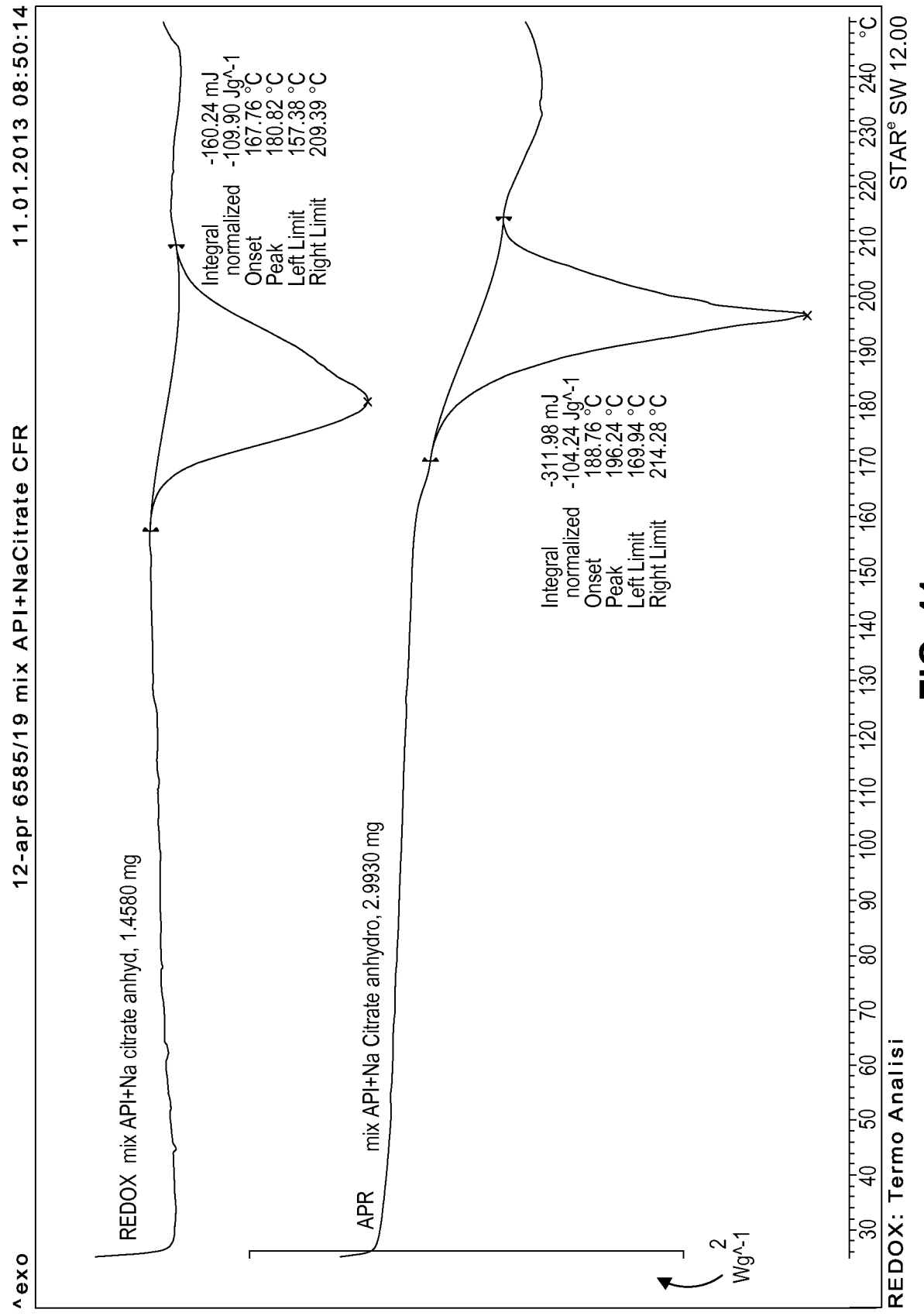

^exo
12-apr 6585/19 mix API+NaCitrate CFR
11.01.2013 08:50:14
REDOX mix API+Na citrate anhyd, 1.4580 mg
Integral -160.24 mJ
normalized -109.90 Jg^-1
Onset 167.76 °C
Peak 180.82 °C
Left Limit 157.38 °C
Right Limit 209.39 °C
APR mix API+Na Citrate anhydro, 2.9930 mg
Integral -311.98 mJ
normalized -104.24 Jg^-1
Onset 188.76 °C
Peak 196.24 °C
Left Limit 169.94 °C
Right Limit 214.28 °C
2
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 41

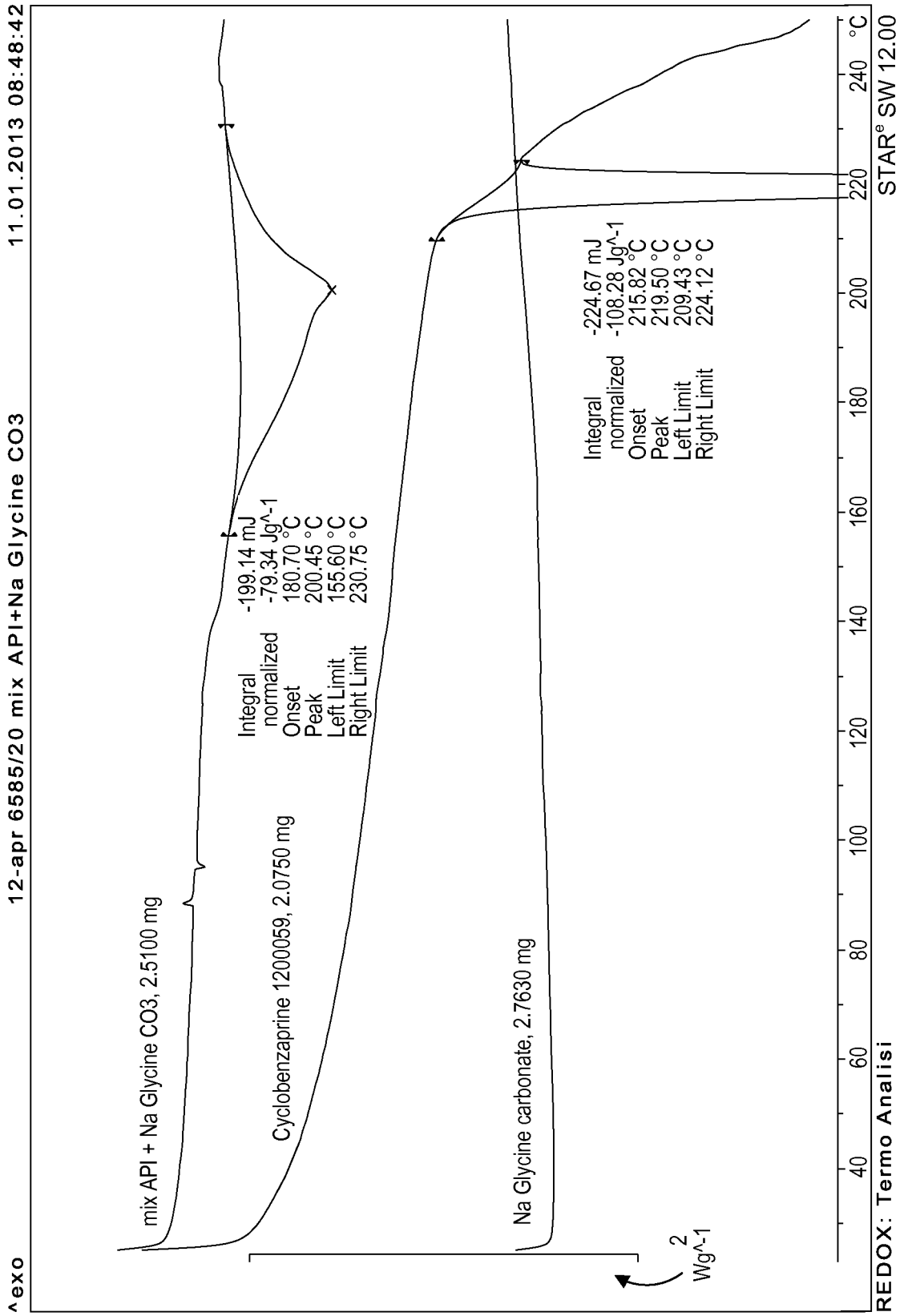

^exo
12-apr 6585/20 mix API+Na Glycine CO3
11.01.2013 08:48:42
mix API + Na Glycine CO3, 2.5100 mg
Cyclobenzaprine 1200059, 2.0750 mg
Integral -199.14 mJ
normalized -79.34 Jg^-1
Onset 180.70 °C
Peak 200.45 °C
Left Limit 155.60 °C
Right Limit 230.75 °C
Na Glycine carbonate, 2.7630 mg
Integral -224.67 mJ
normalized -108.28 Jg^-1
Onset 215.82 °C
Peak 219.50 °C
Left Limit 209.43 °C
Right Limit 224.12 °C
2
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 42

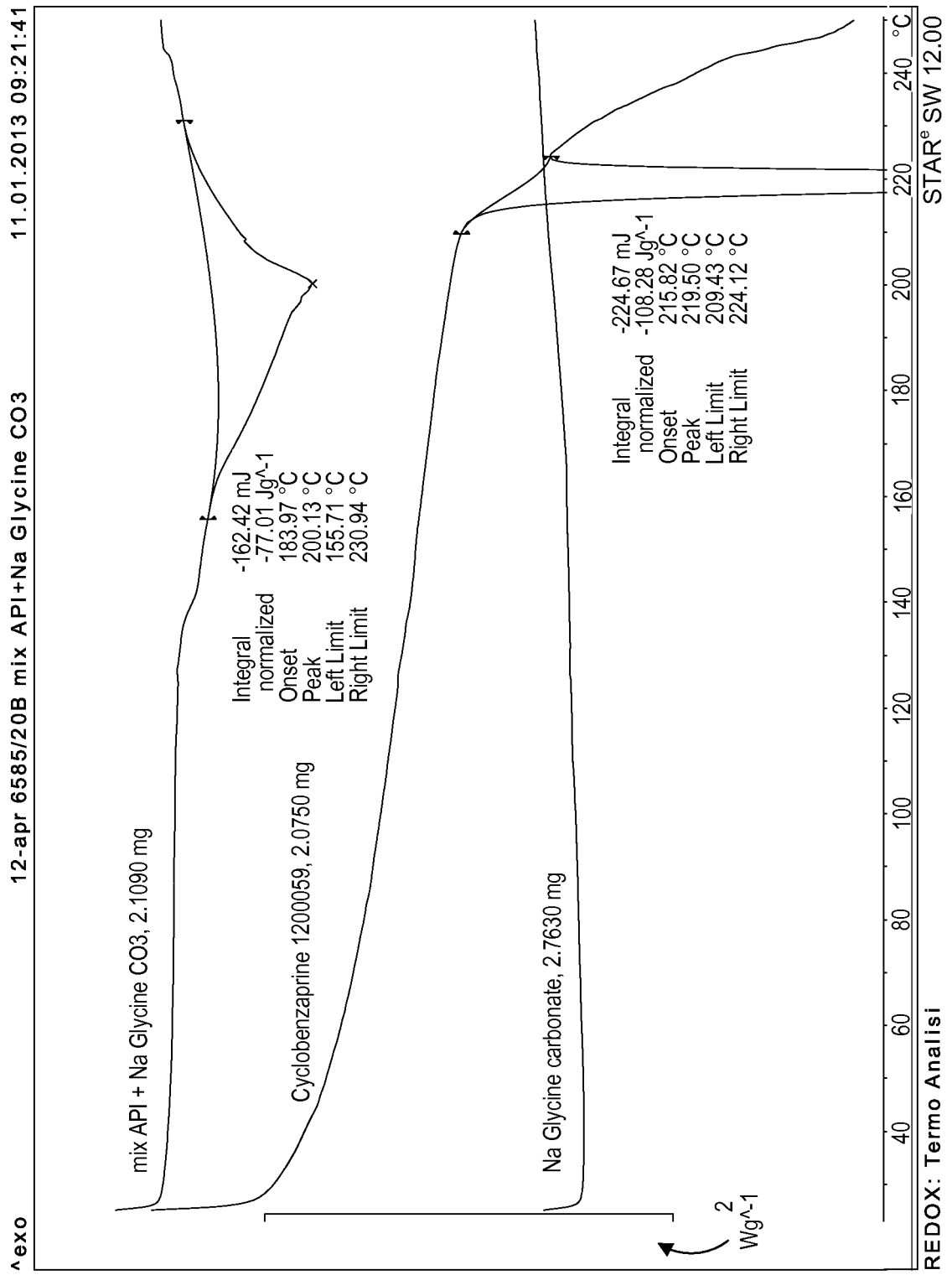

^exo
12-apr 6585/20B mix API+Na Glycine CO3
11.01.2013 09:21:41
mix API + Na Glycine CO3, 2.1090 mg
Integral -162.42 mJ
normalized -77.01 Jg^-1
Onset 183.97 °C
Peak 200.13 °C
Left Limit 155.71 °C
Right Limit 230.94 °C
Cyclobenzaprine 1200059, 2.0750 mg
Na Glycine carbonate, 2.7630 mg
Integral -224.67 mJ
normalized -108.28 Jg^-1
Onset 215.82 °C
Peak 219.50 °C
Left Limit 209.43 °C
Right Limit 224.12 °C
2
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 43

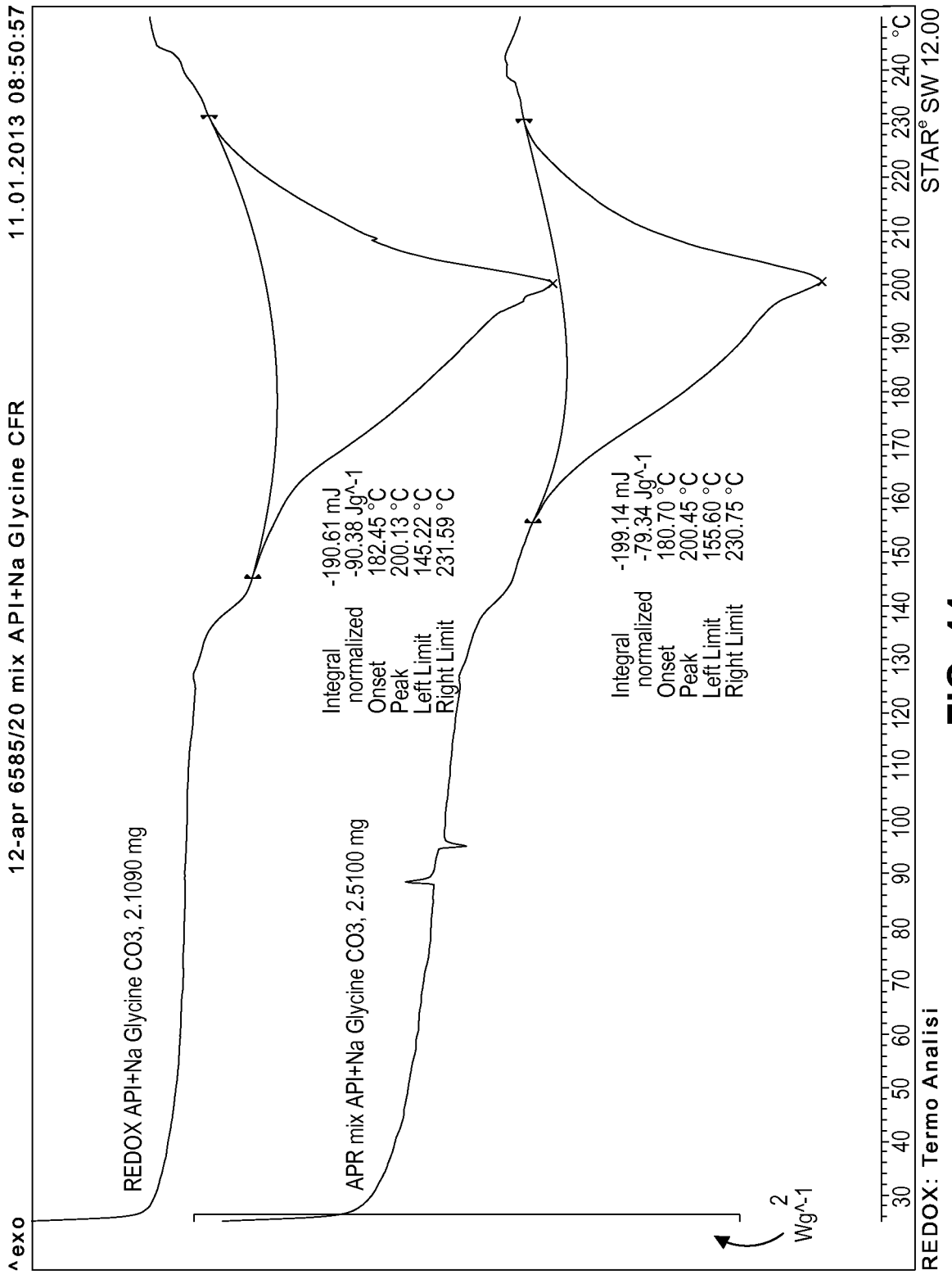

^exo
12-apr 6585/20 mix API+Na Glycine CFR
11.01.2013 08:50:57
REDOX API+Na Glycine CO3, 2.1090 mg
APR mix API+Na Glycine CO3, 2.5100 mg
Integral -190.61 mJ
normalized -90.38 Jg^-1
Onset 182.45 °C
Peak 200.13 °C
Left Limit 145.22 °C
Right Limit 231.59 °C
Integral -199.14 mJ
normalized -79.34 Jg^-1
Onset 180.70 °C
Peak 200.45 °C
Left Limit 155.60 °C
Right Limit 230.75 °C
2
Wg^-1
REDOX: Termo Analisi
STARe SW 12.00
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C

FIG. 44

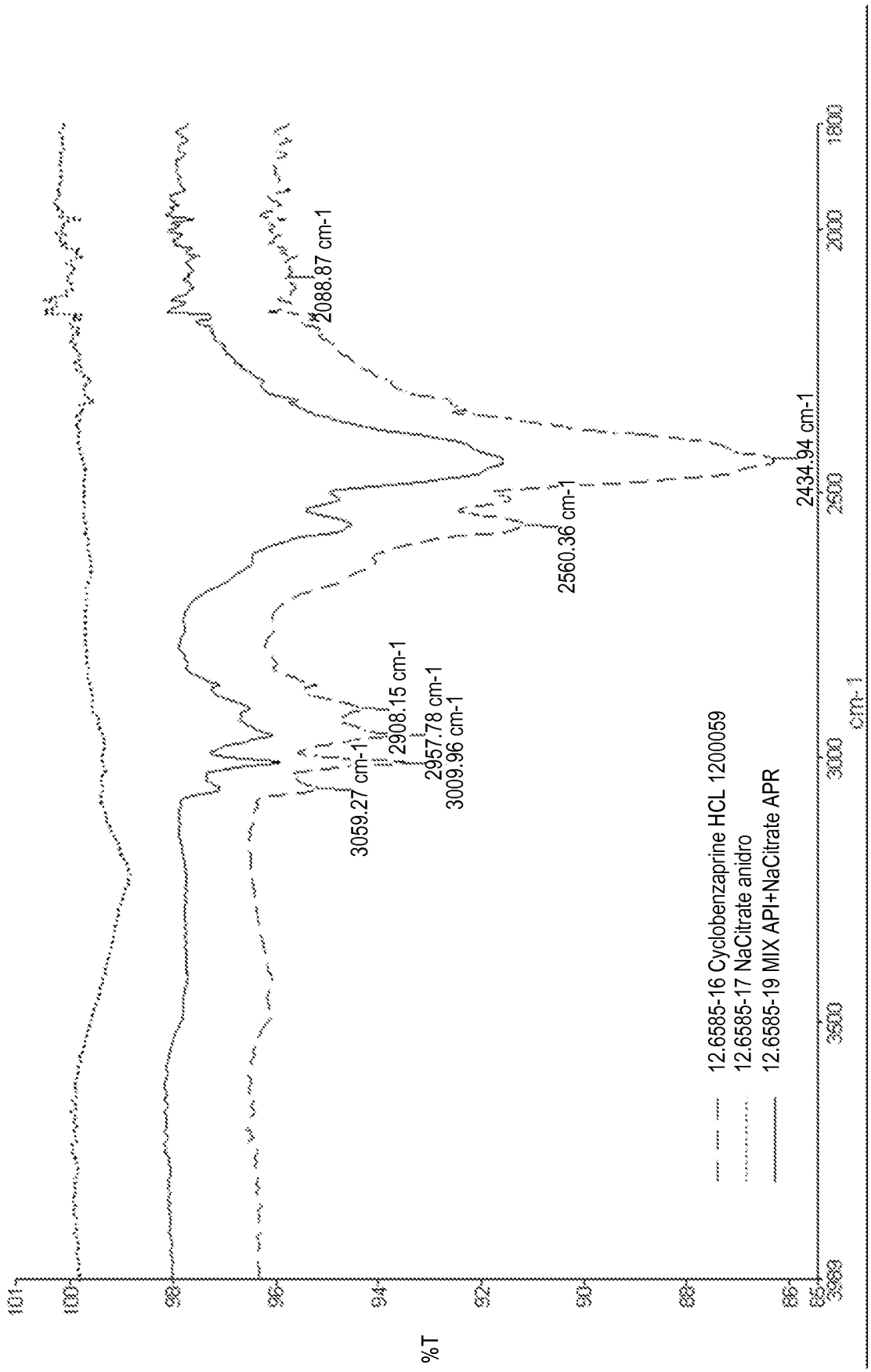

3059.27 cm-1
2908.15 cm-1
2957.78 cm-1
3009.96 cm-1
2560.36 cm-1
2088.87 cm-1
2434.94 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-17 NaCitrate anidro
12.6585-19 MIX API+NaCitrate APR
%T
cm-1

FIG. 45

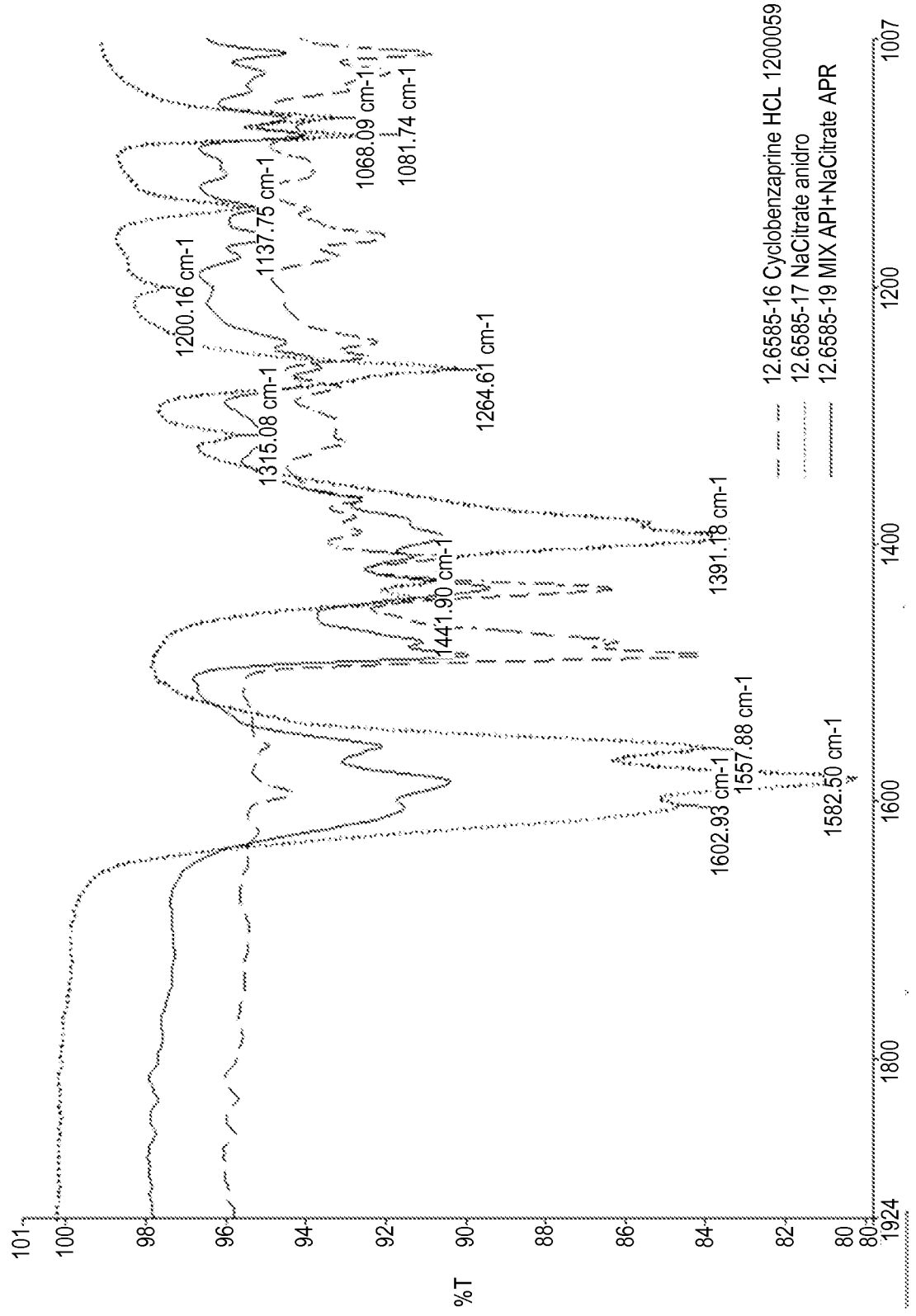

12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-17 NaCitrate anidro
12.6585-19 MIX API+NaCitrate APR
%T
1200.16 cm-1
1137.75 cm-1
1068.09 cm-1
1081.74 cm-1
1315.08 cm-1
1264.61 cm-1
1391.18 cm-1
1441.90 cm-1
1557.88 cm-1
1602.93 cm-1
1582.50 cm-1

FIG. 46

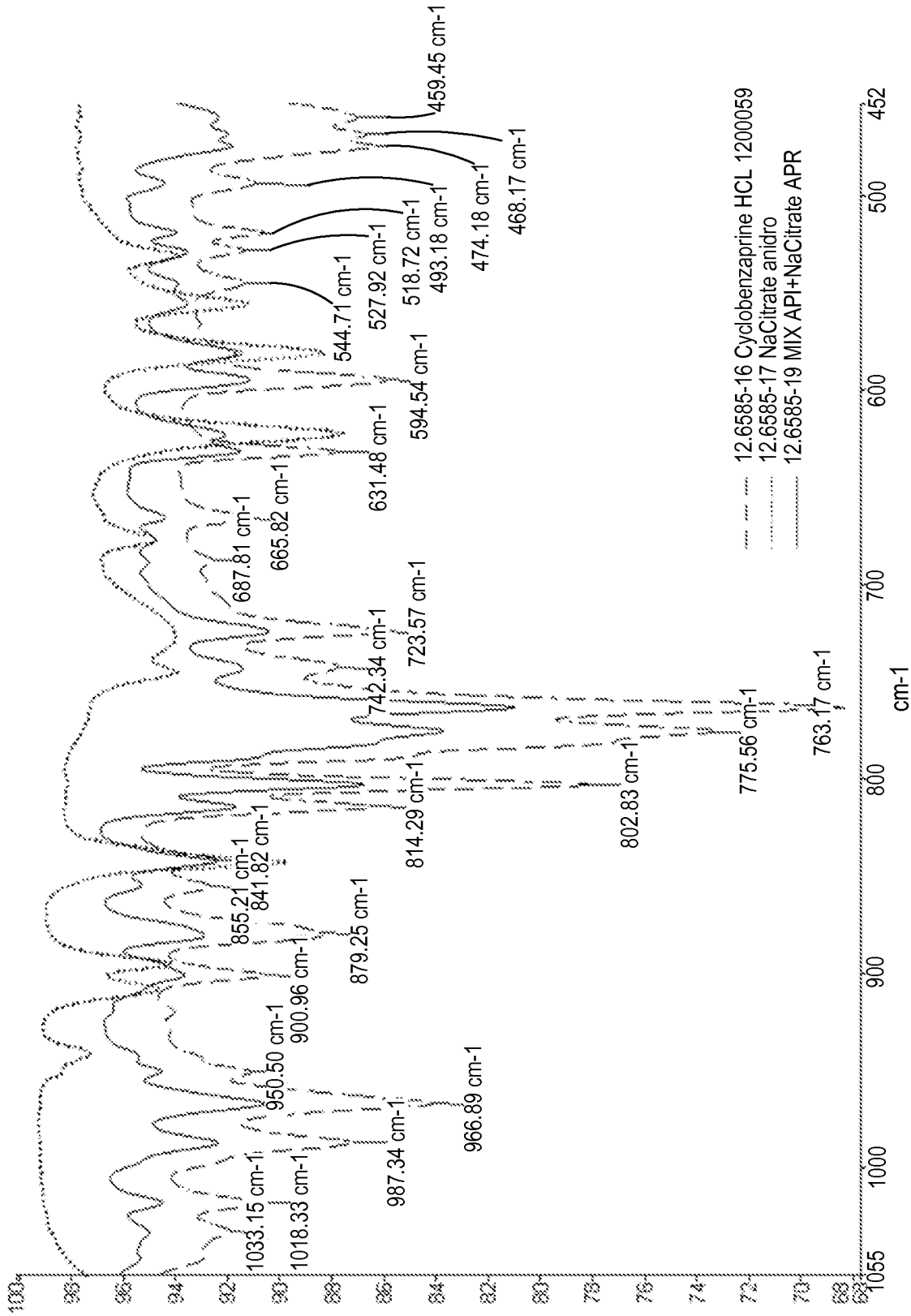

12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-17 NaCitrate anidro
12.6585-19 MIX API+NaCitrate APR
1033.15 cm-1
1018.33 cm-1
987.34 cm-1
966.89 cm-1
950.50 cm-1
900.96 cm-1
879.25 cm-1
855.21 cm-1
841.82 cm-1
814.29 cm-1
802.83 cm-1
775.56 cm-1
763.17 cm-1
742.34 cm-1
723.57 cm-1
687.81 cm-1
665.82 cm-1
631.48 cm-1
594.54 cm-1
544.71 cm-1
527.92 cm-1
518.72 cm-1
493.18 cm-1
474.18 cm-1
468.17 cm-1
459.45 cm-1
cm-1

FIG. 47

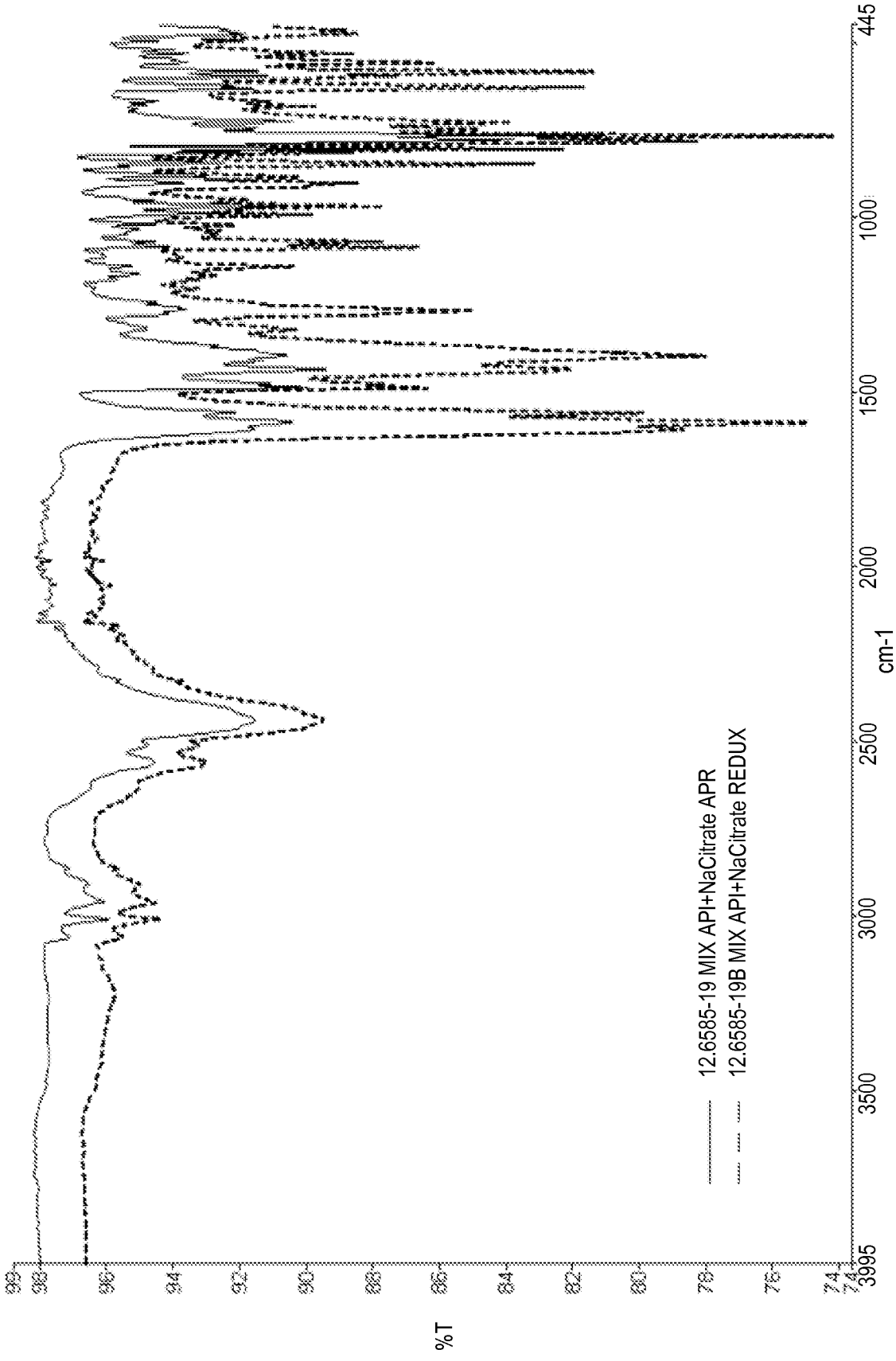

12.6585-19 MIX API+NaCitrate APR
12.6585-19B MIX API+NaCitrate REDUX
%T
cm-1
3995
3500
3000
2500
2000
1500
1000
445

FIG. 48

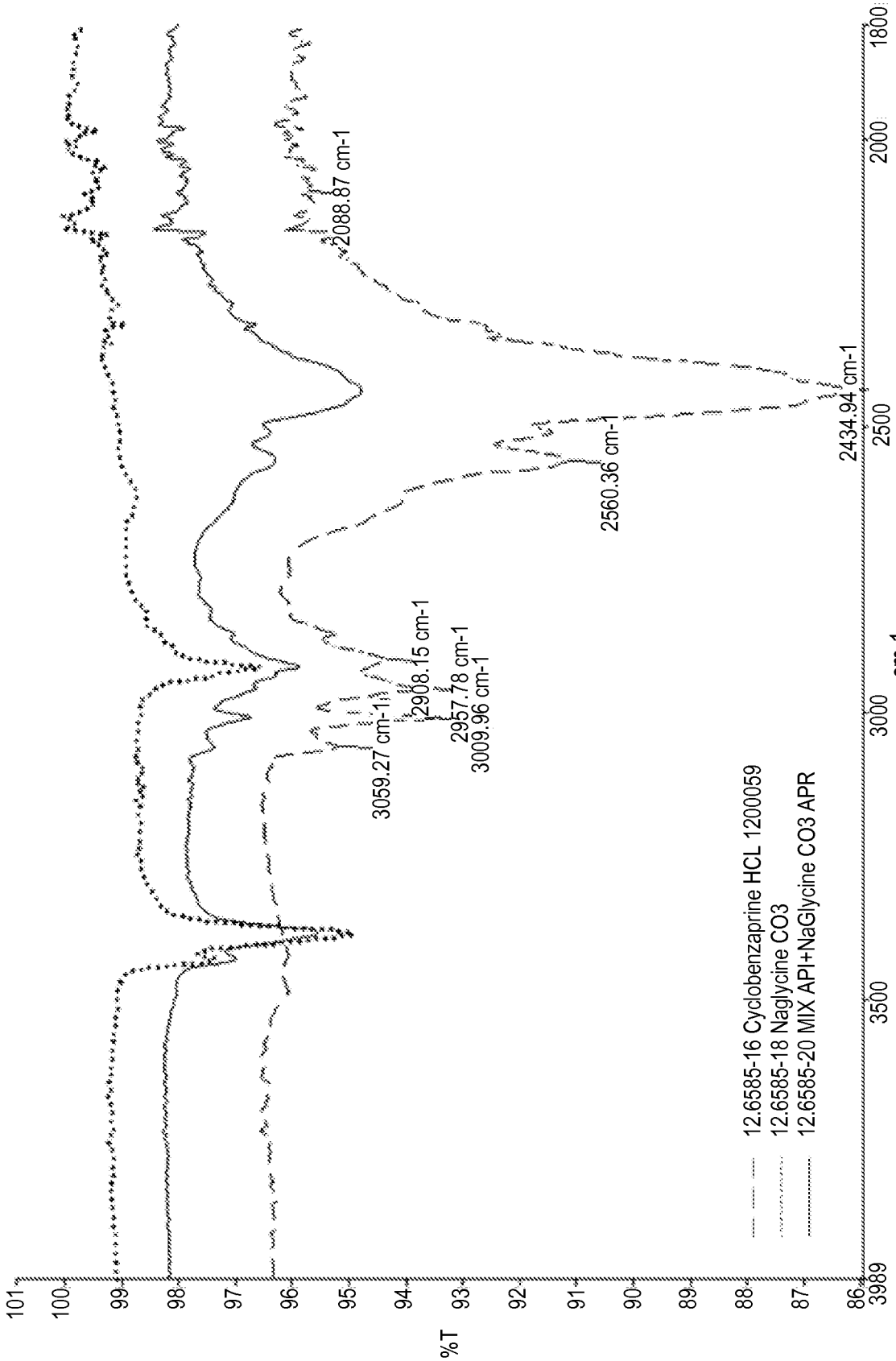

12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-18 Naglycine CO3
12.6585-20 MIX API+NaGlycine CO3 APR
%T
cm-1
3059.27 cm-1
2908.15 cm-1
2957.78 cm-1
3009.96 cm-1
2560.36 cm-1
2434.94 cm-1
2088.87 cm-1

FIG. 49

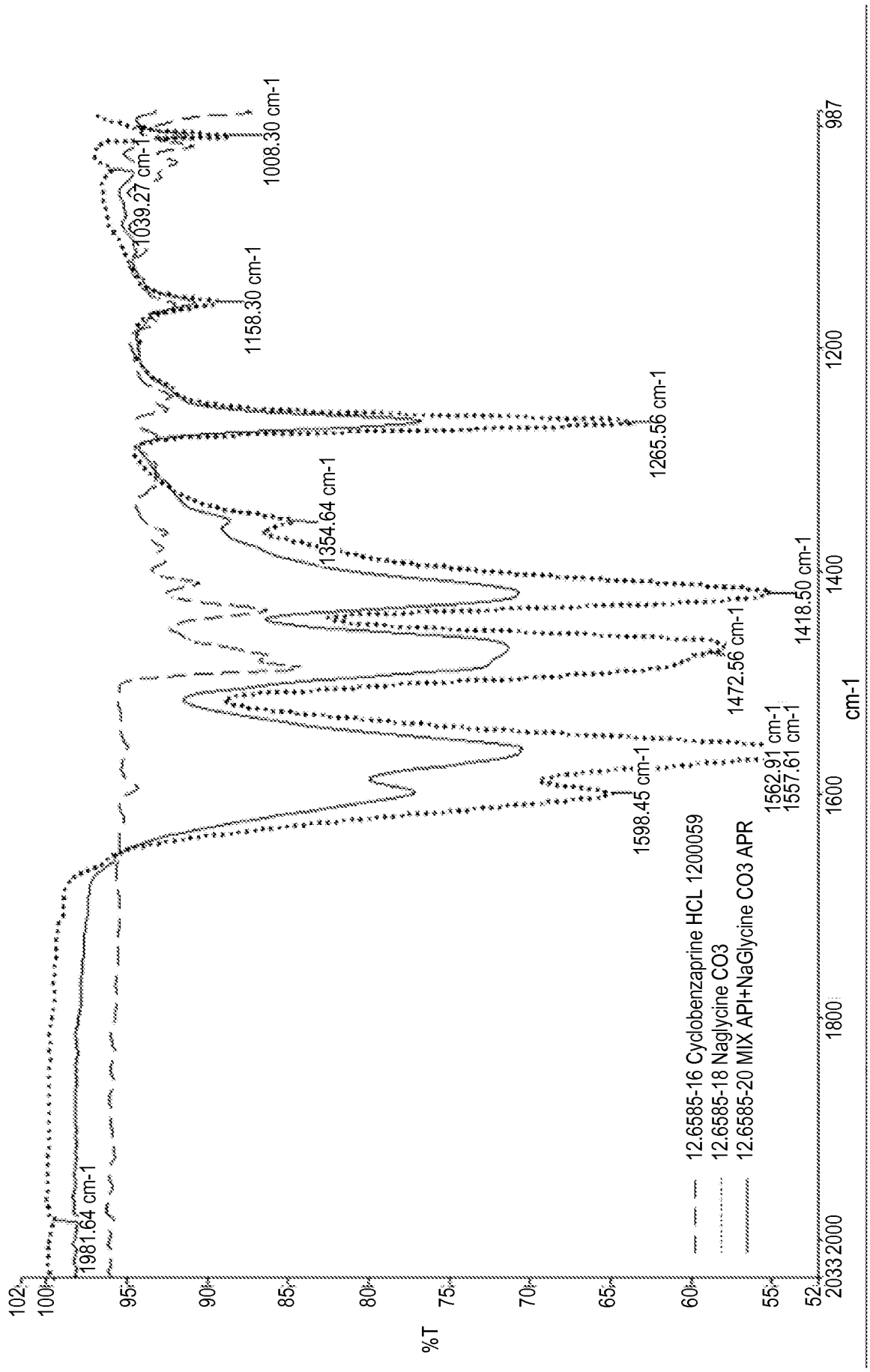

1981.64 cm-1
1598.45 cm-1
1562.91 cm-1
1557.61 cm-1
1472.56 cm-1
1418.50 cm-1
1354.64 cm-1
1265.56 cm-1
1158.30 cm-1
1039.27 cm-1
1008.30 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-18 Naglycine CO3
12.6585-20 MIX API+NaGlycine CO3 APR
%T
cm-1
2033 2000 1800 1600 1400 1200 987
102 100 95 90 85 80 75 70 65 60 55 52

FIG. 50

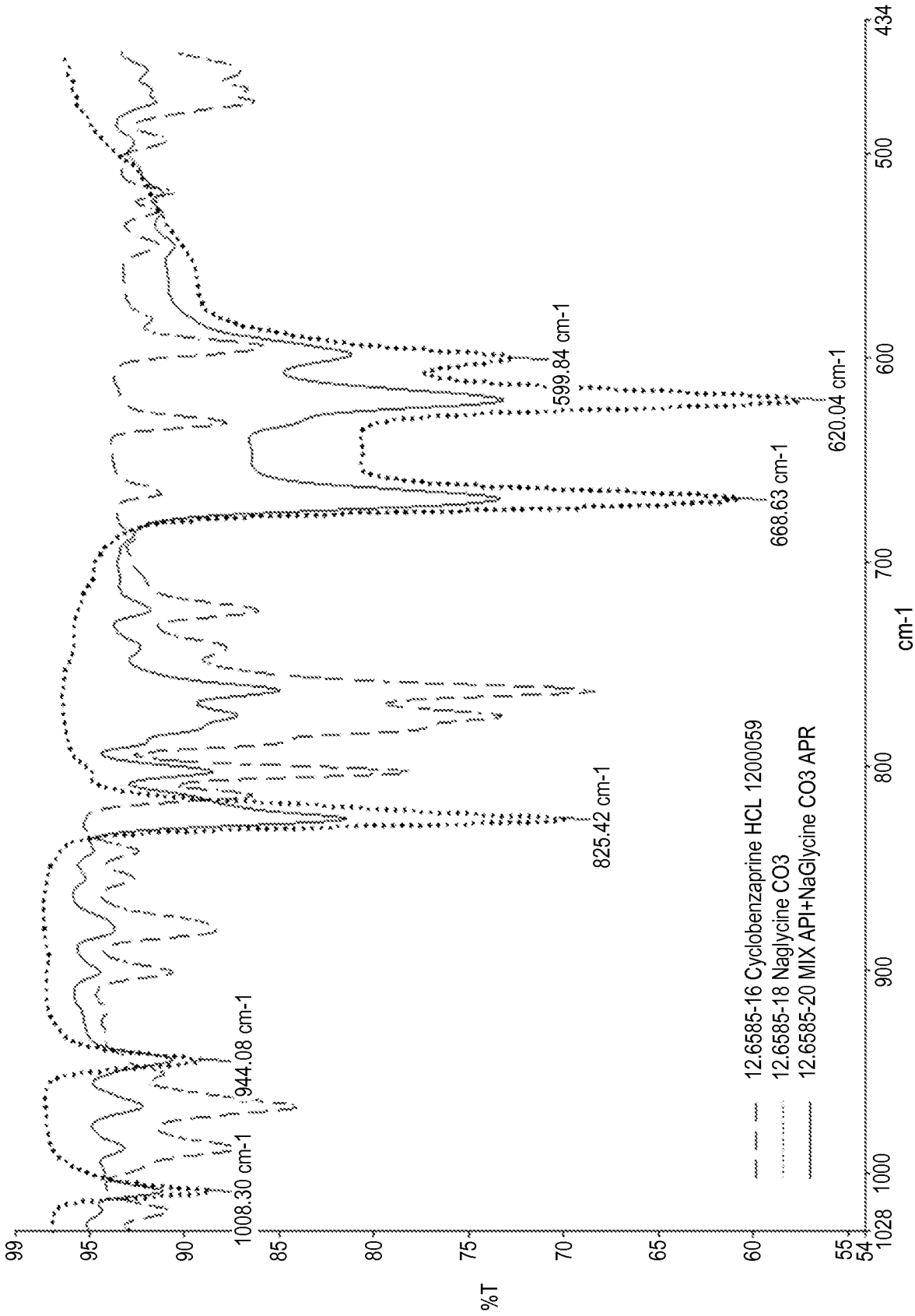

99
95
90
85
80
75
70
65
60
55
54
%T
1028
1000
900
800
700
600
500
434
cm-1
1008.30 cm-1
944.08 cm-1
825.42 cm-1
668.63 cm-1
599.84 cm-1
620.04 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-18 Naglycine CO3
12.6585-20 MIX API+NaGlycine CO3 APR

FIG. 51

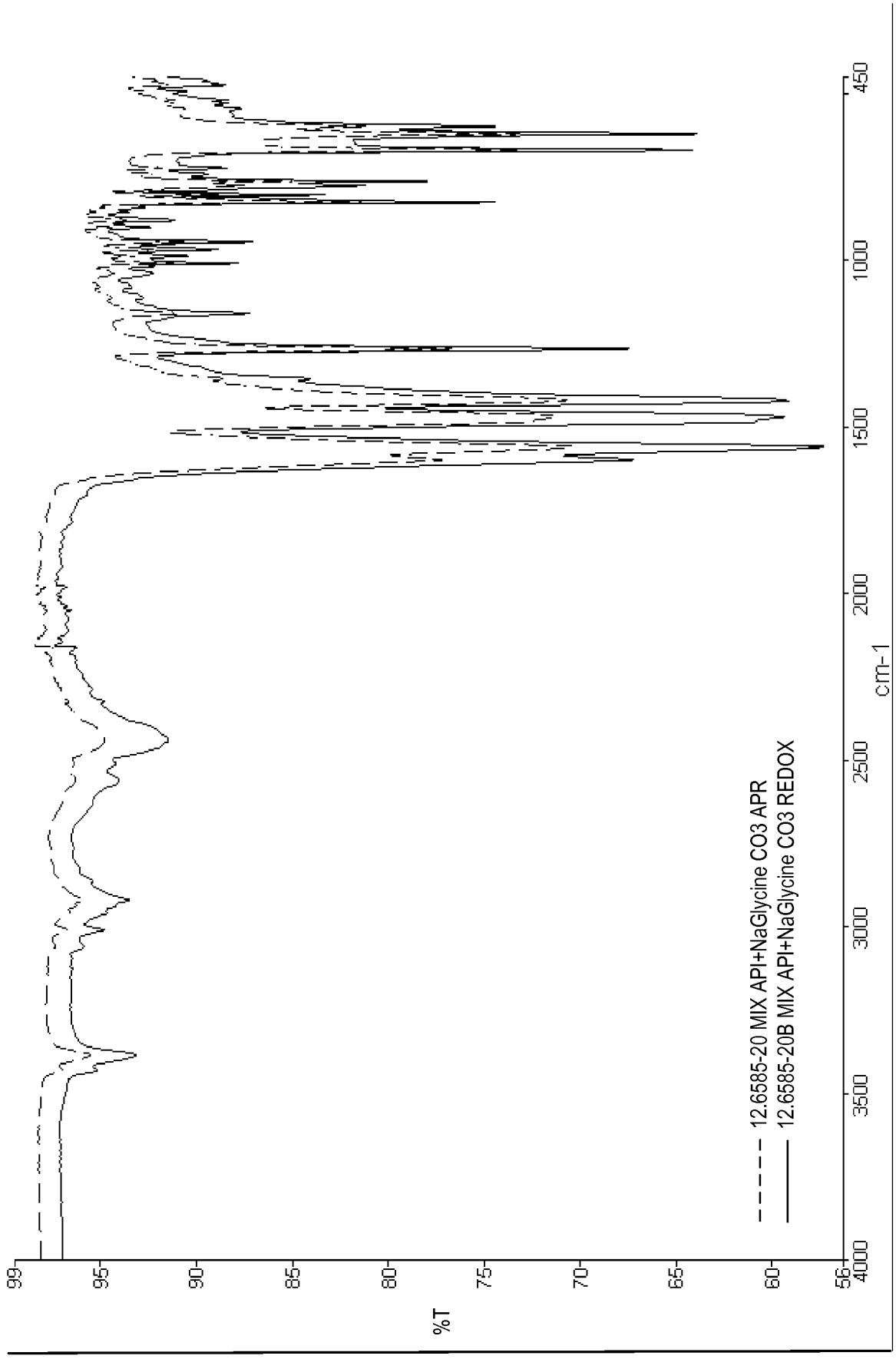

99
95
90
85
80
75
70
65
60
56
%T
4000
3500
3000
2500
2000
1500
1000
450
cm-1
12.6585-20 MIX API+NaGlycine CO3 APR
12.6585-20B MIX API+NaGlycine CO3 REDOX

FIG. 52

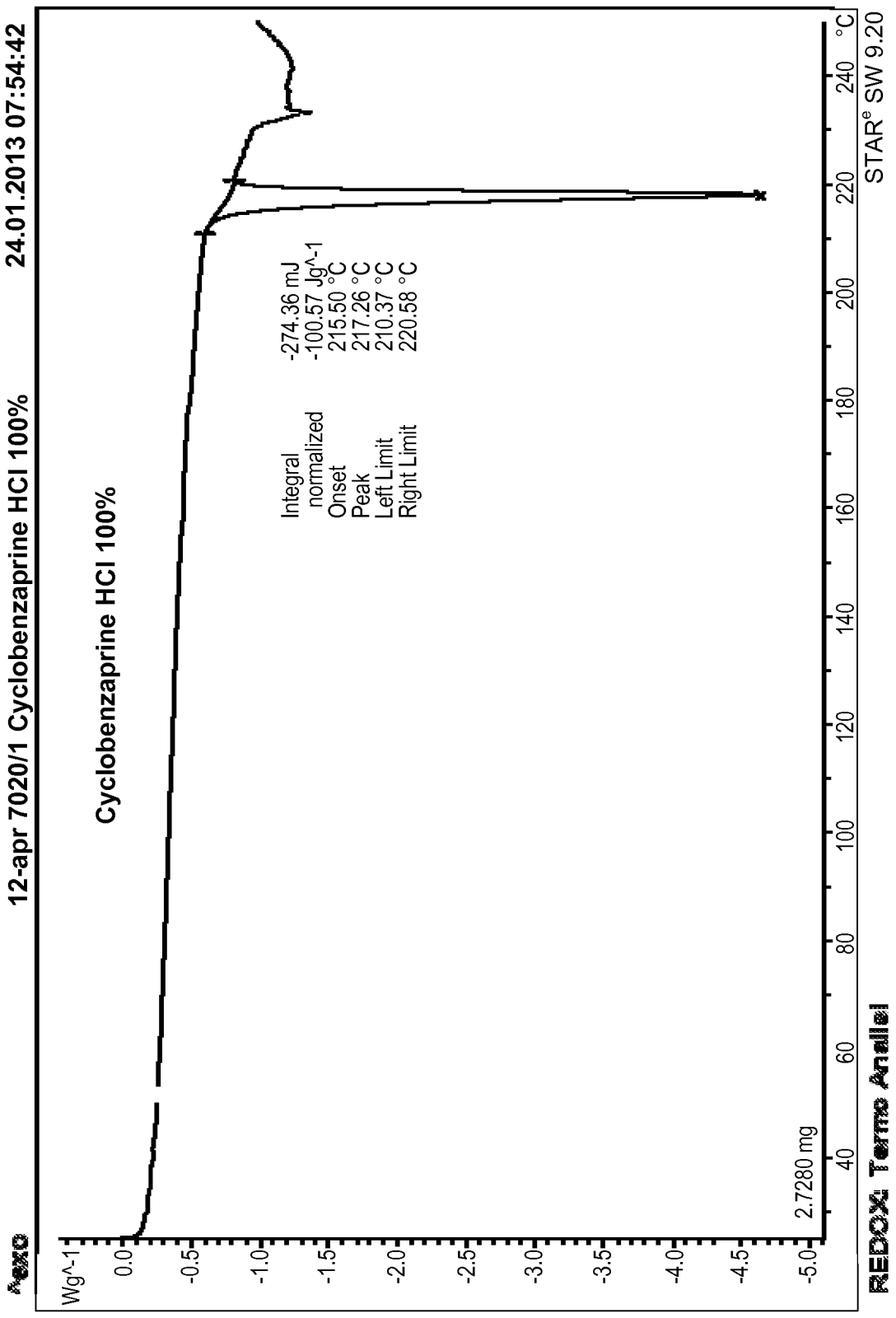

12-apr 7020/1 Cyclobenzaprine HCl 100%
24.01.2013 07:54:42
Cyclobenzaprine HCl 100%
Integral -274.36 mJ
normalized -100.57 Jg^-1
Onset 215.50 °C
Peak 217.26 °C
Left Limit 210.37 °C
Right Limit 220.58 °C
Wg^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
-4.5
-5.0
40
60
80
100
120
140
160
180
200
220
240
°C
2.7280 mg
REDOX: Termo Analisi
STARe SW 9.20

FIG. 53

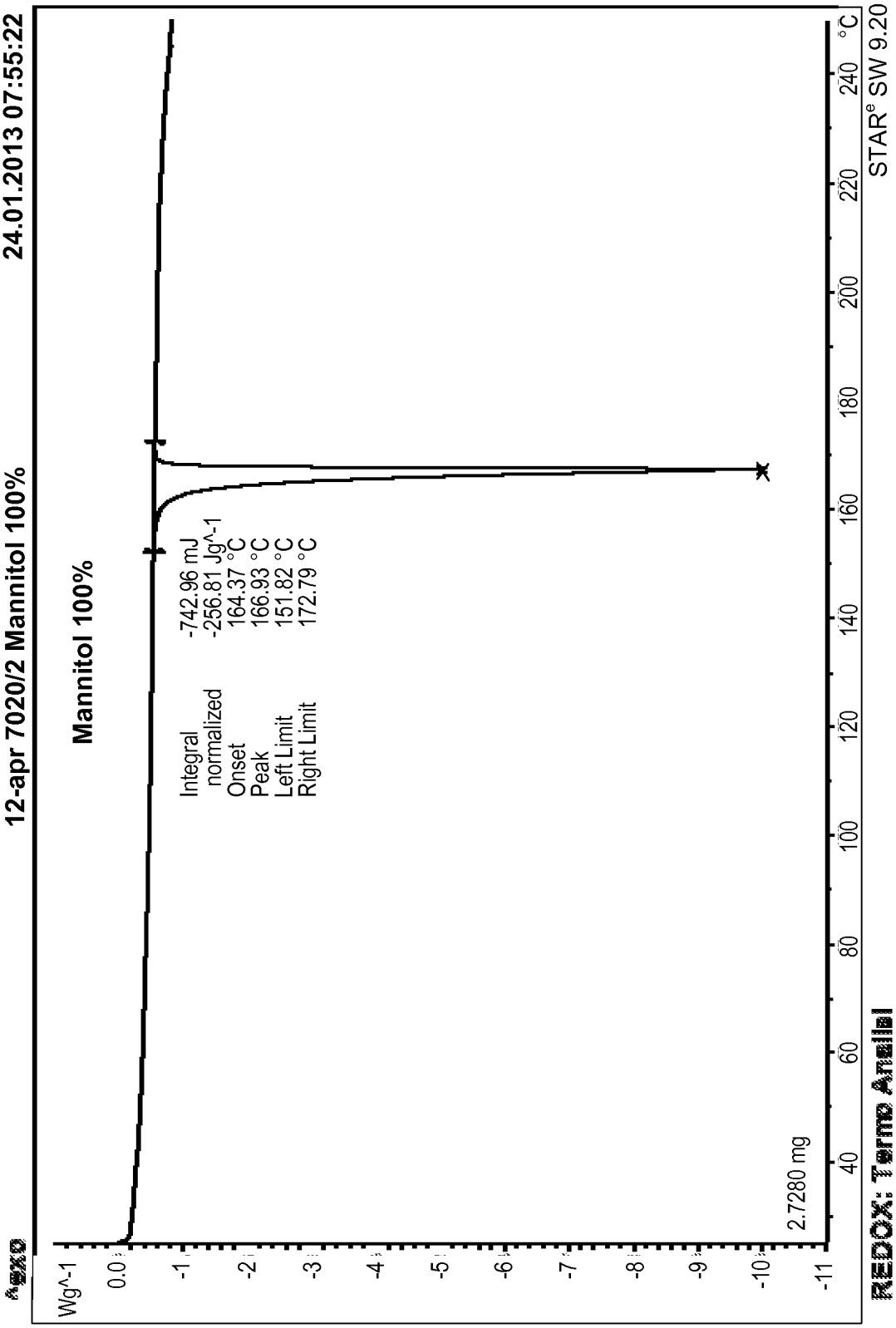

24.01.2013 07:55:22
12-apr 7020/2 Mannitol 100%
Mannitol 100%
Integral -742.96 mJ
normalized -256.81 Jg^-1
Onset 164.37 °C
Peak 166.93 °C
Left Limit 151.82 °C
Right Limit 172.79 °C
2.7280 mg
Wg^-1
0.0
-1
-2
-3
-4
-5
-6
-7
-8
-9
-10
-11
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 54

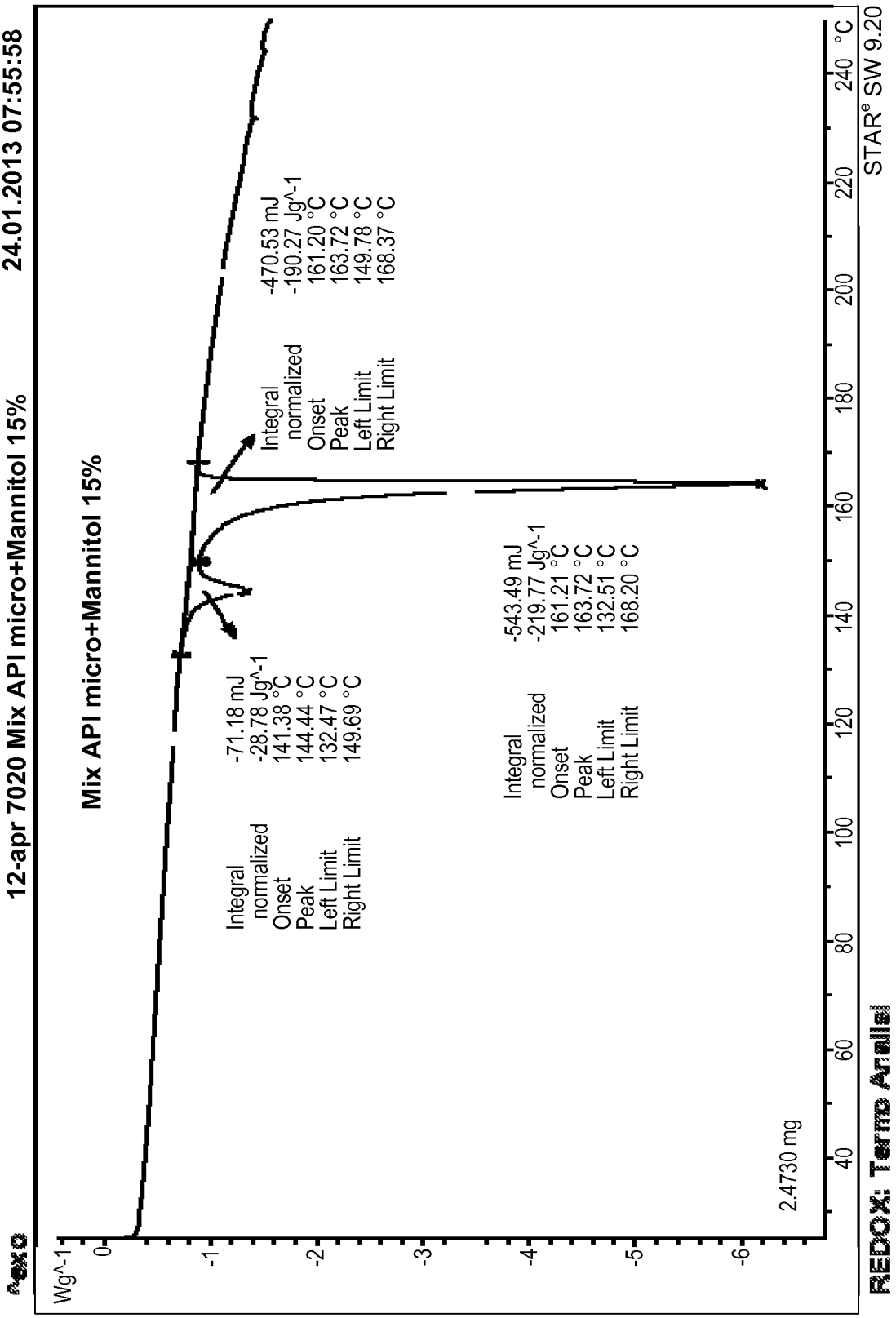

12-apr 7020 Mix API micro+Mannitol 15%
24.01.2013 07:55:58
Mix API micro+Mannitol 15%
Integral -71.18 mJ
normalized -28.78 Jg^-1
Onset 141.38 °C
Peak 144.44 °C
Left Limit 132.47 °C
Right Limit 149.69 °C
Integral -470.53 mJ
normalized -190.27 Jg^-1
Onset 161.20 °C
Peak 163.72 °C
Left Limit 149.78 °C
Right Limit 168.37 °C
Integral -543.49 mJ
normalized -219.77 Jg^-1
Onset 161.21 °C
Peak 163.72 °C
Left Limit 132.51 °C
Right Limit 168.20 °C
2.4730 mg
Wg^-1
0
-1
-2
-3
-4
-5
-6
40
60
80
100
120
140
160
180
200
220
240 °C
STARe SW 9.20
REDOX: Termo Analisi

FIG. 55

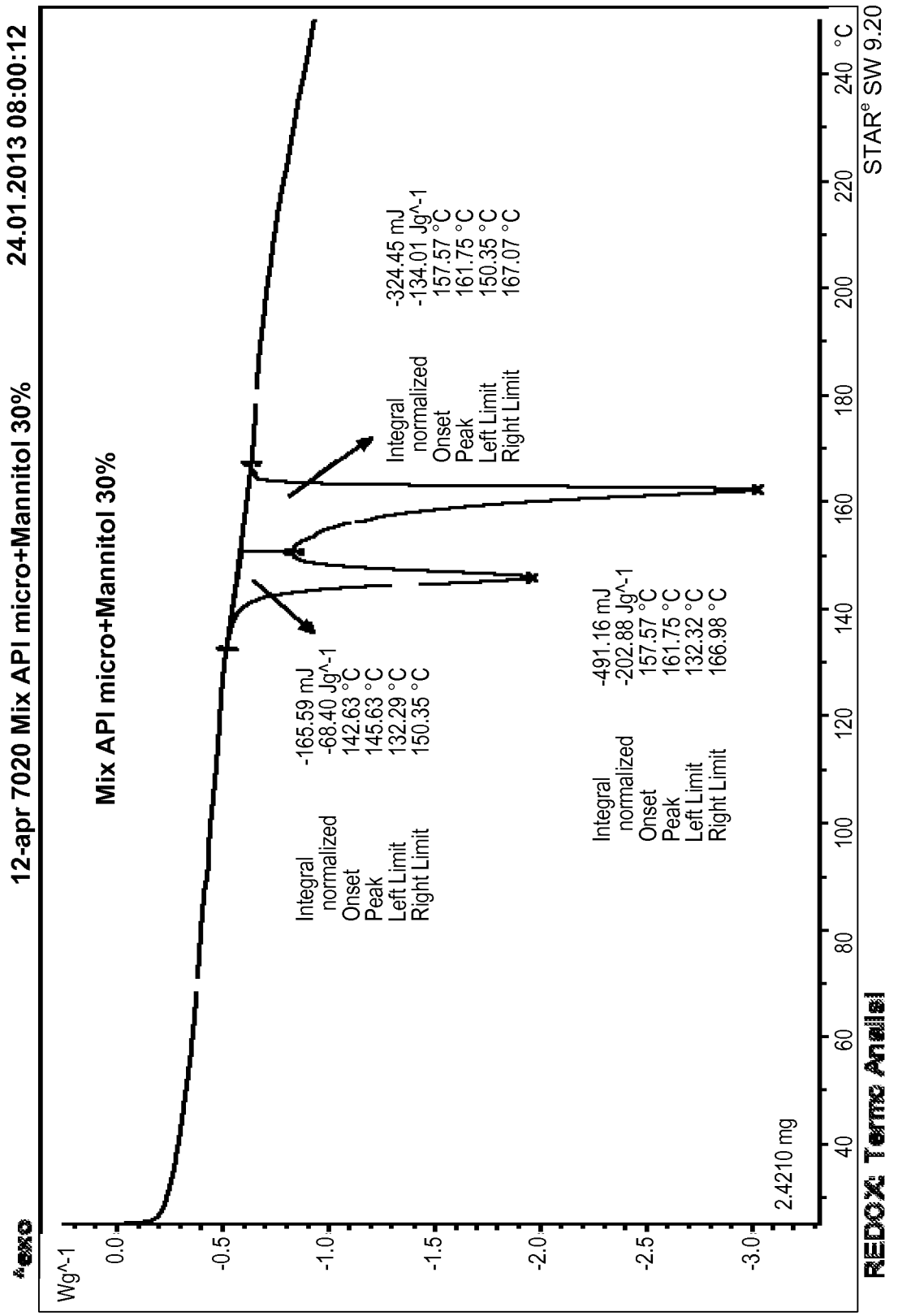

12-apr 7020 Mix API micro+Mannitol 30%
24.01.2013 08:00:12
Mix API micro+Mannitol 30%
Integral -165.59 mJ
normalized -68.40 Jg^-1
Onset 142.63 °C
Peak 145.63 °C
Left Limit 132.29 °C
Right Limit 150.35 °C
Integral -491.16 mJ
normalized -202.88 Jg^-1
Onset 157.57 °C
Peak 161.75 °C
Left Limit 132.32 °C
Right Limit 166.98 °C
Integral -324.45 mJ
normalized -134.01 Jg^-1
Onset 157.57 °C
Peak 161.75 °C
Left Limit 150.35 °C
Right Limit 167.07 °C
2.4210 mg
Wg^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
40
60
80
100
120
140
160
180
200
220
240 °C
STARe SW 9.20
REDOX Terme Analisi

FIG. 56

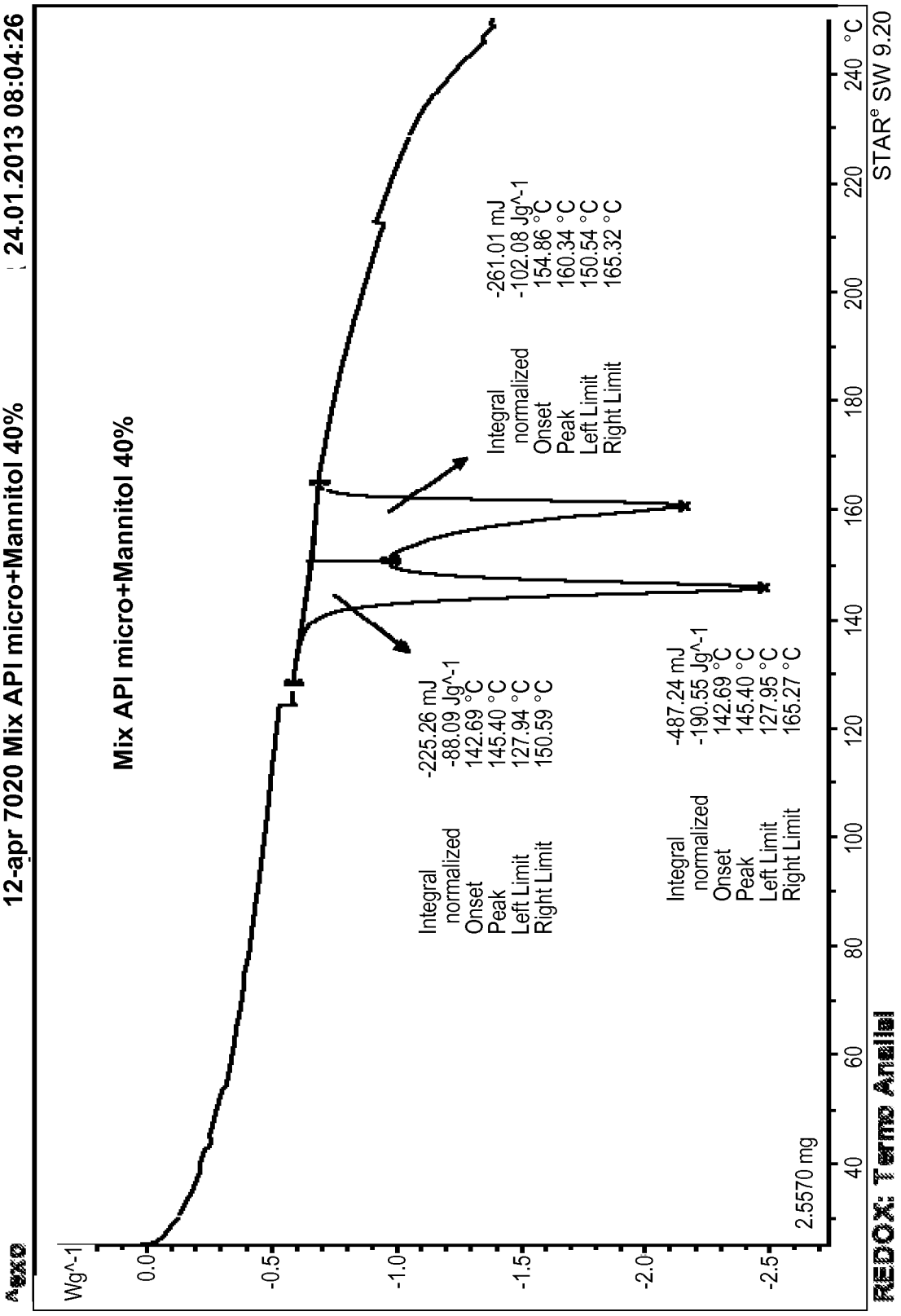

12-apr 7020 Mix API micro+Mannitol 40%
24.01.2013 08:04:26
Mix API micro+Mannitol 40%
Wg^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
40
60
80
100
120
140
160
180
200
220
240 °C
2.5570 mg
Integral -225.26 mJ
normalized -88.09 Jg^-1
Onset 142.69 °C
Peak 145.40 °C
Left Limit 127.94 °C
Right Limit 150.59 °C
Integral -487.24 mJ
normalized -190.55 Jg^-1
Onset 142.69 °C
Peak 145.40 °C
Left Limit 127.95 °C
Right Limit 165.27 °C
Integral -261.01 mJ
normalized -102.08 Jg^-1
Onset 154.86 °C
Peak 160.34 °C
Left Limit 150.54 °C
Right Limit 165.32 °C
STARe SW 9.20
REDOX: Termo Analisi

FIG. 57

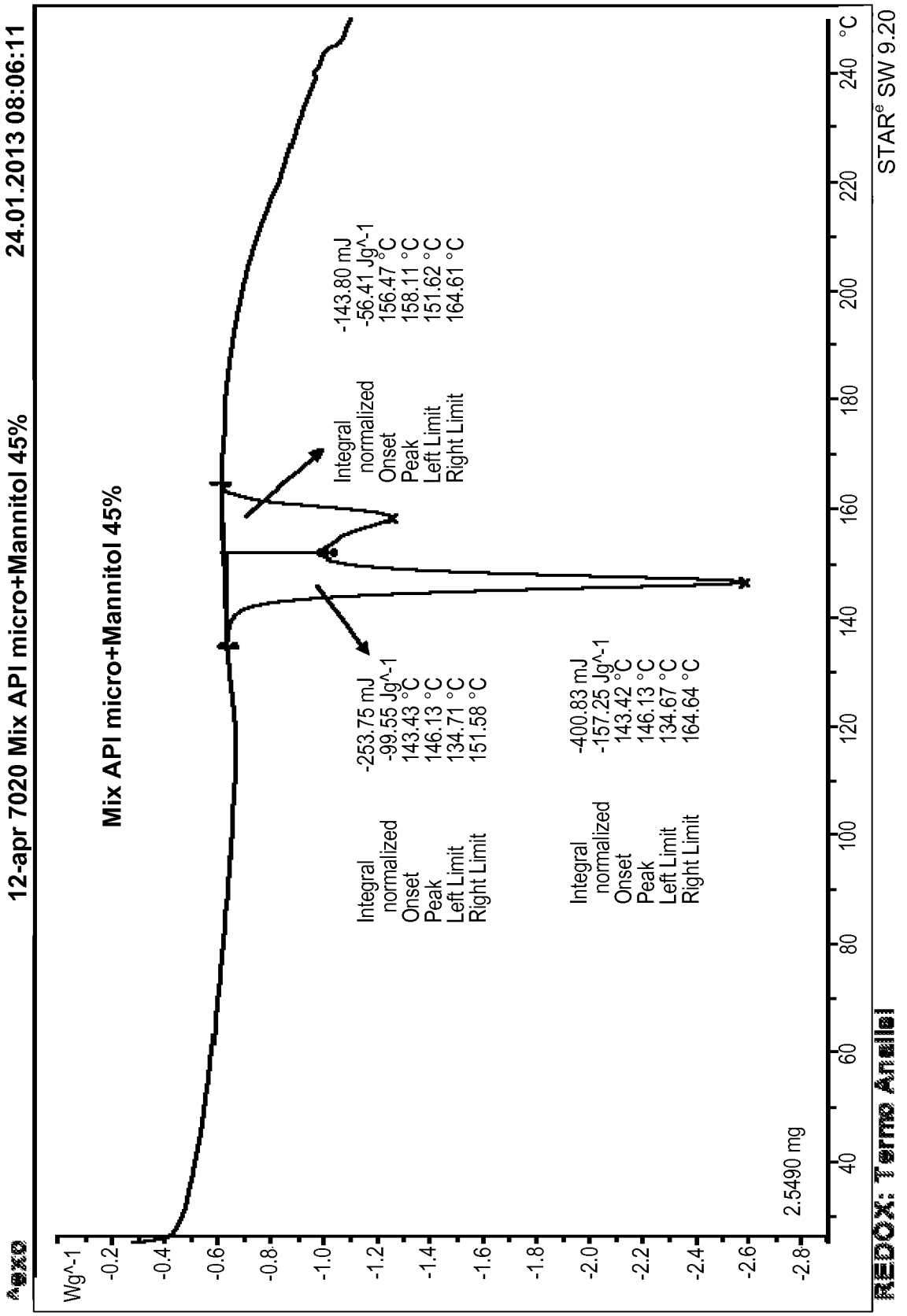

12-apr 7020 Mix API micro+Mannitol 45%
24.01.2013 08:06:11
Mix API micro+Mannitol 45%
Integral -253.75 mJ
normalized -99.55 Jg^-1
Onset 143.43 °C
Peak 146.13 °C
Left Limit 134.71 °C
Right Limit 151.58 °C
Integral -400.83 mJ
normalized -157.25 Jg^-1
Onset 143.42 °C
Peak 146.13 °C
Left Limit 134.67 °C
Right Limit 164.64 °C
Integral -143.80 mJ
normalized -56.41 Jg^-1
Onset 156.47 °C
Peak 158.11 °C
Left Limit 151.62 °C
Right Limit 164.61 °C
2.5490 mg
Wg^-1
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 58

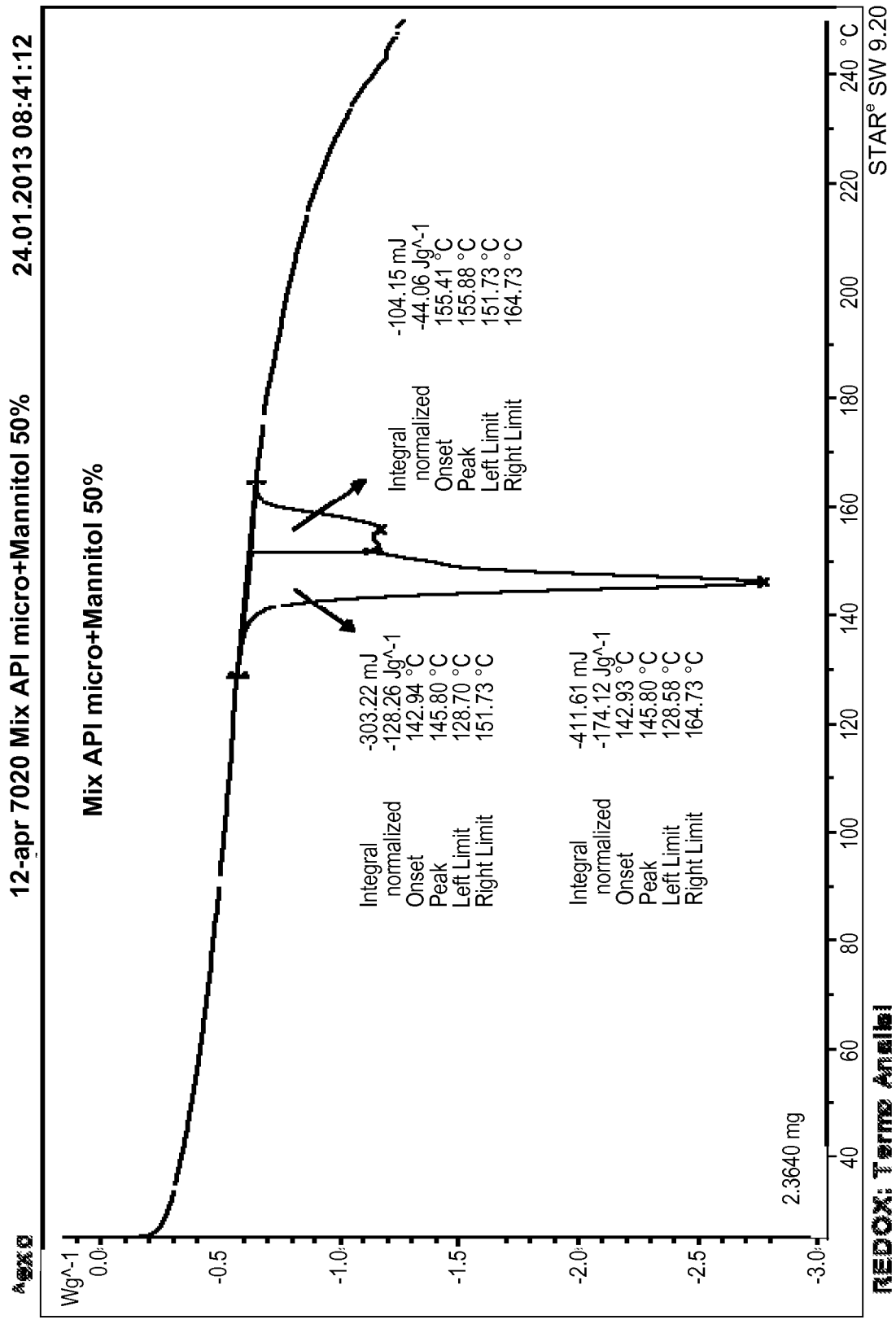

12-apr 7020 Mix API micro+Mannitol 50%
24.01.2013 08:41:12
Mix API micro+Mannitol 50%
Integral -303.22 mJ
normalized -128.26 Jg^-1
Onset 142.94 °C
Peak 145.80 °C
Left Limit 128.70 °C
Right Limit 151.73 °C
Integral -411.61 mJ
normalized -174.12 Jg^-1
Onset 142.93 °C
Peak 145.80 °C
Left Limit 128.58 °C
Right Limit 164.73 °C
Integral -104.15 mJ
normalized -44.06 Jg^-1
Onset 155.41 °C
Peak 155.88 °C
Left Limit 151.73 °C
Right Limit 164.73 °C
2.3640 mg
Wg^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
40
60
80
100
120
140
160
180
200
220
240 °C
STARe SW 9.20
REDOX: Termo Analisi

FIG. 59

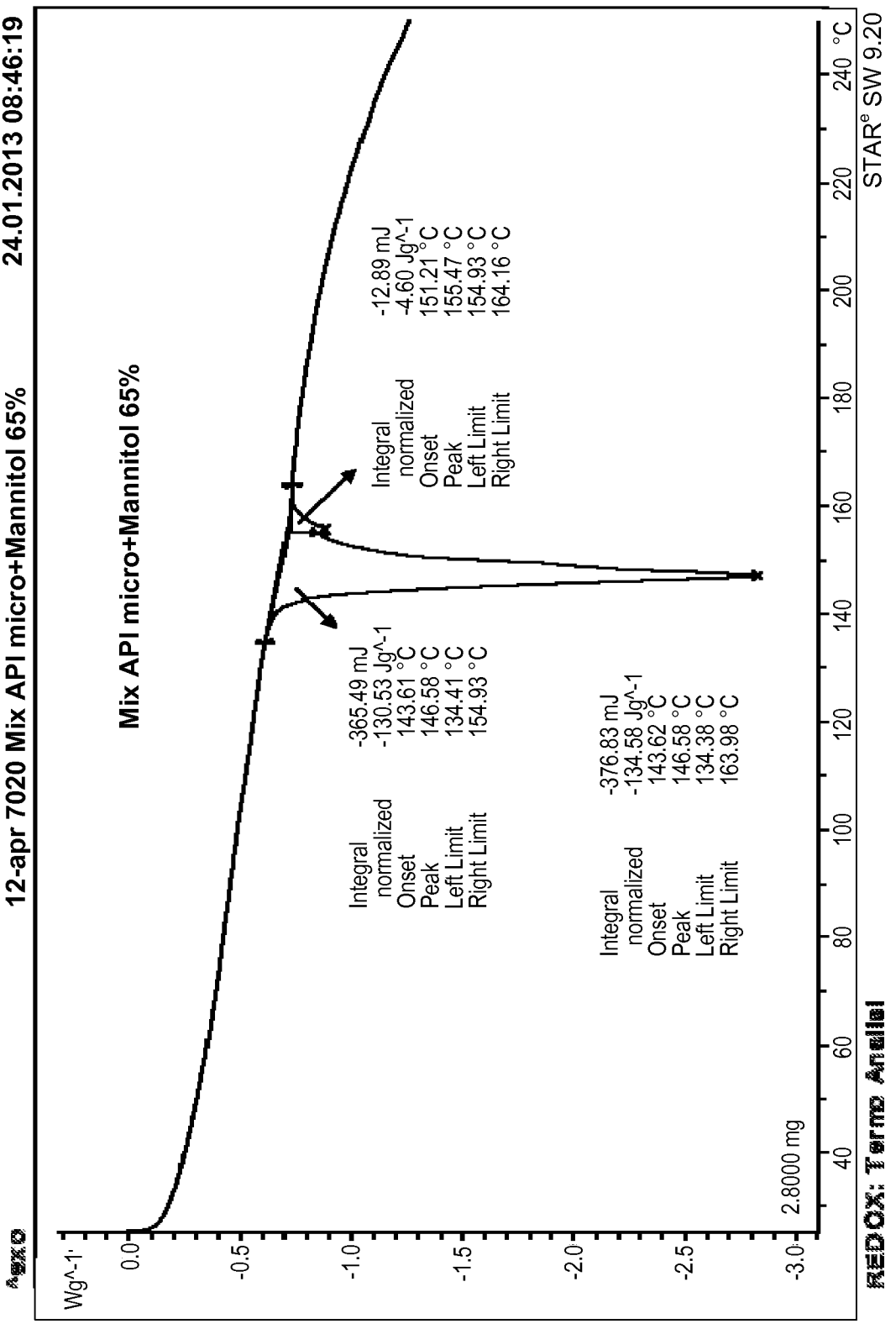

12-apr 7020 Mix API micro+Mannitol 65%
24.01.2013 08:46:19
Mix API micro+Mannitol 65%
Integral -365.49 mJ
normalized -130.53 Jg^-1
Onset 143.61 °C
Peak 146.58 °C
Left Limit 134.41 °C
Right Limit 154.93 °C
Integral -12.89 mJ
normalized -4.60 Jg^-1
Onset 151.21 °C
Peak 155.47 °C
Left Limit 154.93 °C
Right Limit 164.16 °C
Integral -376.83 mJ
normalized -134.58 Jg^-1
Onset 143.62 °C
Peak 146.58 °C
Left Limit 134.38 °C
Right Limit 163.98 °C
2.8000 mg
Wg^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
40
60
80
100
120
140
160
180
200
220
240 °C
STARe SW 9.20
REDOX: Termo Analisi

FIG. 60

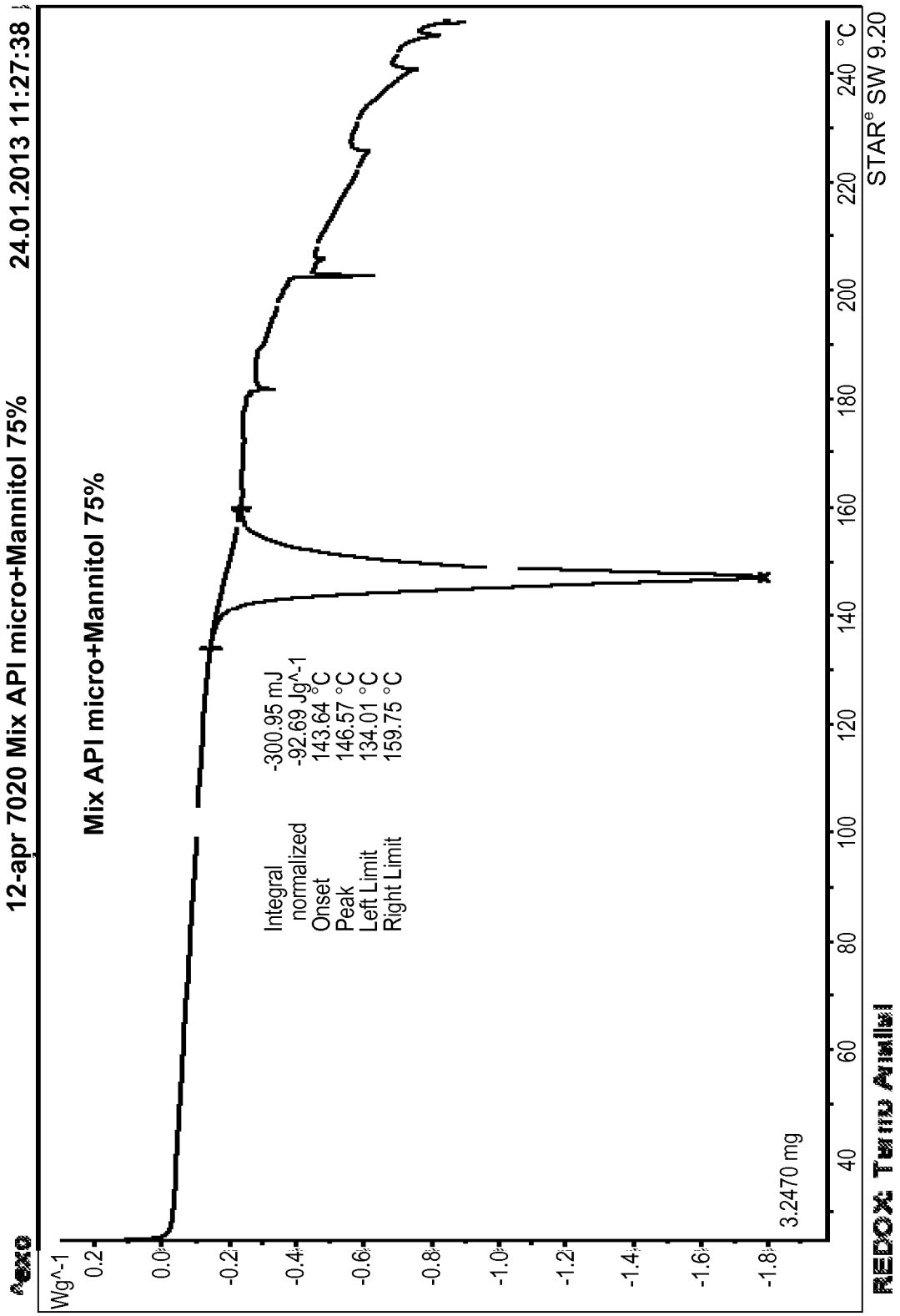

12-apr 7020 Mix API micro+Mannitol 75%
24.01.2013 11:27:38
Mix API micro+Mannitol 75%
Integral -300.95 mJ
normalized -92.69 Jg^-1
Onset 143.64 °C
Peak 146.57 °C
Left Limit 134.01 °C
Right Limit 159.75 °C
3.2470 mg
Exo
Wg^-1
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
40
60
80
100
120
140
160
180
200
220
240 °C
STARe SW 9.20
REDOX: Temu Analysi

FIG. 61

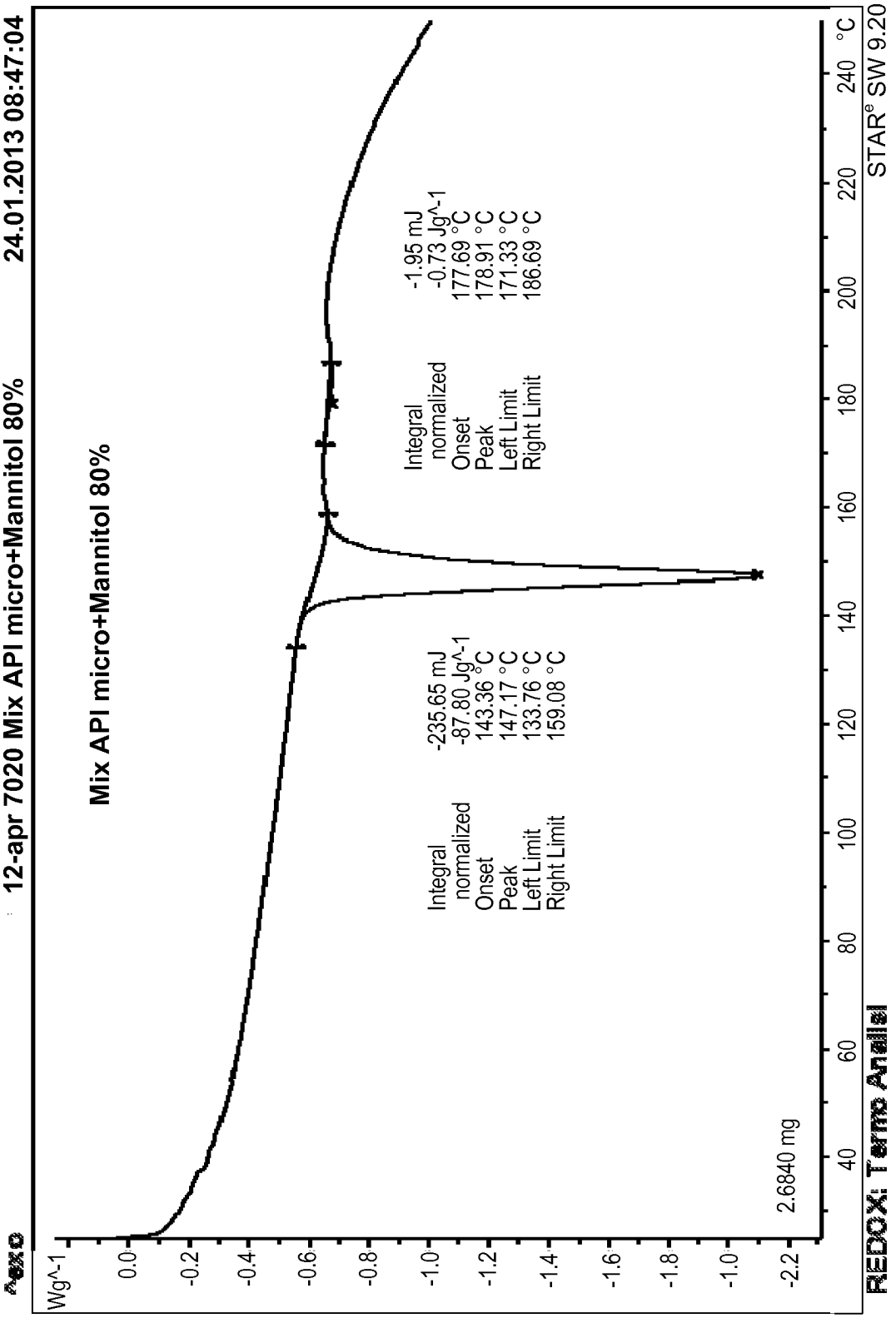

12-apr 7020 Mix API micro+Mannitol 80%
24.01.2013 08:47:04
Mix API micro+Mannitol 80%
Integral -235.65 mJ
normalized -87.80 Jg^-1
Onset 143.36 °C
Peak 147.17 °C
Left Limit 133.76 °C
Right Limit 159.08 °C
Integral -1.95 mJ
normalized -0.73 Jg^-1
Onset 177.69 °C
Peak 178.91 °C
Left Limit 171.33 °C
Right Limit 186.69 °C
2.6840 mg
Wg^-1
°C
STARe SW 9.20
REDOX: Termo Analisi

FIG. 62

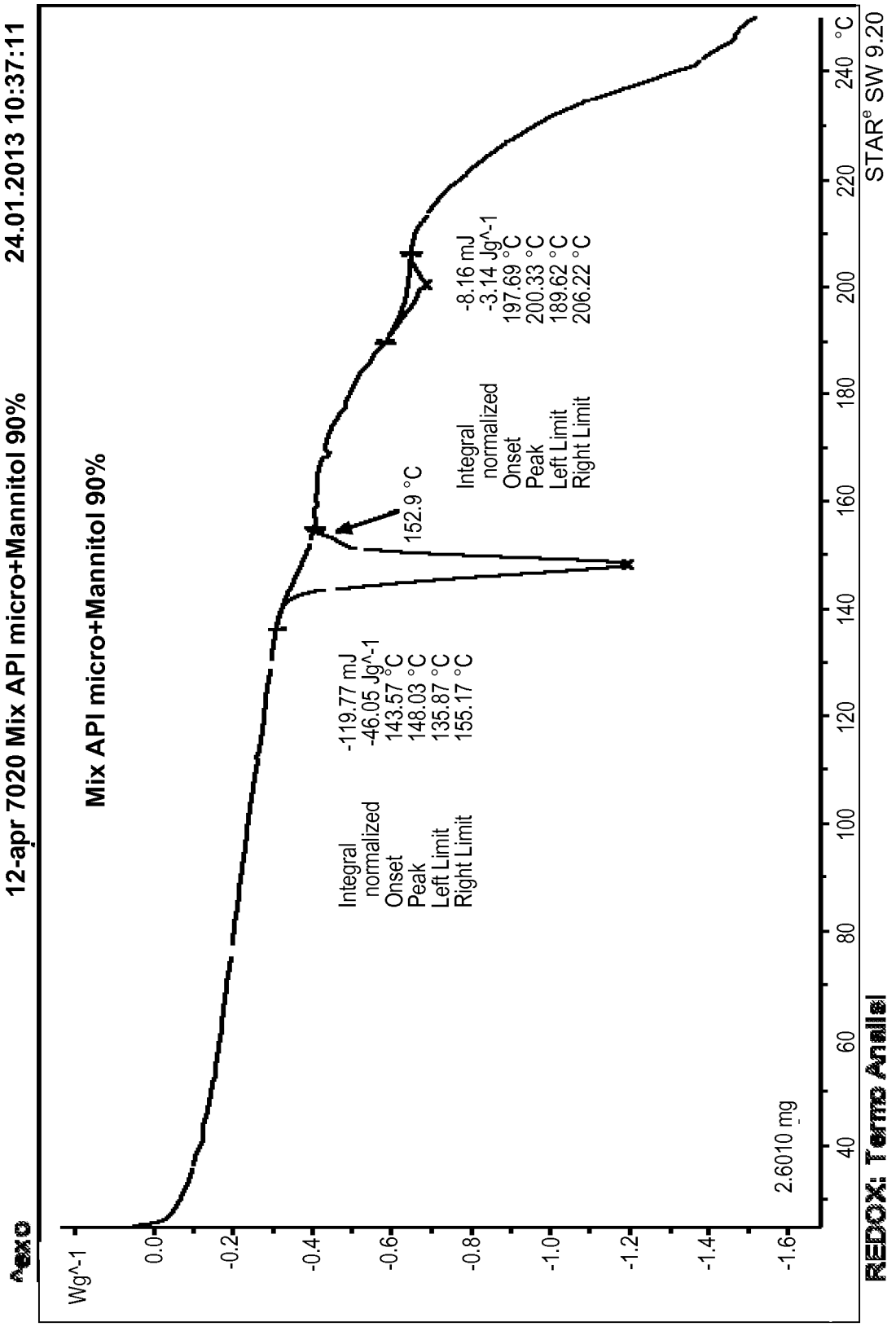

12-apr 7020 Mix API micro+Mannitol 90%
24.01.2013 10:37:11
Mix API micro+Mannitol 90%
Exo
Wg^-1
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
40
60
80
100
120
140
160
180
200
220
240 °C
2.6010 mg
Integral -119.77 mJ
normalized -46.05 Jg^-1
Onset 143.57 °C
Peak 148.03 °C
Left Limit 135.87 °C
Right Limit 155.17 °C
152.9 °C
Integral -8.16 mJ
normalized -3.14 Jg^-1
Onset 197.69 °C
Peak 200.33 °C
Left Limit 189.62 °C
Right Limit 206.22 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 63

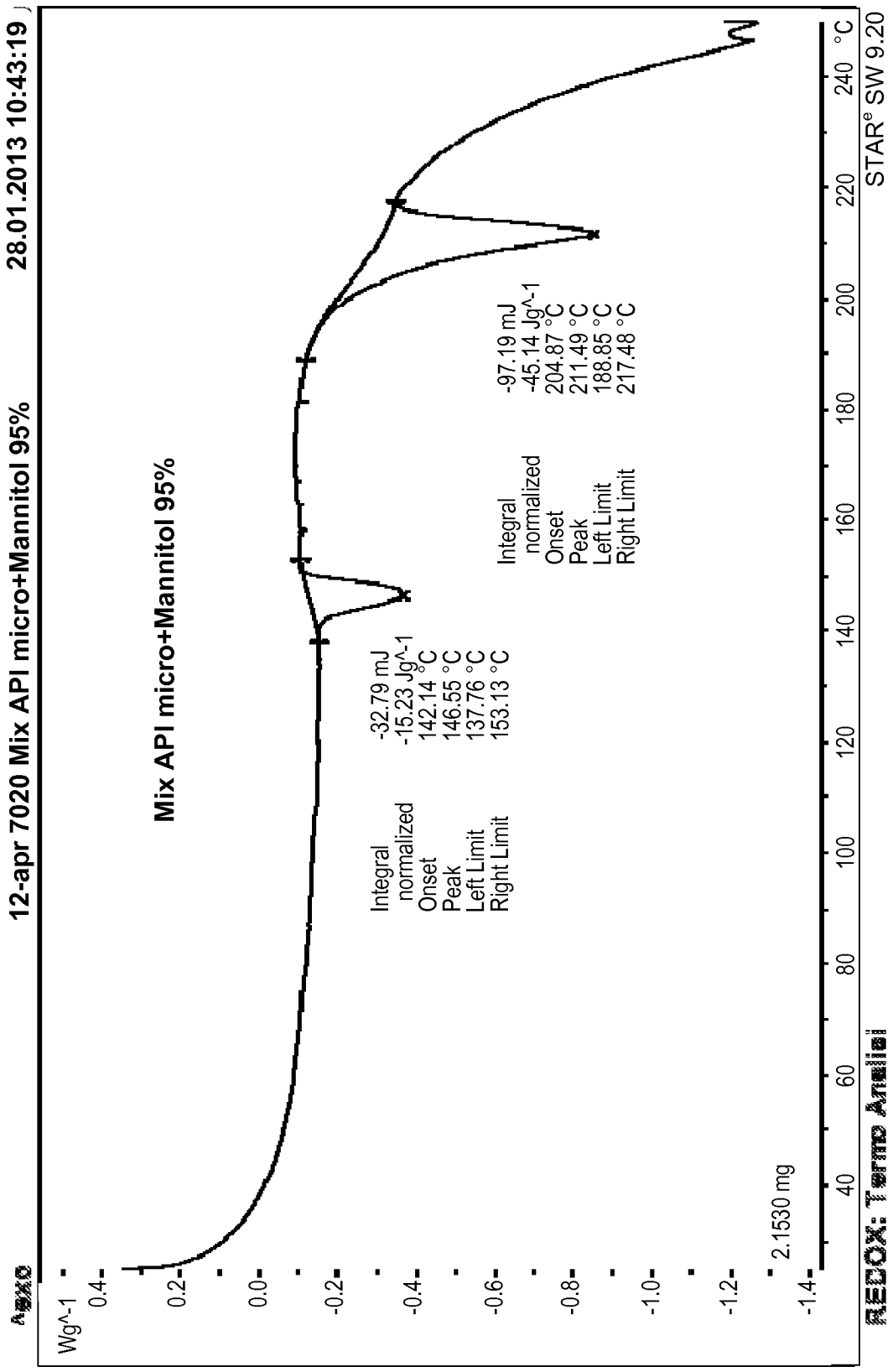

12-apr 7020 Mix API micro+Mannitol 95%
28.01.2013 10:43:19
Mix API micro+Mannitol 95%
Integral -32.79 mJ
normalized -15.23 Jg^-1
Onset 142.14 °C
Peak 146.55 °C
Left Limit 137.76 °C
Right Limit 153.13 °C
Integral -97.19 mJ
normalized -45.14 Jg^-1
Onset 204.87 °C
Peak 211.49 °C
Left Limit 188.85 °C
Right Limit 217.48 °C
Wg^-1
0.4
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
2.1530 mg
40
60
80
100
120
140
160
180
200
220
240 °C
STARe SW 9.20
REDOX: Termo Analisi

FIG. 64

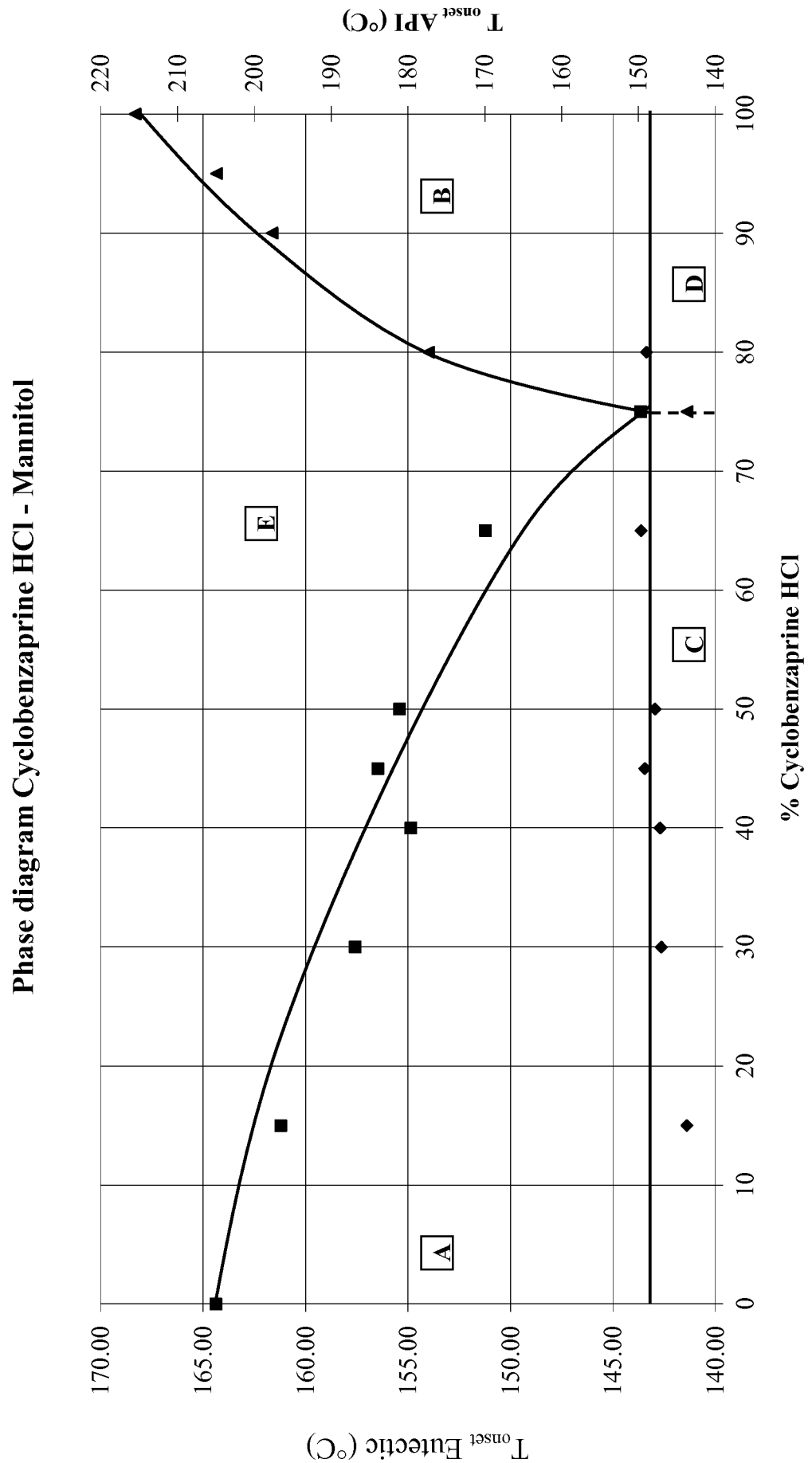

Phase diagram Cyclobenzaprine HCl - Mannitol
T onset API (°C)
T onset Eutectic (°C)
% Cyclobenzaprine HCl
A
B
C
D
E
220
210
200
190
180
170
160
150
140
100
90
80
70
60
50
40
30
20
10
0
170.00
165.00
160.00
155.00
150.00
145.00
140.00

FIG. 65

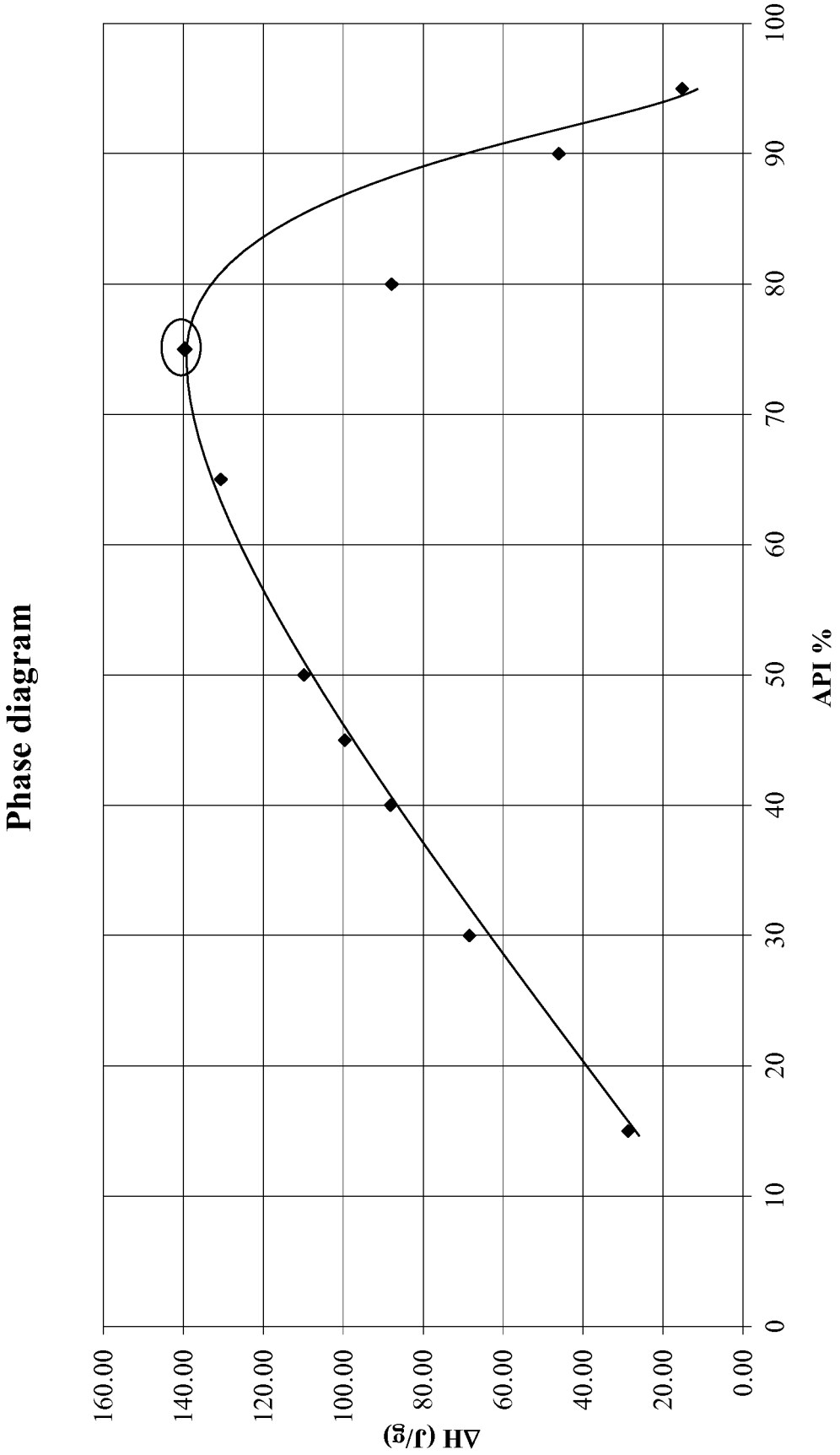

Phase diagram
ΔH (J/g)
160.00
140.00
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
10
20
30
40
50
60
70
80
90
100
API %

FIG. 66

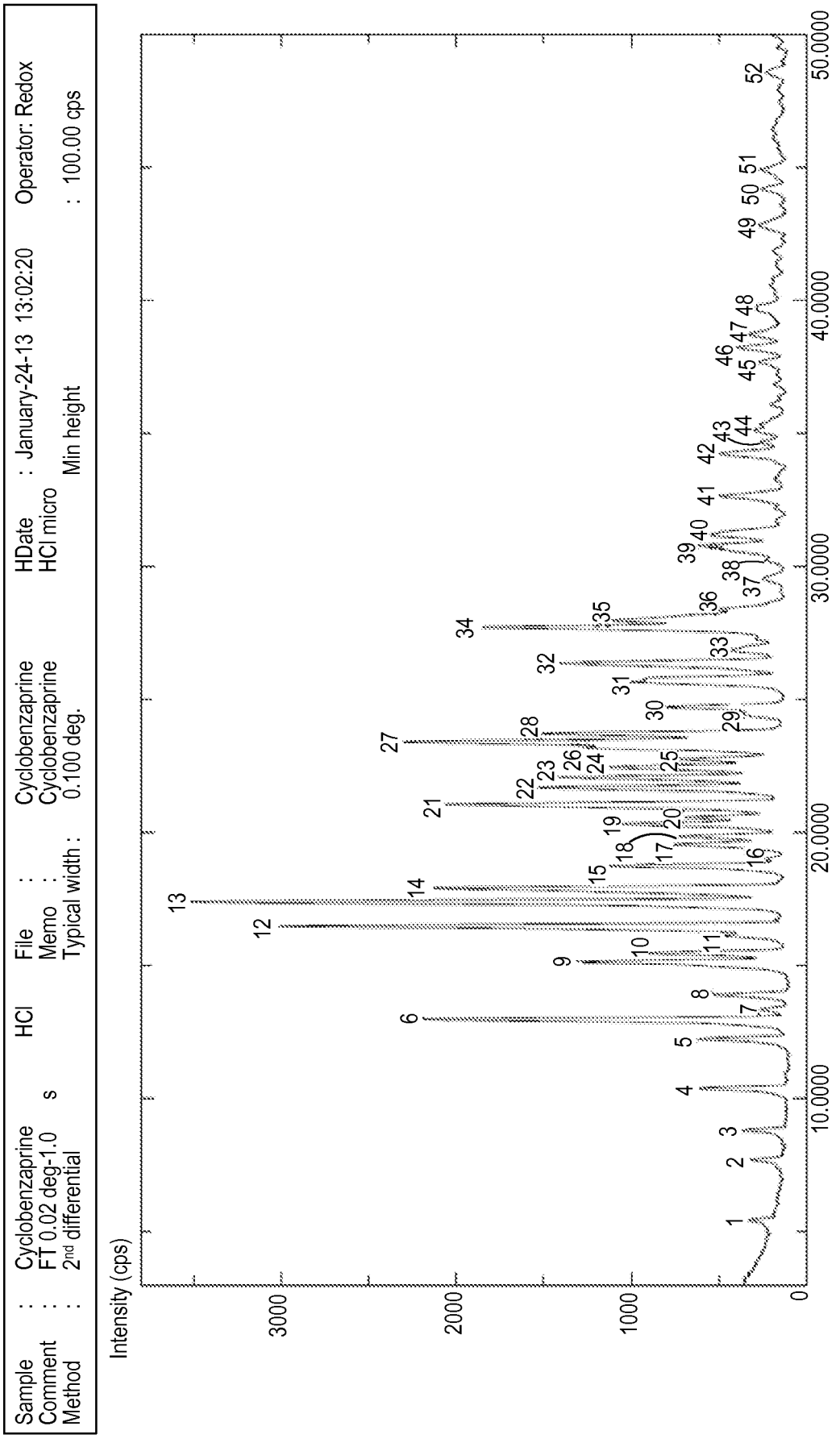

Peak Search
Sample : Cyclobenzaprine HCl
Comment : FT 0.02 deg-1.0 s
Method : 2nd differential
File : Cyclobenzaprine
Memo : Cyclobenzaprine
Typical width : 0.100 deg.
HDate : January-24-13 13:02:20
HCl micro
Min height
Operator: Redox
: 100.00 cps
Intensity (cps)
3000
2000
1000
0
10.0000
20.0000
30.0000
40.0000
50.0000
2theta (deg.)
February-06-2013 12:25:16 Page-1

FIG. 67

Peak Search

Sample : Cyclobenzaprine HCl File : Cyclobenzaprine HDate : January-24-13 13:02:20 Operator : Redox
Comment : FT 0.02 deg-1.0 s Memo : Cyclobenzaprine HCl micro
Method : 2nd differential Typical width : 0.100 deg. Min. height : 100.00 cps

Peak no.	2theta	Flex Width	d-value	Intensity	I/Io	Peak no.	2theta	Flex Width	d-value	Intensity	I/Io
1	5.440	0.141	16.2318	331	10	31	25.640	0.141	3.4715	977	28
2	7.720	0.141	11.4423	318	10	32	26.360	0.235	3.3783	1411	41
3	8.820	0.141	10.0176	363	11	33	26.820	0.165	3.3214	433	13
4	10.400	0.165	8.4989	613	18	34	27.700	0.165	3.2178	1850	53
5	12.260	0.165	7.2134	617	18	35	27.960	0.141	3.1885	1106	32
6	12.980	0.141	6.8148	2186	63	36	28.400	0.141	3.1401	500	15
7	13.360	0.165	6.6219	262	8	37	29.540	0.212	3.0214	248	8
8	13.920	0.165	6.3567	532	16	38	30.600	0.118	2.9191	451	13
9	15.140	0.141	5.8471	1306	38	39	30.780	0.165	2.9025	615	18
10	15.480	0.165	5.7194	898	26	40	31.140	0.165	2.8697	528	16
11	16.120	0.118	5.4938	469	14	41	32.640	0.188	2.7412	488	14
12	16.500	0.165	5.3681	3015	86	42	34.220	0.259	2.6182	493	14
13	17.400	0.165	5.0924	3523	100	43	34.660	0.188	2.5859	263	8
14	17.920	0.141	4.9458	2138	61	44	35.080	0.259	2.5559	291	9
15	18.700	0.165	4.7262	1128	33	45	37.680	0.188	2.3853	276	8
16	19.020	0.118	4.6622	237	7	46	38.220	0.259	2.3528	390	12
17	19.560	0.188	4.5347	758	22	47	38.720	0.259	2.3236	325	10
18	19.860	0.165	4.4668	728	21	48	39.780	0.165	2.2641	282	9
19	20.320	0.165	4.3667	1063	31	49	42.780	0.212	2.1120	267	8
20	20.580	0.165	4.3121	691	20	50	44.160	0.188	2.0492	251	8
21	21.060	0.188	4.2149	2070	59	51	44.900	0.118	2.0171	265	8
22	21.680	0.188	4.0958	1530	44	52	48.540	0.165	1.8740	230	7
23	22.080	0.165	4.0225	1414	41						
24	22.460	0.212	3.9553	1139	33						
25	22.760	0.165	3.9038	735	21						
26	23.180	0.141	3.8340	1242	36						
27	23.400	0.165	3.7985	2304	66						
28	23.720	0.165	3.7479	1516	44						
29	24.440	0.188	3.6391	358	11						
30	24.720	0.165	3.5985	800	23						

February-06-2013 12:25:17 Page 2

FIG. 68

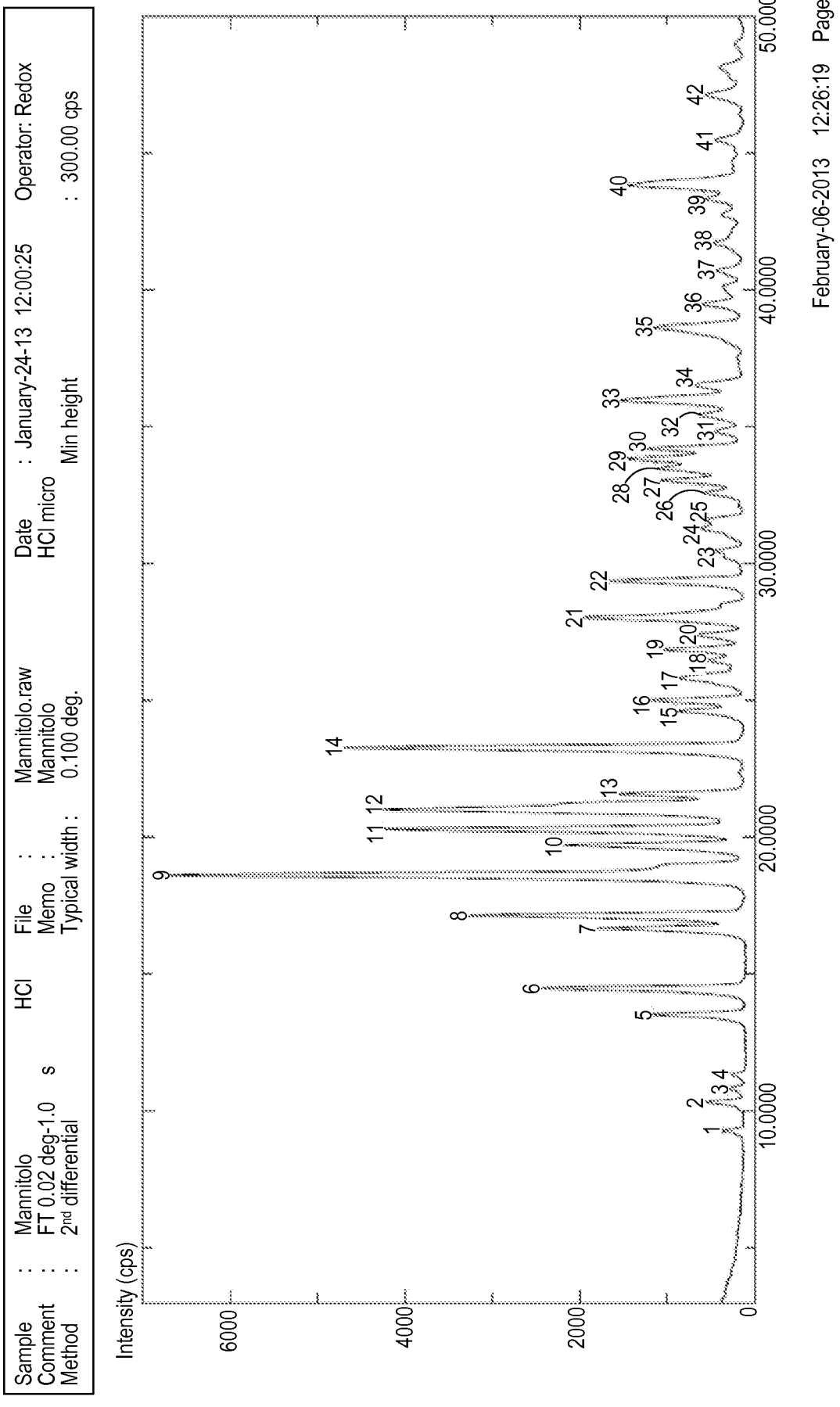

Peak Search
Sample : Mannitolo HCl File : Mannitolo.raw Date : January-24-13 12:00:25 Operator: Redox
Comment : FT 0.02 deg-1.0 s Memo : Mannitolo HCl micro
Method : 2nd differential Typical width : 0.100 deg. Min height : 300.00 cps
Intensity (cps)
6000
4000
2000
0
10.0000
20.0000
30.0000
40.0000
50.0000
February-06-2013 12:26:19 Page-1

FIG. 69

Peak Search

Sample : Mamitolo File : Mamitolo.raw Date : January-24-13 12:00:25 Operator : Redox
Comment : FT 0.02 deg-1.0 s Memo : Mamitolo
Method : 2nd differential Typical width : 0.100 deg. Min. height : 300.00 cps

Peak no.	2theta	Flex Width	d-value	Intensity	I/Io	Peak no.	2theta	Flex Width	d-value	Intensity	I/Io
1	9.260	*****	9.5425	322	5	31	34.880	*****	2.5701	415	7
2	10.340	0.165	8.5481	54	9	32	35.420	0.212	2.5322	635	10
3	10.800	*****	8.1850	282	5	33	35.960	0.329	2.4954	1541	24
4	11.340	*****	7.7965	256	4	34	36.500	0.329	2.4597	700	11
5	13.540	0.165	6.5342	1169	18	35	38.620	0.259	2.3294	1157	18
6	14.500	0.165	6.1037	2439	37	36	39.460	0.212	2.2817	599	9
7	16.080	0.165	5.5106	1812	28	37	40.680	*****	2.2161	435	7
8	17.160	0.165	5.1631	3268	49	38	41.700	0.165	2.1642	476	8
9	18.640	0.188	4.7563	6688	100	39	43.320	0.188	2.0869	557	9
10	19.720	0.188	4.4982	2186	33	40	43.840	*****	2.0634	1437	22
11	20.300	0.188	4.3710	4237	64	41	45.460	0.212	1.9935	458	7
12	21.020	0.188	4.2229	4246	64	42	47.100	0.259	1.9279	560	9
13	21.580	0.188	4.1145	1551	24	43					
14	23.280	0.188	3.8178	4700	71	44					
15	24.620	0.165	3.6129	876	14	45					
16	25.020	0.188	3.5561	1183	18	46					
17	25.820	0.306	3.4477	856	13	47					
18	26.480	0.188	3.3632	536	9	48					
19	26.880	0.188	3.3141	1024	16	49					
20	27.400	0.235	3.2524	657	10	50					
21	28.020	0.188	3.1818	1976	30	51					
22	29.380	0.188	3.0375	1669	25	52					
23	30.400	*****	2.9379	389	6						
24	31.260	0.188	2.8590	611	10						
25	31.620	0.212	2.8273	542	9						
26	32.580	0.188	2.7461	595	9						
27	33.040	0.188	2.7089	1075	17						
28	33.480	0.188	2.6743	1100	17						
29	33.820	0.212	2.6482	1467	22						
30	34.200	0.188	2.6196	1231	19						

February-06-2013 12:26:19 Page 2

FIG. 70

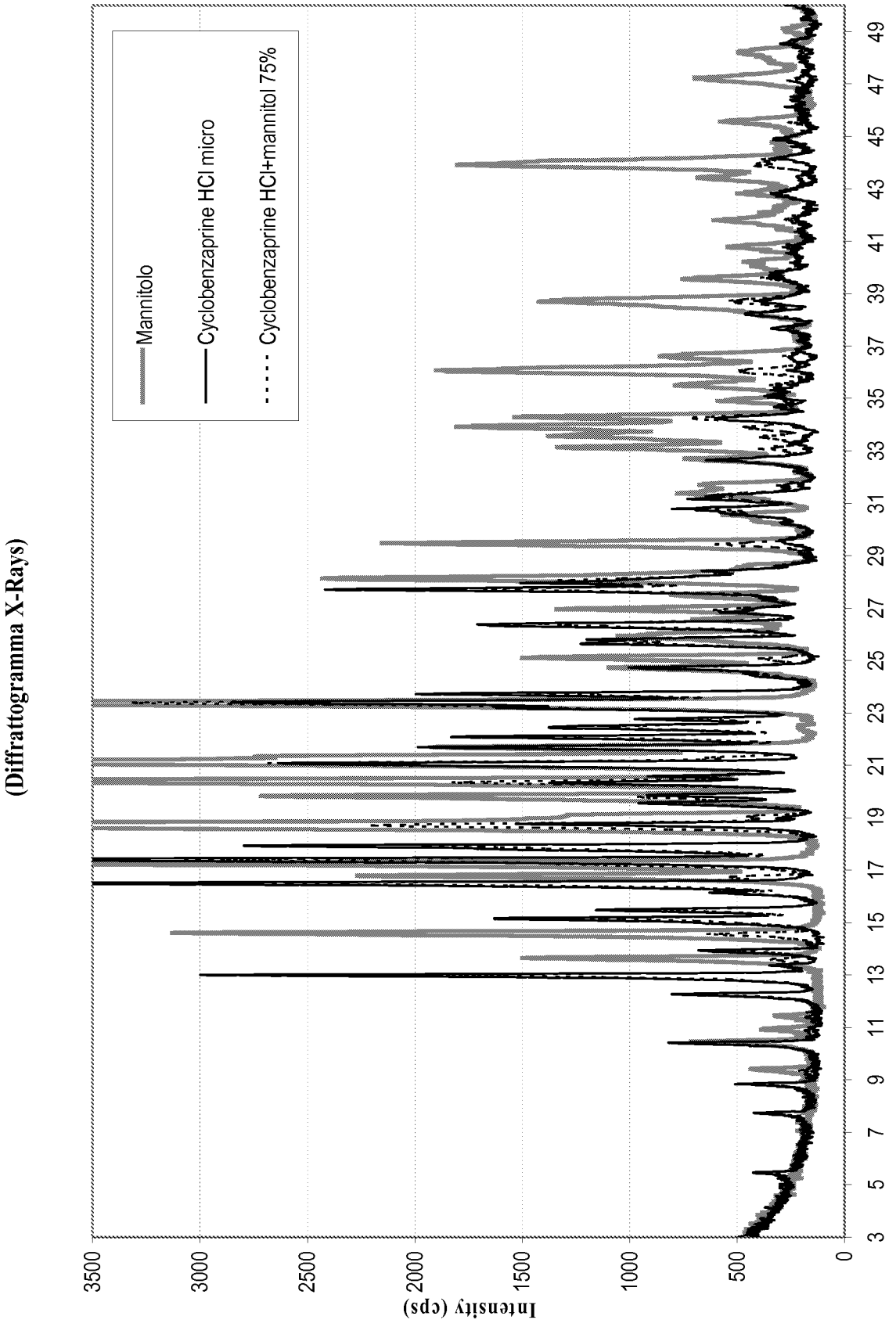

(Diffrattogramma X-Rays)
Mannitolo
Cyclobenzaprine HCl micro
Cyclobenzaprine HCl+mannitol 75%
Intensity (cps)
3500
3000
2500
2000
1500
1000
500
0
3 5 7 9 11 13 15 17 19 21 23 25 27 29 31 33 35 37 39 41 43 45 47 49
2 Theta (deg)

FIG. 71

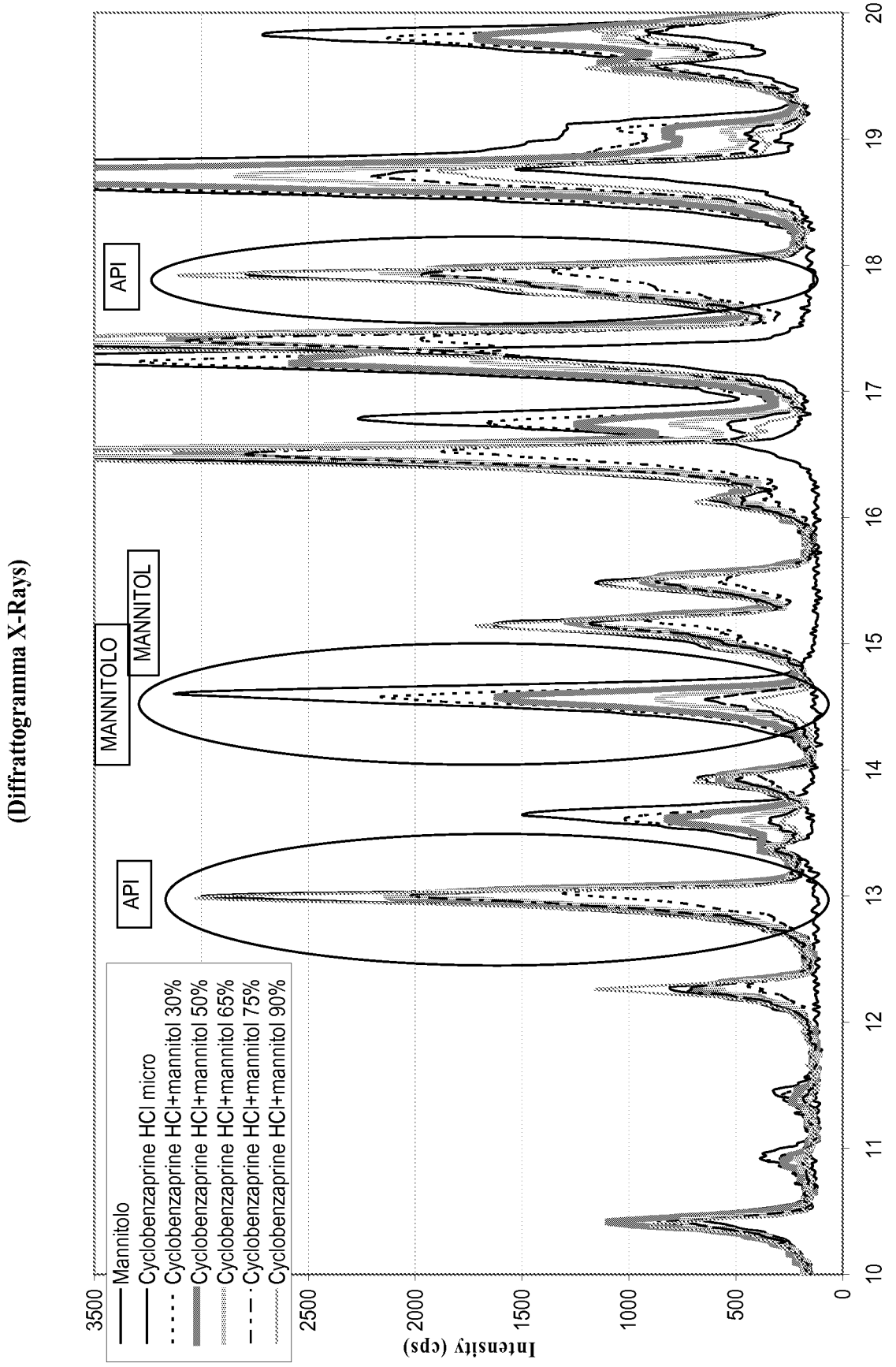

(Diffrattogramma X-Rays)
Mannitolo
Cyclobenzaprine HCl micro
Cyclobenzaprine HCl+mannitol 30%
Cyclobenzaprine HCl+mannitol 50%
Cyclobenzaprine HCl+mannitol 65%
Cyclobenzaprine HCl+mannitol 75%
Cyclobenzaprine HCl+mannitol 90%
API
MANNITOLO
MANNITOL
API
Intensity (cps)
3500
2500
2000
1500
1000
500
0
10
11
12
13
14
15
16
17
18
19
20
2 Theta (deg)

FIG. 72

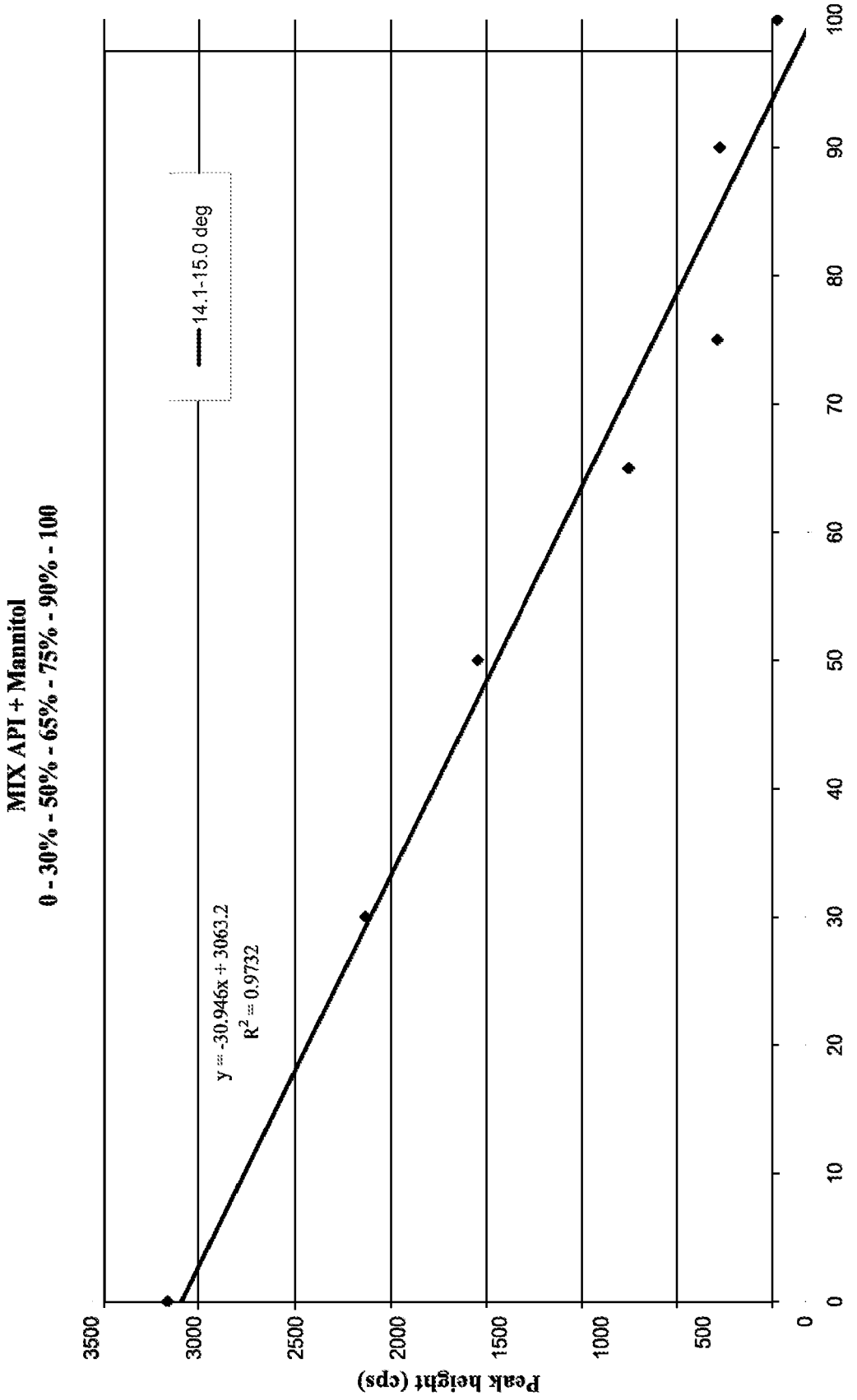

MIX API + Mannitol
0 - 30% - 50% - 65% - 75% - 90% - 100
14.1-15.0 deg
y = -30.946x + 3063.2
R2 = 0.9732
Peak height (cps)
API %
3500
3000
2500
2000
1500
1000
500
0
0
10
20
30
40
50
60
70
80
90
100

FIG. 73

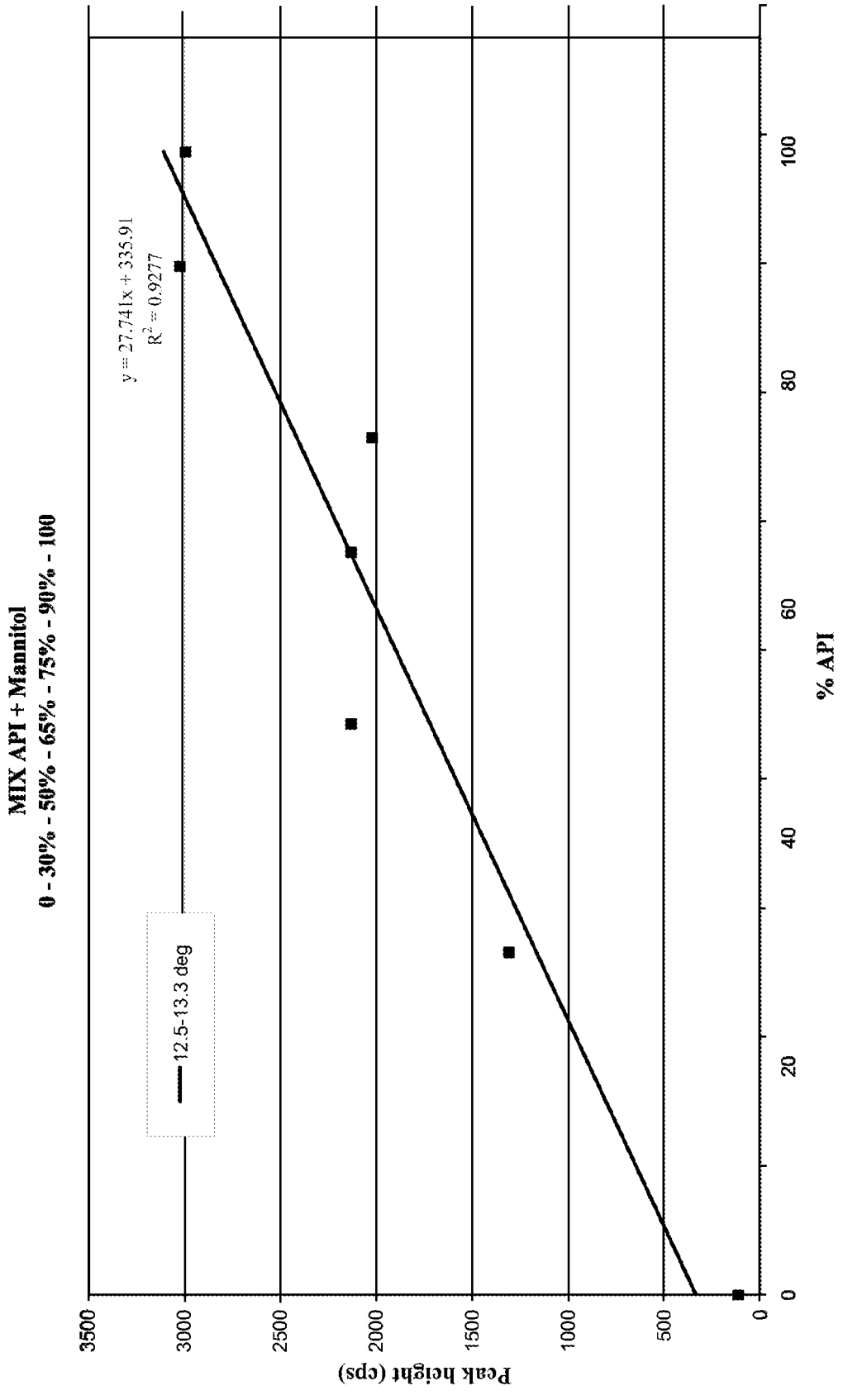

MIX API + Mannitol
0 - 30% - 50% - 65% - 75% - 90% - 100
y = 27.741x + 335.91
R² = 0.9277
12.5-13.3 deg
Peak height (cps)
3500
3000
2500
2000
1500
1000
500
0
0
20
40
60
80
100
% API

FIG. 74

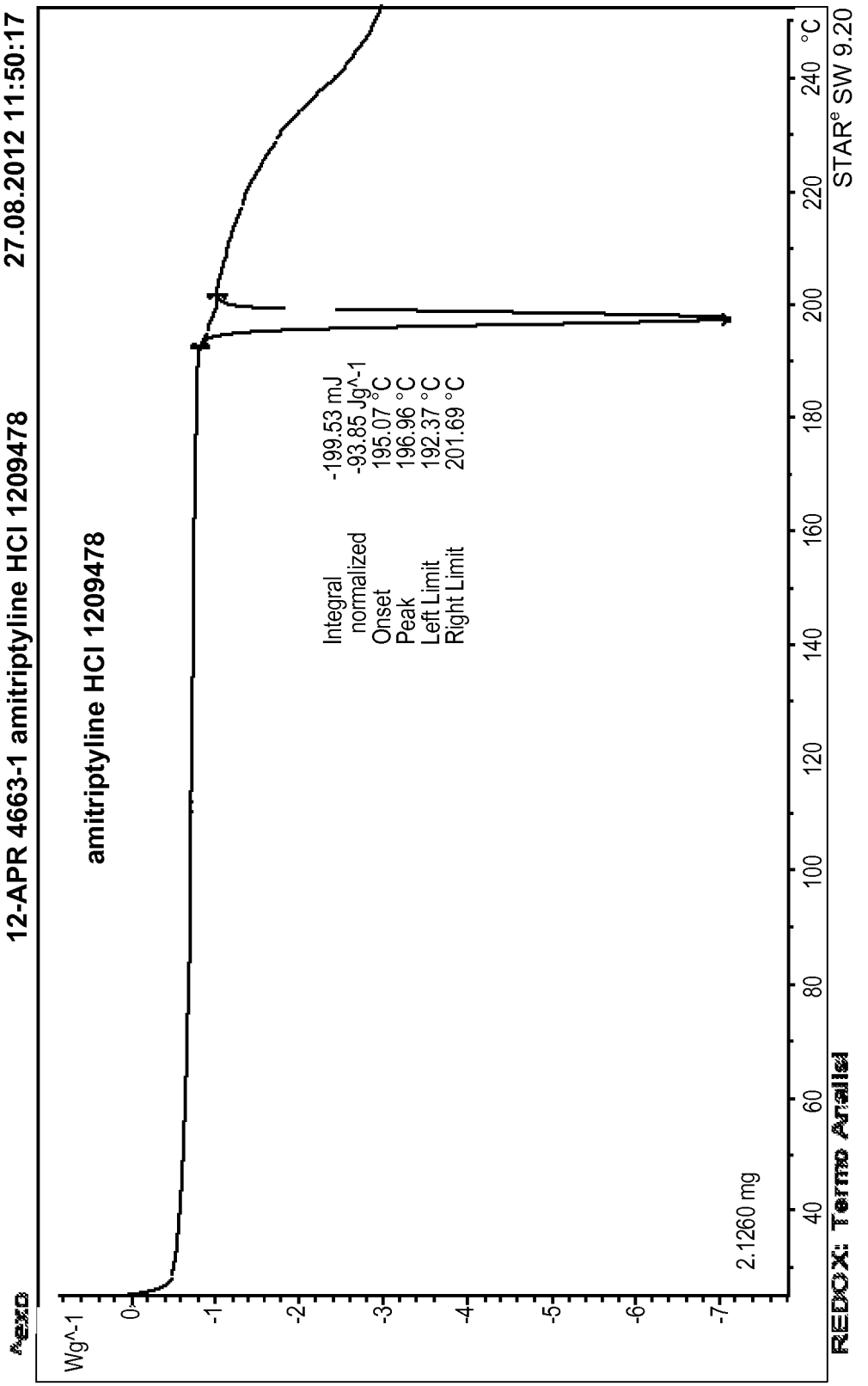

12-APR 4663-1 amitriptyline HCl 1209478
27.08.2012 11:50:17
amitriptyline HCl 1209478
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.96 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
2.1260 mg
Wg^-1
0
-1
-2
-3
-4
-5
-6
-7
40
60
80
100
120
140
160
180
200
220
240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 75

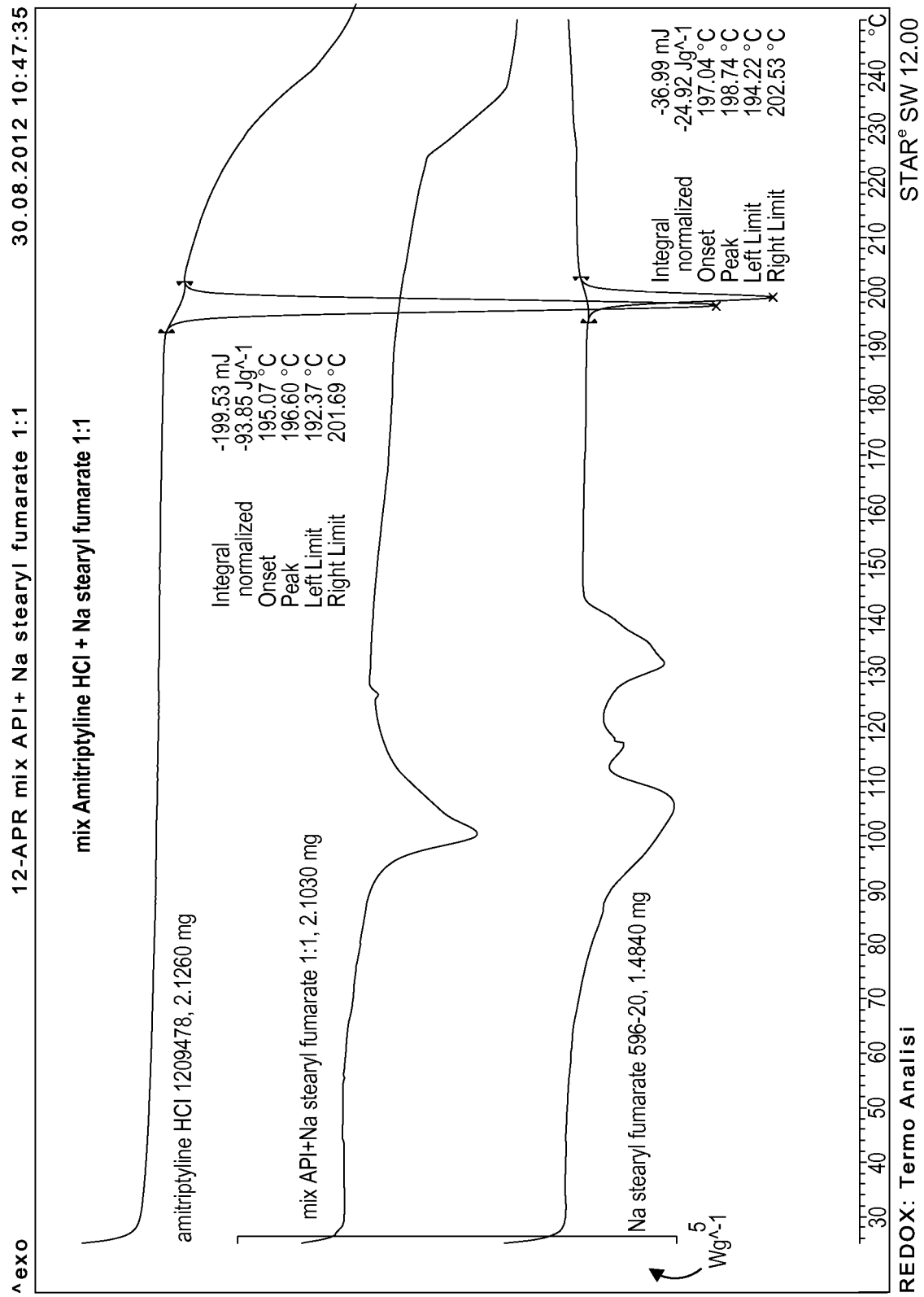

^exo
12-APR mix API+ Na stearyl fumarate 1:1
30.08.2012 10:47:35
mix Amitriptyline HCl + Na stearyl fumarate 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API+Na stearyl fumarate 1:1, 2.1030 mg
Integral -36.99 mJ
normalized -24.92 Jg^-1
Onset 197.04 °C
Peak 198.74 °C
Left Limit 194.22 °C
Right Limit 202.53 °C
Na stearyl fumarate 596-20, 1.4840 mg
5
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 76

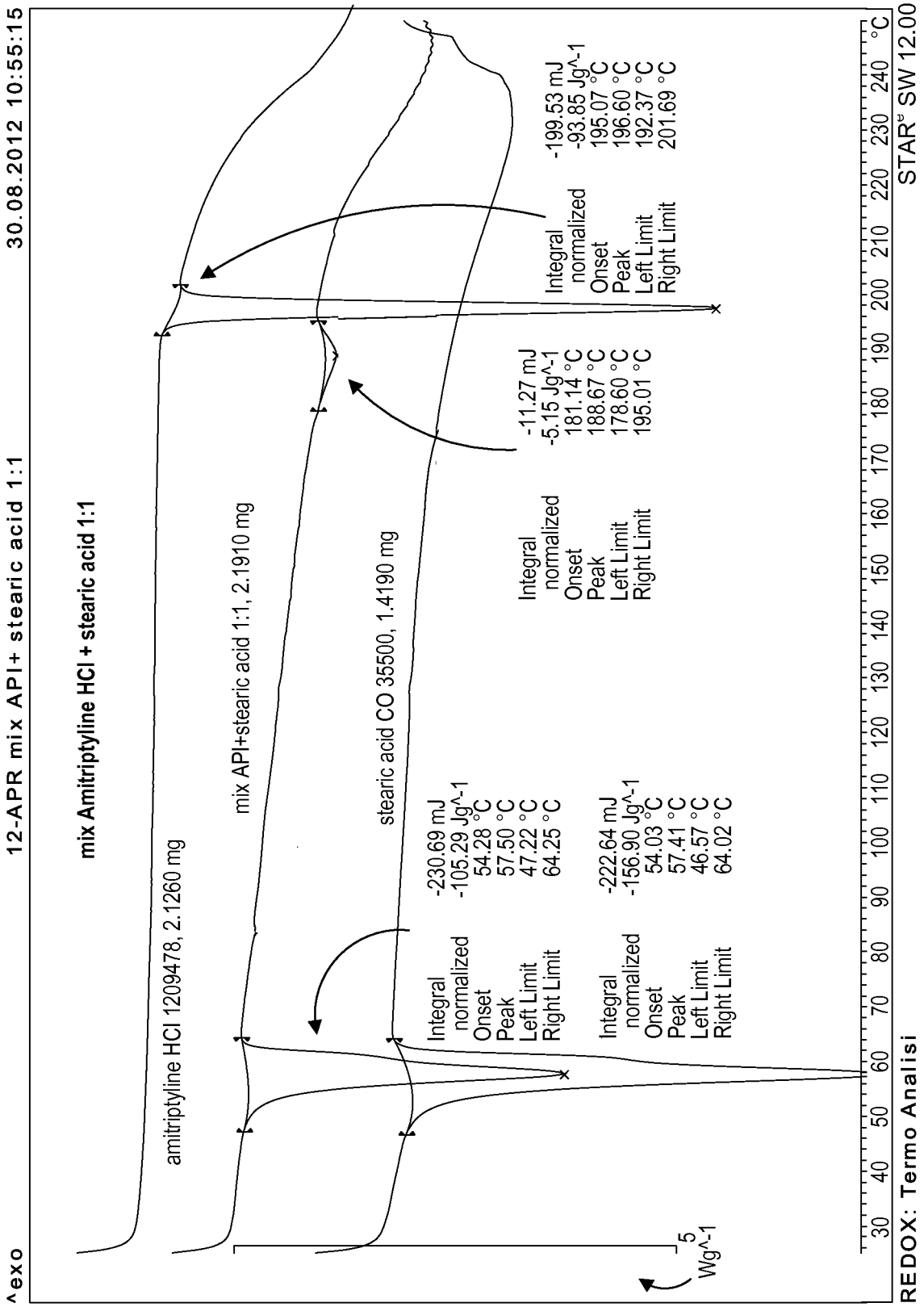

^exo
12-APR mix API+ stearic acid 1:1
30.08.2012 10:55:15
mix Amitriptyline HCl + stearic acid 1:1
amitriptyline HCl 1209478, 2.1260 mg
mix API+stearic acid 1:1, 2.1910 mg
stearic acid CO 35500, 1.4190 mg
Integral -230.69 mJ
normalized -105.29 Jg^-1
Onset 54.28 °C
Peak 57.50 °C
Left Limit 47.22 °C
Right Limit 64.25 °C
Integral -222.64 mJ
normalized -156.90 Jg^-1
Onset 54.03 °C
Peak 57.41 °C
Left Limit 46.57 °C
Right Limit 64.02 °C
Integral -11.27 mJ
normalized -5.15 Jg^-1
Onset 181.14 °C
Peak 188.67 °C
Left Limit 178.60 °C
Right Limit 195.01 °C
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
5
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 77

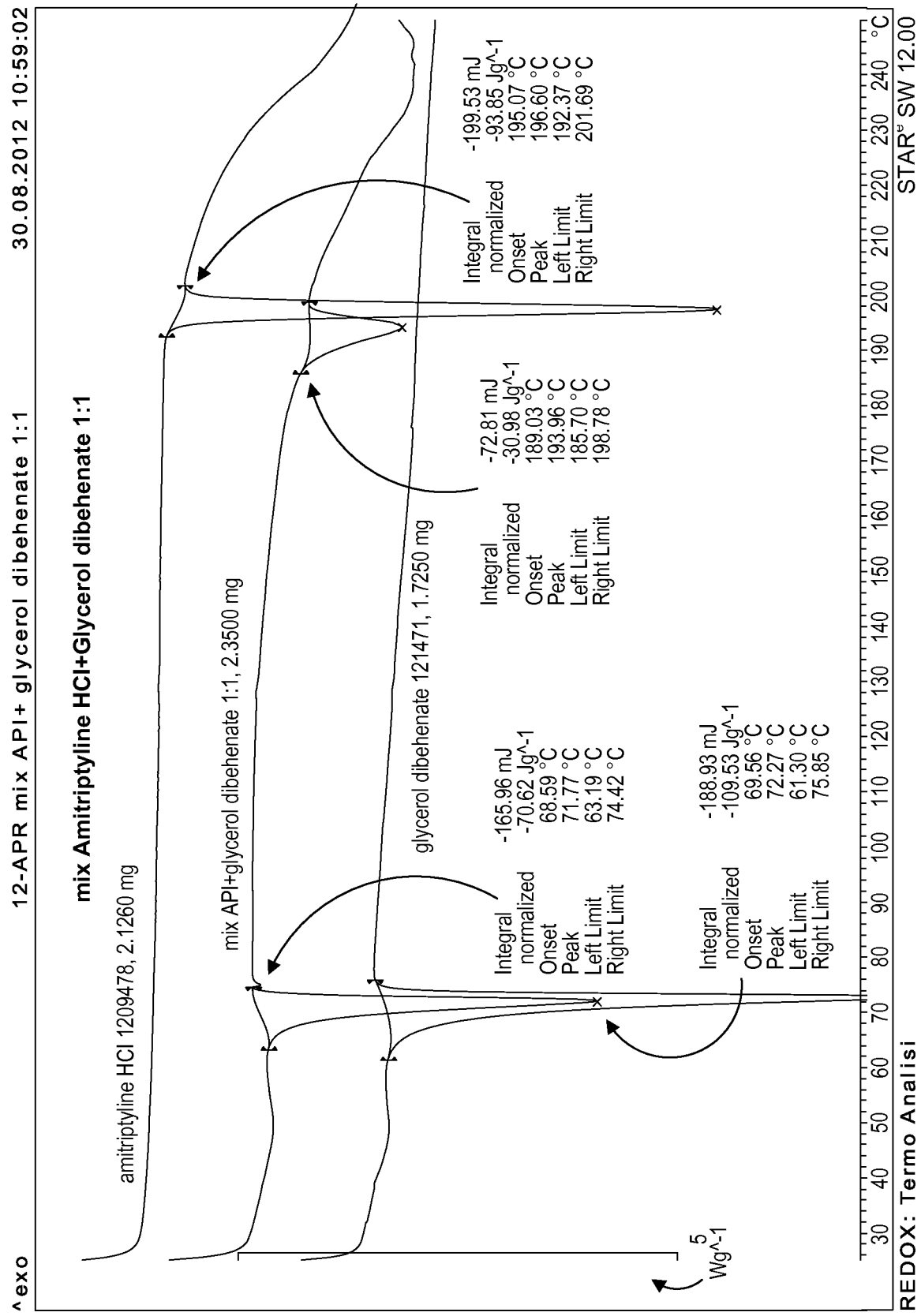

12-APR mix API+ glycerol dibehenate 1:1
30.08.2012 10:59:02
mix Amitriptyline HCl+Glycerol dibehenate 1:1
amitriptyline HCl 1209478, 2.1260 mg
mix API+glycerol dibehenate 1:1, 2.3500 mg
glycerol dibehenate 121471, 1.7250 mg
Integral -165.96 mJ
normalized -70.62 Jg^-1
Onset 68.59 °C
Peak 71.77 °C
Left Limit 63.19 °C
Right Limit 74.42 °C
Integral -72.81 mJ
normalized -30.98 Jg^-1
Onset 189.03 °C
Peak 193.96 °C
Left Limit 185.70 °C
Right Limit 198.78 °C
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
Integral -188.93 mJ
normalized -109.53 Jg^-1
Onset 69.56 °C
Peak 72.27 °C
Left Limit 61.30 °C
Right Limit 75.85 °C
^exo
5
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 78

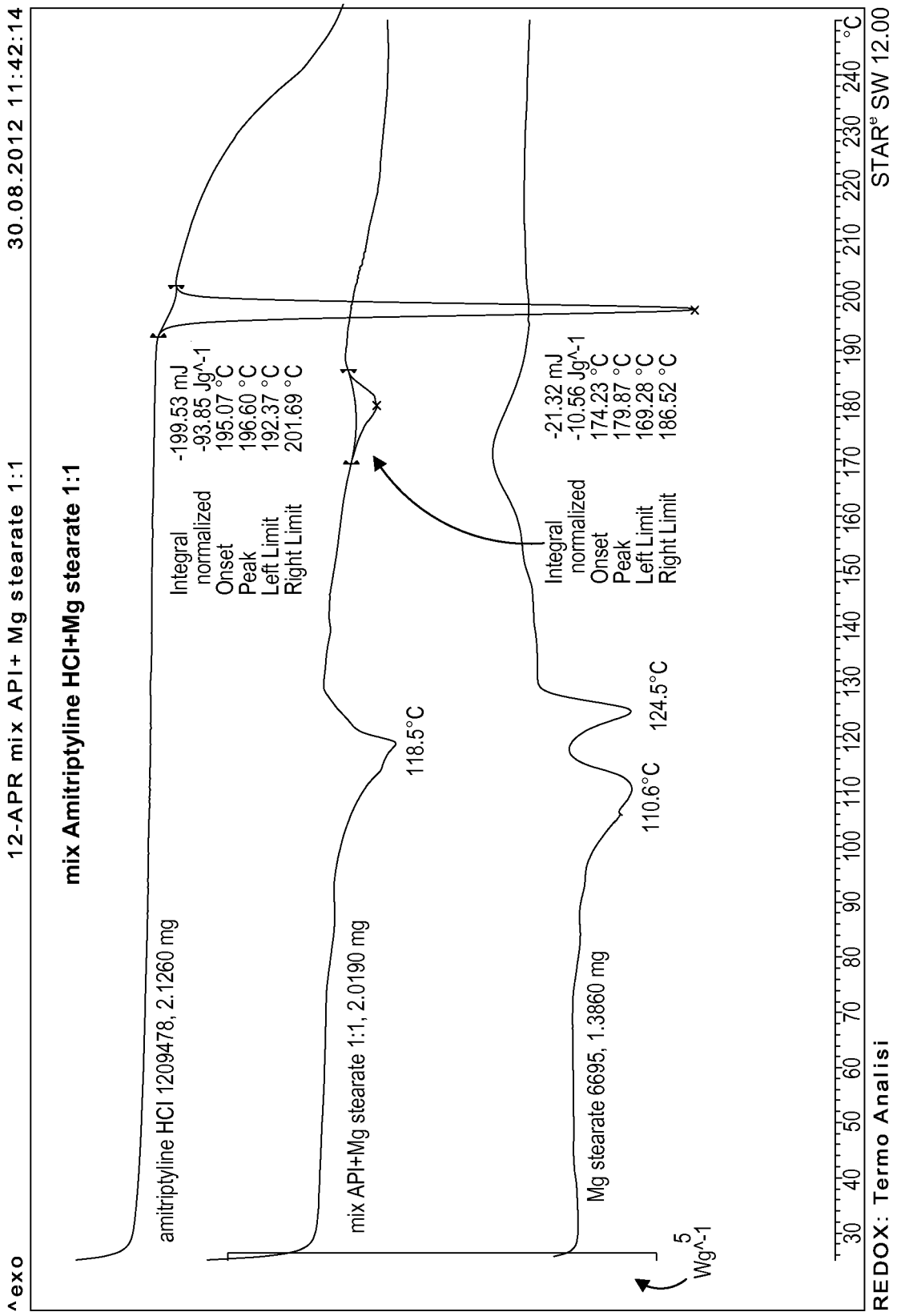

^exo
12-APR mix API+ Mg stearate 1:1
30.08.2012 11:42:14
mix Amitriptyline HCl+Mg stearate 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API+Mg stearate 1:1, 2.0190 mg
118.5°C
Mg stearate 6695, 1.3860 mg
110.6°C
124.5°C
Integral -21.32 mJ
normalized -10.56 Jg^-1
Onset 174.23 °C
Peak 179.87 °C
Left Limit 169.28 °C
Right Limit 186.52 °C
5
Wg^-1
REDOX: Termo Analisi
STARe SW 12.00
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C

FIG. 79

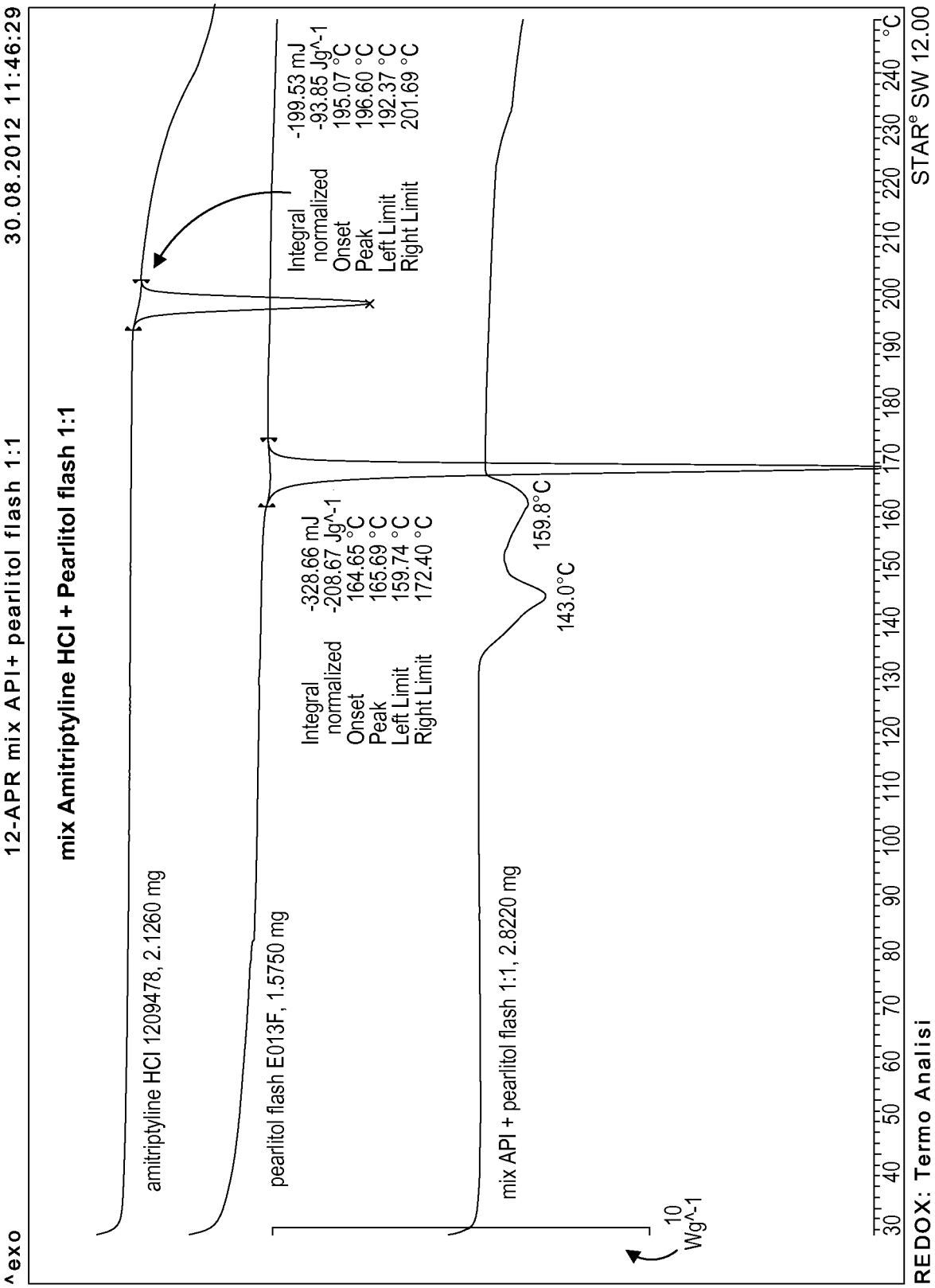

^exo
12-APR mix API+ pearlitol flash 1:1
30.08.2012 11:46:29
mix Amitriptyline HCl + Pearlitol flash 1:1
amitriptyline HCl 1209478, 2.1260 mg
pearlitol flash E013F, 1.5750 mg
mix API + pearlitol flash 1:1, 2.8220 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
Integral -328.66 mJ
normalized -208.67 Jg^-1
Onset 164.65 °C
Peak 165.69 °C
Left Limit 159.74 °C
Right Limit 172.40 °C
159.8°C
143.0°C
10
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 80

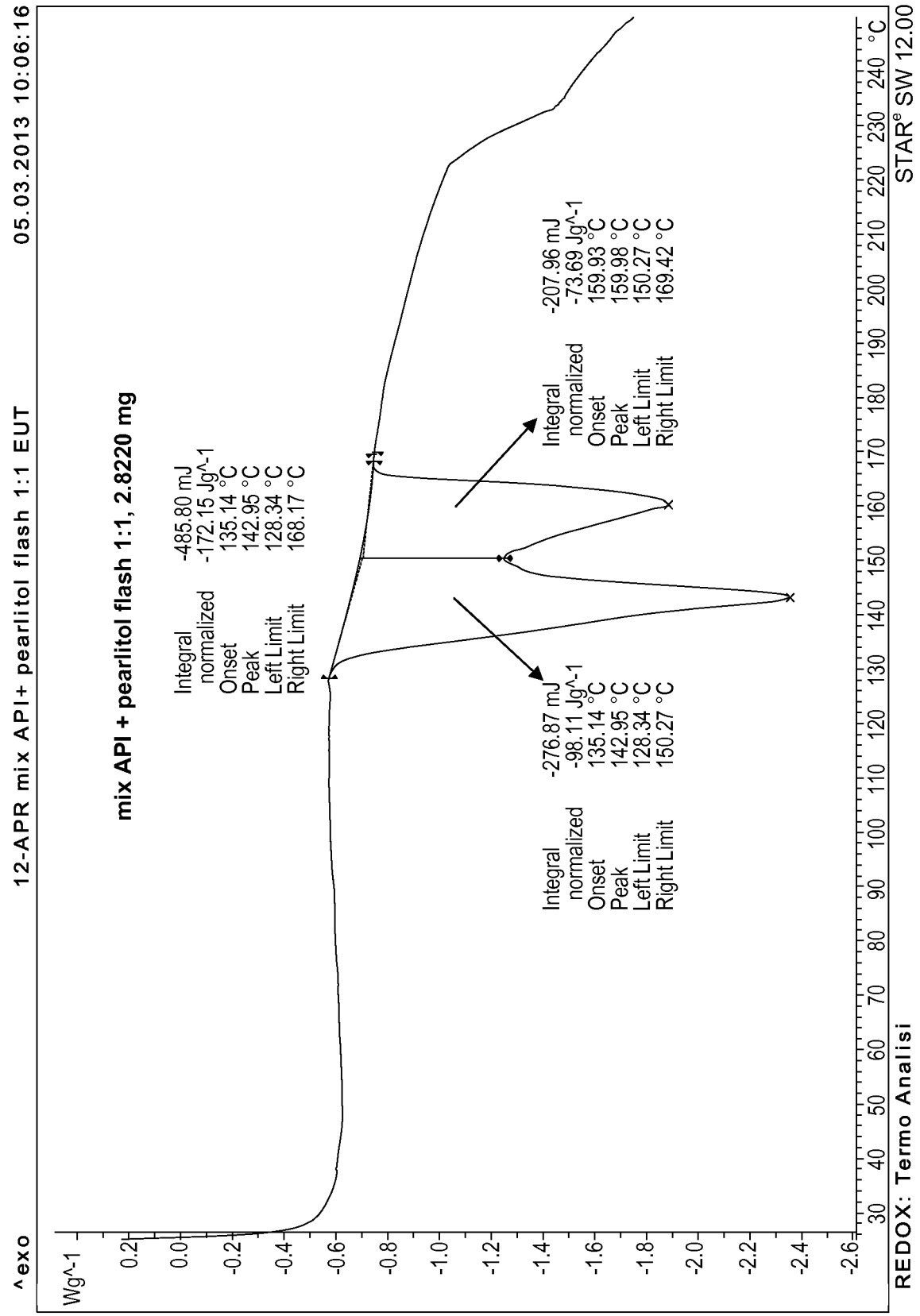

^exo
12-APR mix API+ pearlitol flash 1:1 EUT
05.03.2013 10:06:16
mix API + pearlitol flash 1:1, 2.8220 mg
Integral -485.80 mJ
normalized -172.15 Jg^-1
Onset 135.14 °C
Peak 142.95 °C
Left Limit 128.34 °C
Right Limit 168.17 °C
Integral -276.87 mJ
normalized -98.11 Jg^-1
Onset 135.14 °C
Peak 142.95 °C
Left Limit 128.34 °C
Right Limit 150.27 °C
Integral -207.96 mJ
normalized -73.69 Jg^-1
Onset 159.93 °C
Peak 159.98 °C
Left Limit 150.27 °C
Right Limit 169.42 °C
Wg^-1
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
-2.0
-2.2
-2.4
-2.6
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 81

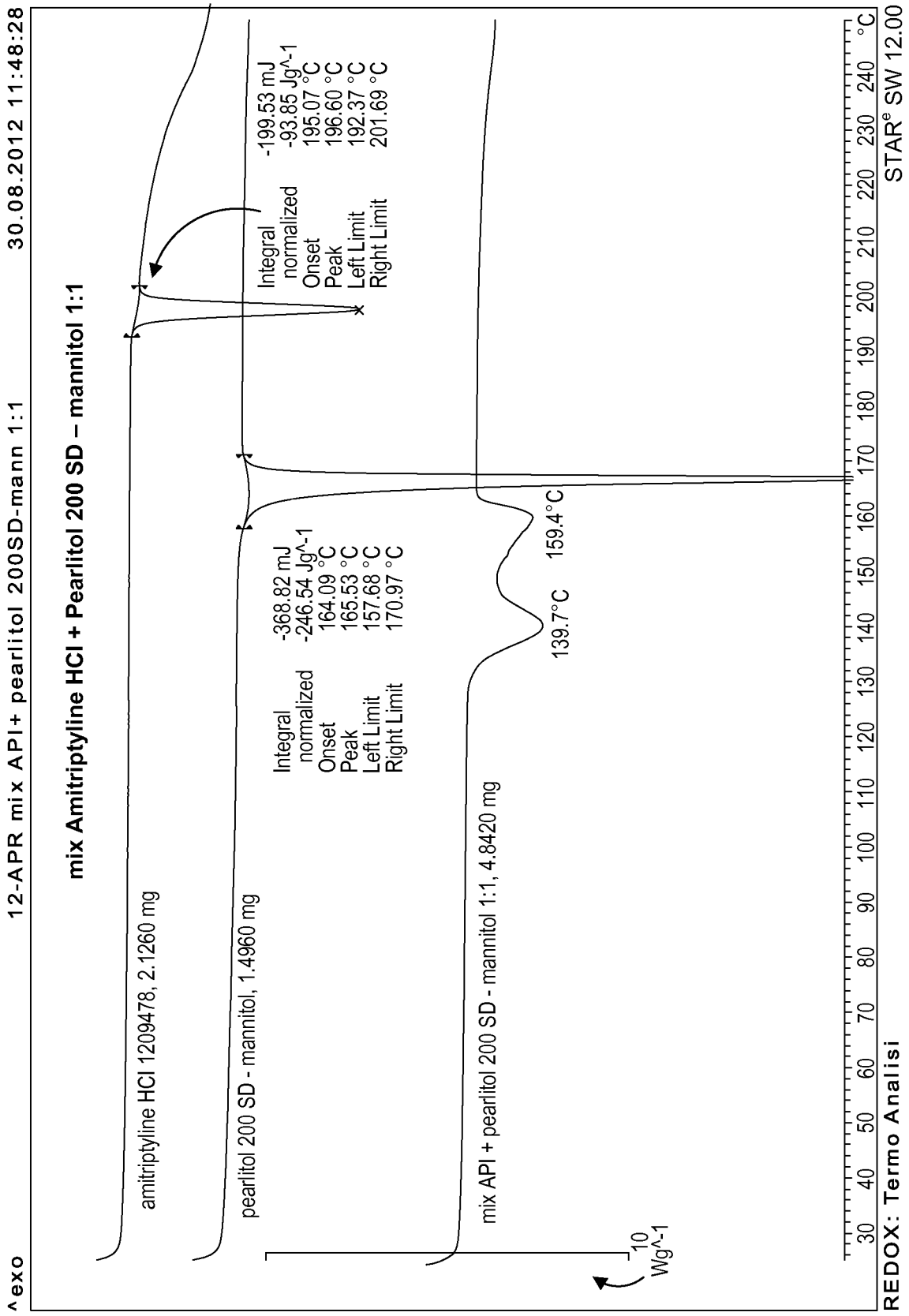

^exo
12-APR mix API+ pearlitol 200SD-mann 1:1
30.08.2012 11:48:28
mix Amitriptyline HCl + Pearlitol 200 SD – mannitol 1:1
amitriptyline HCl 1209478, 2.1260 mg
pearlitol 200 SD - mannitol, 1.4960 mg
mix API + pearlitol 200 SD - mannitol 1:1, 4.8420 mg
Integral -368.82 mJ
normalized -246.54 Jg^-1
Onset 164.09 °C
Peak 165.53 °C
Left Limit 157.68 °C
Right Limit 170.97 °C
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
139.7°C
159.4°C
10
Wg^-1
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 82

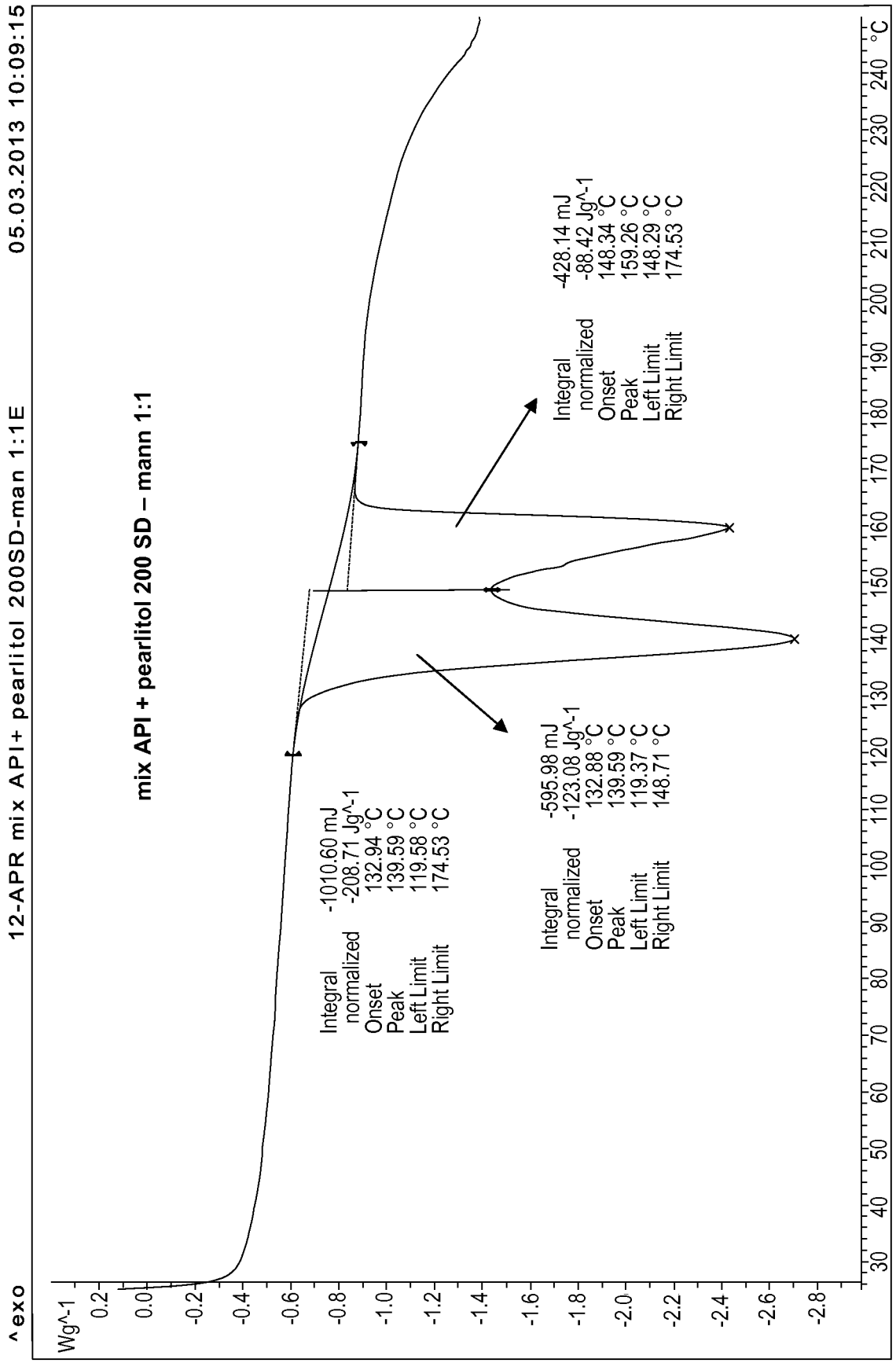

^exo
12-APR mix API+ pearlitol 200SD-man 1:1E
05.03.2013 10:09:15
mix API + pearlitol 200 SD – mann 1:1
Wg^-1
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
-2.0
-2.2
-2.4
-2.6
-2.8
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
Integral -1010.60 mJ
normalized -208.71 Jg^-1
Onset 132.94 °C
Peak 139.59 °C
Left Limit 119.58 °C
Right Limit 174.53 °C
Integral -595.98 mJ
normalized -123.08 Jg^-1
Onset 132.88 °C
Peak 139.59 °C
Left Limit 119.37 °C
Right Limit 148.71 °C
Integral -428.14 mJ
normalized -88.42 Jg^-1
Onset 148.34 °C
Peak 159.26 °C
Left Limit 148.29 °C
Right Limit 174.53 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 83

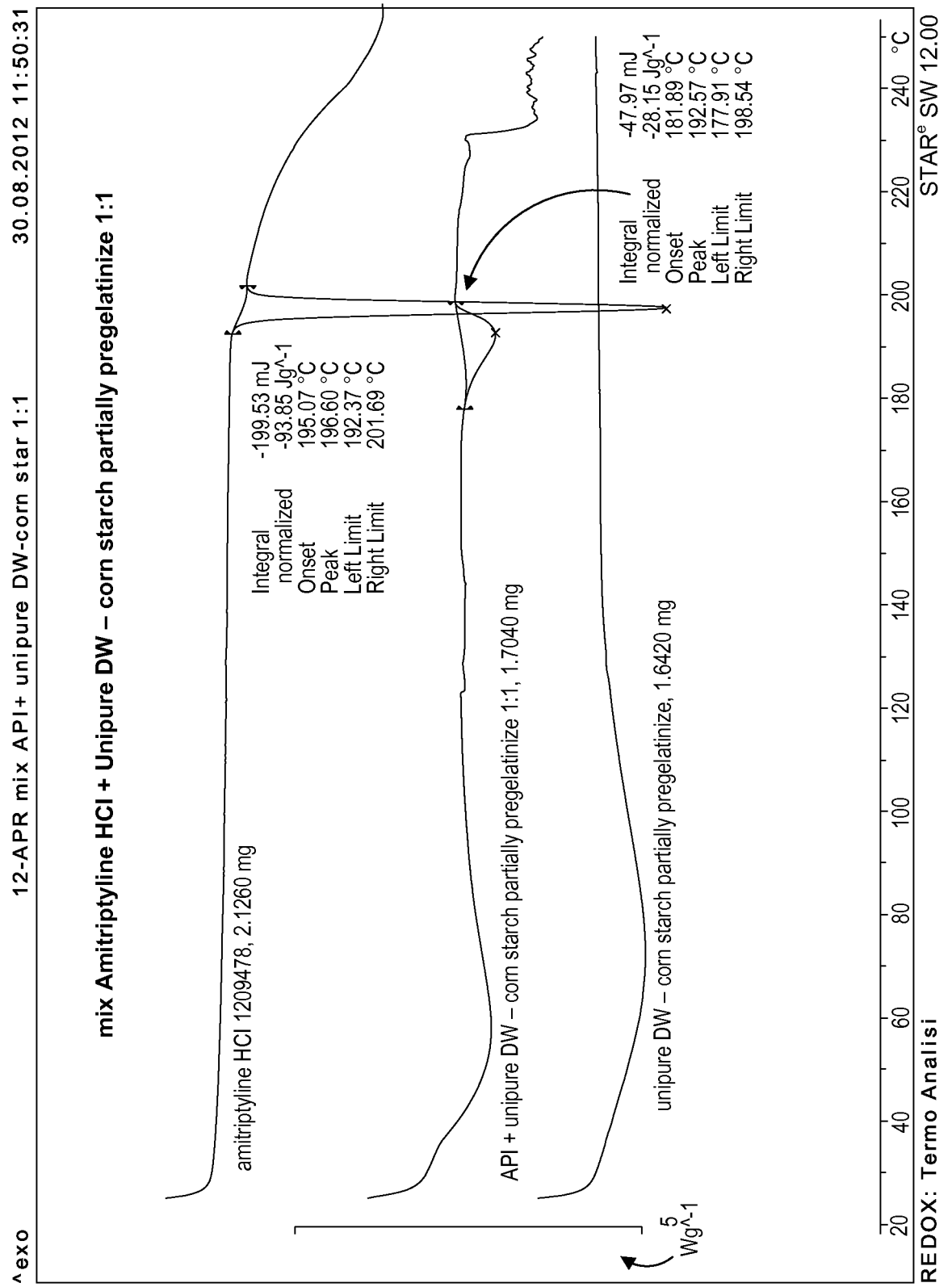

^exo
12-APR mix API+ unipure DW-corn star 1:1
30.08.2012 11:50:31
mix Amitriptyline HCl + Unipure DW – corn starch partially pregelatinize 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
API + unipure DW – corn starch partially pregelatinize 1:1, 1.7040 mg
unipure DW – corn starch partially pregelatinize, 1.6420 mg
Integral -47.97 mJ
normalized -28.15 Jg^-1
Onset 181.89 °C
Peak 192.57 °C
Left Limit 177.91 °C
Right Limit 198.54 °C
5
Wg^-1
20 40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 84

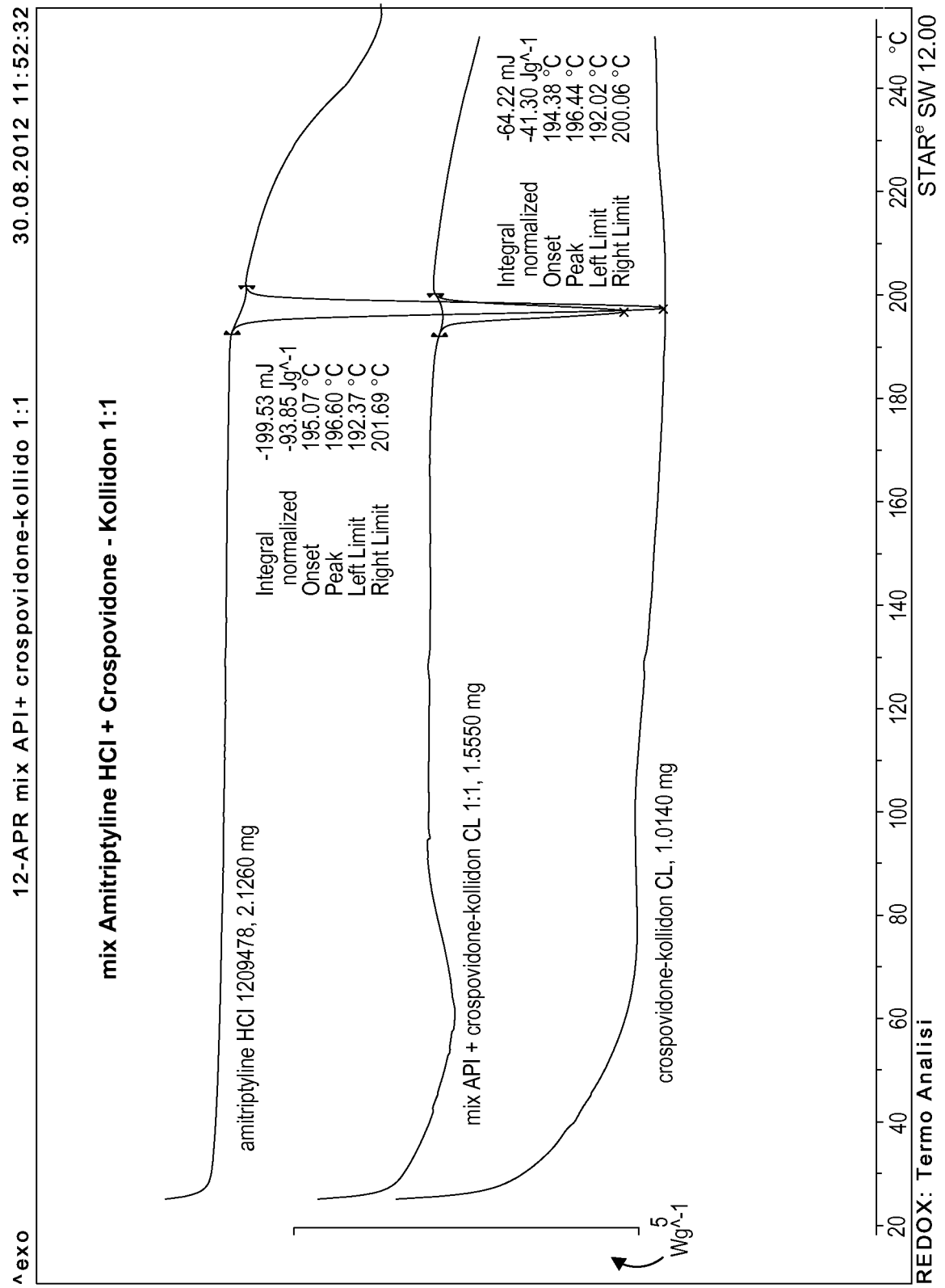

^exo
12-APR mix API+ crospovidone-kollido 1:1
30.08.2012 11:52:32
mix Amitriptyline HCl + Crospovidone - Kollidon 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + crospovidone-kollidon CL 1:1, 1.5550 mg
Integral -64.22 mJ
normalized -41.30 Jg^-1
Onset 194.38 °C
Peak 196.44 °C
Left Limit 192.02 °C
Right Limit 200.06 °C
crospovidone-kollidon CL, 1.0140 mg
5
Wg^-1
20 40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 85

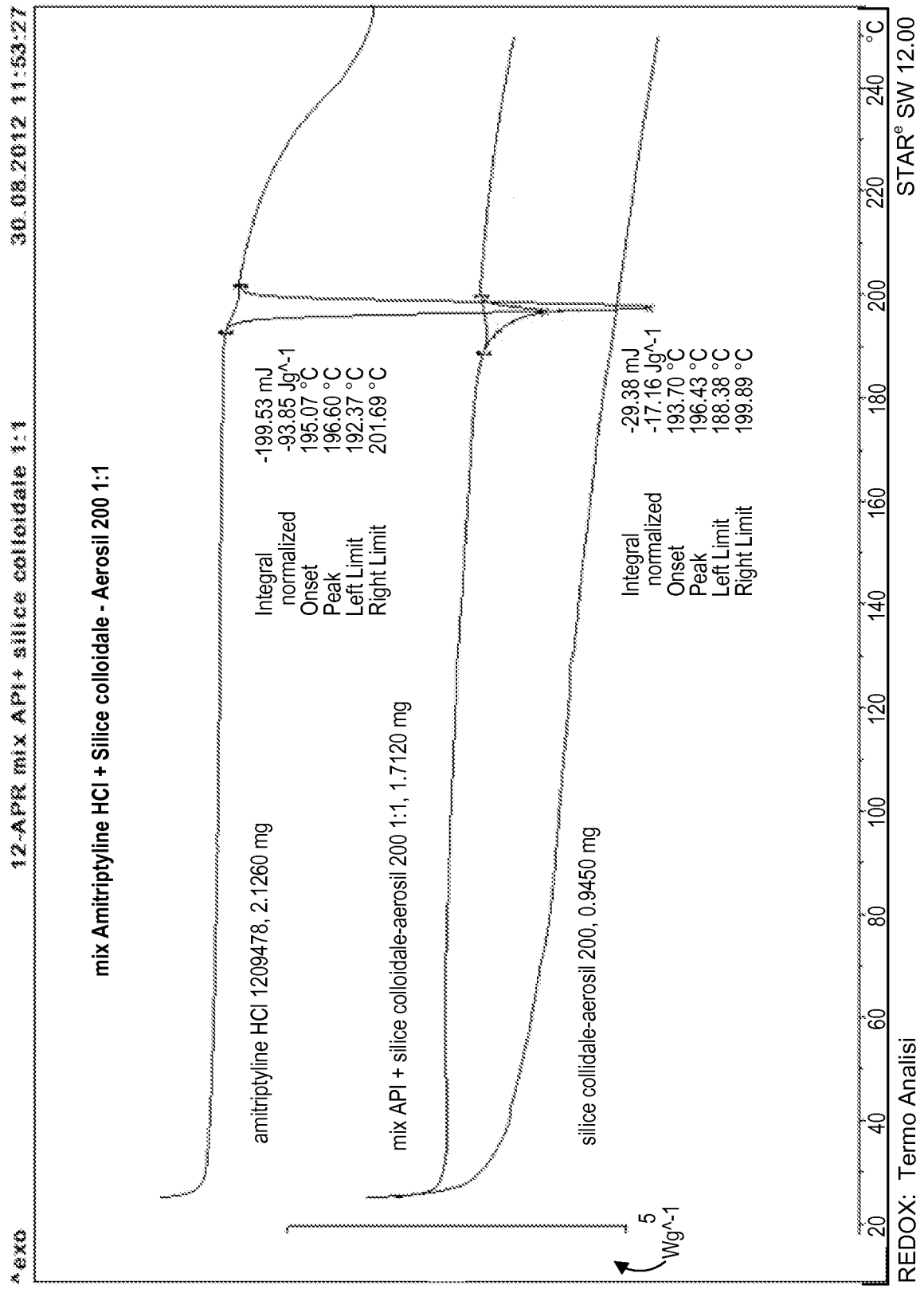

exo
12-APR mix API+ silice colloidale 1:1
30.08.2012 11:53:27
mix Amitriptyline HCl + Silice colloidale - Aerosil 200 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + silice colloidale-aerosil 200 1:1, 1.7120 mg
silice collidale-aerosil 200, 0.9450 mg
Integral -29.38 mJ
normalized -17.16 Jg^-1
Onset 193.70 °C
Peak 196.43 °C
Left Limit 188.38 °C
Right Limit 199.89 °C
5
Wg^-1
20 40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 86

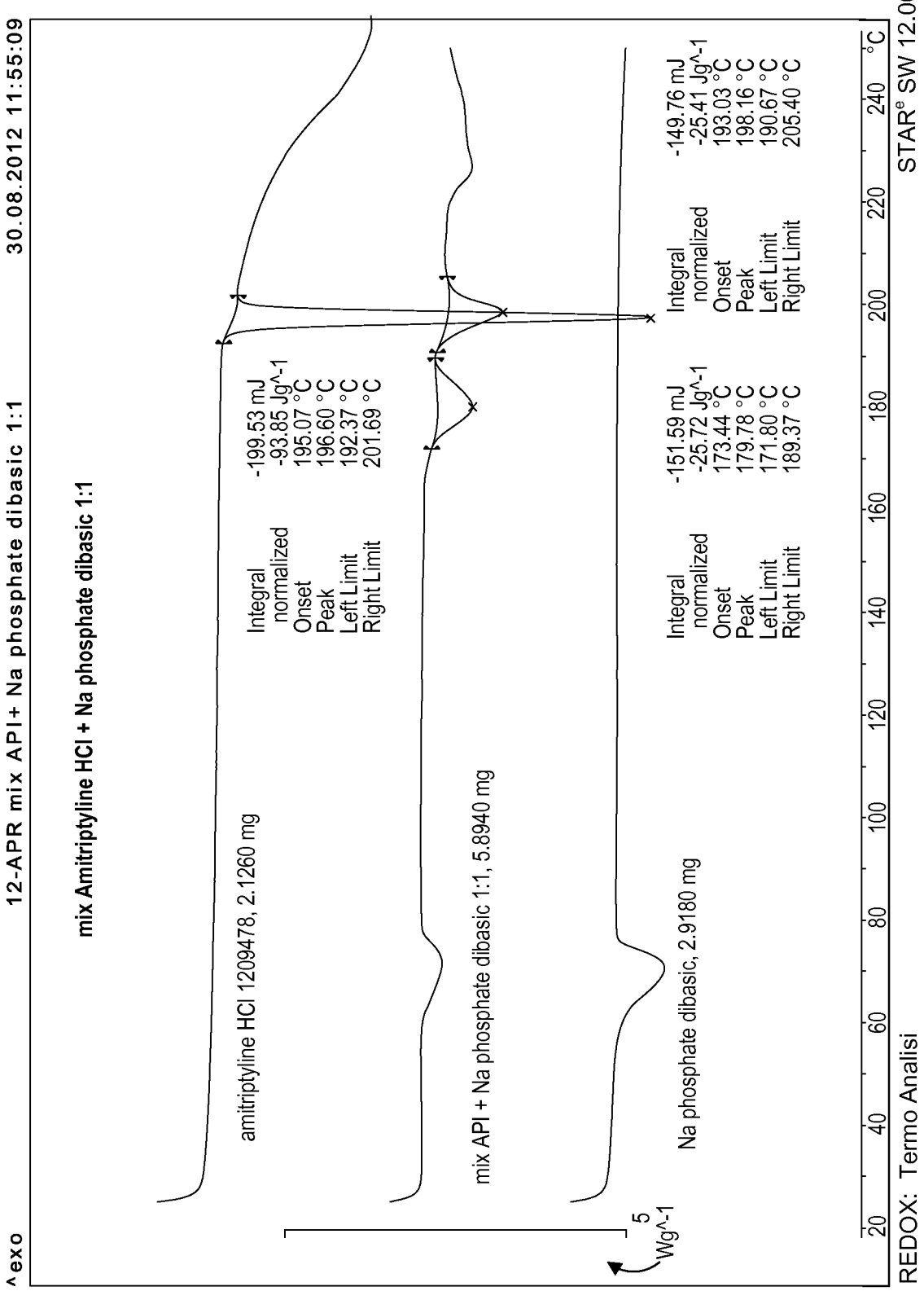

^exo
12-APR mix API+ Na phosphate dibasic 1:1
30.08.2012 11:55:09
mix Amitriptyline HCl + Na phosphate dibasic 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + Na phosphate dibasic 1:1, 5.8940 mg
Integral -151.59 mJ
normalized -25.72 Jg^-1
Onset 173.44 °C
Peak 179.78 °C
Left Limit 171.80 °C
Right Limit 189.37 °C
Na phosphate dibasic, 2.9180 mg
Integral -149.76 mJ
normalized -25.41 Jg^-1
Onset 193.03 °C
Peak 198.16 °C
Left Limit 190.67 °C
Right Limit 205.40 °C
5
Wg^-1
20 40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 87

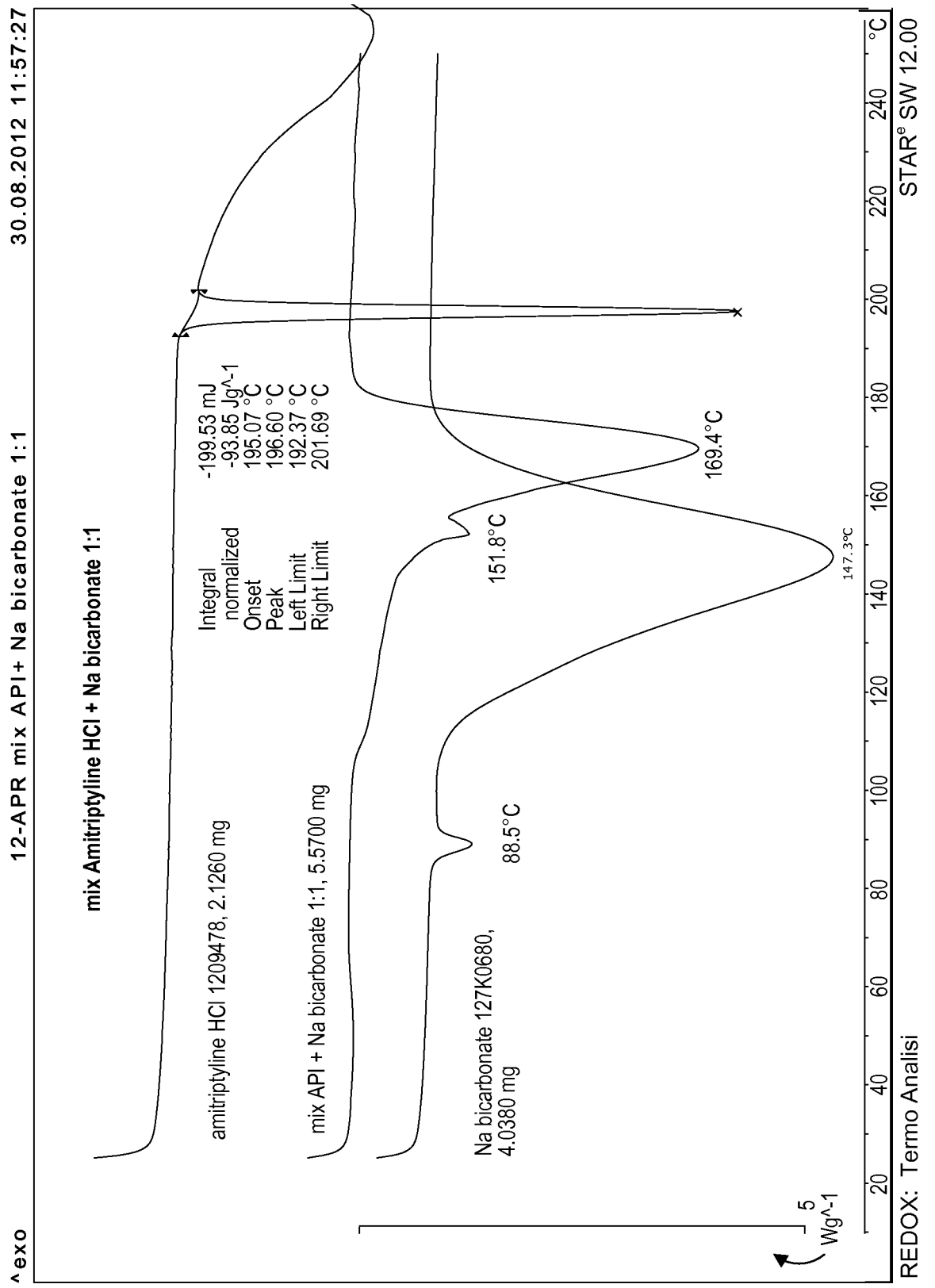

^exo
12-APR mix API+ Na bicarbonate 1:1
30.08.2012 11:57:27
mix Amitriptyline HCl + Na bicarbonate 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + Na bicarbonate 1:1, 5.5700 mg
Na bicarbonate 127K0680, 4.0380 mg
88.5°C
151.8°C
147.3°C
169.4°C
5
Wg^-1
20 40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 88

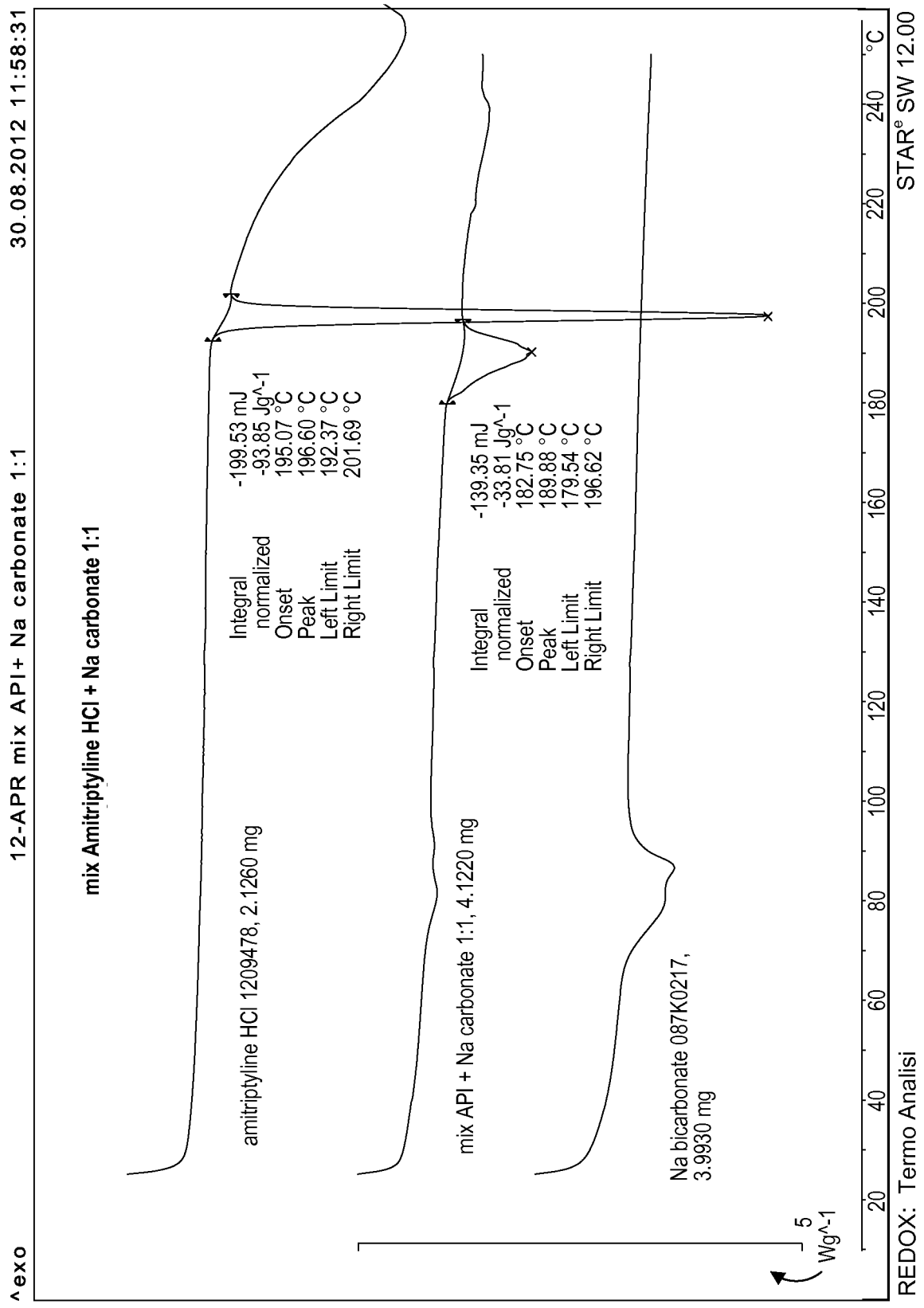

^exo
12-APR mix API+ Na carbonate 1:1
30.08.2012 11:58:31
mix Amitriptyline HCl + Na carbonate 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + Na carbonate 1:1, 4.1220 mg
Integral -139.35 mJ
normalized -33.81 Jg^-1
Onset 182.75 °C
Peak 189.88 °C
Left Limit 179.54 °C
Right Limit 196.62 °C
Na bicarbonate 087K0217,
3.9930 mg
5
Wg^-1
20 40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 89

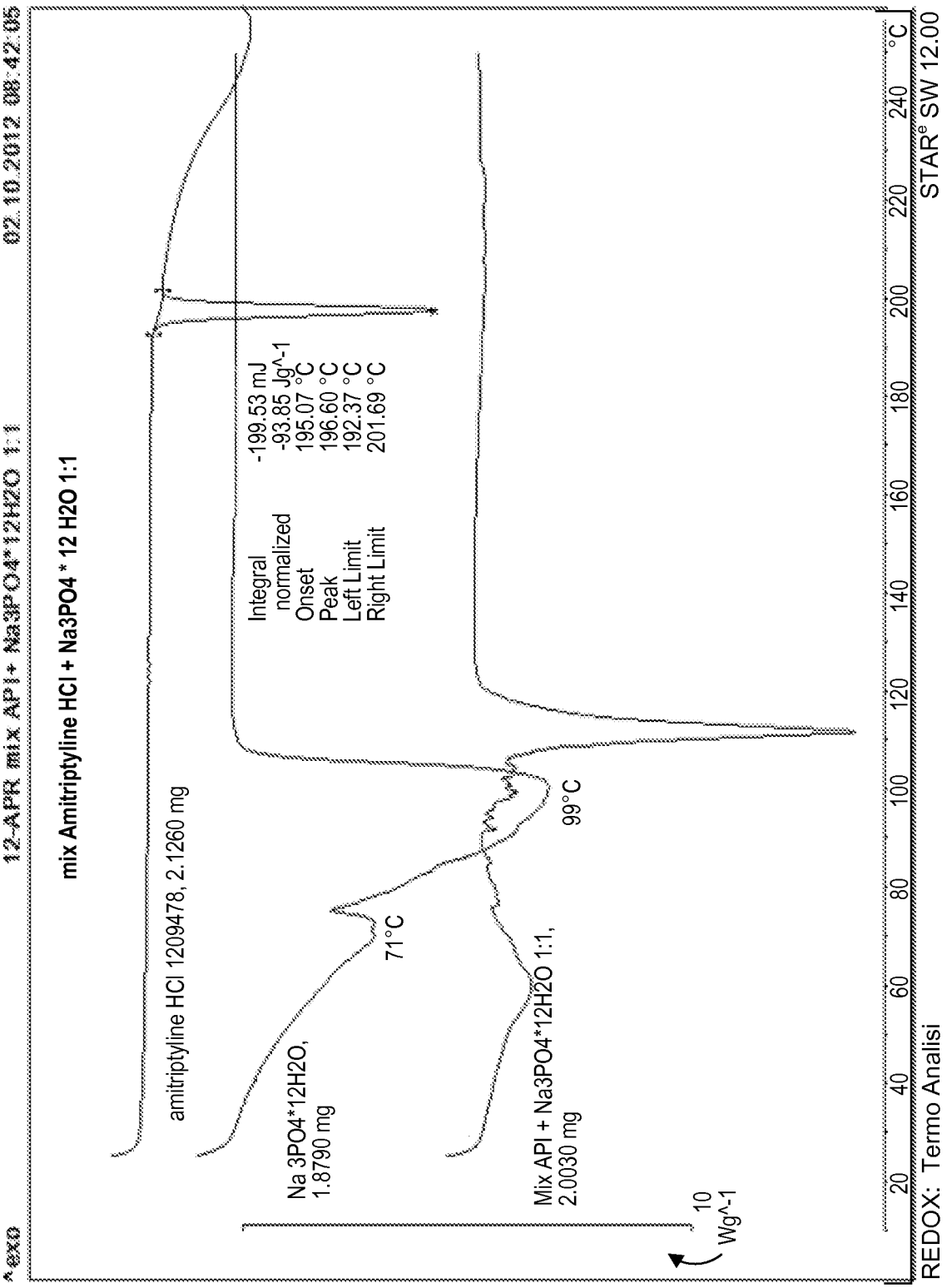

12-APR mix API+ Na3PO4*12H2O 1:1
02.10.2012 08:42:05
mix Amitriptyline HCl + Na3PO4 * 12 H2O 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
Na 3PO4*12H2O,
1.8790 mg
71°C
Mix API + Na3PO4*12H2O 1:1,
2.0030 mg
99°C
exo
10
Wg^-1
20 40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 90

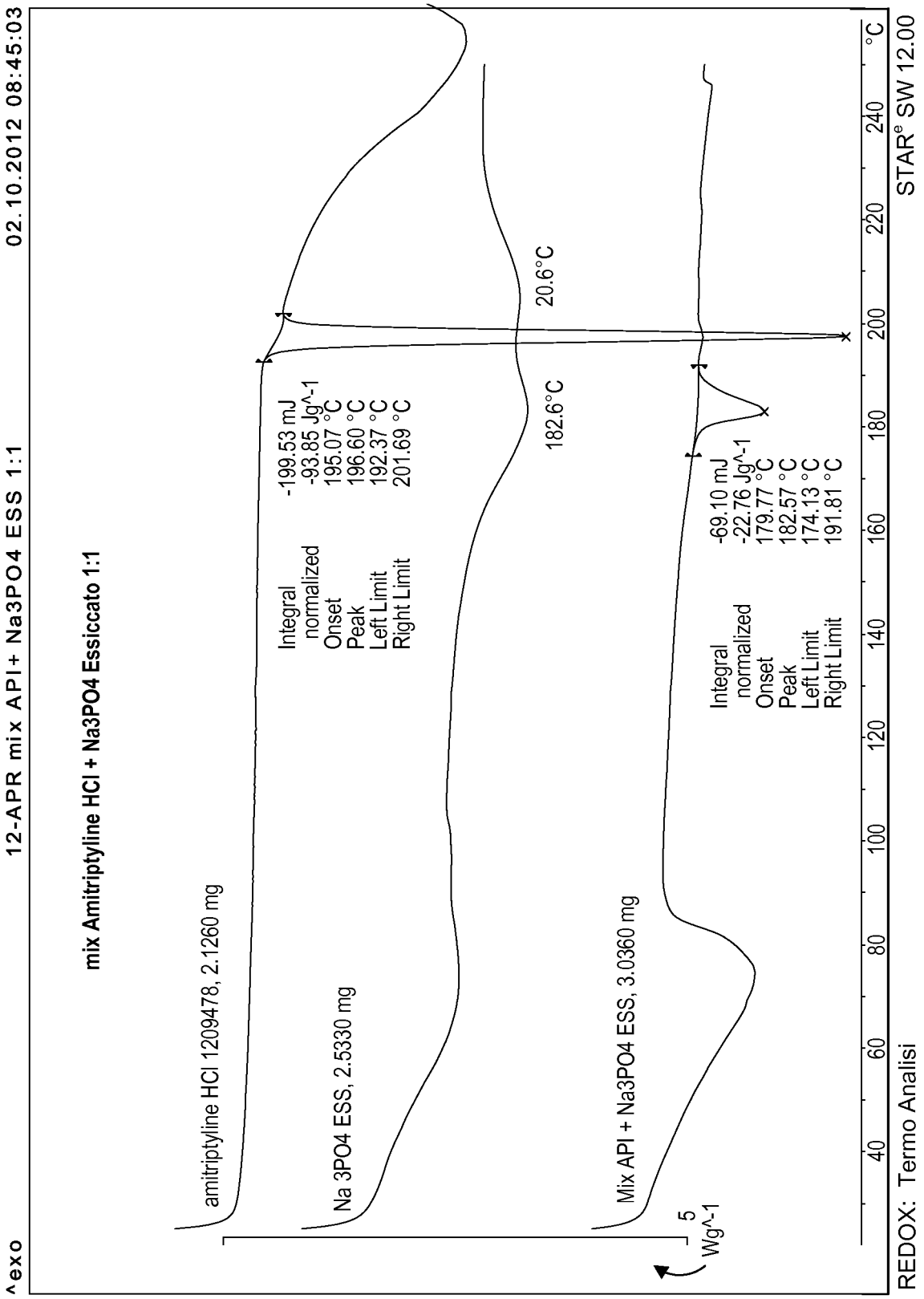

^exo
12-APR mix API+ Na3PO4 ESS 1:1
02.10.2012 08:45:03
mix Amitriptyline HCl + Na3PO4 Essiccato 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
20.6°C
Na 3PO4 ESS, 2.5330 mg
182.6°C
Mix API + Na3PO4 ESS, 3.0360 mg
Integral -69.10 mJ
normalized -22.76 Jg^-1
Onset 179.77 °C
Peak 182.57 °C
Left Limit 174.13 °C
Right Limit 191.81 °C
5
Wg^-1
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 91

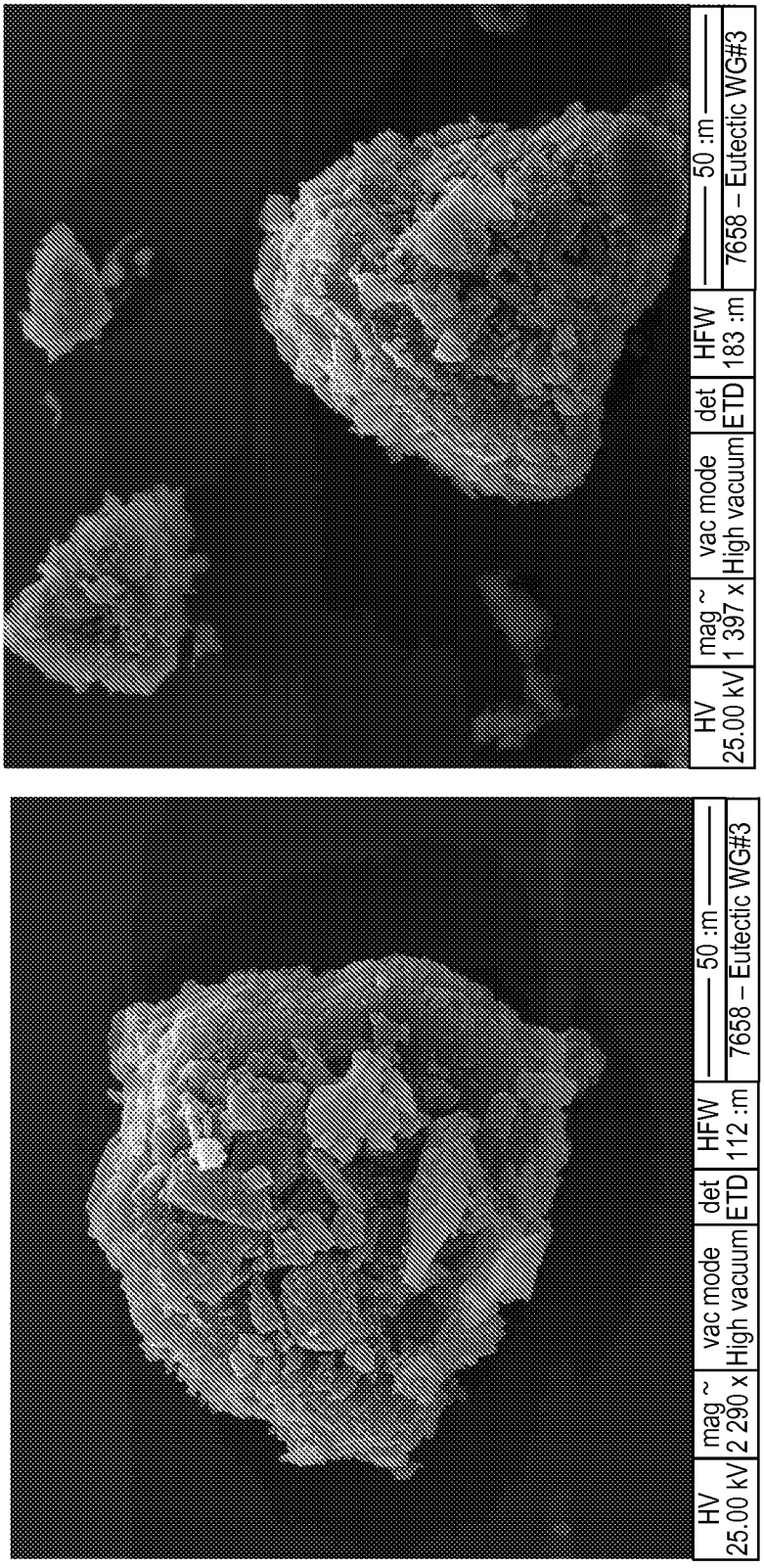

HV
25.00 kV
mag ~
1 397 x
vac mode
High vacuum
det
ETD
HFW
183 :m
50 :m
7658 – Eutectic WG#3
HV
25.00 kV
mag ~
2 290 x
vac mode
High vacuum
det
ETD
HFW
112 :m
50 :m
7658 – Eutectic WG#3

FIG. 92

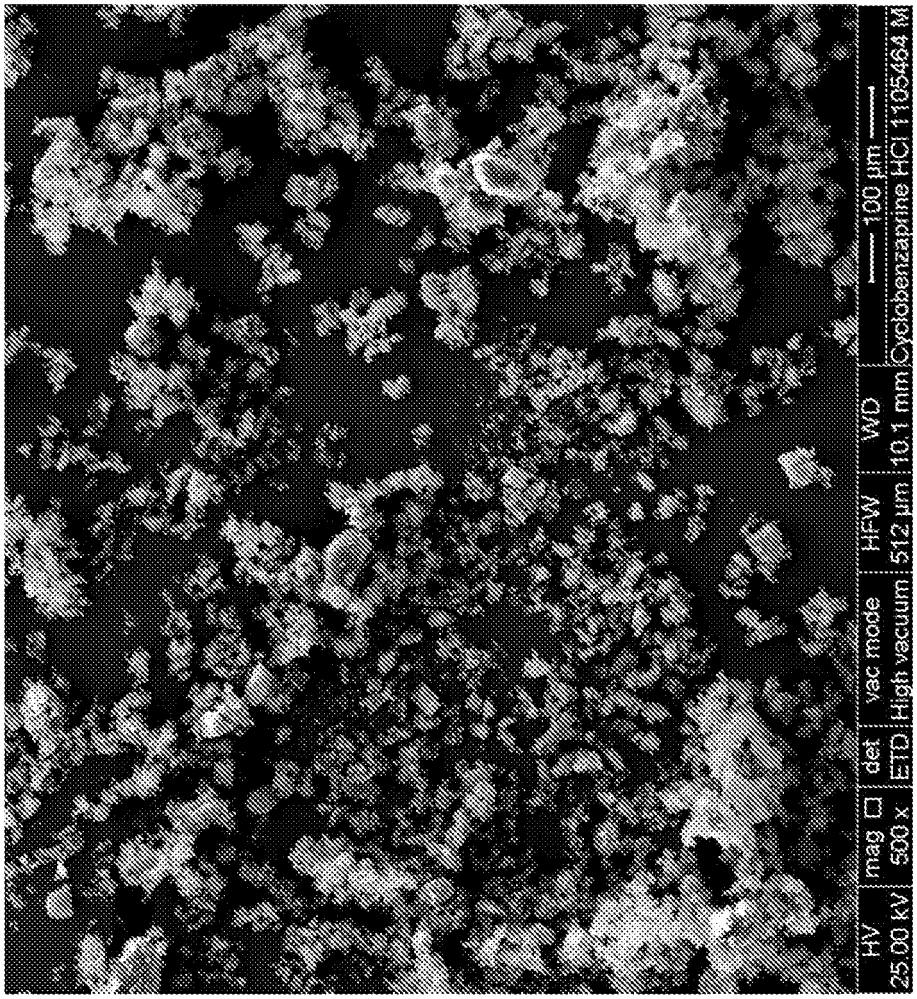

HV
25.00 kV
mag
500 x
det
ETD
vac mode
High vacuum
HFW
512 µm
WD
10.1 mm
100 µm
Cyclobenzaprine HCl 1105464 M

FIG. 93

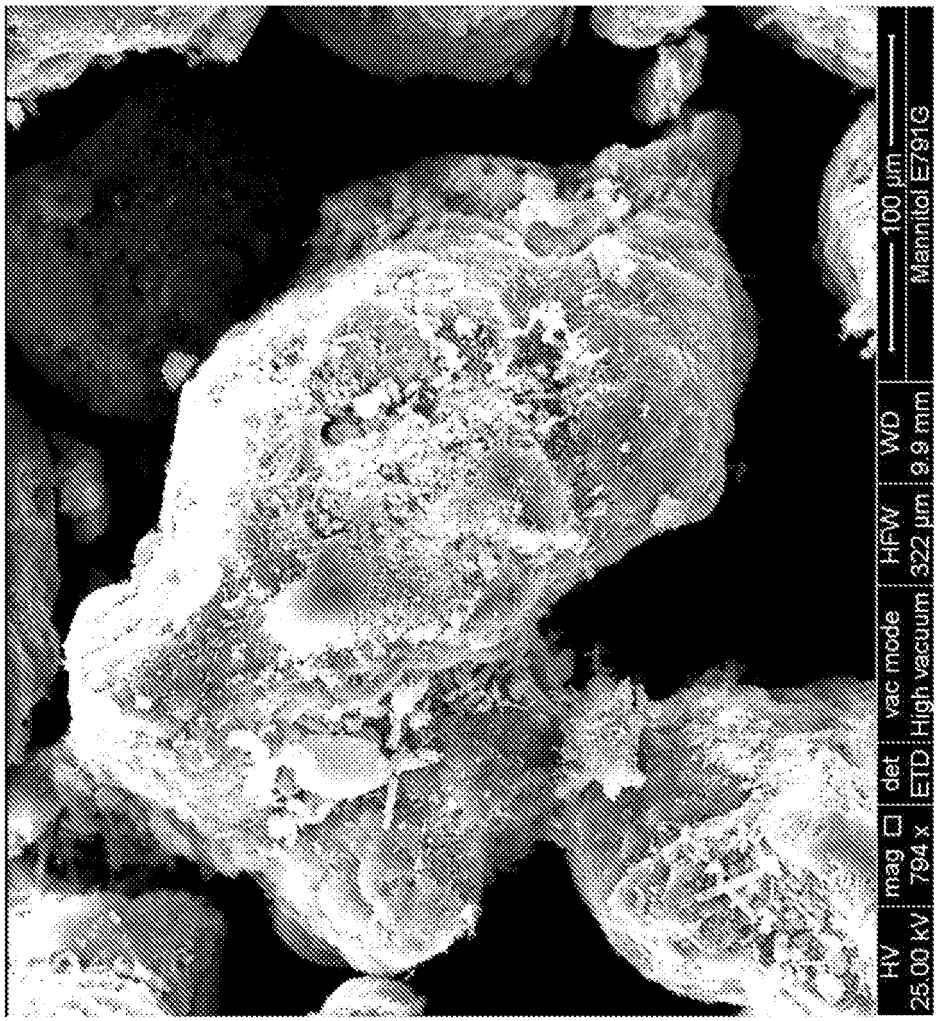

HV
25.00 kV
mag
794 x
det
ETD
vac mode
High vacuum
HFW
322 µm
WD
9.9 mm
100 µm
Mannitol E791G

FIG. 94

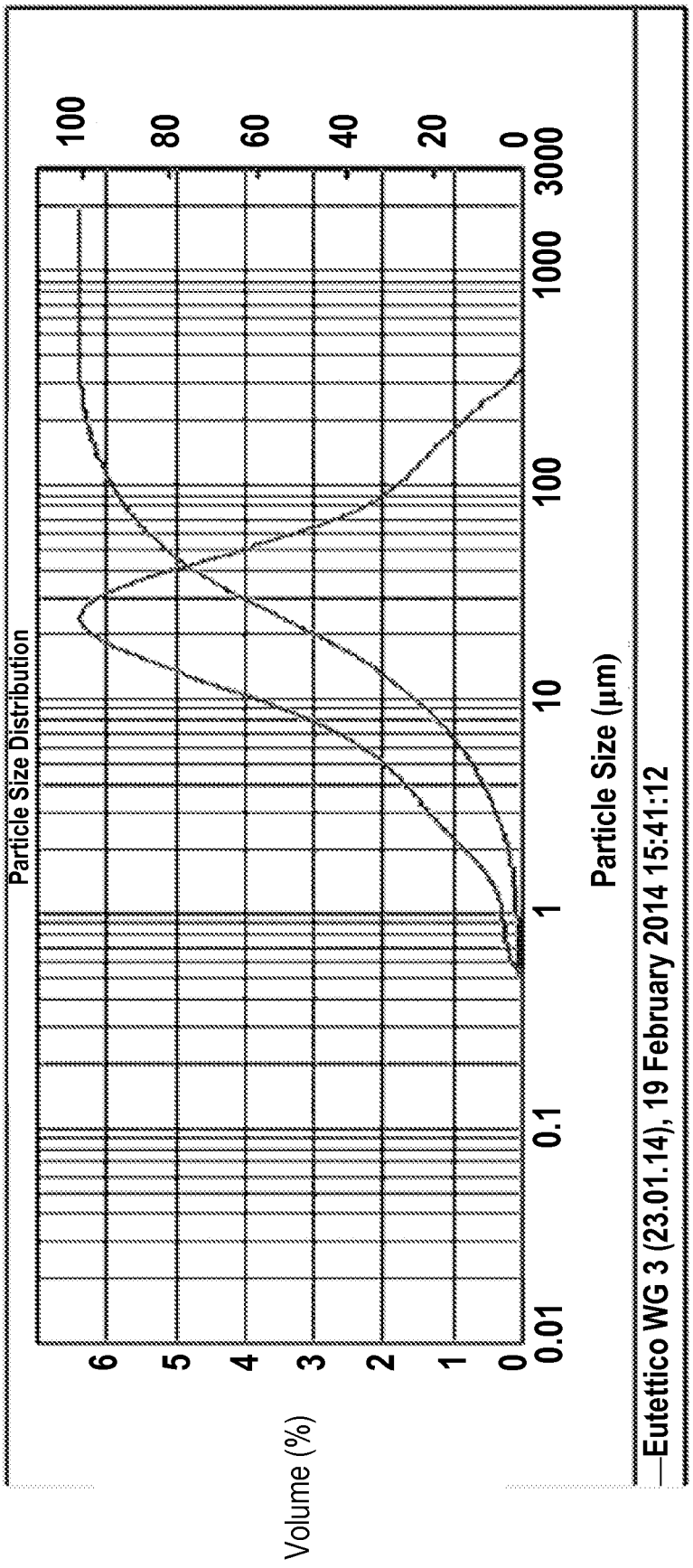

Particle Size Distribution
Volume (%)
0
1
2
3
4
5
6
0
20
40
60
80
100
0.01
0.1
1
10
100
1000
3000
Particle Size (µm)
—Eutettico WG 3 (23.01.14), 19 February 2014 15:41:12

FIG. 95

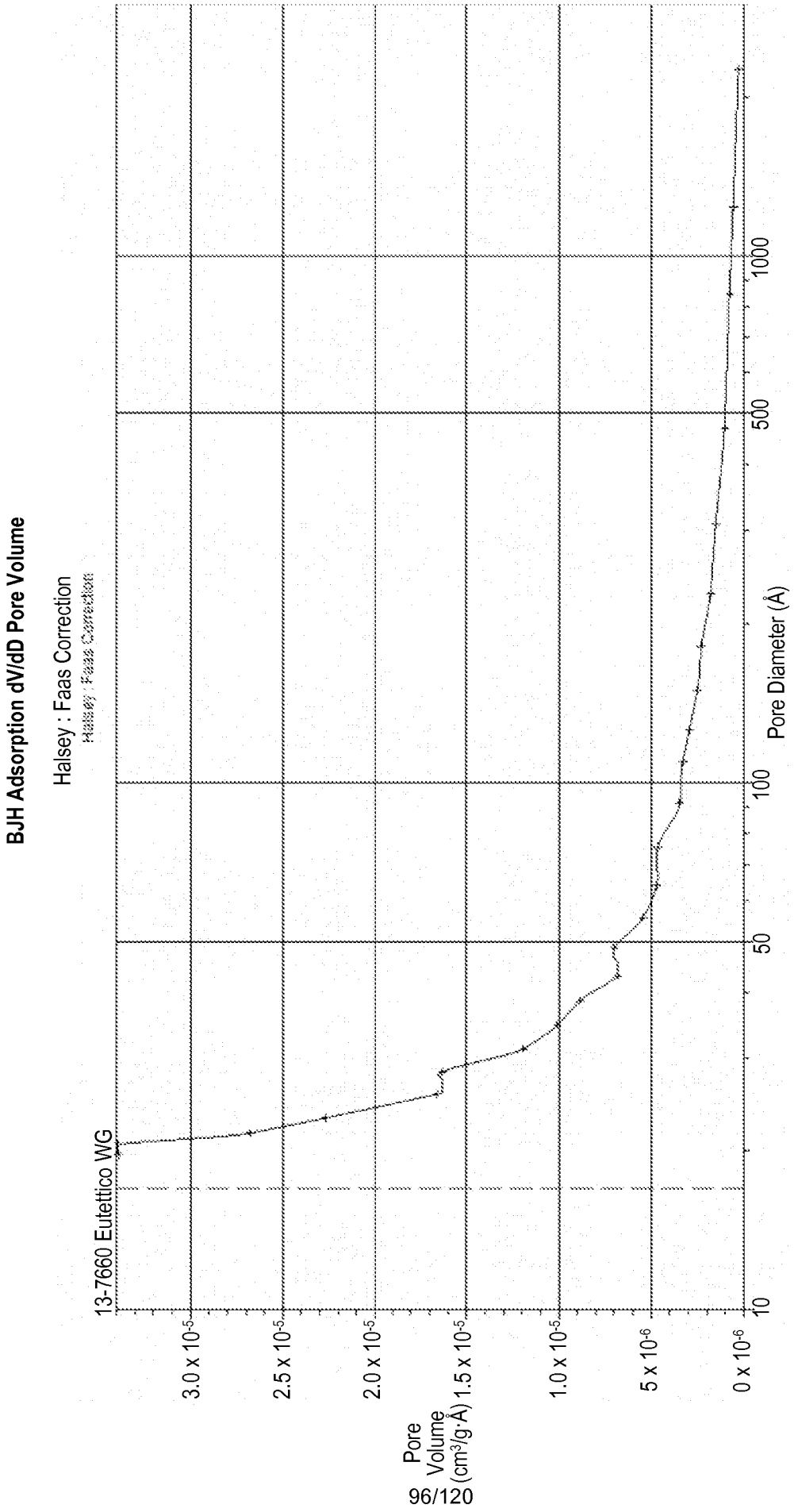

BJH Adsorption dV/dD Pore Volume
Halsey : Faas Correction
Halsey: Faas Correction
13-7660 Eutettico WG
Pore Volume (cm³/g·Å)
3.0 x 10⁻⁵
2.5 x 10⁻⁵
2.0 x 10⁻⁵
1.5 x 10⁻⁵
1.0 x 10⁻⁵
5 x 10⁻⁶
0 x 10⁻⁶
10
50
100
500
1000
Pore Diameter (Å)

FIG. 96

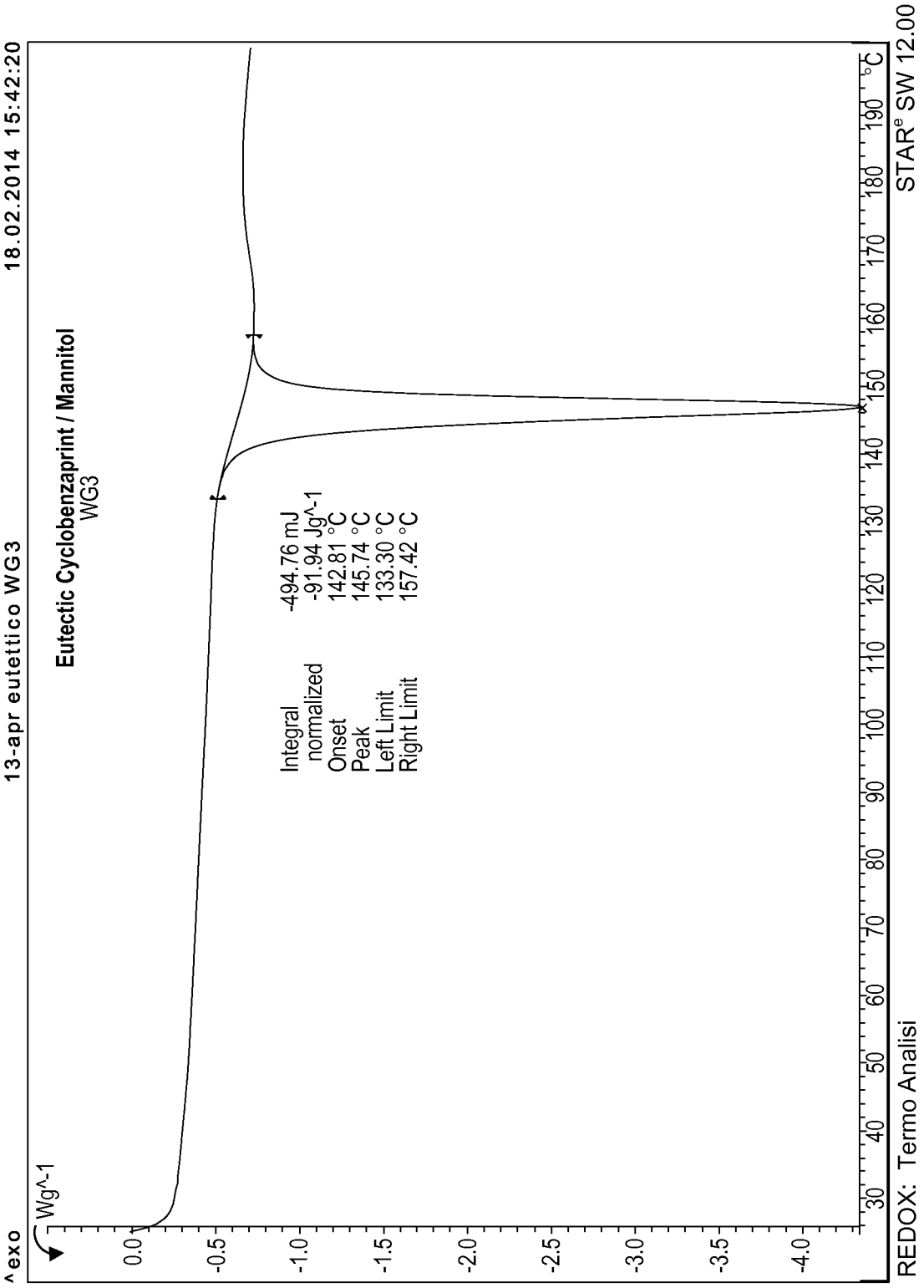

13-apr eutettico WG3
18.02.2014 15:42:20
Eutectic Cyclobenzaprint / Mannitol
WG3
Integral -494.76 mJ
normalized -91.94 Jg^-1
Onset 142.81 °C
Peak 145.74 °C
Left Limit 133.30 °C
Right Limit 157.42 °C
^exo
Wg^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 97

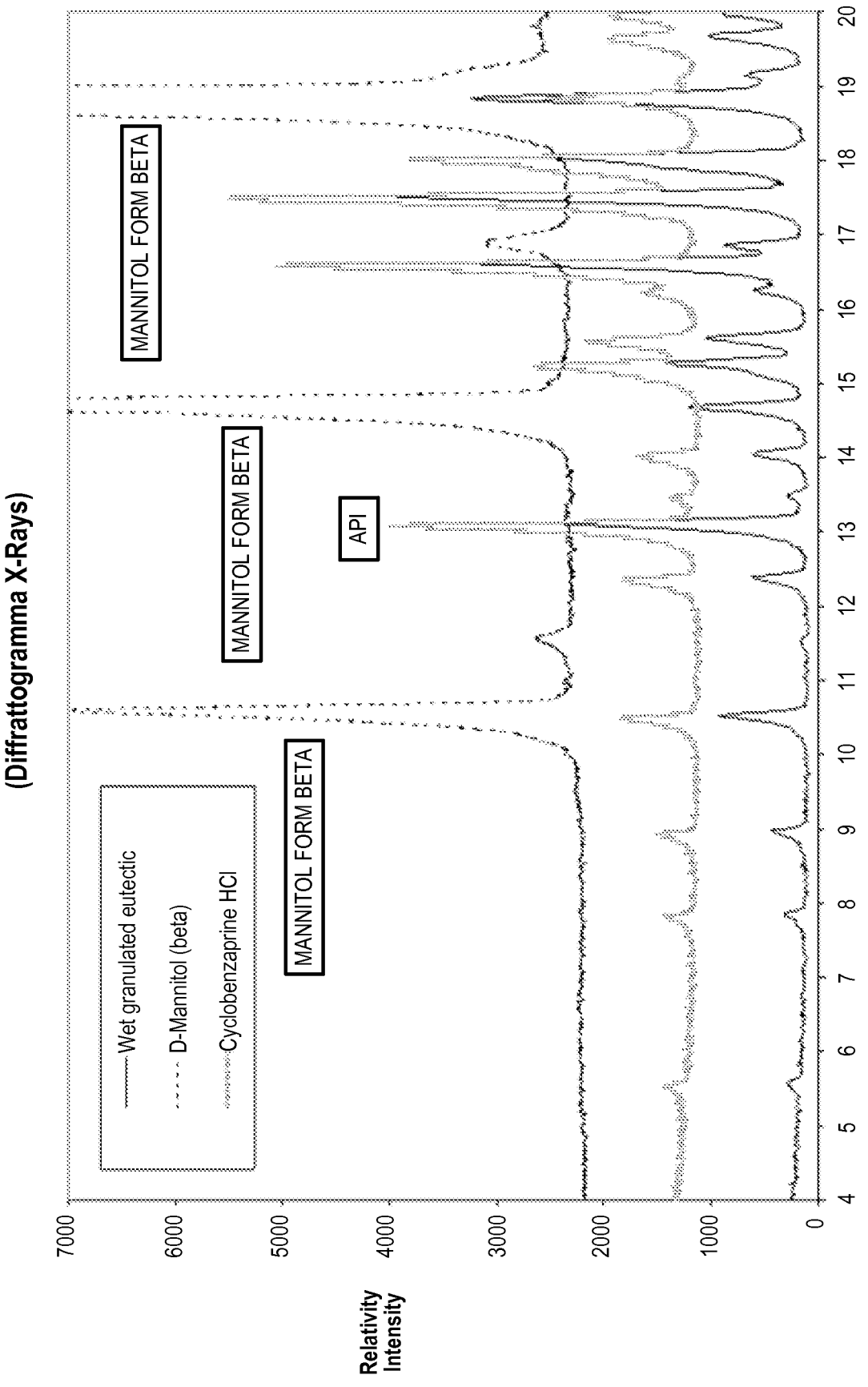

(Diffrattogramma X-Rays)
Wet granulated eutectic
D-Mannitol (beta)
Cyclobenzaprine HCl
MANNITOL FORM BETA
API
MANNITOL FORM BETA
MANNITOL FORM BETA
Relativity Intensity
2 Theta (deg)
7000
6000
5000
4000
3000
2000
1000
0
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20

FIG. 98

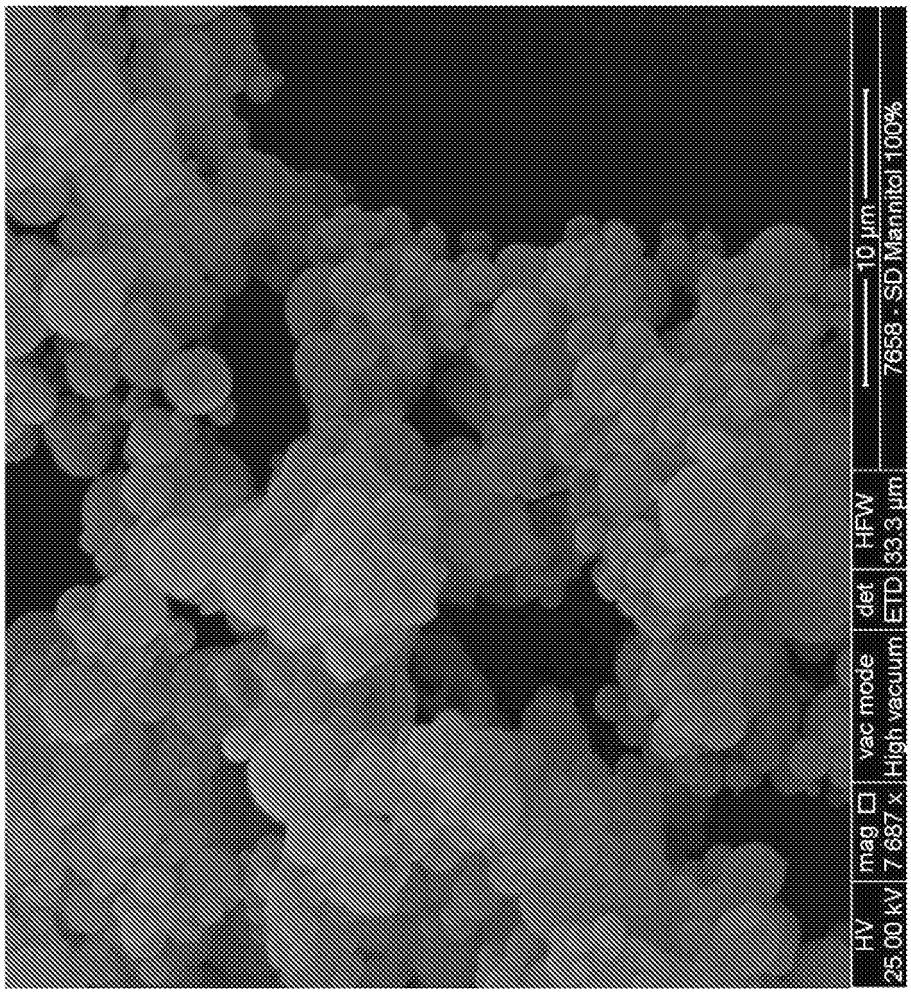

HV
25.00 kV
mag
7 687 x
vac mode
High vacuum
det
ETD
HFW
33.3 µm
10 µm
7658 - SD Mannitol 100%

FIG. 99

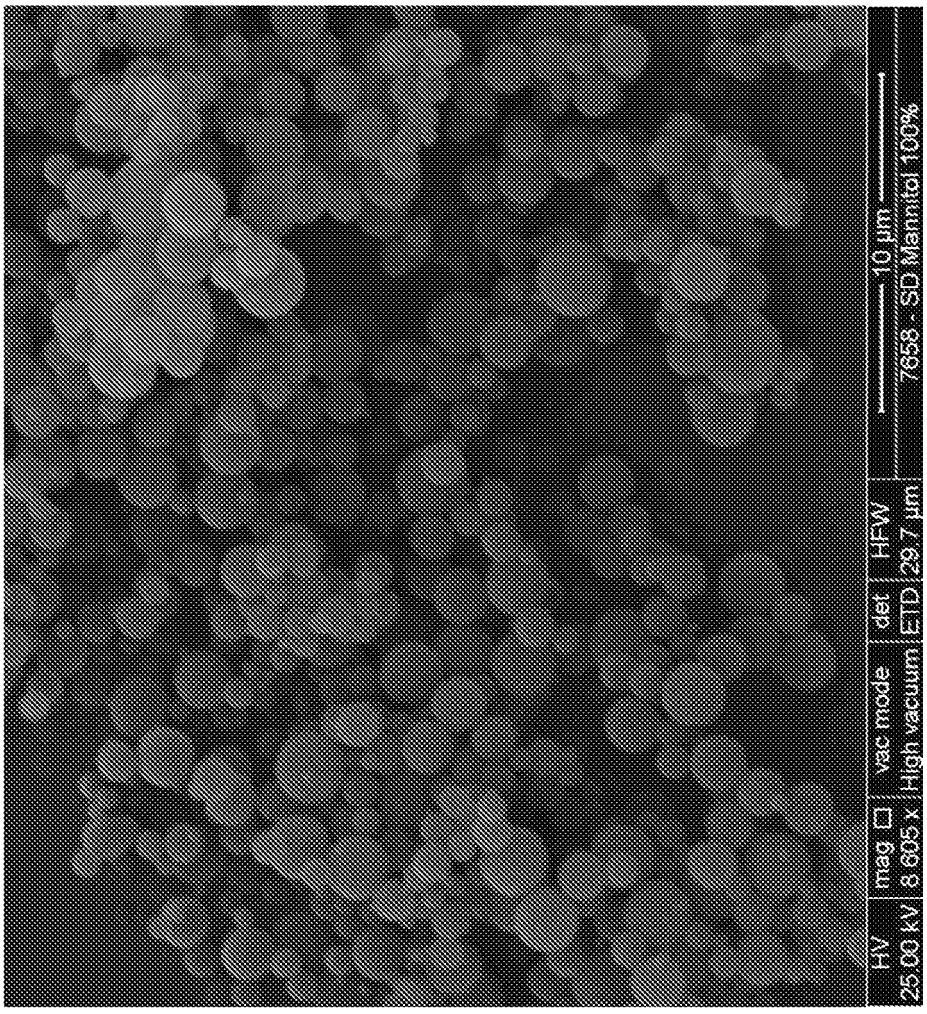

HV
25.00 kV
mag
8 605 x
vac mode
High vacuum
det
ETD
HFW
29.7 µm
10 µm
7658 - SD Mannitol 100%

FIG. 100

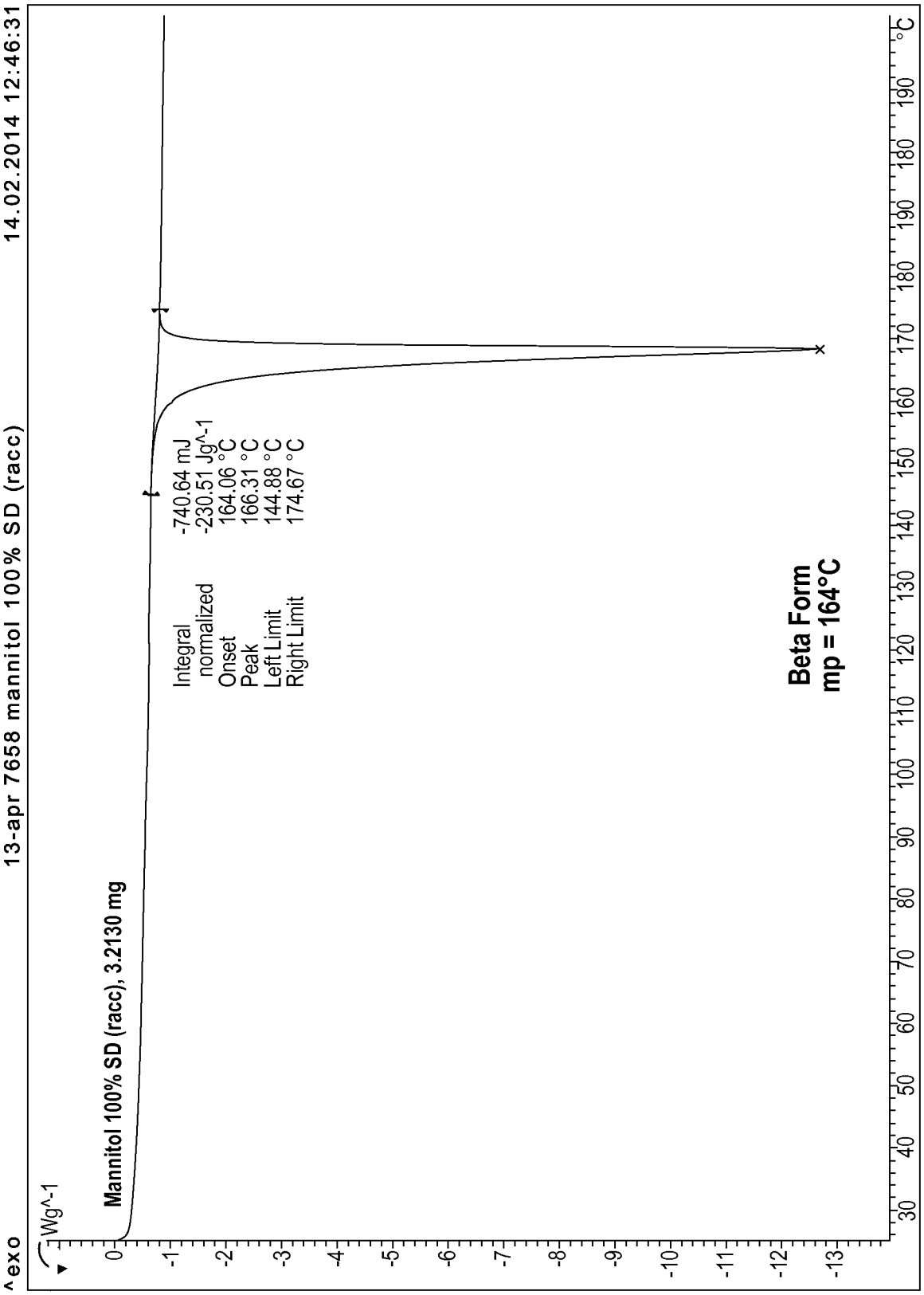

^exo
13-apr 7658 mannitol 100% SD (racc)
14.02.2014 12:46:31
Wg^-1
Mannitol 100% SD (racc), 3.2130 mg
Integral -740.64 mJ
normalized -230.51 Jg^-1
Onset 164.06 °C
Peak 166.31 °C
Left Limit 144.88 °C
Right Limit 174.67 °C
Beta Form
mp = 164°C
REDOX: Termo Analisi
STARe SW 12.00
°C

FIG. 101

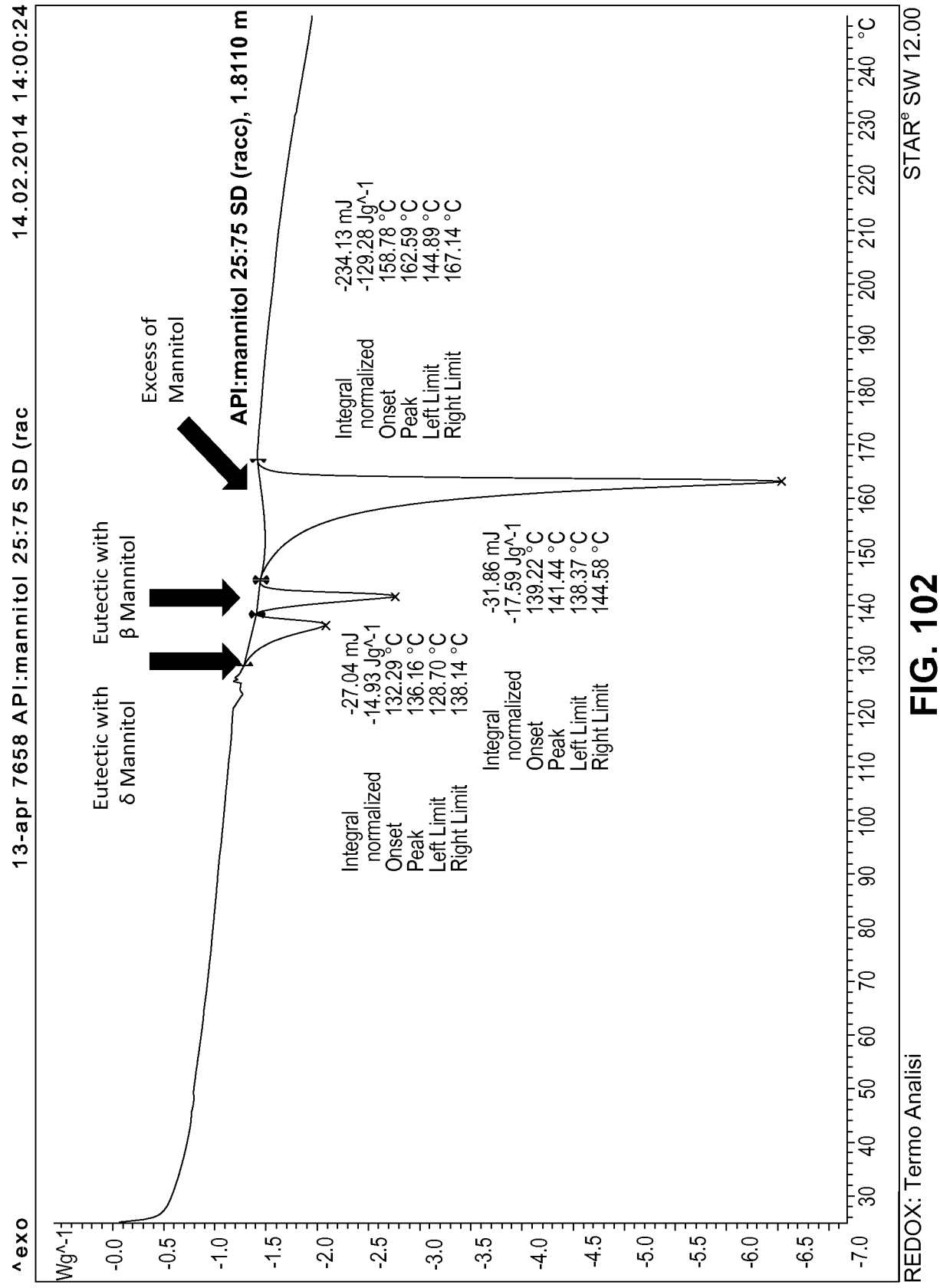

^exo
13-apr 7658 API:mannitol 25:75 SD (rac
14.02.2014 14:00:24
Wg^-1
-0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
-4.5
-5.0
-5.5
-6.0
-6.5
-7.0
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
Eutectic with δ Mannitol
Eutectic with β Mannitol
Excess of Mannitol
API:mannitol 25:75 SD (racc), 1.8110 m
Integral -27.04 mJ
normalized -14.93 Jg^-1
Onset 132.29 °C
Peak 136.16 °C
Left Limit 128.70 °C
Right Limit 138.14 °C
Integral -31.86 mJ
normalized -17.59 Jg^-1
Onset 139.22 °C
Peak 141.44 °C
Left Limit 138.37 °C
Right Limit 144.58 °C
Integral -234.13 mJ
normalized -129.28 Jg^-1
Onset 158.78 °C
Peak 162.59 °C
Left Limit 144.89 °C
Right Limit 167.14 °C
REDOX: Termo Analisi
STARe SW 12.00

FIG. 102

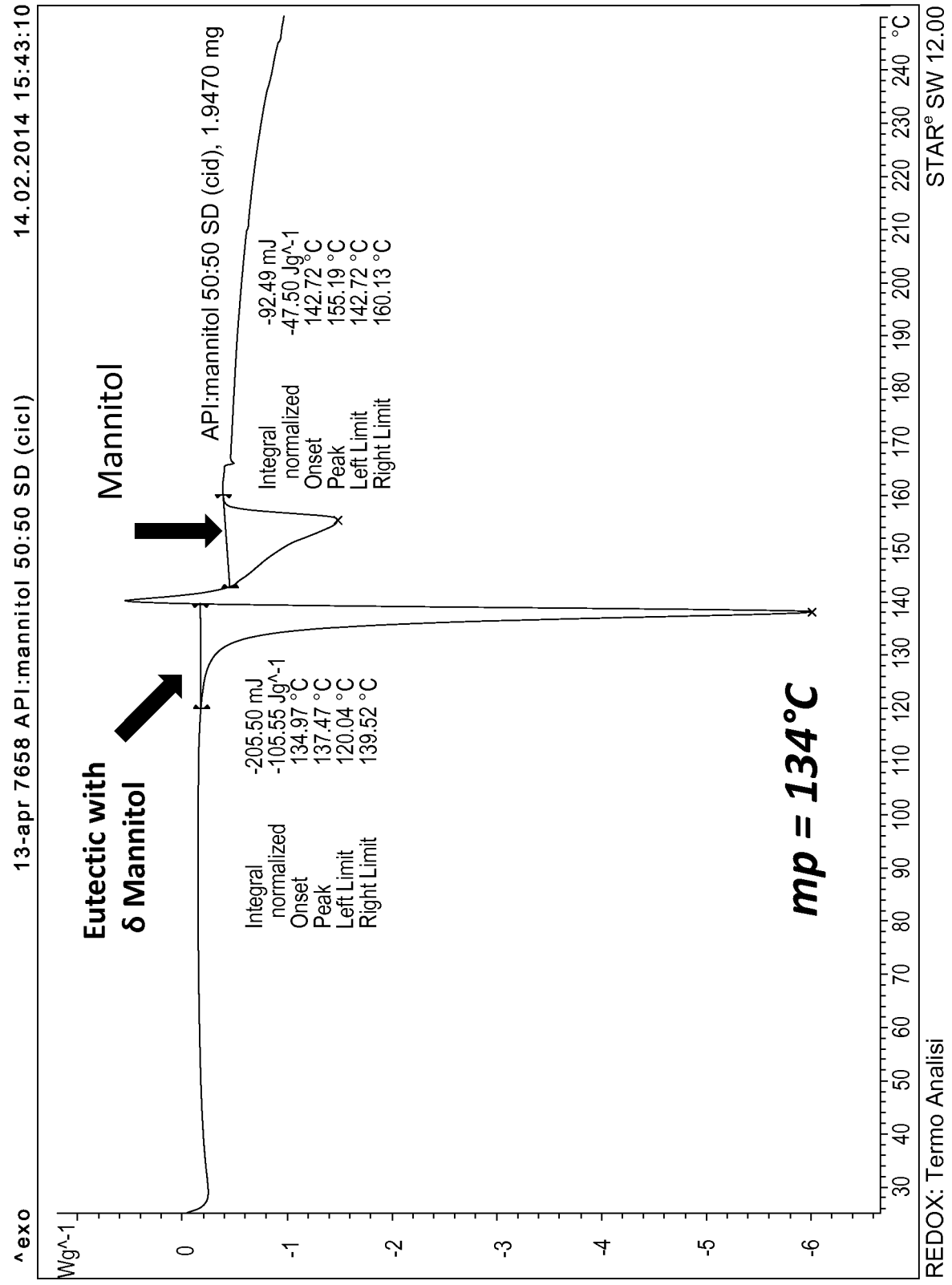

^exo
13-apr 7658 API:mannitol 50:50 SD (cicl)
14.02.2014 15:43:10
Wg^-1
0
-1
-2
-3
-4
-5
-6
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00
Eutectic with
δ Mannitol
Integral -205.50 mJ
normalized -105.55 Jg^-1
Onset 134.97 °C
Peak 137.47 °C
Left Limit 120.04 °C
Right Limit 139.52 °C
mp = 134°C
Mannitol
API:mannitol 50:50 SD (cid), 1.9470 mg
Integral -92.49 mJ
normalized -47.50 Jg^-1
Onset 142.72 °C
Peak 155.19 °C
Left Limit 142.72 °C
Right Limit 160.13 °C

FIG. 103

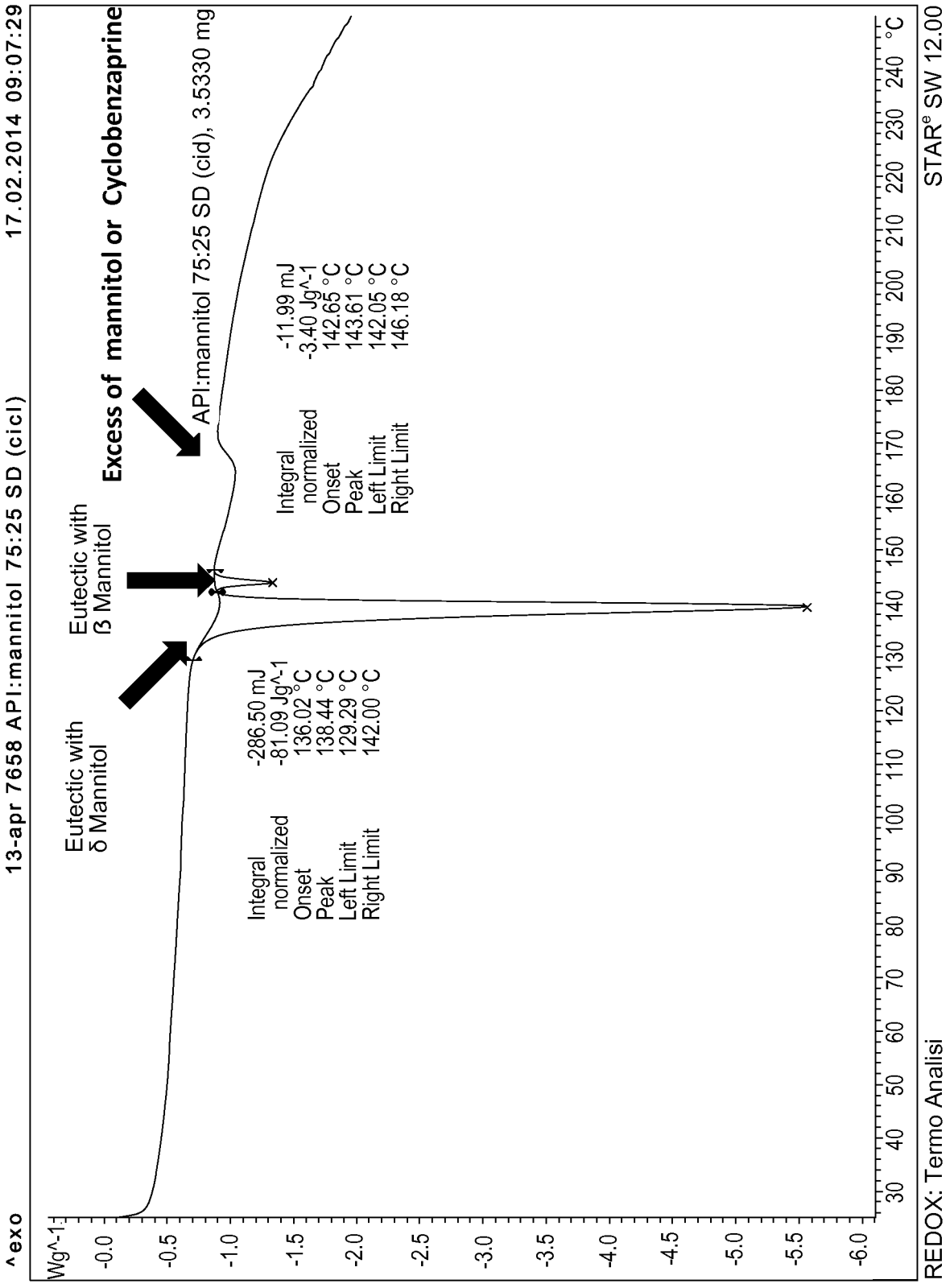

^exo
13-apr 7658 API:mannitol 75:25 SD (cicl)
17.02.2014 09:07:29
Wg^-1
Eutectic with δ Mannitol
Eutectic with β Mannitol
Excess of mannitol or Cyclobenzaprine
API:mannitol 75:25 SD (cid), 3.5330 mg
Integral -286.50 mJ
normalized -81.09 Jg^-1
Onset 136.02 °C
Peak 138.44 °C
Left Limit 129.29 °C
Right Limit 142.00 °C
Integral -11.99 mJ
normalized -3.40 Jg^-1
Onset 142.65 °C
Peak 143.61 °C
Left Limit 142.05 °C
Right Limit 146.18 °C
REDOX: Termo Analisi
STARe SW 12.00
°C

FIG. 104

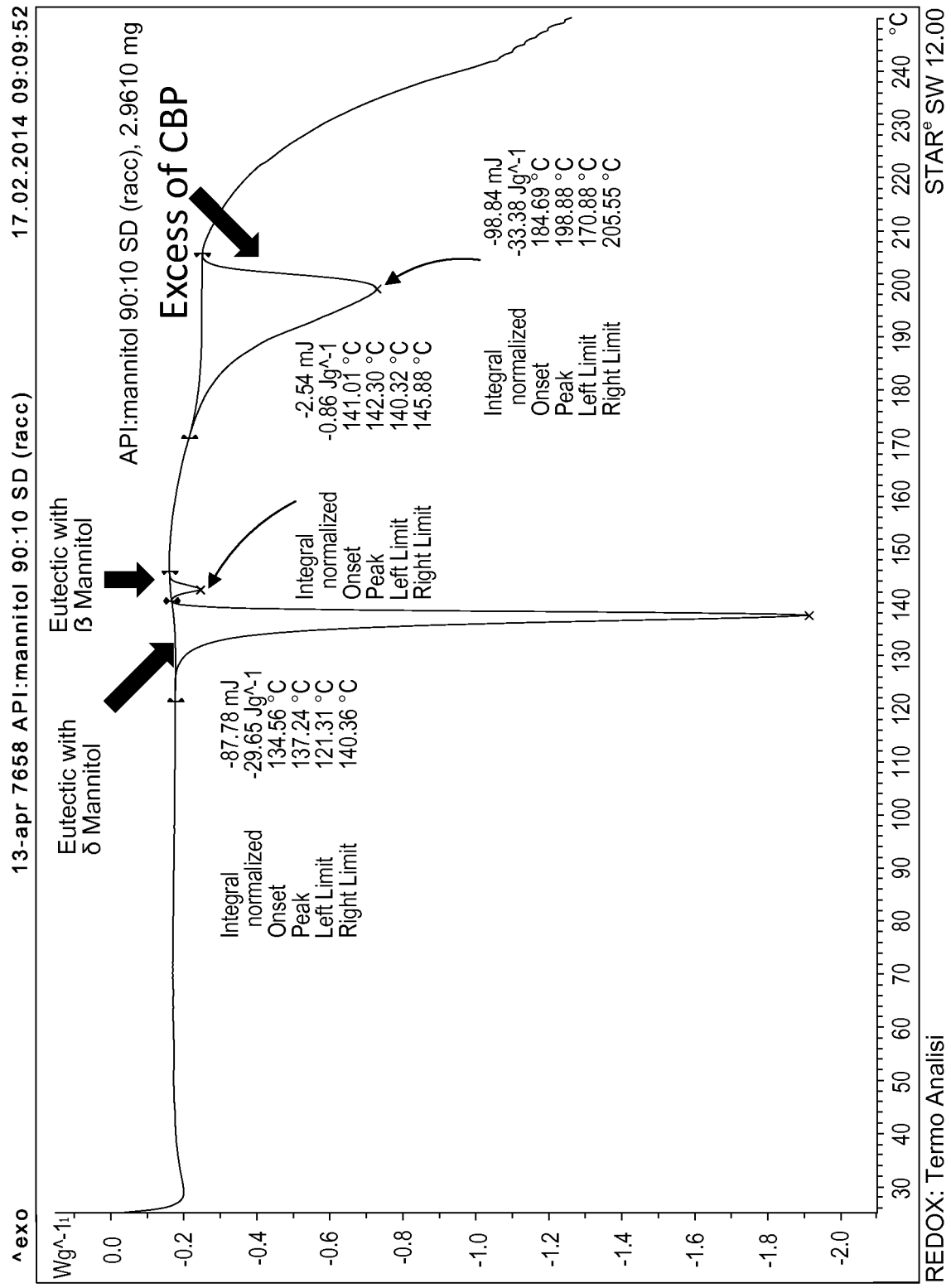

^exo
13-apr 7658 API:mannitol 90:10 SD (racc)
17.02.2014 09:09:52
Wg^-1
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
-2.0
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
REDOX: Termo Analisi
STARe SW 12.00
Eutectic with δ Mannitol
Eutectic with ß Mannitol
API:mannitol 90:10 SD (racc), 2.9610 mg
Excess of CBP
Integral -87.78 mJ
normalized -29.65 Jg^-1
Onset 134.56 °C
Peak 137.24 °C
Left Limit 121.31 °C
Right Limit 140.36 °C
Integral -2.54 mJ
normalized -0.86 Jg^-1
Onset 141.01 °C
Peak 142.30 °C
Left Limit 140.32 °C
Right Limit 145.88 °C
Integral -98.84 mJ
normalized -33.38 Jg^-1
Onset 184.69 °C
Peak 198.88 °C
Left Limit 170.88 °C
Right Limit 205.55 °C

FIG. 105

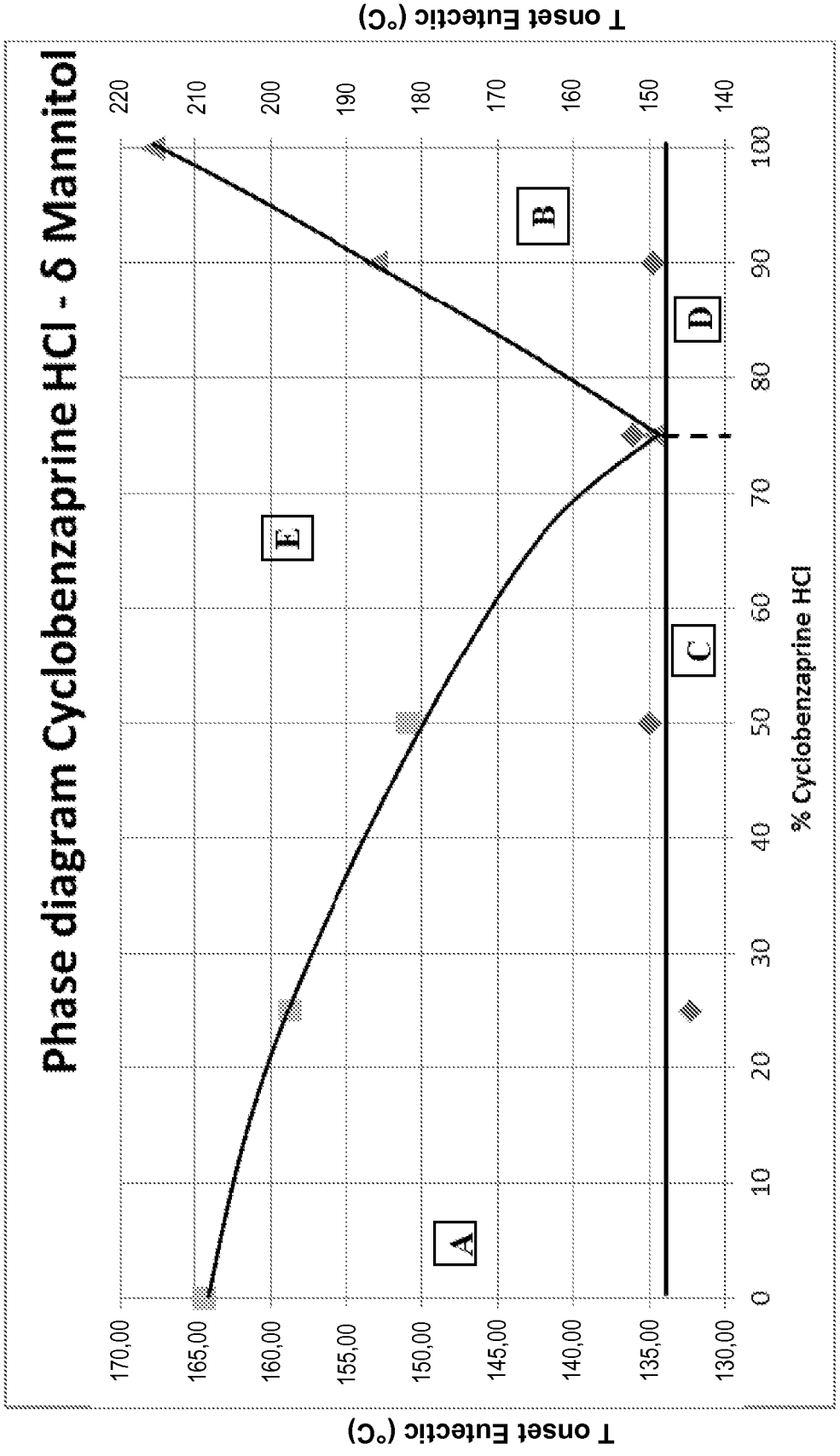

Phase diagram Cyclobenzaprine HCl - δ Mannitol
T onset Eutectic (°C)
% Cyclobenzaprine HCl
T onset Eutectic (°C)
A
B
C
D
E
170,00
165,00
160,00
155,00
150,00
145,00
140,00
135,00
130,00
220
210
200
190
180
170
160
150
140
0
10
20
30
40
50
60
70
80
90
100

FIG. 106

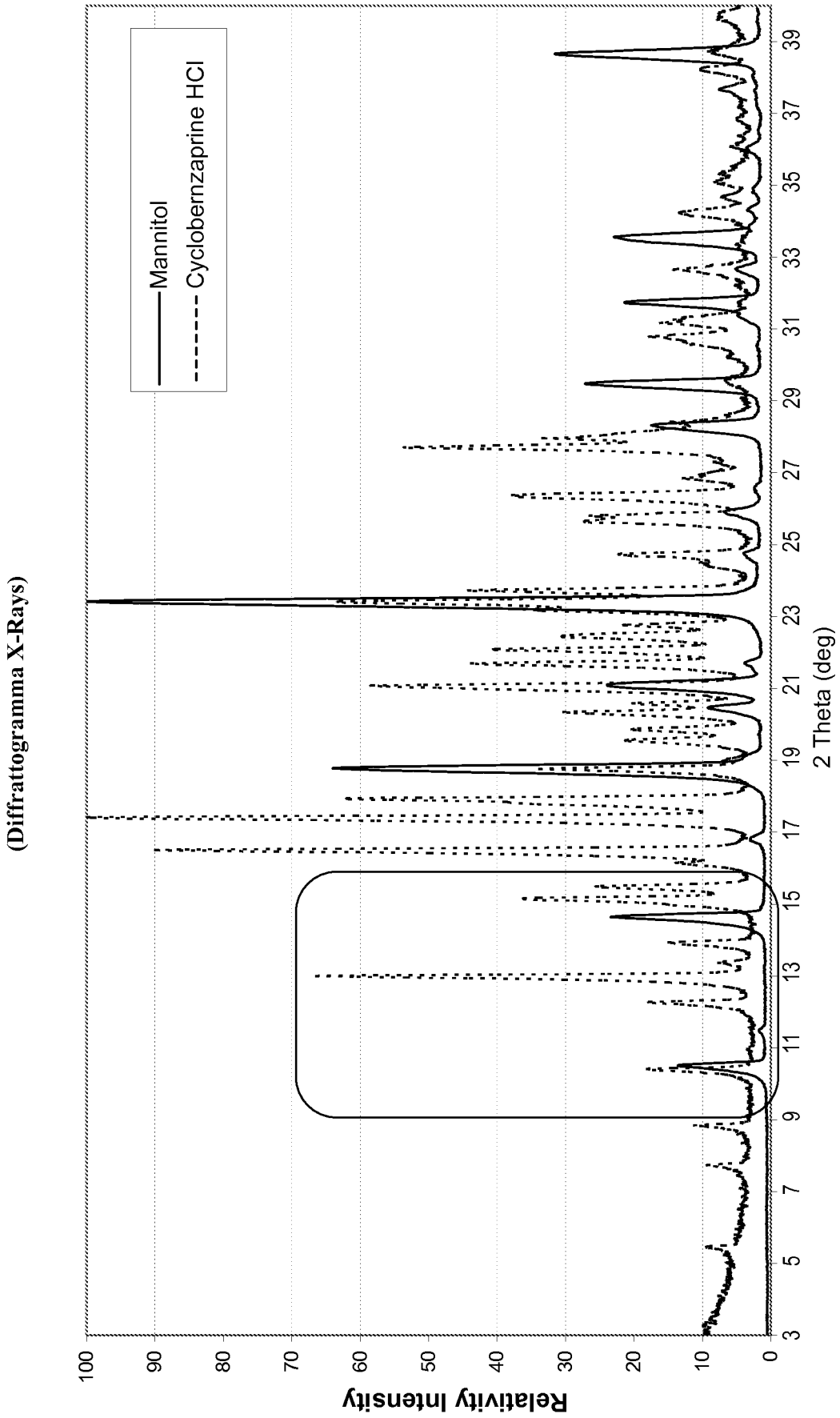

(Diffrattogramma X-Rays)
Mannitol
Ciclobernzaprine HCl
Relativity Intensity
2 Theta (deg)
0
10
20
30
40
50
60
70
80
90
100
3
5
7
9
11
13
15
17
19
21
23
25
27
29
31
33
35
37
39

FIG. 107

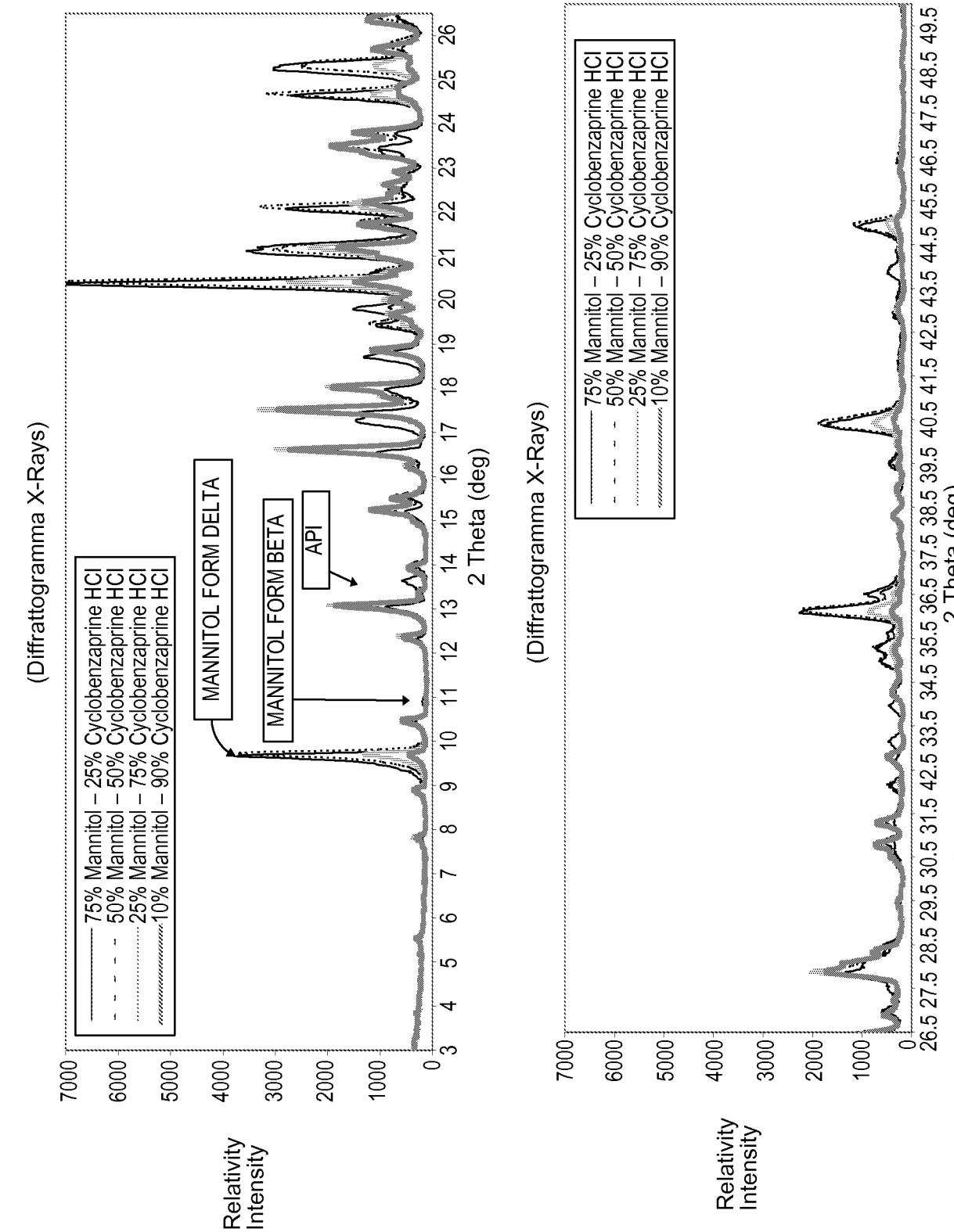

(Diffrattogramma X-Rays)
75% Mannitol – 25% Cyclobenzaprine HCl
50% Mannitol – 50% Cyclobenzaprine HCl
25% Mannitol – 75% Cyclobenzaprine HCl
10% Mannitol – 90% Cyclobenzaprine HCl
MANNITOL FORM DELTA
MANNITOL FORM BETA
API
Relativity Intensity
2 Theta (deg)
(Diffrattogramma X-Rays)
75% Mannitol – 25% Cyclobenzaprine HCl
50% Mannitol – 50% Cyclobenzaprine HCl
25% Mannitol – 75% Cyclobenzaprine HCl
10% Mannitol – 90% Cyclobenzaprine HCl
Relativity Intensity
2 Theta (deg)

FIG. 108

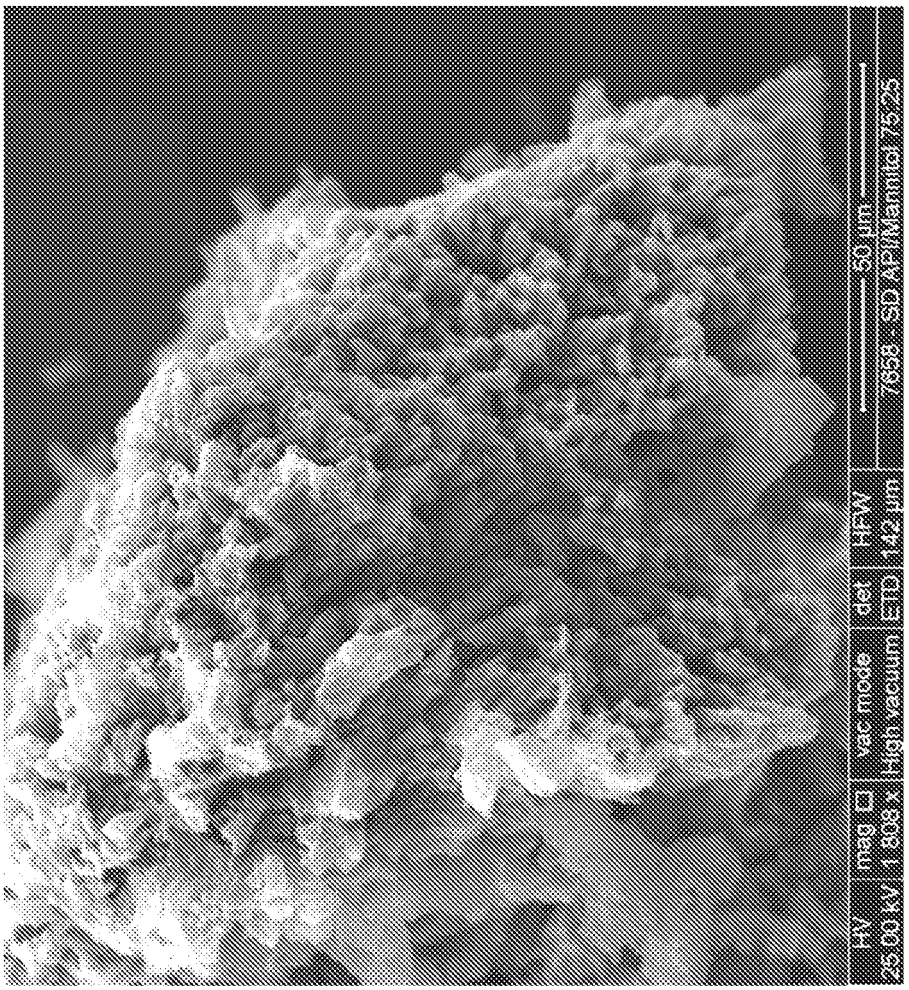

HV
25.00 kV
mag
1 308 x
High vacuum
det
ETD
HFW
142 µm
50 µm
7668
SO Mantiq 75.25

FIG. 109

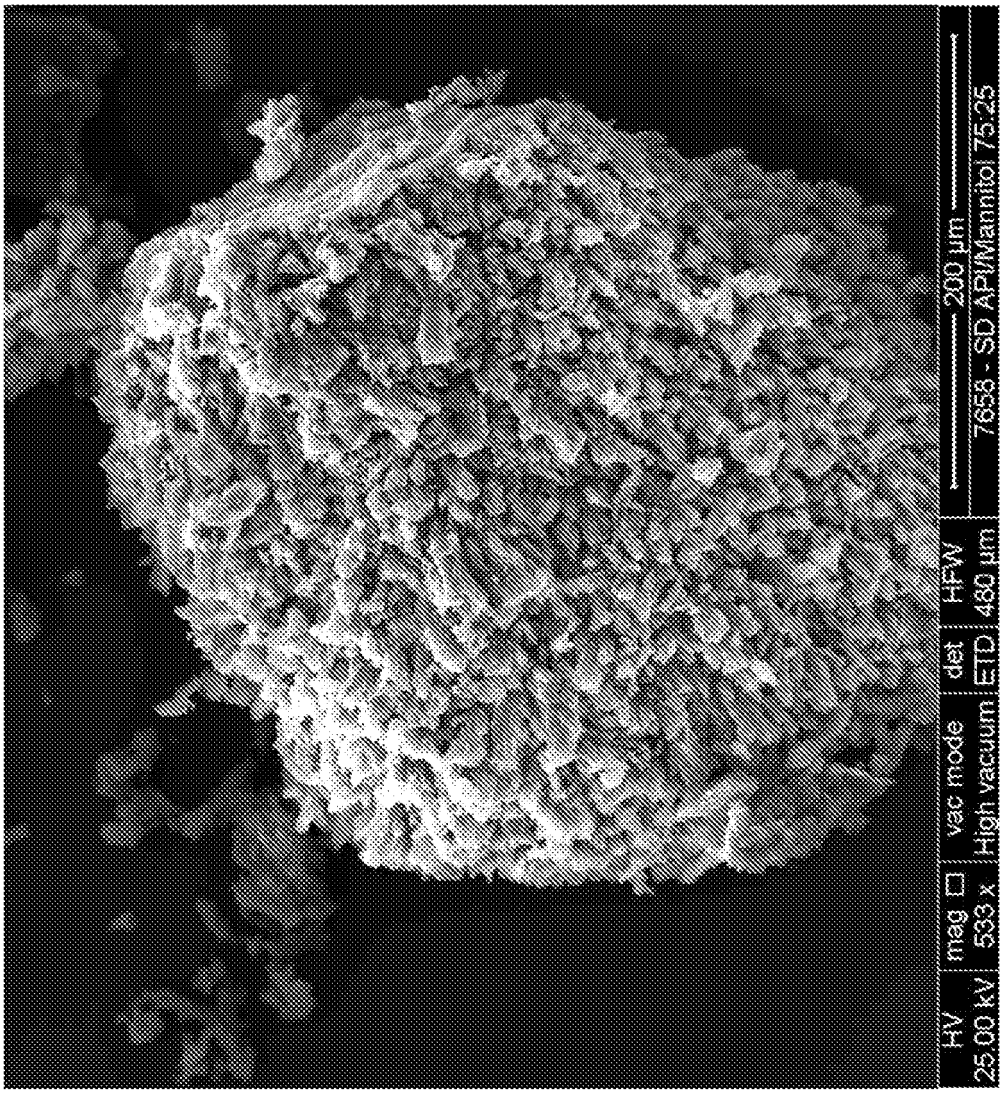

HV
25.00 kV
mag
533 x
vac mode
High vacuum
det
ETD
HFW
480 µm
200 µm
7658 - SD API/Mannitol 75:25

FIG. 110

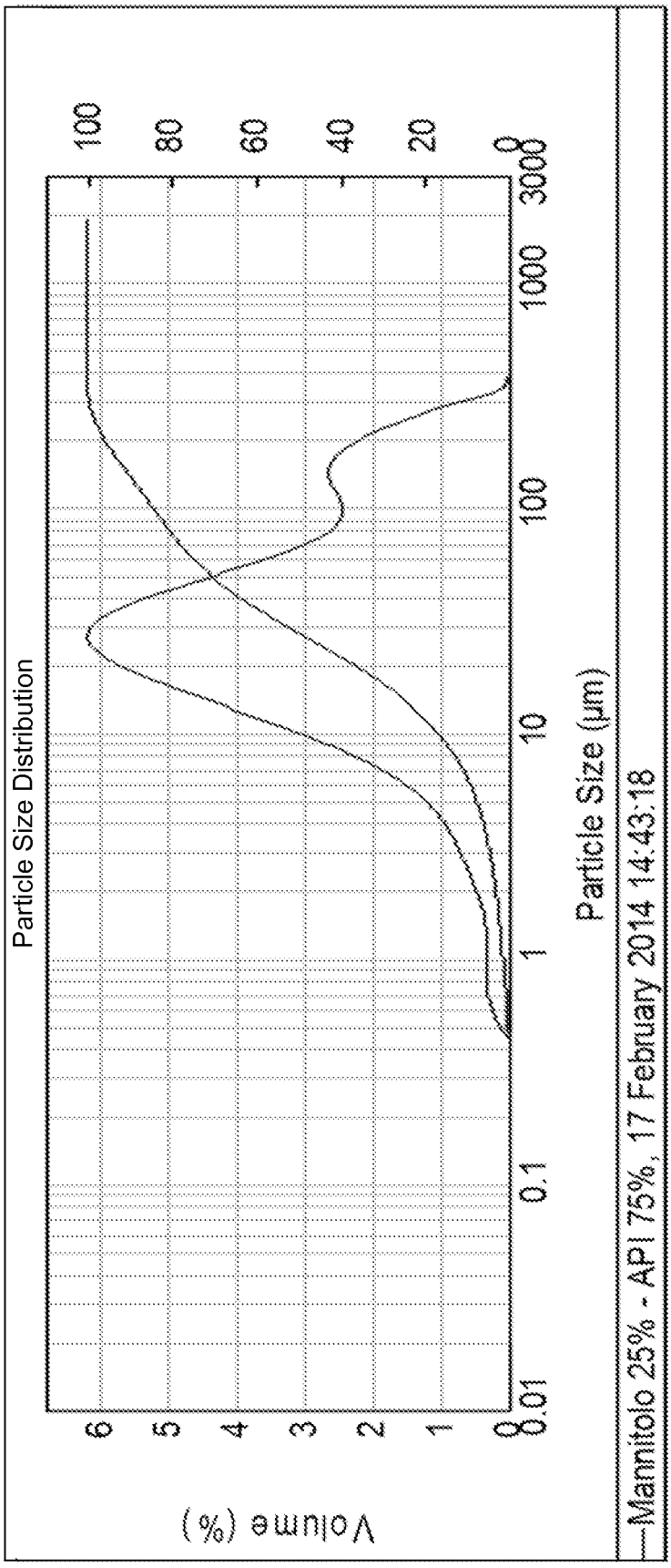

Particle Size Distribution
Volume (%)
0
1
2
3
4
5
6
0.01
0.1
1
10
100
1000
3000
0
20
40
60
80
100
Particle Size (µm)
Mannitolo 25% - API 75%, 17 February 2014 14:43:18

FIG. 111

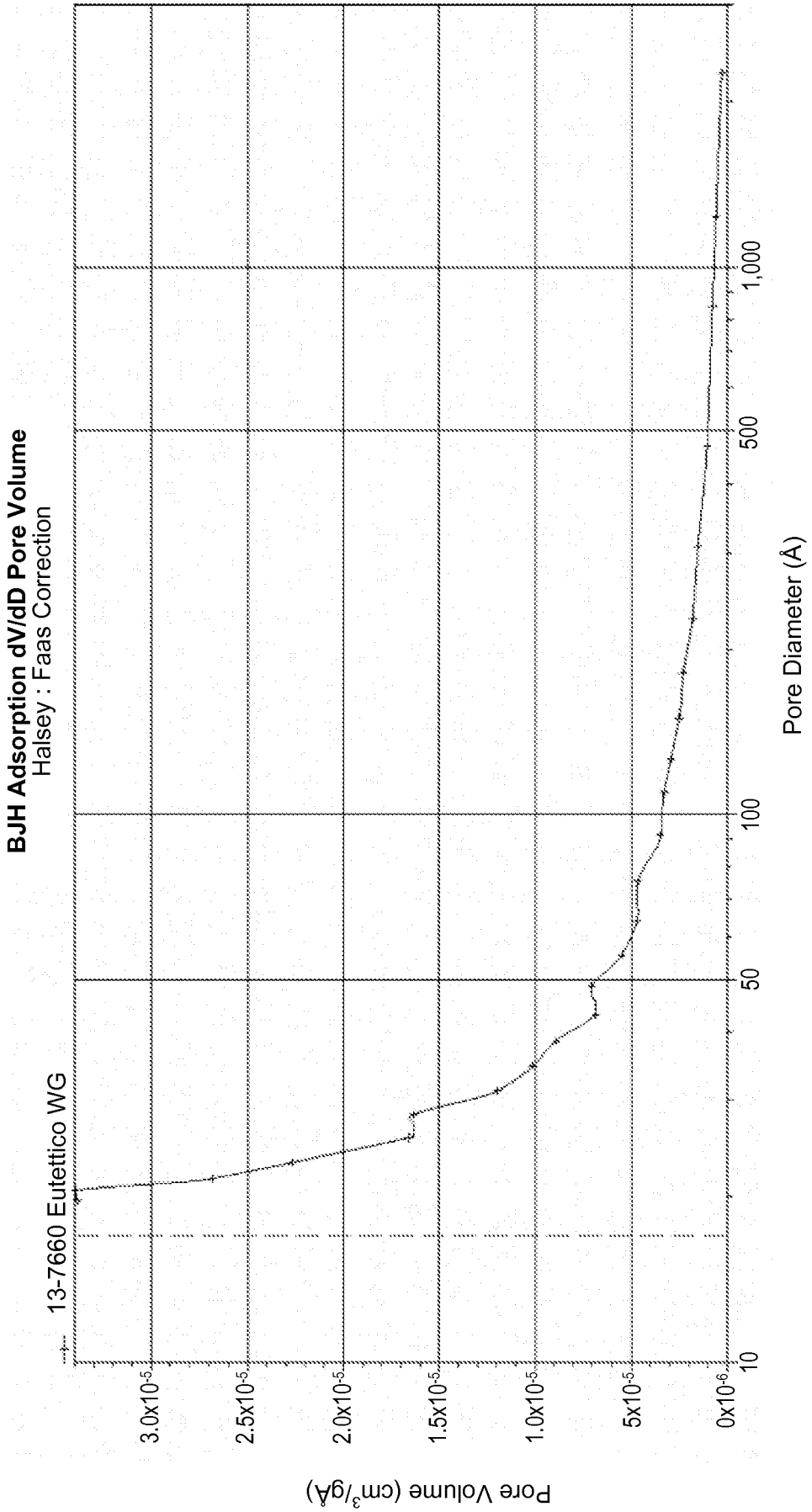

BJH Adsorption dV/dD Pore Volume
Halsey : Faas Correction
13-7660 Eutettico WG
Pore Volume (cm³/gÅ)
3.0x10-5
2.5x10-5
2.0x10-5
1.5x10-5
1.0x10-5
5x10-5
0x10-6
10
50
100
500
1,000
Pore Diameter (Å)

FIG. 112

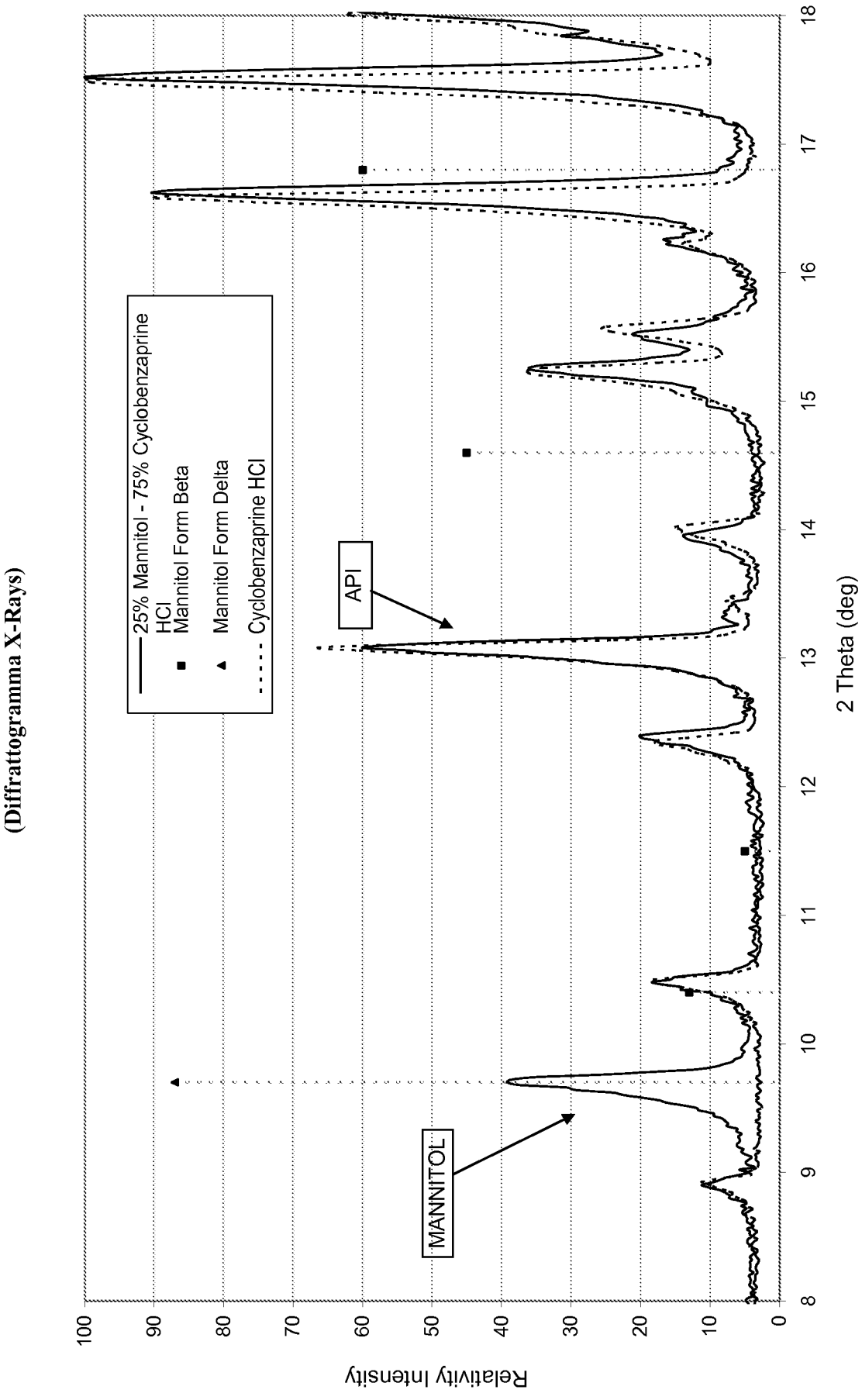

(Diffrattogramma X-Rays)
25% Mannitol - 75% Cyclobenzaprine HCl
Mannitol Form Beta
Mannitol Form Delta
Cyclobenzaprine HCl
API
MANNITOL
Relativity Intensity
2 Theta (deg)
100
90
80
70
60
50
40
30
20
10
0
8
9
10
11
12
13
14
15
16
17
18

FIG. 113

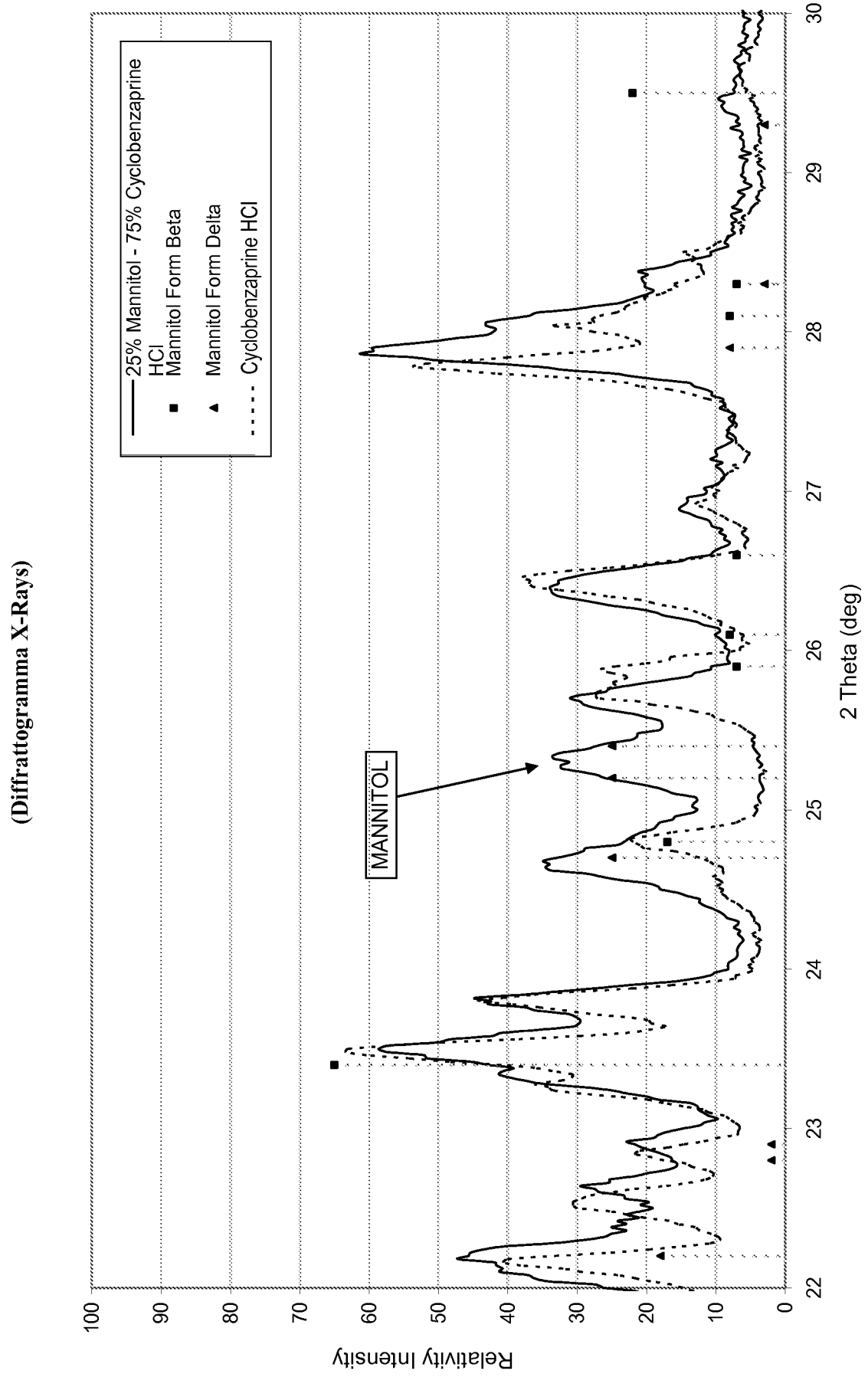

(Diffrattogramma X-Rays)
25% Mannitol - 75% Cyclobenzaprine HCl
Mannitol Form Beta
Mannitol Form Delta
Cyclobenzaprine HCl
MANNITOL
Relativity Intensity
2 Theta (deg)
100
90
80
70
60
50
40
30
20
10
0
22
23
24
25
26
27
28
29
30

FIG. 114

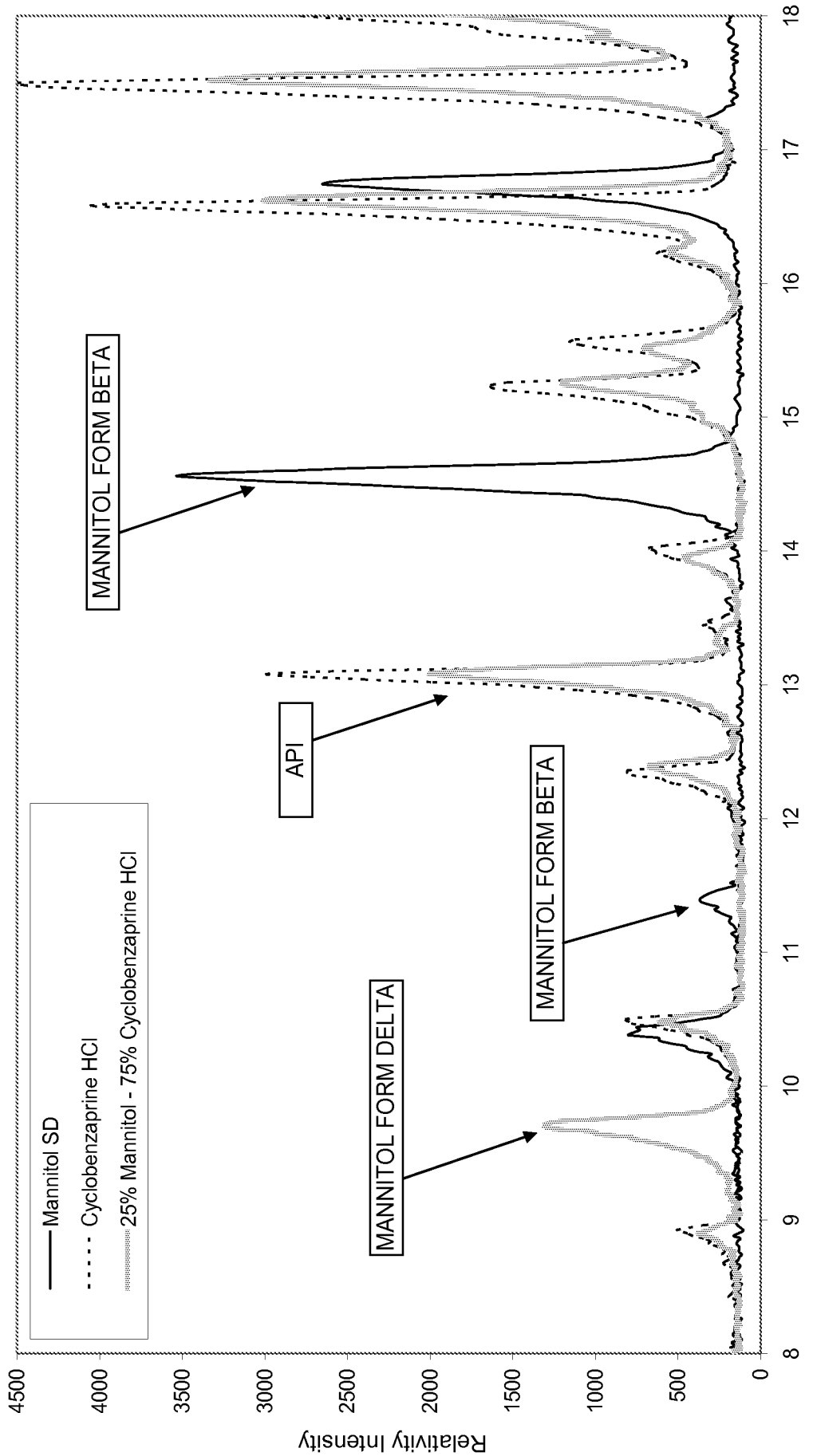

(Diffrattogramma X-Rays)
Mannitol SD
Cyclobenzaprine HCl
25% Mannitol - 75% Cyclobenzaprine HCl
MANNITOL FORM BETA
API
MANNITOL FORM BETA
MANNITOL FORM DELTA
Relativity Intensity
2 Theta (deg)
4500
4000
3500
3000
2500
2000
1500
1000
500
0
8
9
10
11
12
13
14
15
16
17
18

FIG. 115

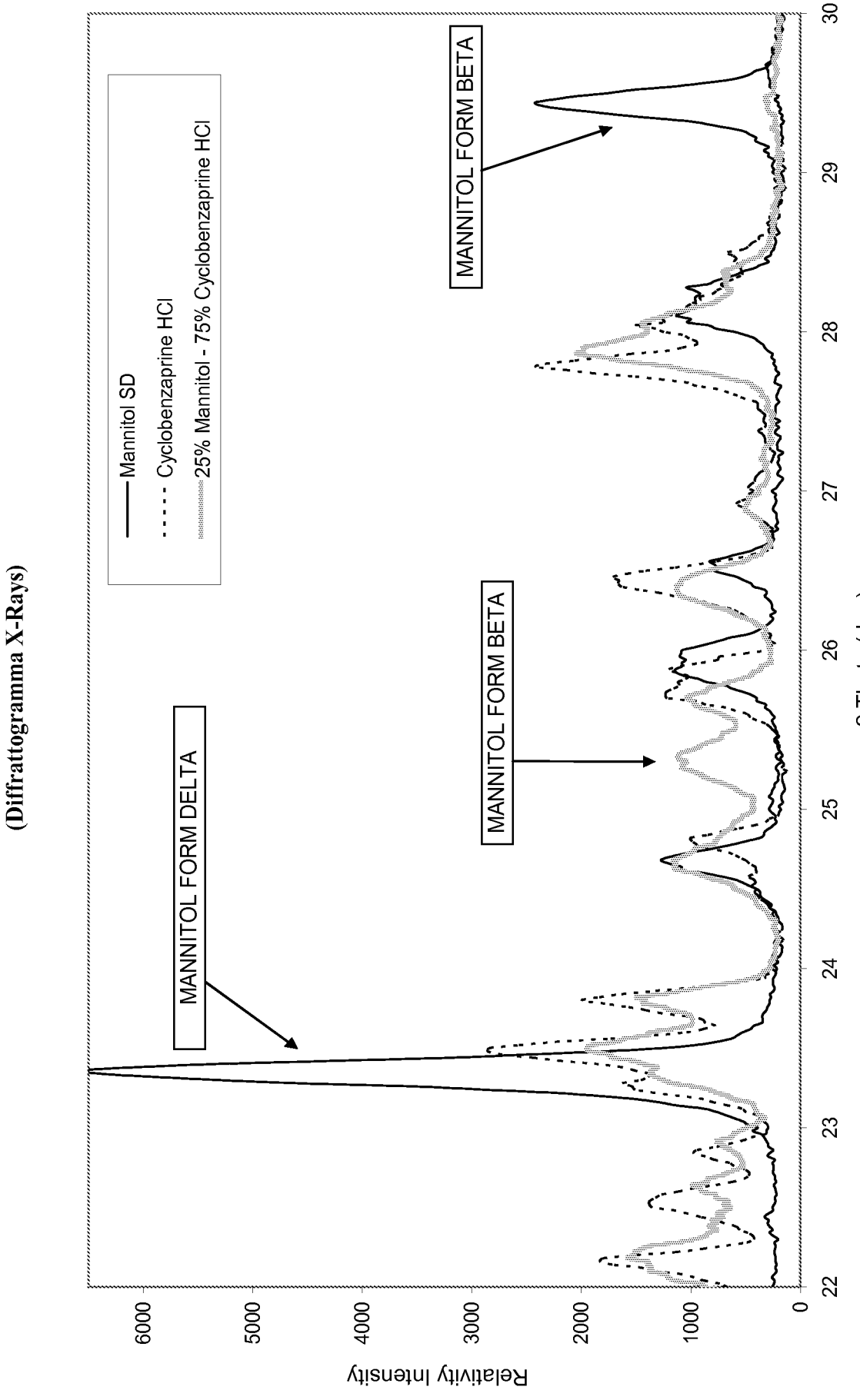

(Diffrattogramma X-Rays)
Mannitol SD
Cyclobenzaprine HCl
25% Mannitol - 75% Cyclobenzaprine HCl
MANNITOL FORM DELTA
MANNITOL FORM BETA
MANNITOL FORM BETA
Relativity Intensity
6000
5000
4000
3000
2000
1000
0
22
23
24
25
26
27
28
29
30
2 Theta (deg)

FIG. 116

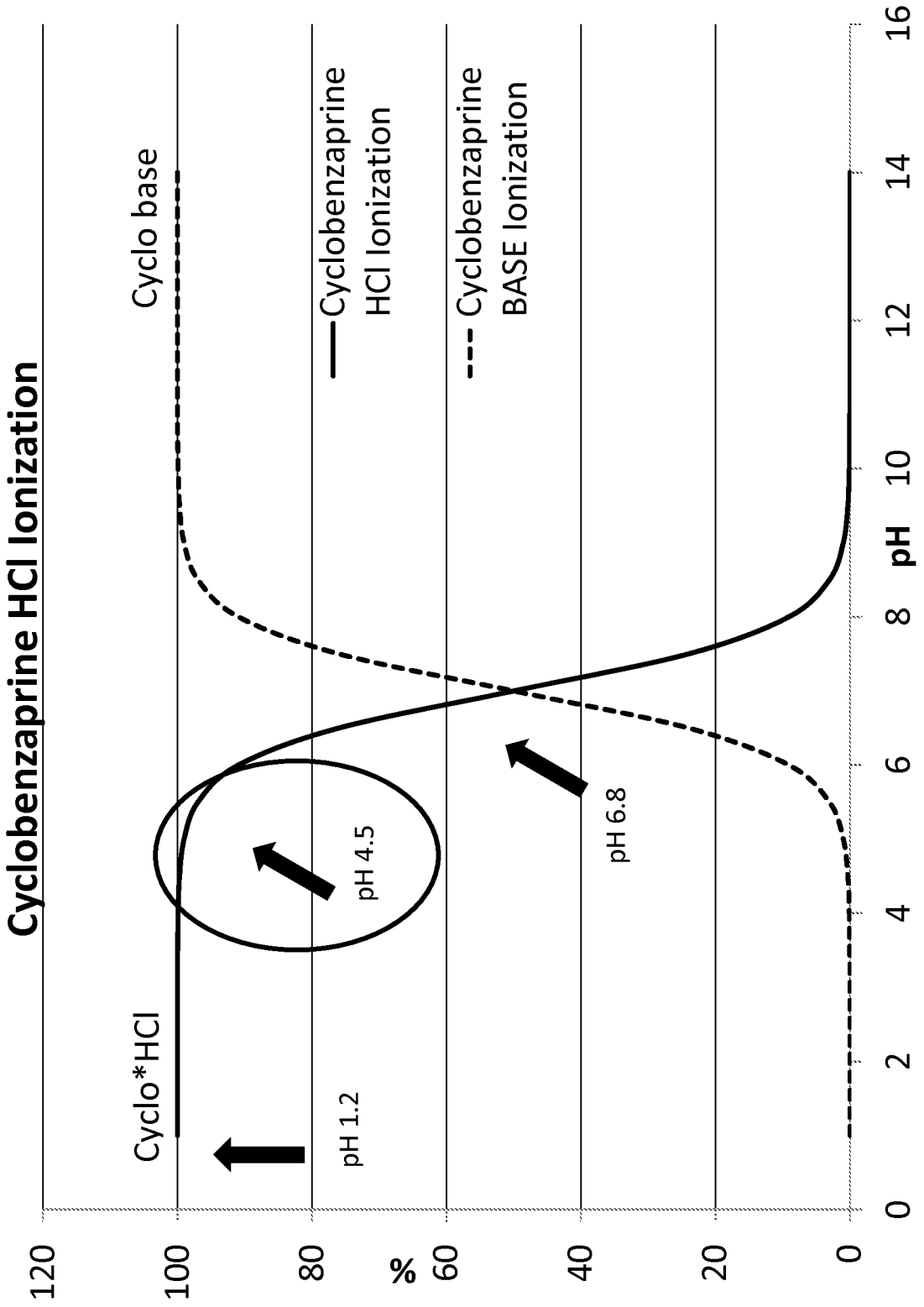

Cyclobenzaprine HCl Ionization
Cyclo base
Cyclobenzaprine HCl Ionization
Cyclobenzaprine BASE Ionization
Cyclo*HCl
pH 1.2
pH 4.5
pH 6.8
%
pH
120
100
80
60
40
20
0
0
2
4
6
8
10
12
14
16

FIG. 117

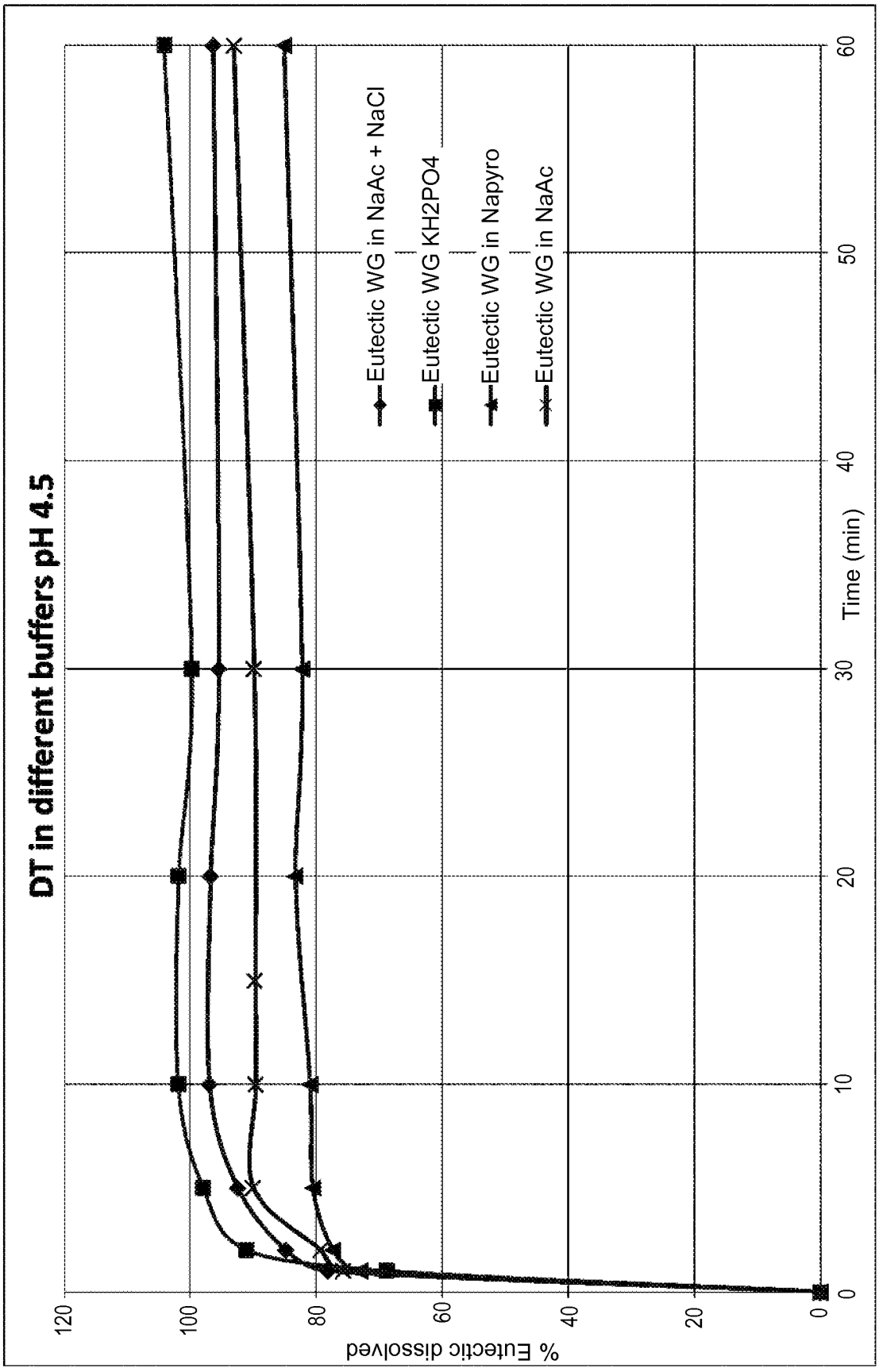

DT in different buffers pH 4.5
% Eutectic dissolved
Time (min)
Eutectic WG in NaAc + NaCl
Eutectic WG KH2PO4
Eutectic WG in Napyro
Eutectic WG in NaAc
0
20
40
60
80
100
120
0
10
20
30
40
50
60

FIG. 118

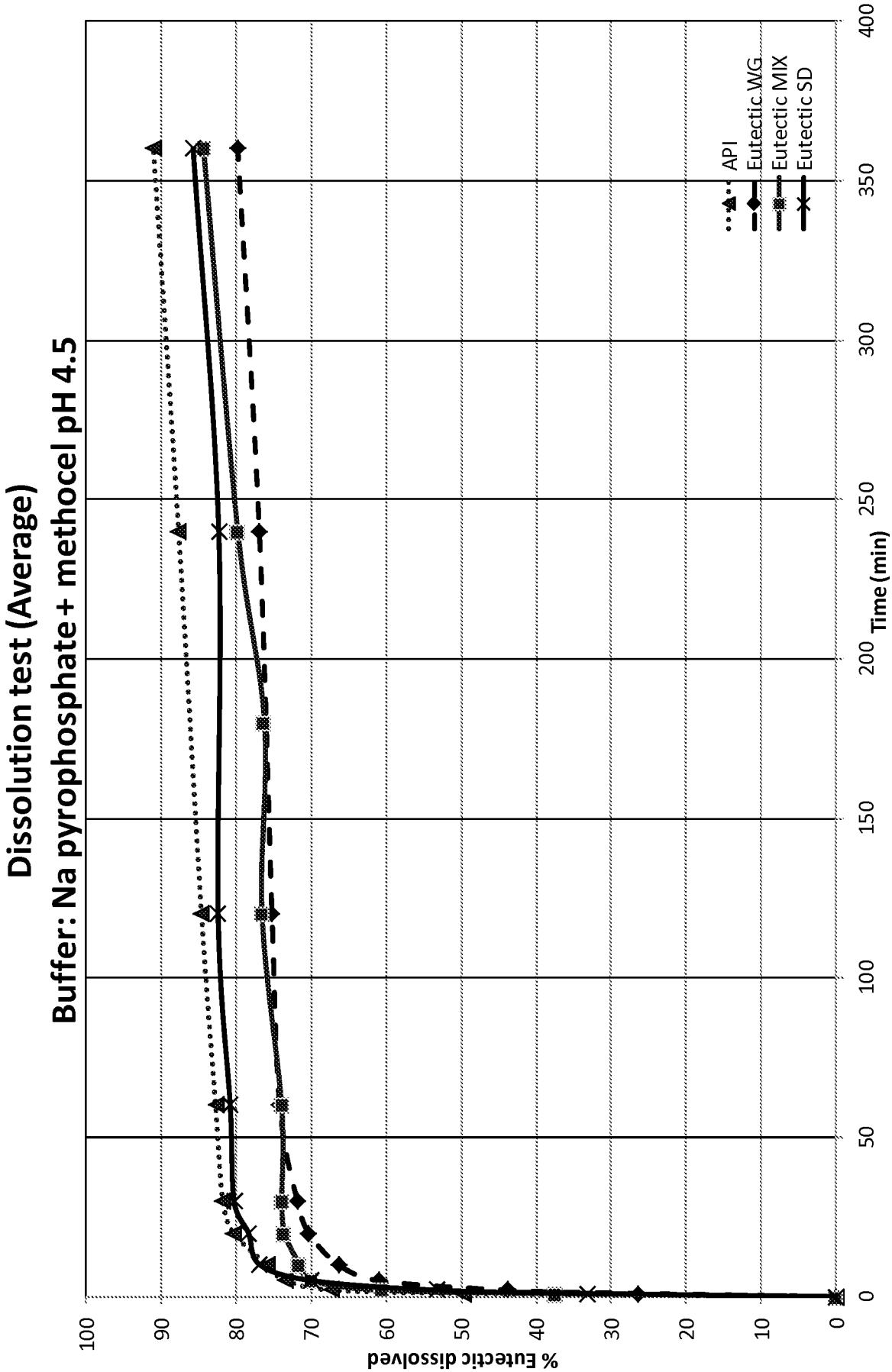

Dissolution test (Average)
Buffer: Na pyrophosphate + methocel pH 4.5
% Eutectic dissolved
Time (min)
API
Eutectic WG
Eutectic MIX
Eutectic SD
0
10
20
30
40
50
60
70
80
90
100
0
50
100
150
200
250
300
350
400

FIG. 119

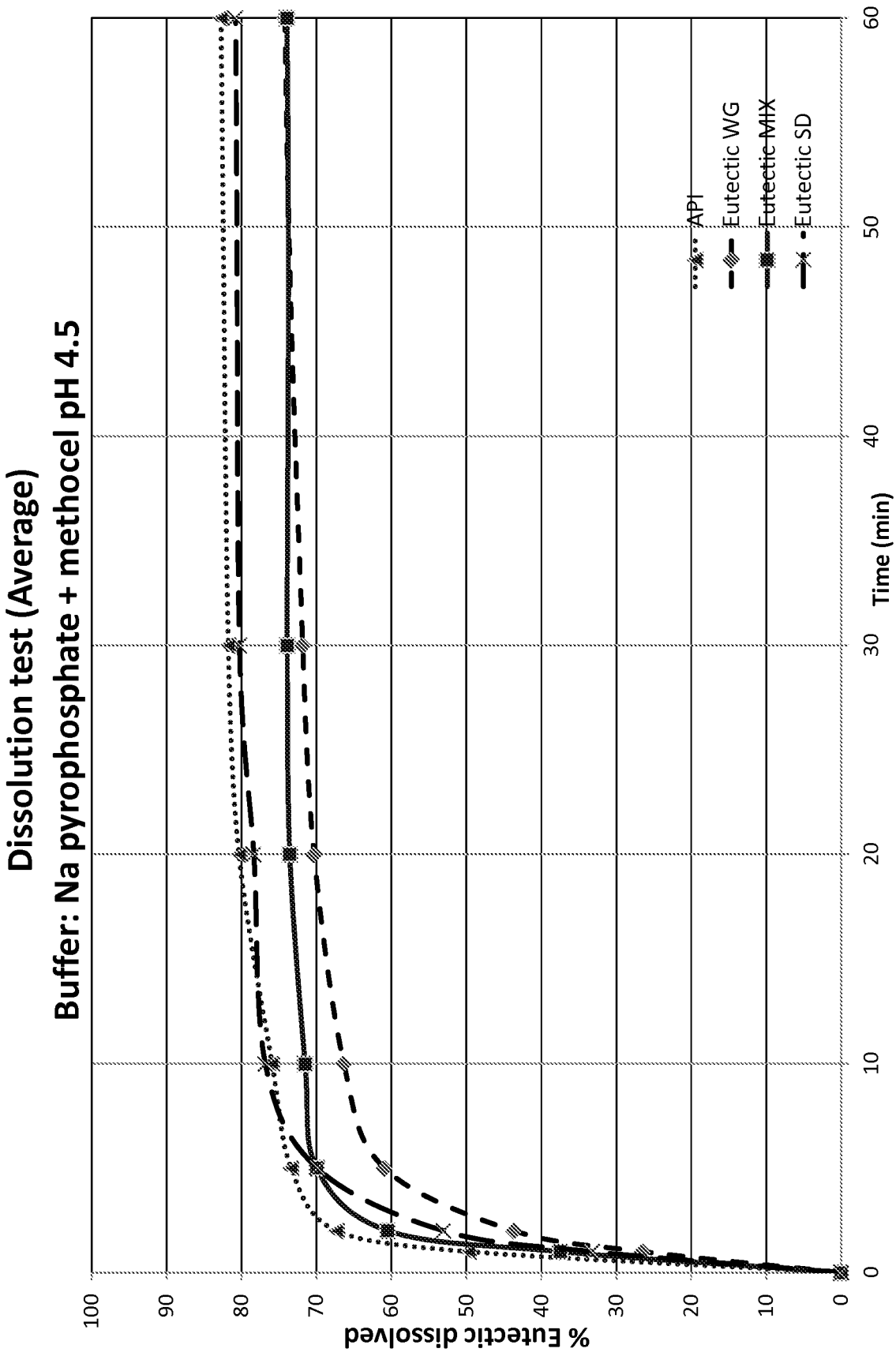

Dissolution test (Average)
Buffer: Na pyrophosphate + methocel pH 4.5
% Eutectic dissolved
Time (min)
API
Eutectic WG
Eutectic MIX
Eutectic SD
0
10
20
30
40
50
60
70
80
90
100

FIG. 120