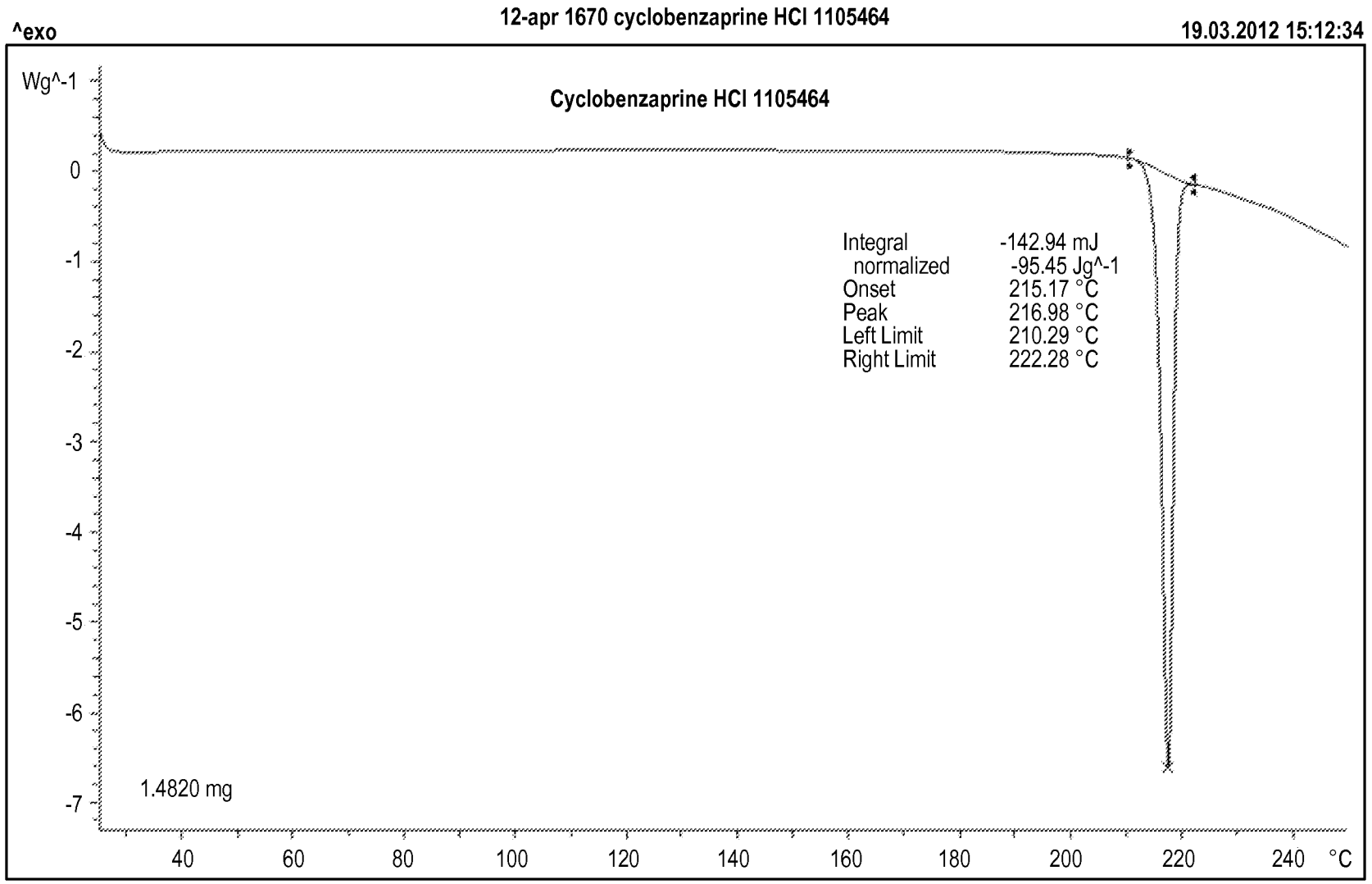

12-apr 1670 cyclobenzaprine HCl 1105464
^exo
19.03.2012 15:12:34
Wg^-1
Cyclobenzaprine HCl 1105464
0
-1
-2
-3
-4
-5
-6
-7
Integral -142.94 mJ
normalized -95.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
1.4820 mg
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: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

**FIG. 1**

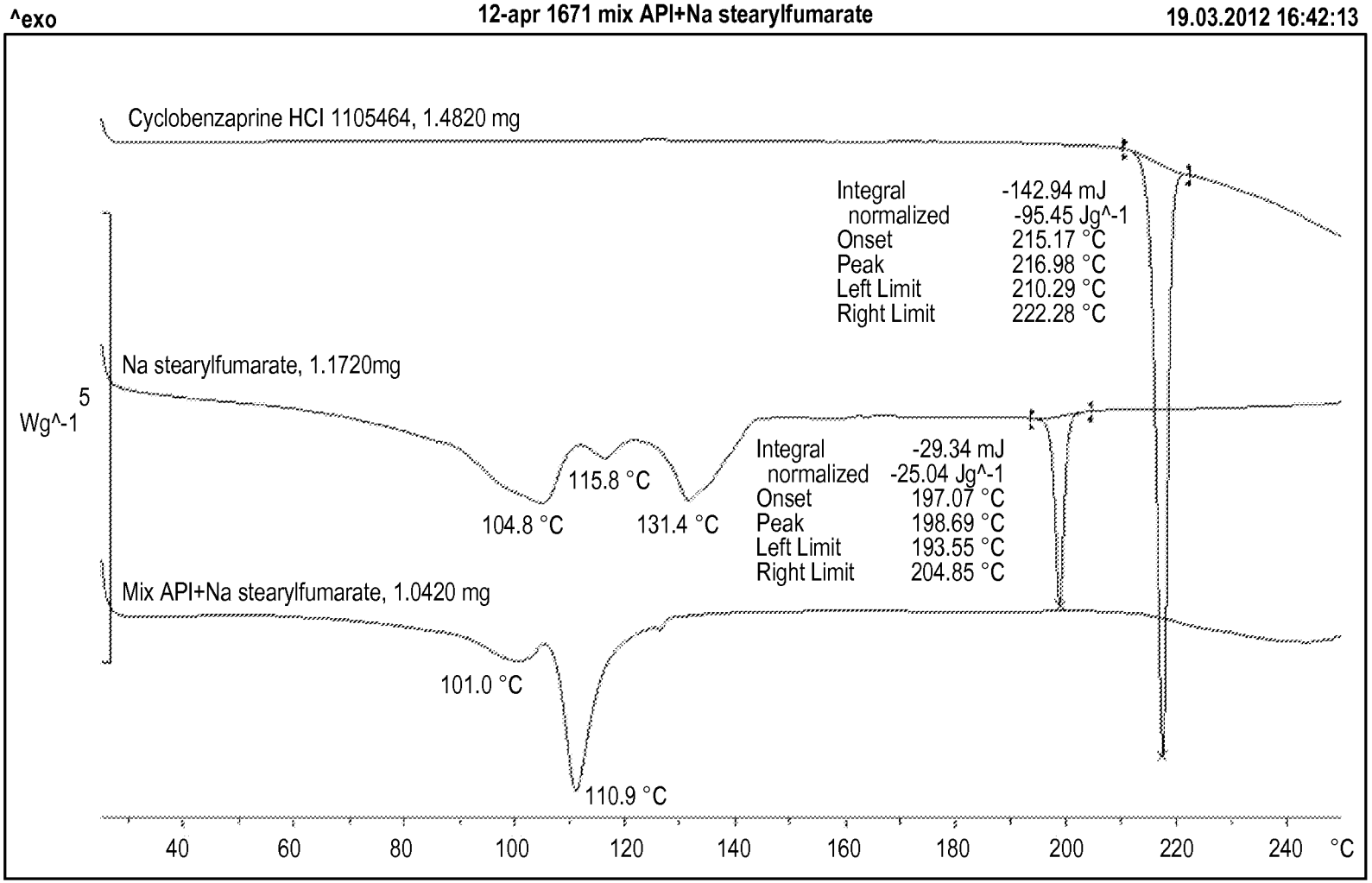

^exo
12-apr 1671 mix API+Na stearylfumarate
19.03.2012 16:42:13
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -95.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Na stearylfumarate, 1.1720mg
5
Wg^-1
115.8 °C
104.8 °C
131.4 °C
Integral -29.34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

FIG. 2

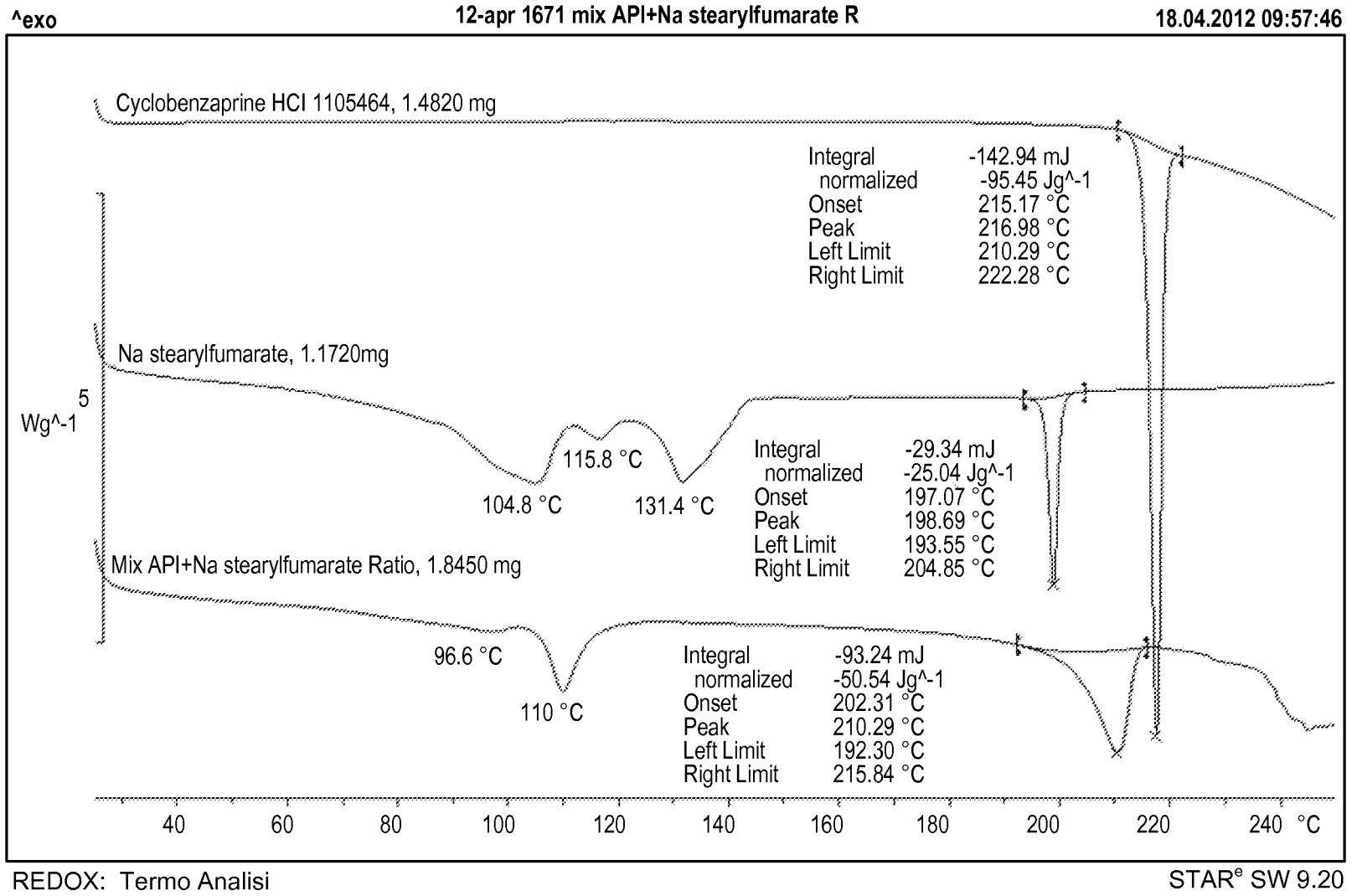

^exo
12-apr 1671 mix API+Na stearylfumarate R
18.04.2012 09:57:46
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -95.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Na stearylfumarate, 1.1720mg
5
Wg^-1
115.8 °C
104.8 °C
131.4 °C
Integral -29.34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

FIG. 3

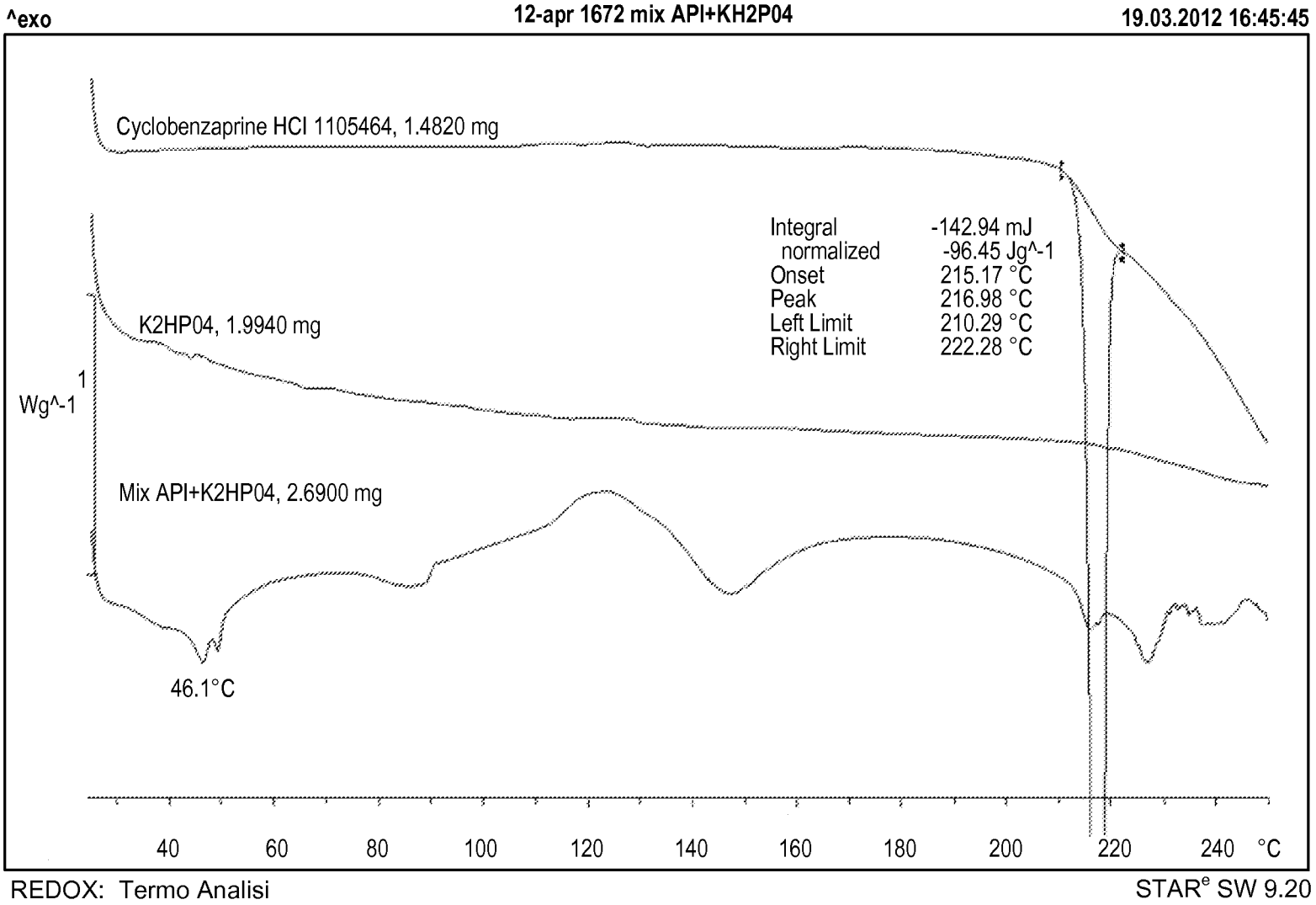

^exo
12-apr 1672 mix API+KH2P04
19.03.2012 16:45:45
Cyclobenzaprine HCl 1105464, 1.4820 mg
K2HP04, 1.9940 mg
Mix API+K2HP04, 2.6900 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Wg^-1
1
46.1°C
40
60
80
100
120
140
160
180
200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

FIG. 4

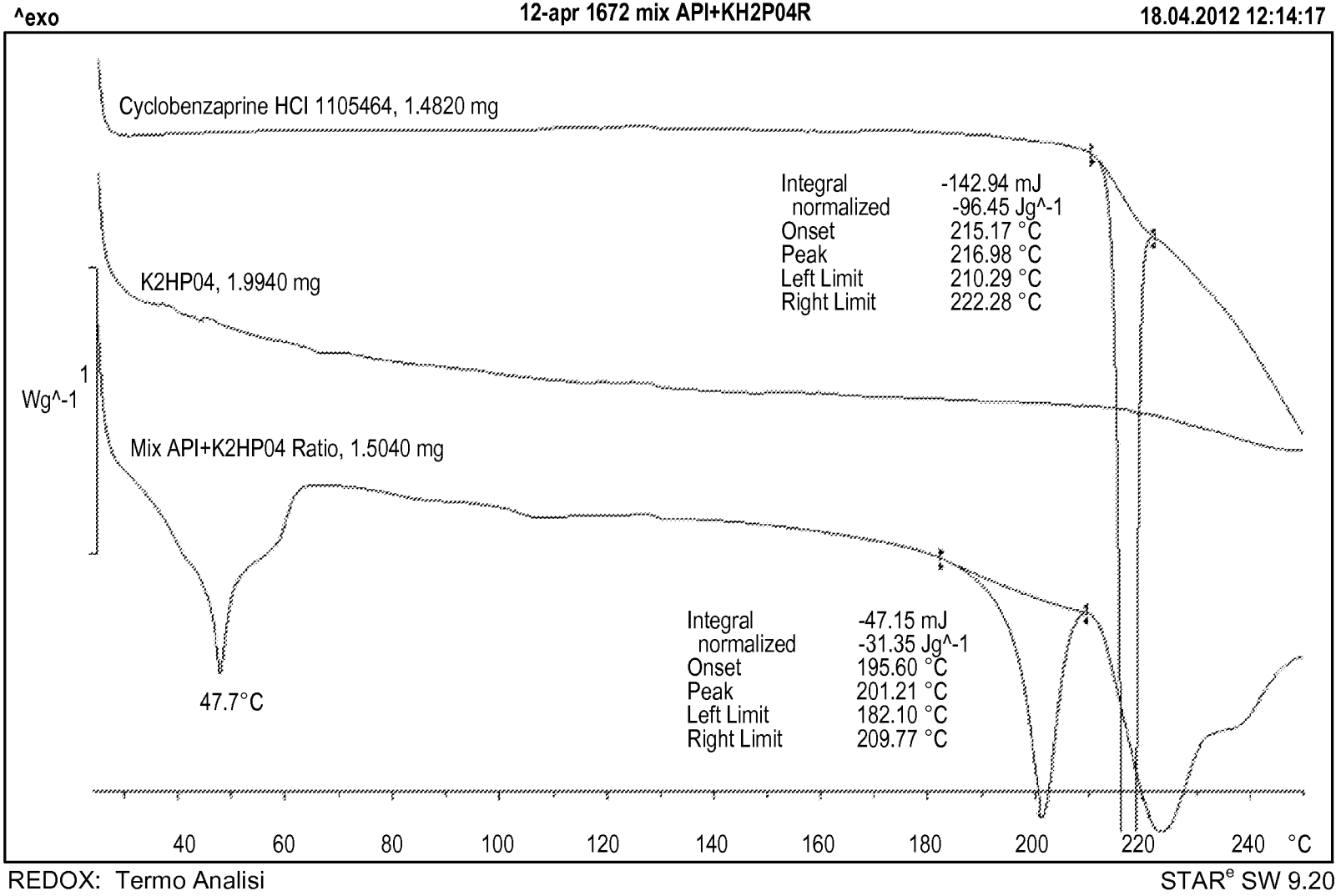

^exo
12-apr 1672 mix API+KH2P04R
18.04.2012 12:14:17
Cyclobenzaprine HCl 1105464, 1.4820 mg
K2HP04, 1.9940 mg
Mix API+K2HP04 Ratio, 1.5040 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Integral -47.15 mJ
normalized -31.35 Jg^-1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

FIG. 5

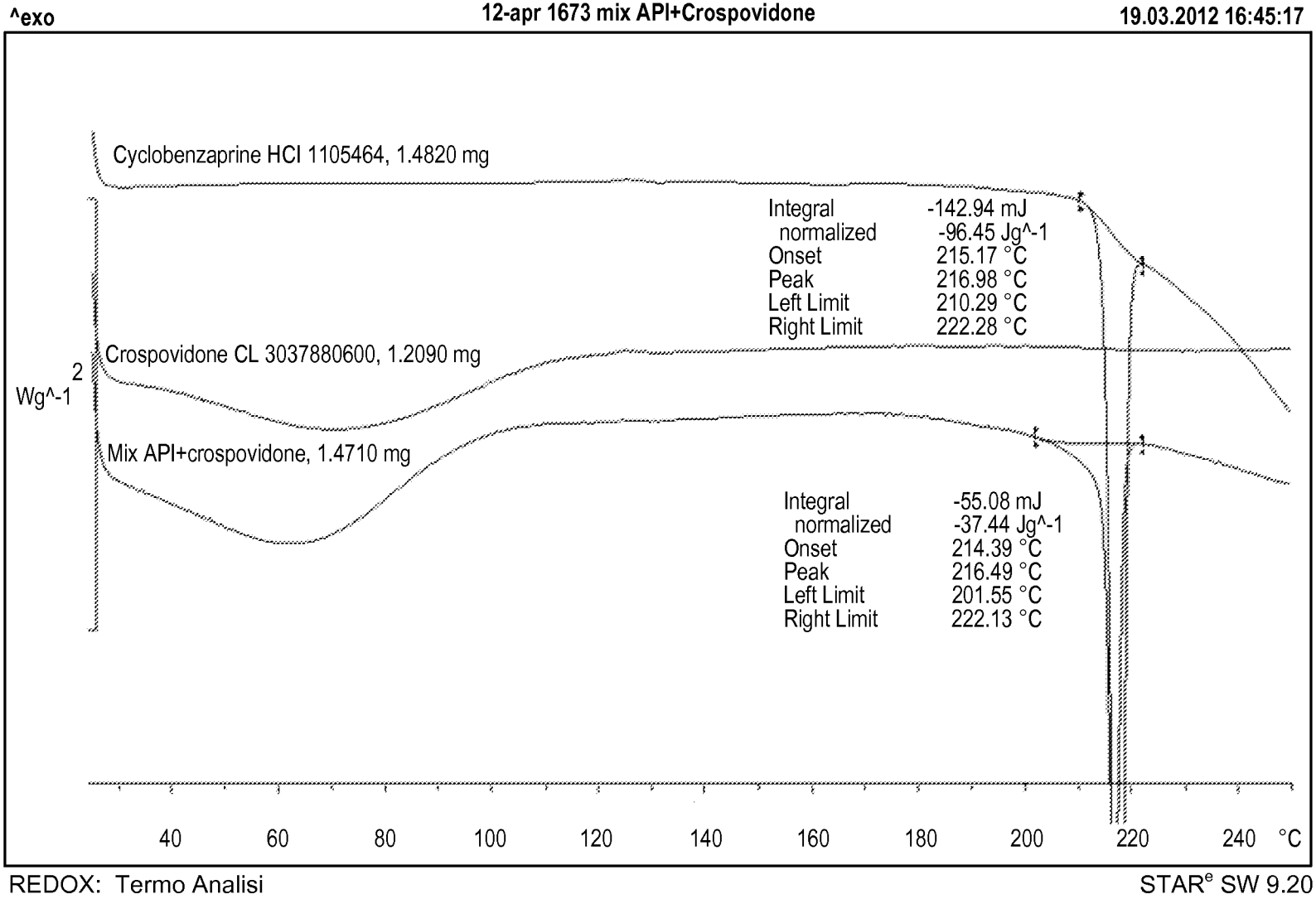

^exo
12-apr 1673 mix API+Crospovidone
19.03.2012 16:45:17
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Crospovidone CL 3037880600, 1.2090 mg
Wg^-1
2
Mix API+crospovidone, 1.4710 mg
Integral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

FIG. 6

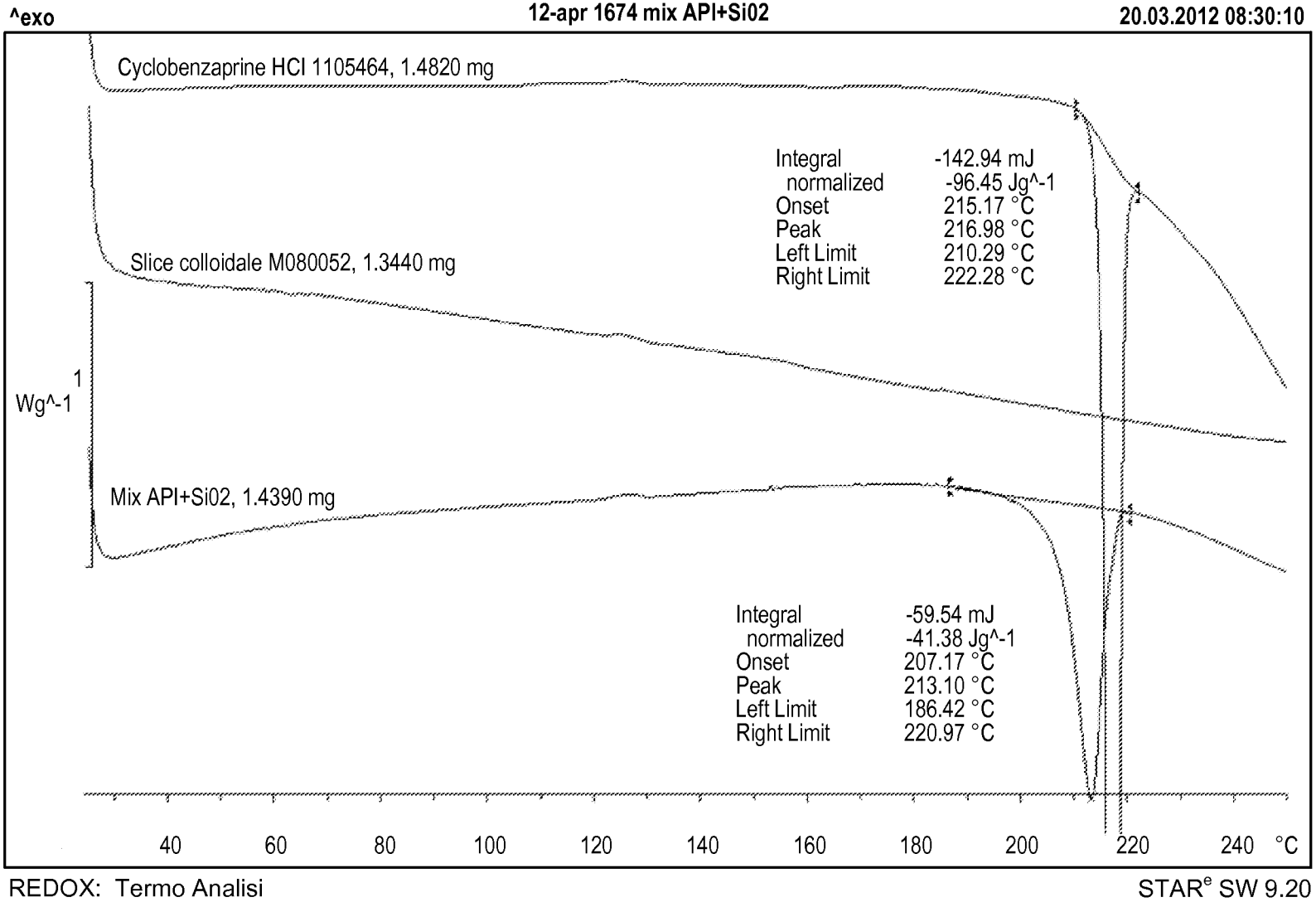

^exo
12-apr 1674 mix API+Si02
20.03.2012 08:30:10
Cyclobenzaprine HCl 1105464, 1.4820 mg
Slice colloidale M080052, 1.3440 mg
Mix API+Si02, 1.4390 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Integral -59.54 mJ
normalized -41.38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

FIG. 7

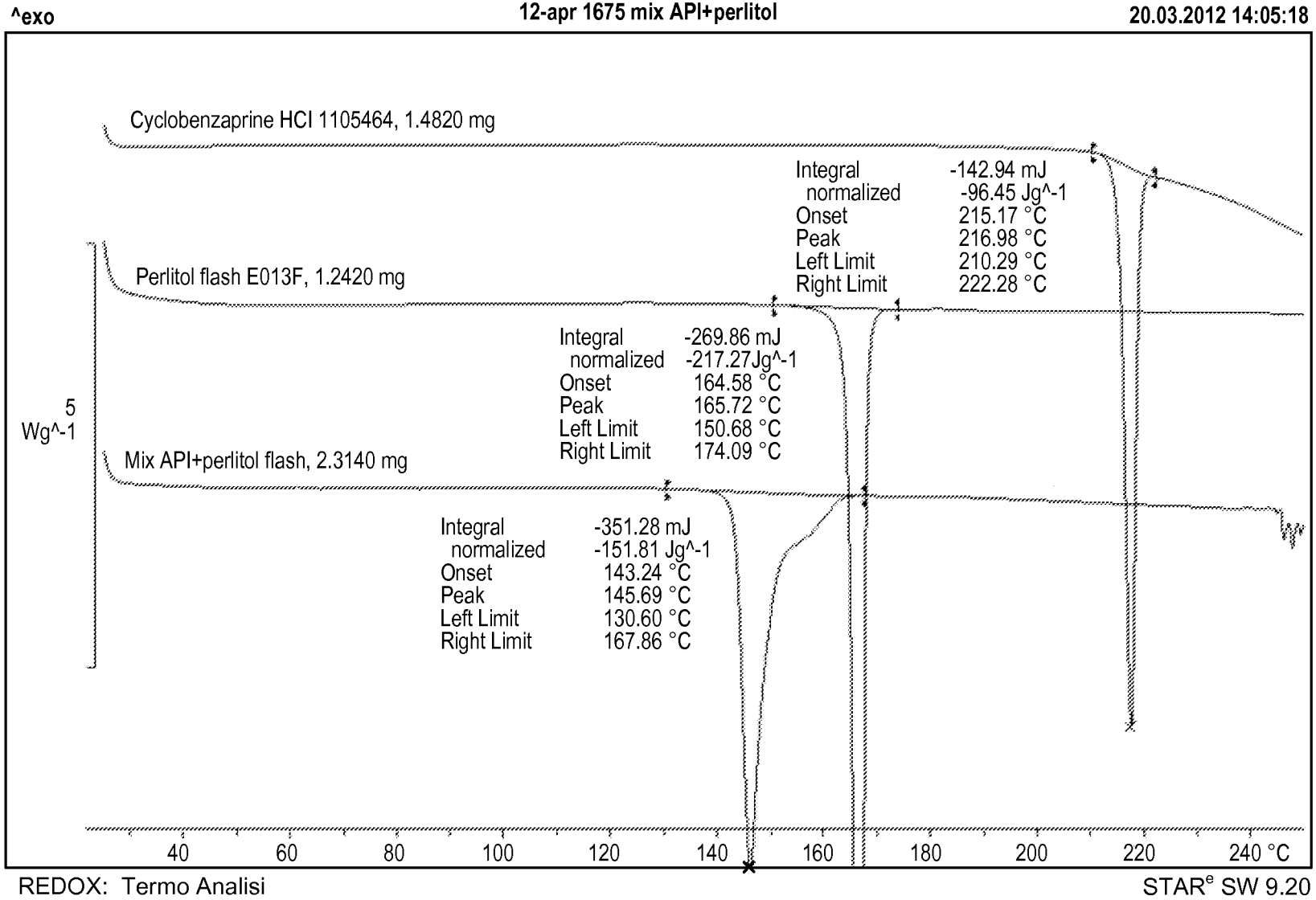

^exo
12-apr 1675 mix API+perlitol
20.03.2012 14:05:18
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Perlitol flash E013F, 1.2420 mg
Integral -269.86 mJ
normalized -217.27Jg^-1
Onset 164.58 °C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

FIG. 8

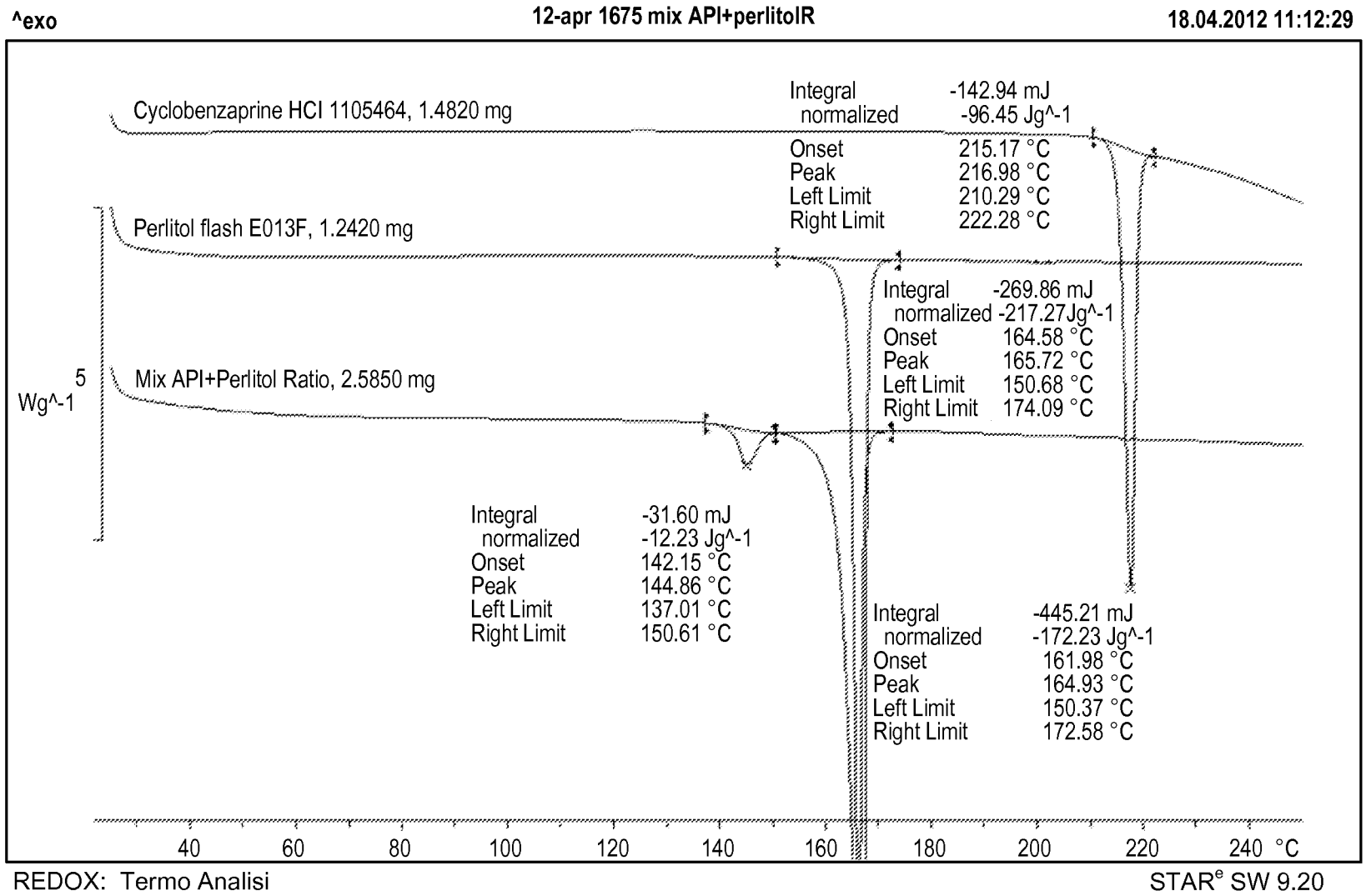

^exo
12-apr 1675 mix API+perlitolR
18.04.2012 11:12:29
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Perlitol flash E013F, 1.2420 mg
Integral -269.86 mJ
normalized -217.27Jg^-1
Onset 164.58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

FIG. 9

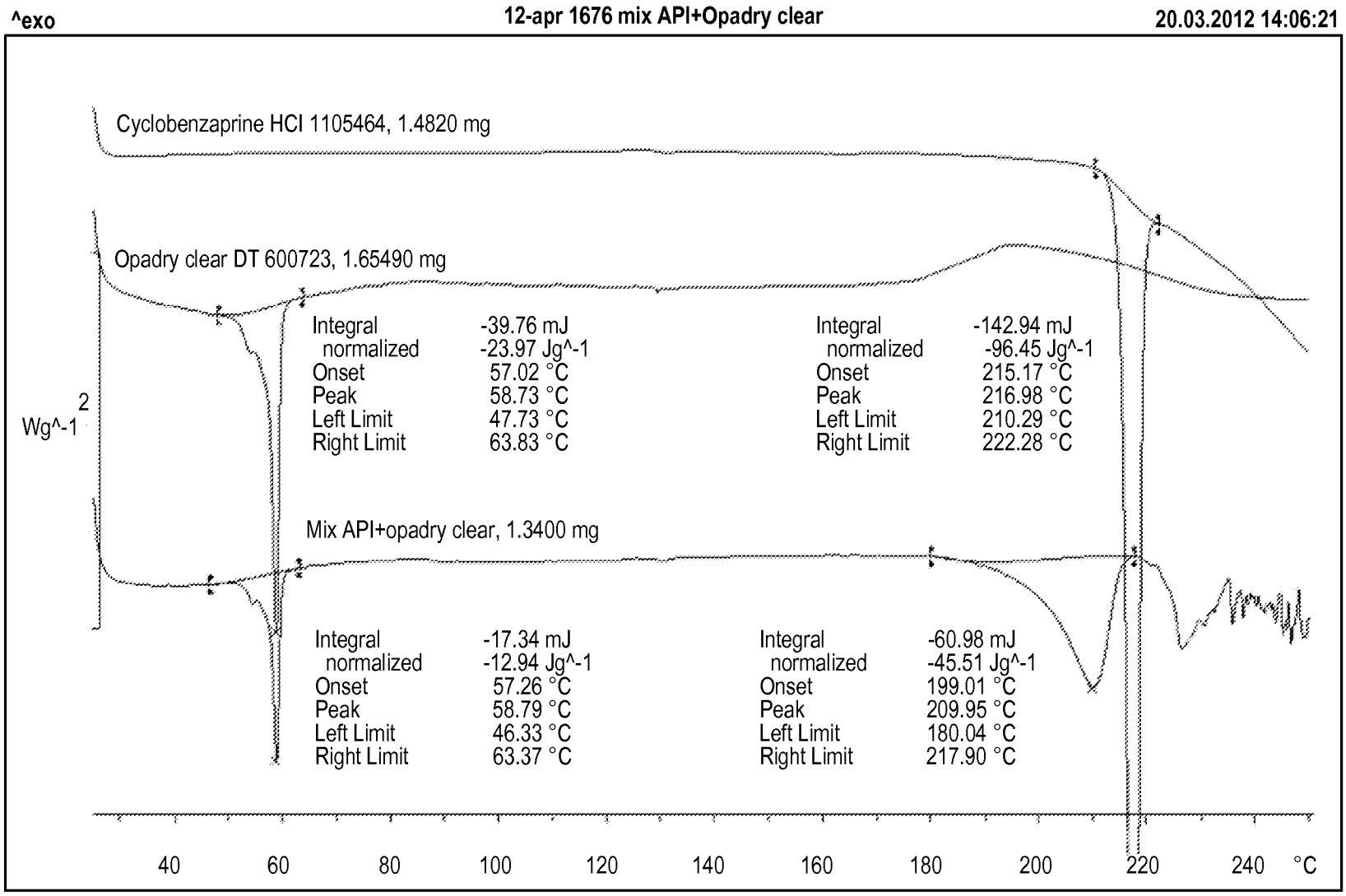

^exo
12-apr 1676 mix API+Opadry clear
20.03.2012 14:06:21
Cyclobenzaprine HCl 1105464, 1.4820 mg
Opadry clear DT 600723, 1.65490 mg
Integral -39.76 mJ
normalized -23.97 Jg^-1
Onset 57.02 °C
Peak 58.73 °C
Left Limit 47.73 °C
Right Limit 63.83 °C
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Wg^-1 2
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
40 60 80 100 120 140 160 180 200 220 240 °C
REDOX: Termo Analisi
STAR^e SW 9.20

FIG. 10

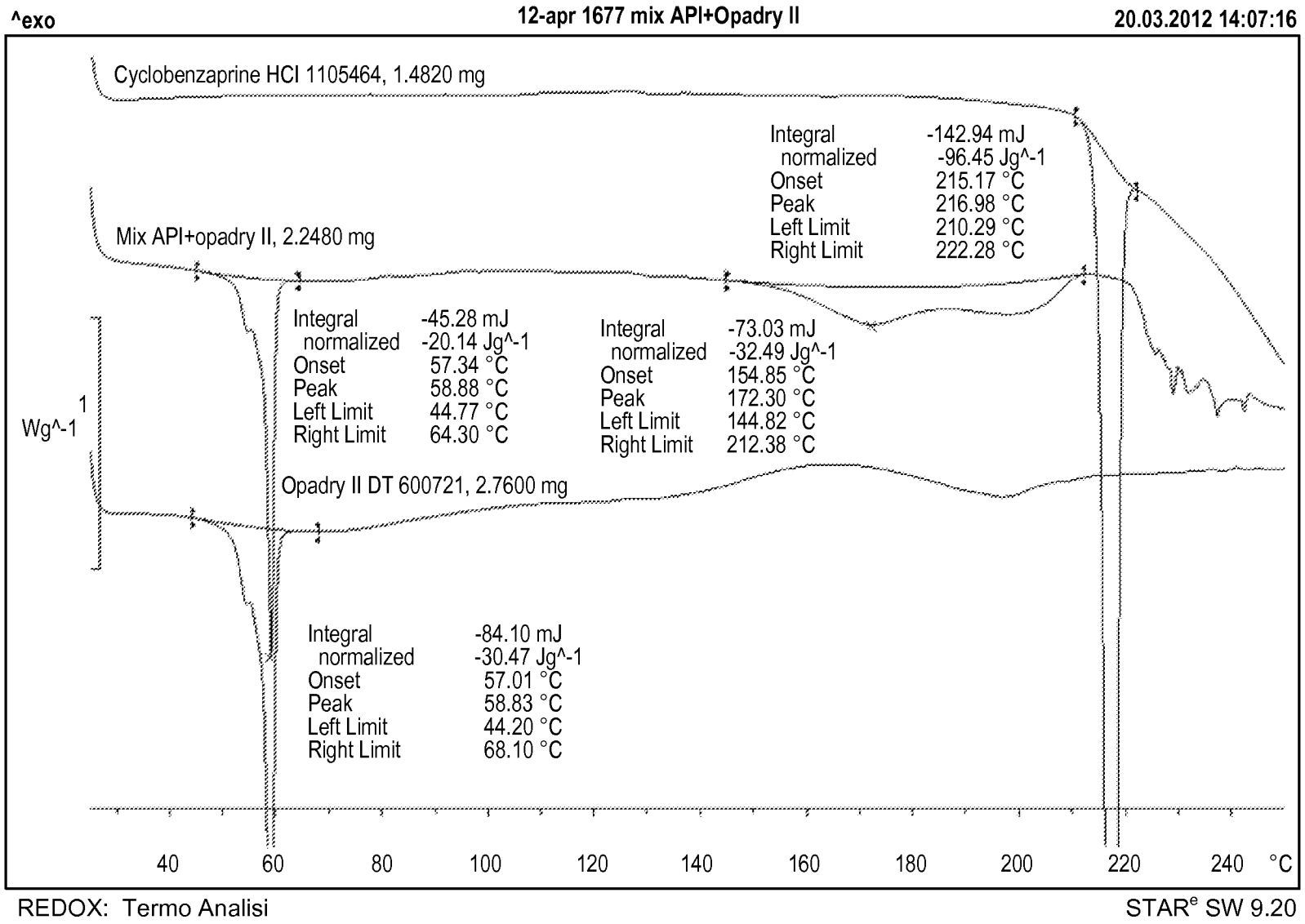

^exo
12-apr 1677 mix API+Opadry II
20.03.2012 14:07:16
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -142.94 mJ
normalized -96.45 Jg^-1
Onset 215.17 °C
Peak 216.98 °C
Left Limit 210.29 °C
Right Limit 222.28 °C
Mix API+opadry II, 2.2480 mg
Integral -45.28 mJ
normalized -20.14 Jg^-1
Onset 57.34 °C
Peak 58.88 °C
Left Limit 44.77 °C
Right Limit 64.30 °C
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
1
Wg^-1
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
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STAR^e SW 9.20

FIG. 11

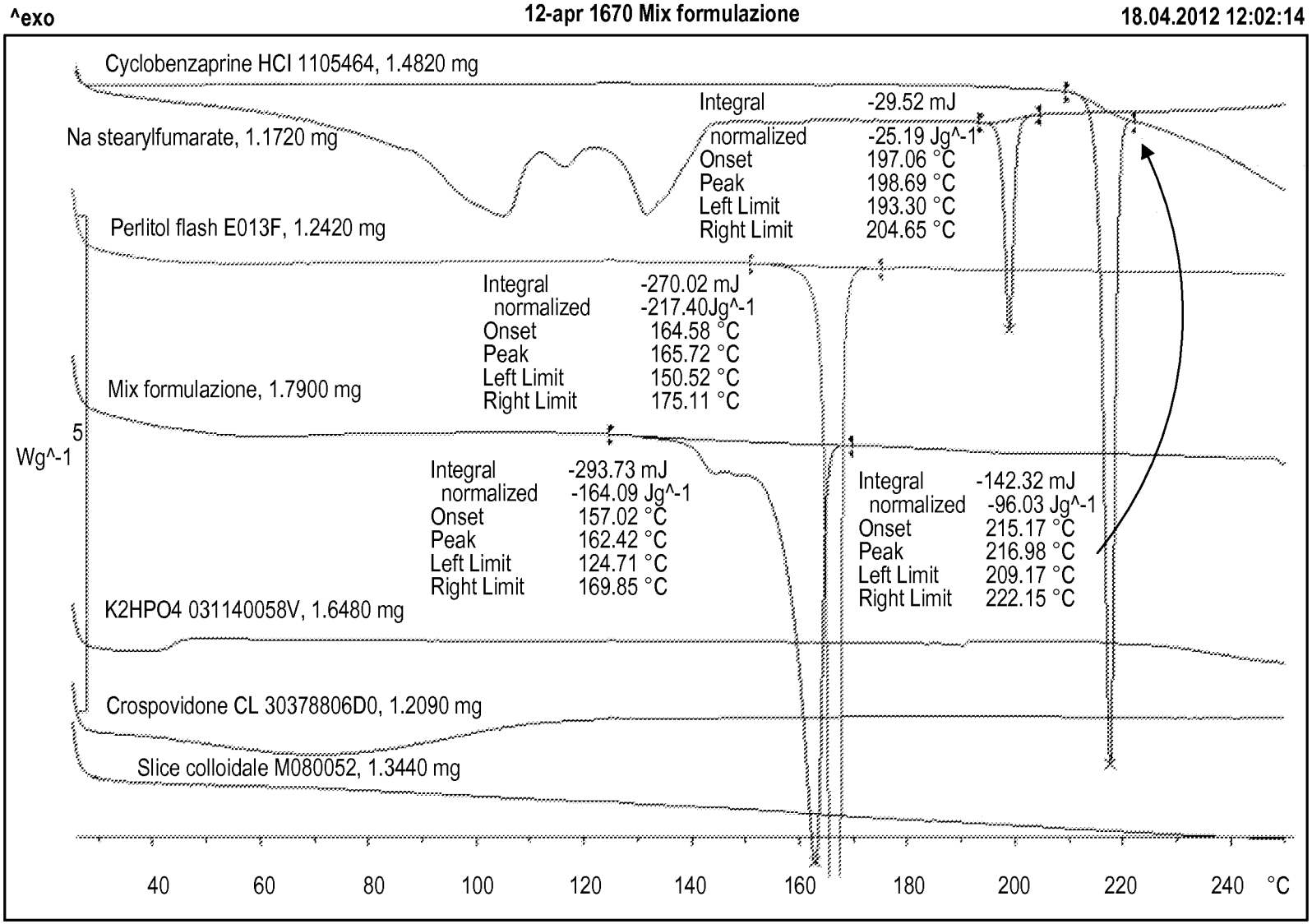

^exo
12-apr 1670 Mix formulazione
18.04.2012 12:02:14
Cyclobenzaprine HCl 1105464, 1.4820 mg
Integral -29.52 mJ
normalized -25.19 Jg^-1
Onset 197.06 °C
Peak 198.69 °C
Left Limit 193.30 °C
Right Limit 204.65 °C
Na stearylfumarate, 1.1720 mg
Perlitol flash E013F, 1.2420 mg
Integral -270.02 mJ
normalized -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
5
Wg^-1
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
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
K2HPO4 031140058V, 1.6480 mg
Crospovidone CL 30378806D0, 1.2090 mg
Slice colloidale M080052, 1.3440 mg
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STAR^e SW 9.20

FIG. 12

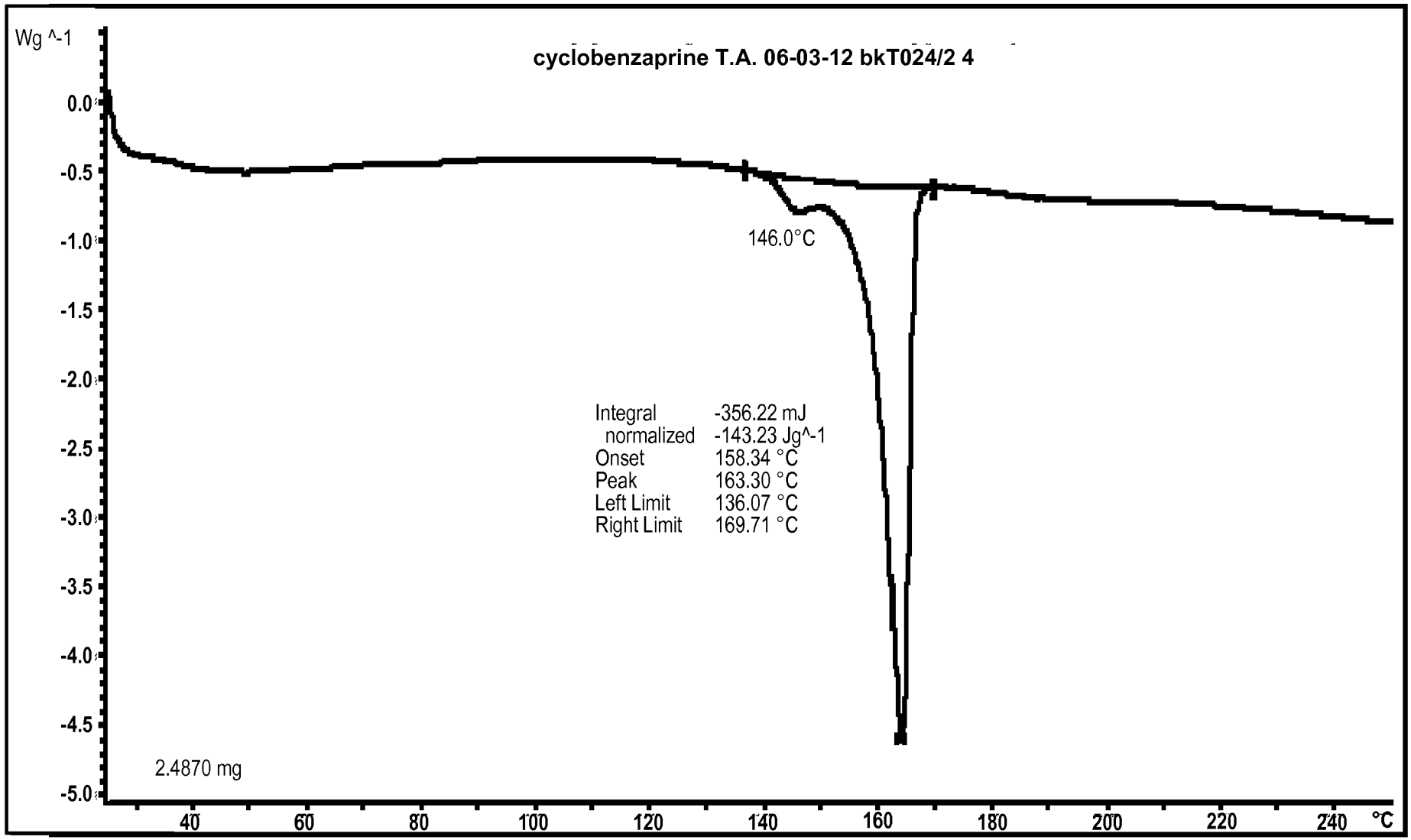

^exo
12-apr 2844 cyclobenzaprine TA bkT0242
16.05.2012 14:48:47
Wg ^-1
cyclobenzaprine T.A. 06-03-12 bkT024/2 4
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
-4.5
-5.0
146.0°C
Integral -356.22 mJ
normalized -143.23 Jg^-1
Onset 158.34 °C
Peak 163.30 °C
Left Limit 136.07 °C
Right Limit 169.71 °C
2.4870 mg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

FIG. 13

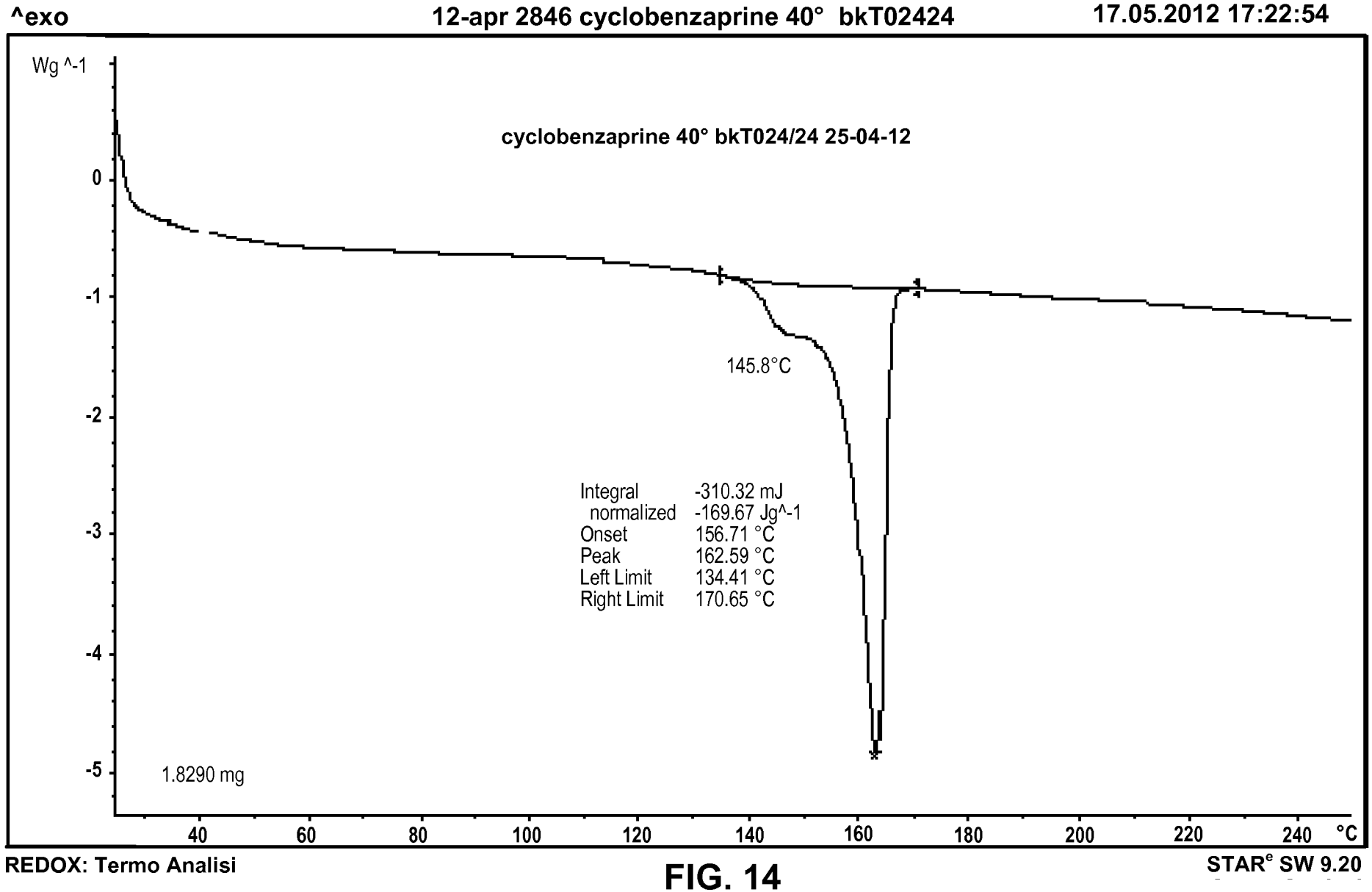

^exo
12-apr 2846 cyclobenzaprine 40° bkT02424
17.05.2012 17:22:54
Wg ^-1
cyclobenzaprine 40° bkT024/24 25-04-12
0
-1
-2
-3
-4
-5
145.8°C
Integral -310.32 mJ
normalized -169.67 Jg^-1
Onset 156.71 °C
Peak 162.59 °C
Left Limit 134.41 °C
Right Limit 170.65 °C
1.8290 mg
40
60
80
100
120
140
160
180
200
220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

FIG. 14

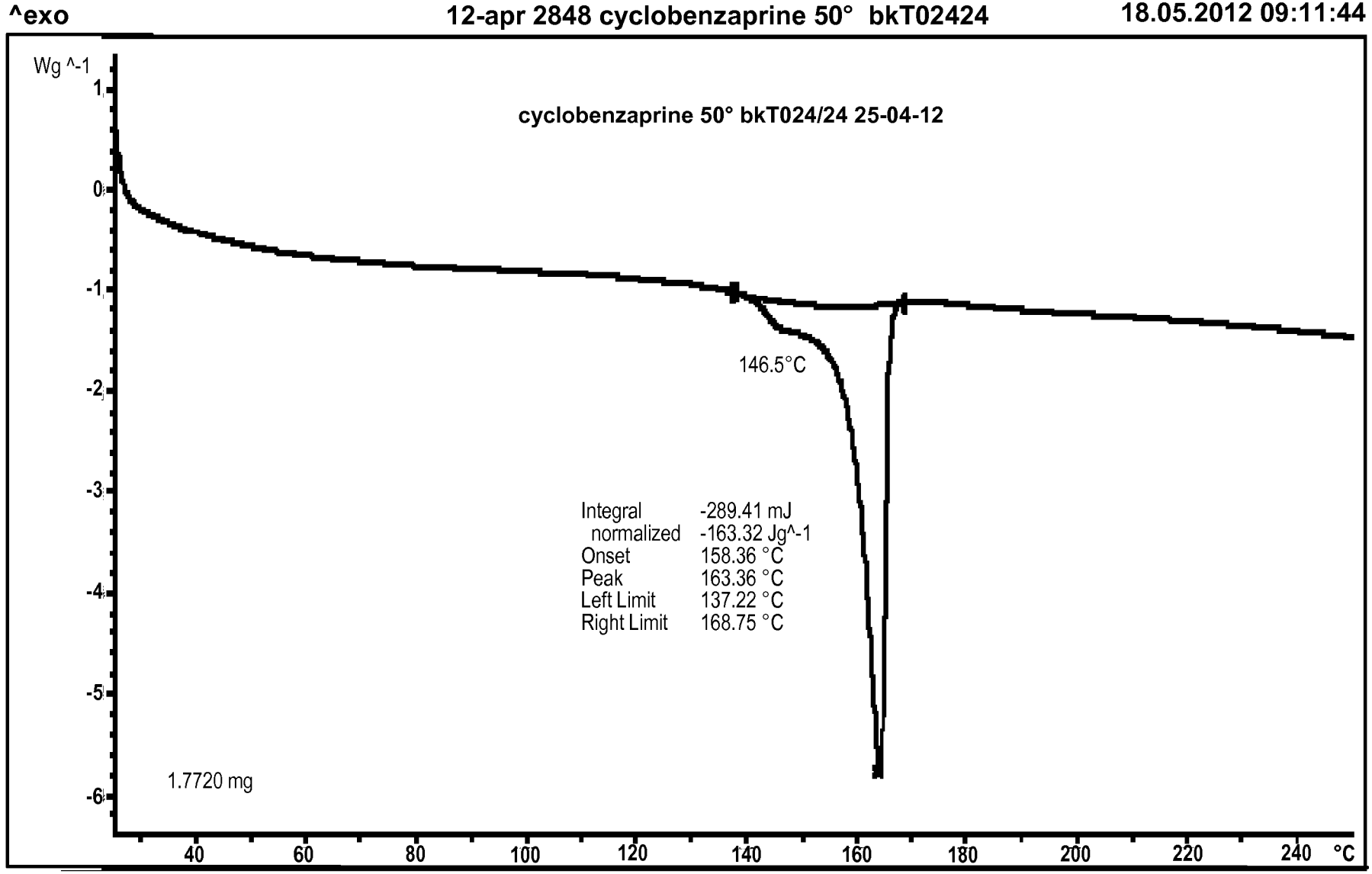

^exo
12-apr 2848 cyclobenzaprine 50° bkT02424
18.05.2012 09:11:44
Wg ^-1
cyclobenzaprine 50° bkT024/24 25-04-12
146.5°C
Integral -289.41 mJ
normalized -163.32 Jg^-1
Onset 158.36 °C
Peak 163.36 °C
Left Limit 137.22 °C
Right Limit 168.75 °C
1.7720 mg
°C
REDOX: Termo Analisi
STAR^e SW 9.20

FIG. 15

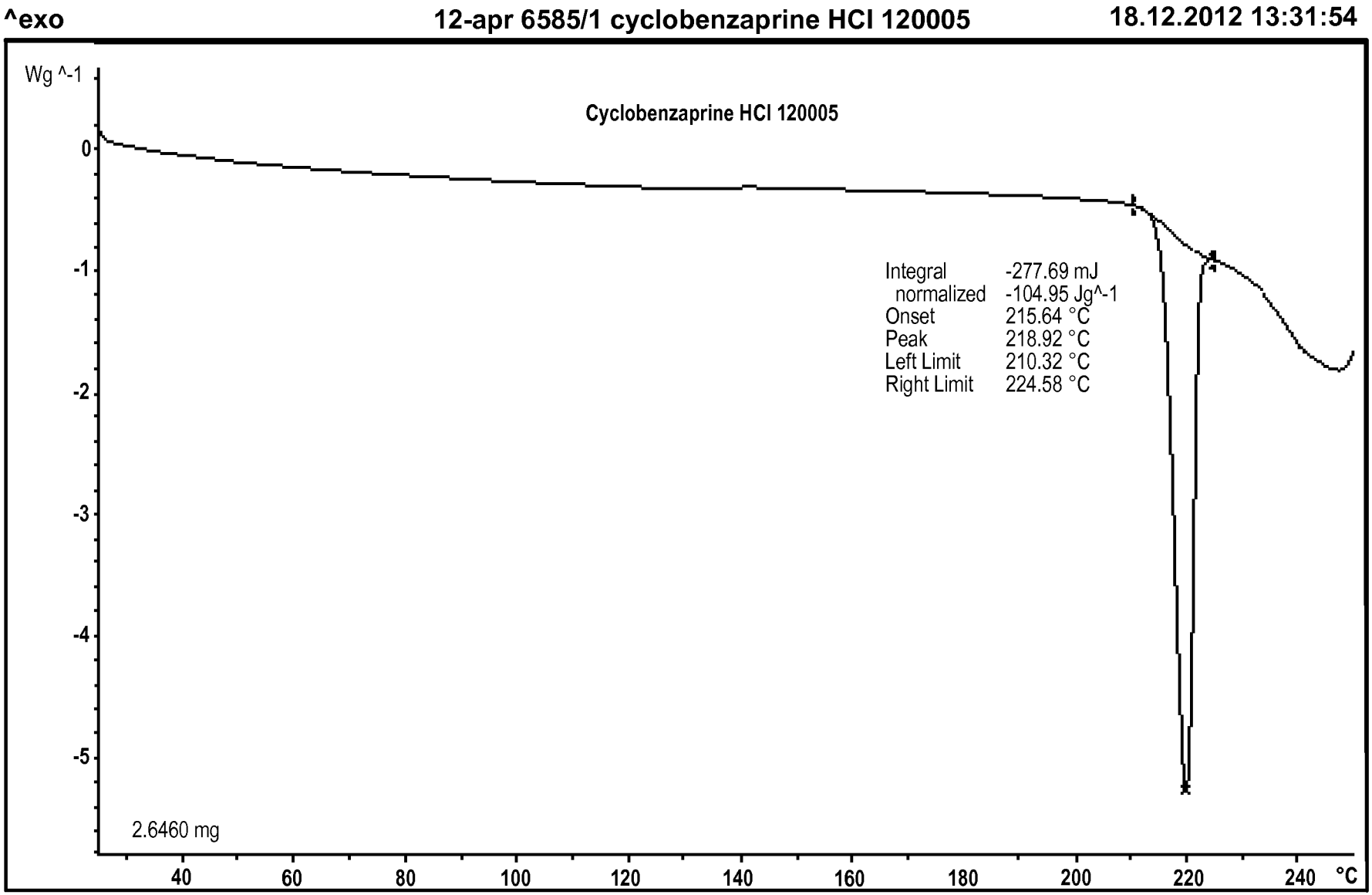

^exo
12-apr 6585/1 cyclobenzaprine HCl 120005
18.12.2012 13:31:54
Wg ^-1
Cyclobenzaprine HCl 120005
0
-1
-2
-3
-4
-5
Integral -277.69 mJ
normalized -104.95 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.32 °C
Right Limit 224.58 °C
2.6460 mg
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo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

FIG. 16

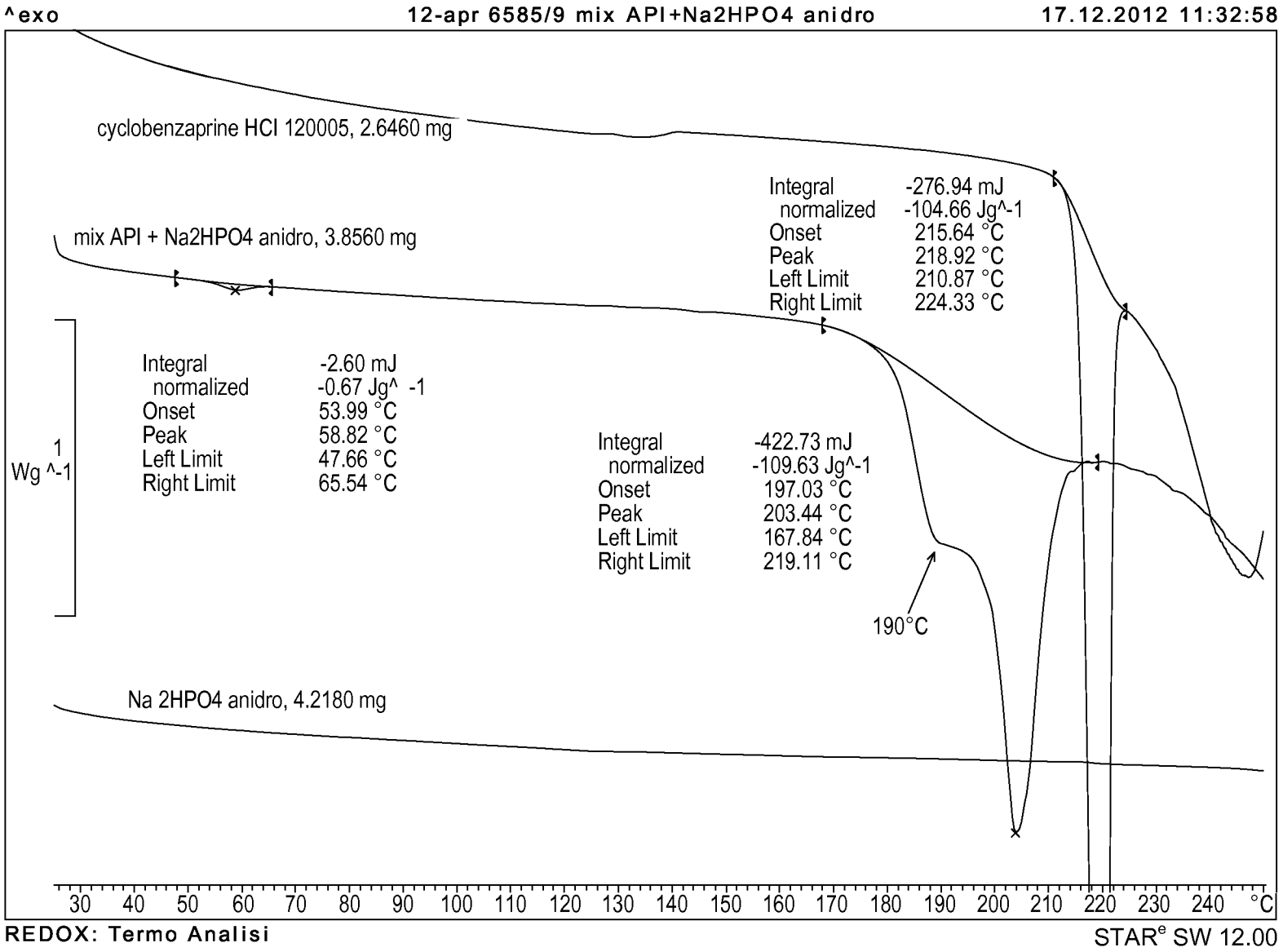

^exo
12-apr 6585/9 mix API+Na2HPO4 anidro
17.12.2012 11:32:58
cyclobenzaprine HCl 120005, 2.6460 mg
mix API + Na2HPO4 anidro, 3.8560 mg
Integral -276.94 mJ
normalized -104.66 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.87 °C
Right Limit 224.33 °C
1
Wg ^-1
Integral -2.60 mJ
normalized -0.67 Jg^ -1
Onset 53.99 °C
Peak 58.82 °C
Left Limit 47.66 °C
Right Limit 65.54 °C
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
190°C
Na 2HPO4 anidro, 4.2180 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
STAR^e SW 12.00

FIG. 17

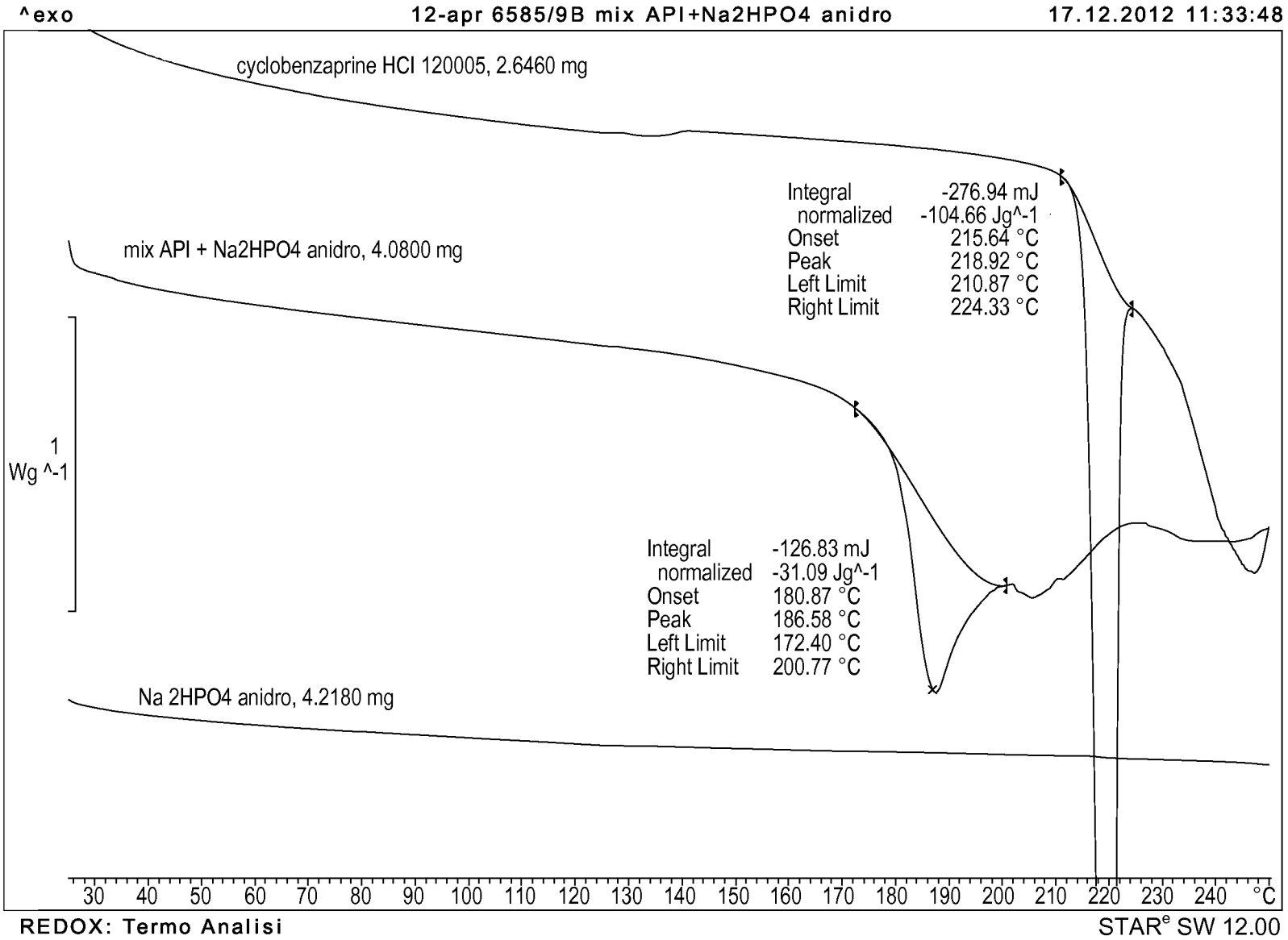

^exo
12-apr 6585/9B mix API+Na2HPO4 anidro
17.12.2012 11:33:48
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -276.94 mJ
normalized -104.66 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.87 °C
Right Limit 224.33 °C
mix API + Na2HPO4 anidro, 4.0800 mg
1
Wg ^-1
Integral -126.83 mJ
normalized -31.09 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
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
STAR^e SW 12.00

FIG. 18

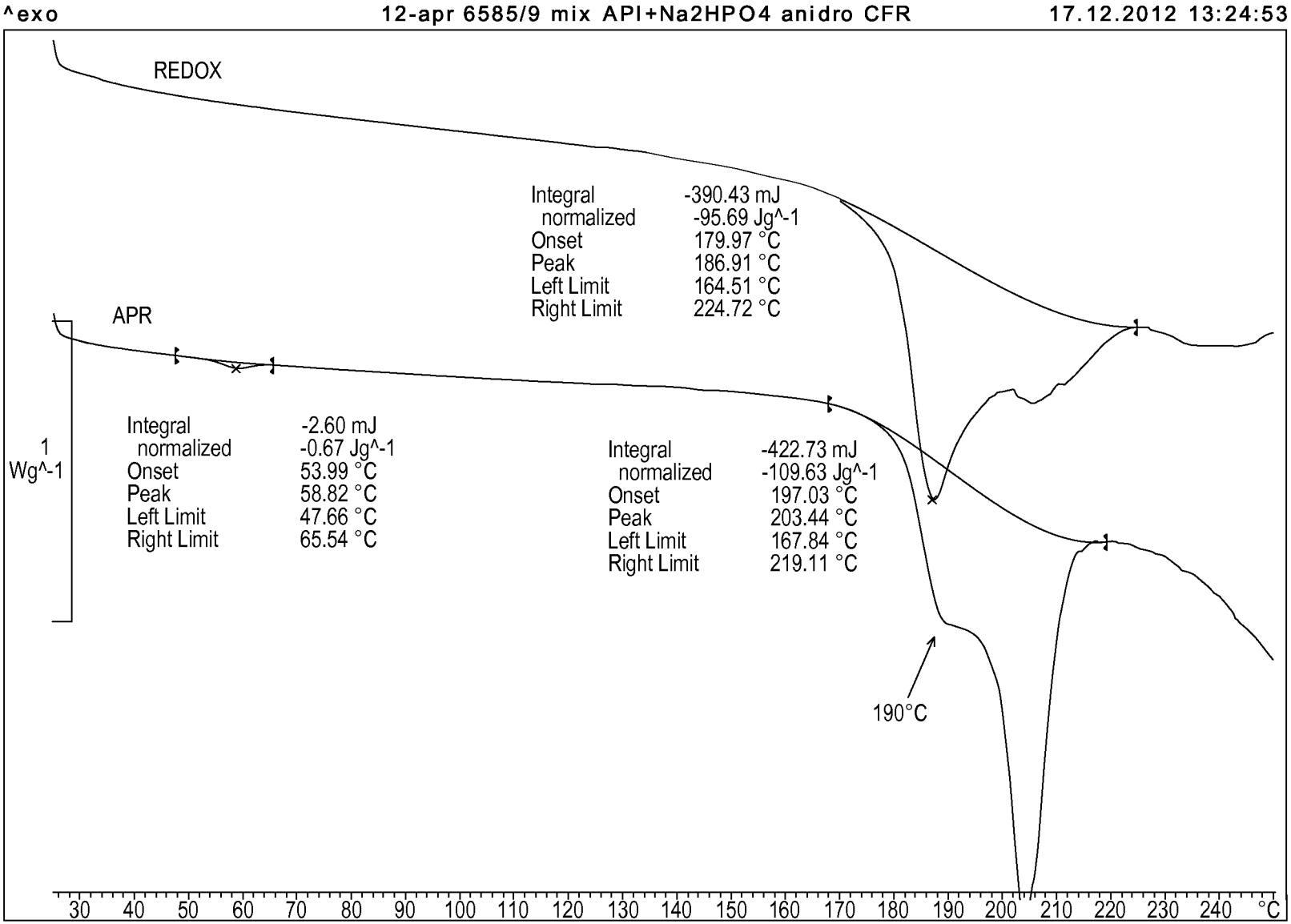

^exo
12-apr 6585/9 mix API+Na2HPO4 anidro CFR
17.12.2012 13:24:53
REDOX
Integral -390.43 mJ
normalized -95.69 Jg^-1
Onset 179.97 °C
Peak 186.91 °C
Left Limit 164.51 °C
Right Limit 224.72 °C
APR
1
Wg^-1
Integral -2.60 mJ
normalized -0.67 Jg^-1
Onset 53.99 °C
Peak 58.82 °C
Left Limit 47.66 °C
Right Limit 65.54 °C
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
190°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
STAR^e SW 12.00

FIG. 19

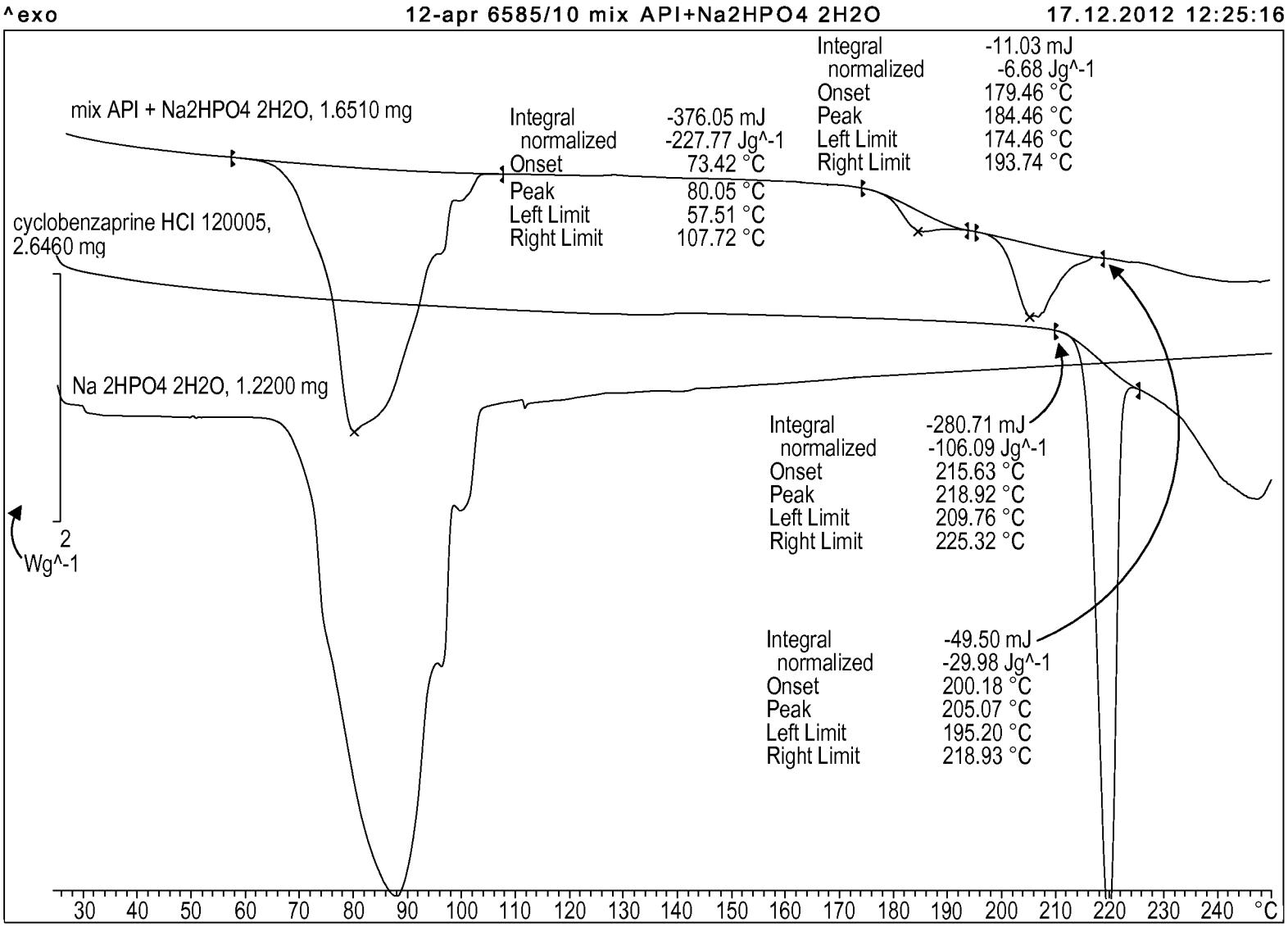

^exo
12-apr 6585/10 mix API+Na2HPO4 2H2O
17.12.2012 12:25:16
mix API + Na2HPO4 2H2O, 1.6510 mg
cyclobenzaprine HCl 120005, 2.6460 mg
Na 2HPO4 2H2O, 1.2200 mg
2
Wg^-1
Integral -376.05 mJ
normalized -227.77 Jg^-1
Onset 73.42 °C
Peak 80.05 °C
Left Limit 57.51 °C
Right Limit 107.72 °C
Integral -11.03 mJ
normalized -6.68 Jg^-1
Onset 179.46 °C
Peak 184.46 °C
Left Limit 174.46 °C
Right Limit 193.74 °C
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
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
STAR^e SW 12.00

FIG. 20

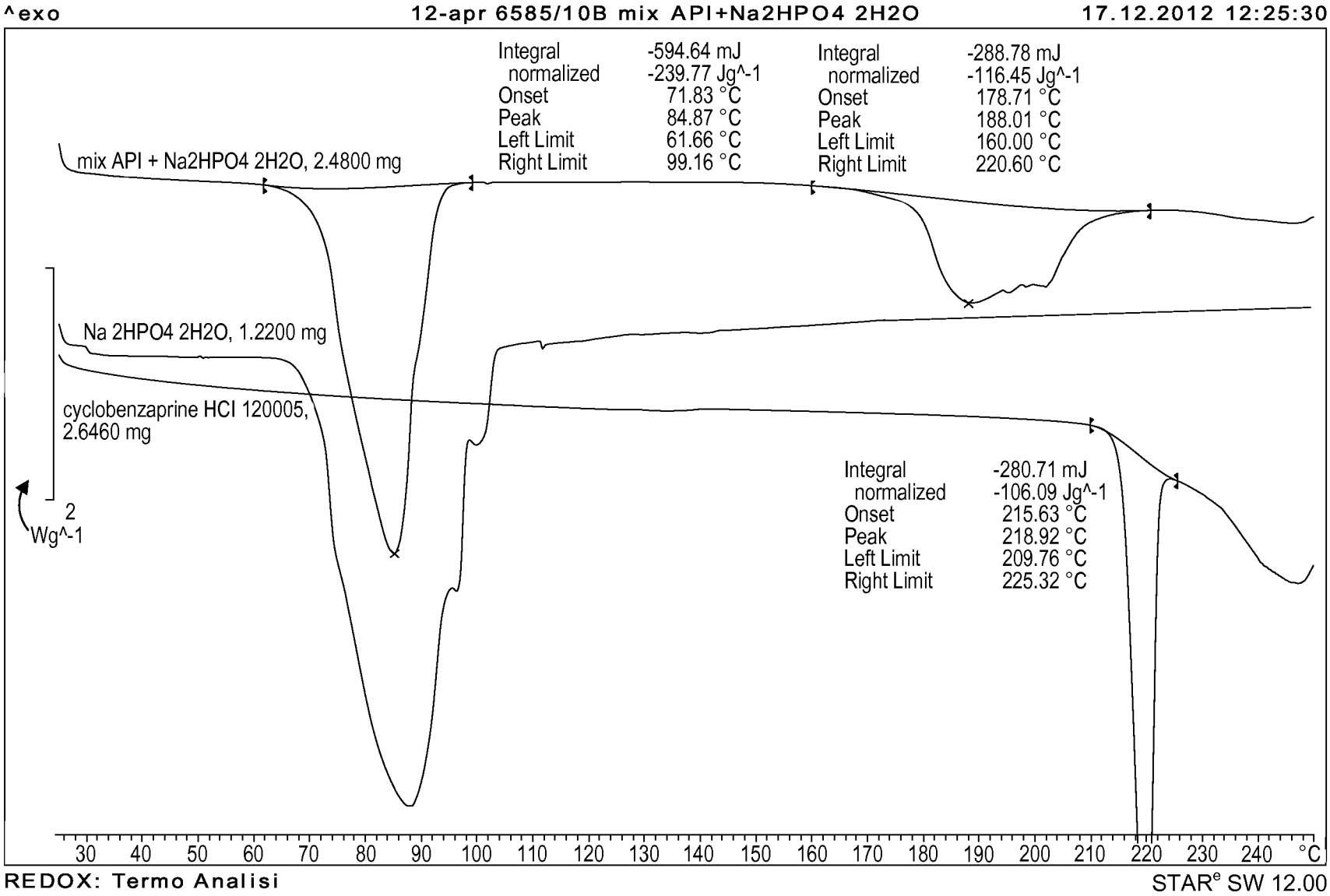

^exo
12-apr 6585/10B mix API+Na2HPO4 2H2O
17.12.2012 12:25:30
Integral -594.64 mJ
normalized -239.77 Jg^-1
Onset 71.83 °C
Peak 84.87 °C
Left Limit 61.66 °C
Right Limit 99.16 °C
Integral -288.78 mJ
normalized -116.45 Jg^-1
Onset 178.71 °C
Peak 188.01 °C
Left Limit 160.00 °C
Right Limit 220.60 °C
mix API + Na2HPO4 2H2O, 2.4800 mg
Na 2HPO4 2H2O, 1.2200 mg
cyclobenzaprine HCl 120005, 2.6460 mg
2
Wg^-1
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
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

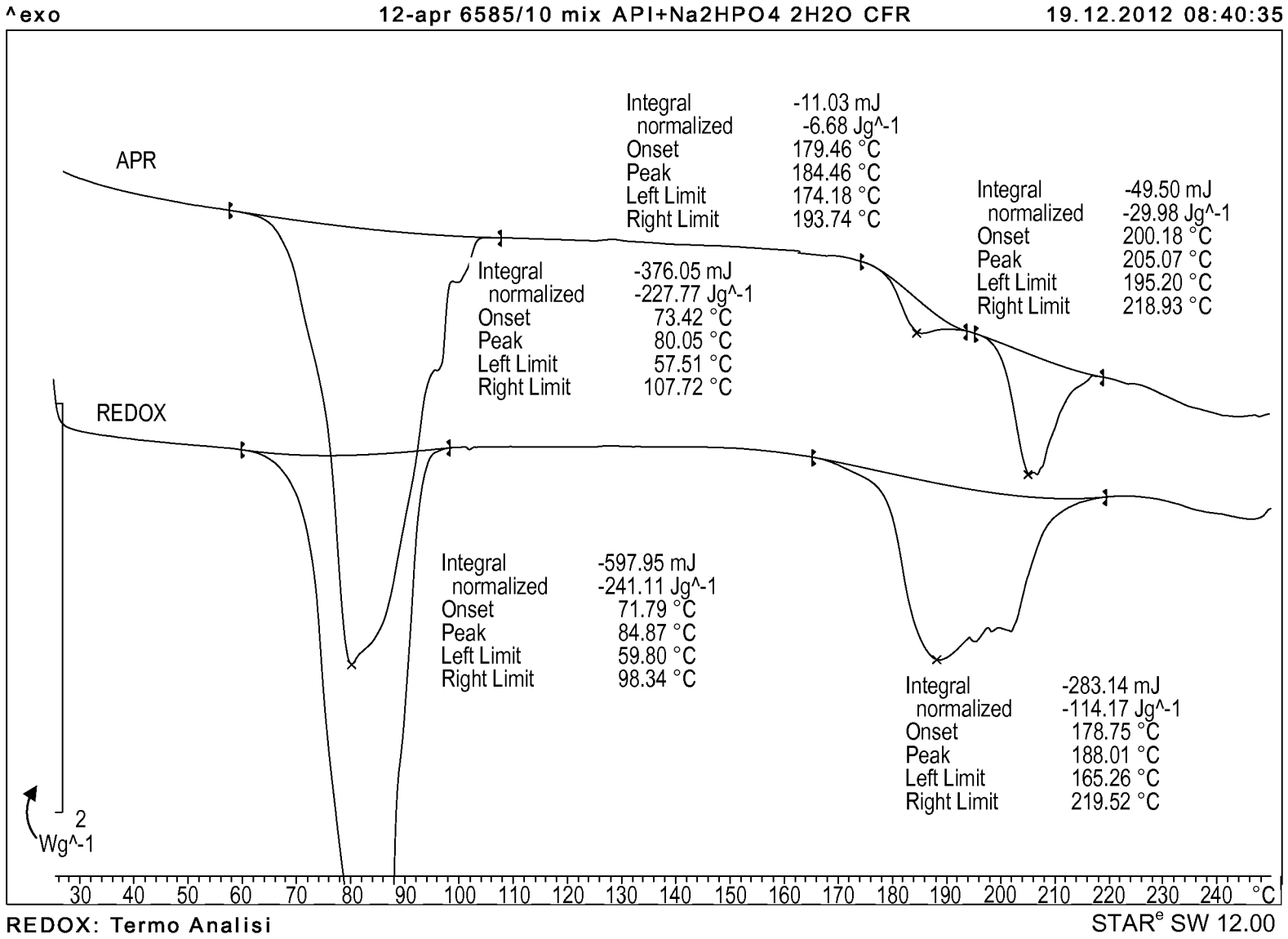

^exo
12-apr 6585/10 mix API+Na2HPO4 2H2O CFR
19.12.2012 08:40:35
APR
Integral -11.03 mJ
normalized -6.68 Jg^-1
Onset 179.46 °C
Peak 184.46 °C
Left Limit 174.18 °C
Right Limit 193.74 °C
Integral -376.05 mJ
normalized -227.77 Jg^-1
Onset 73.42 °C
Peak 80.05 °C
Left Limit 57.51 °C
Right Limit 107.72 °C
Integral -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 -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

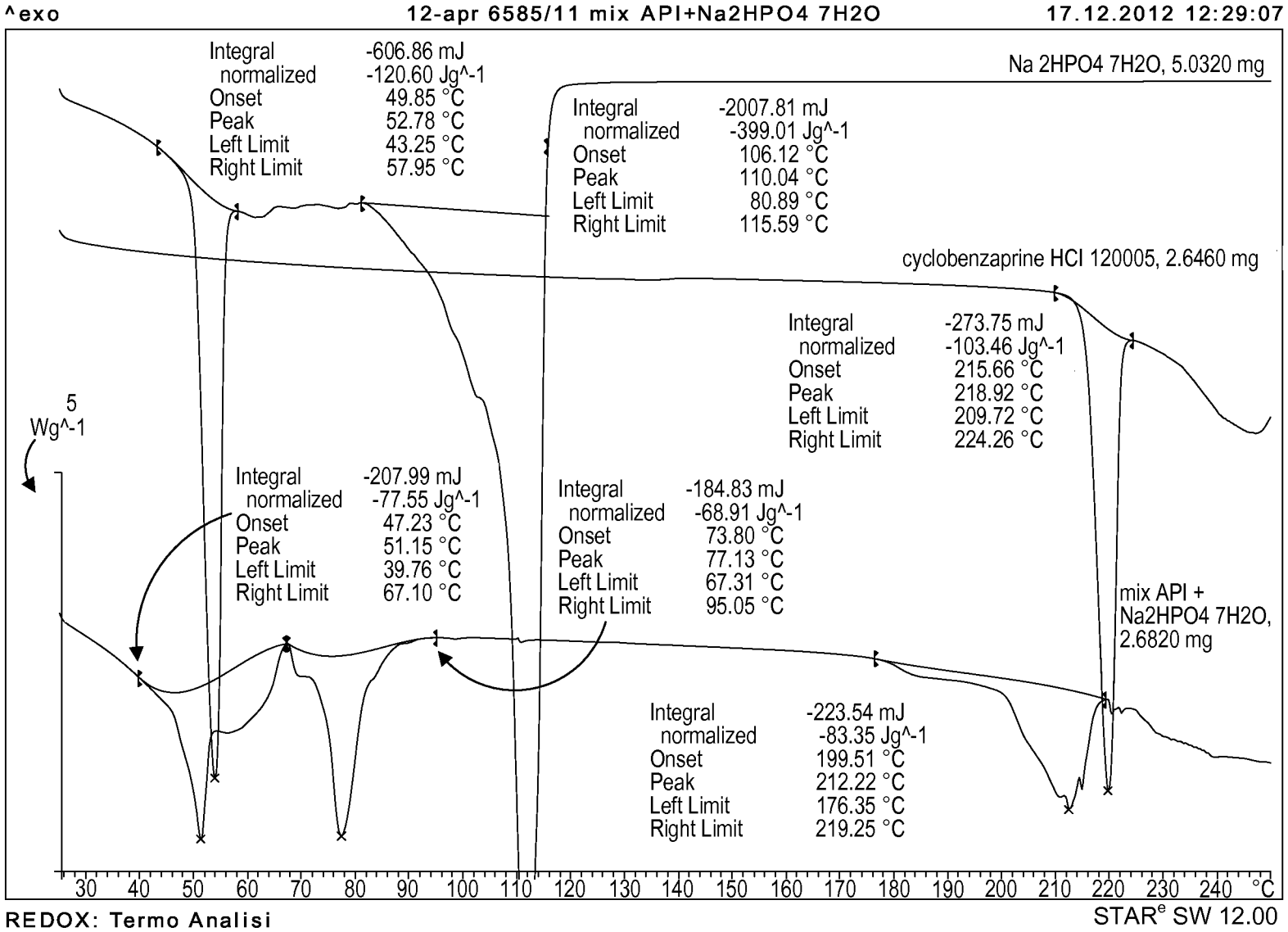

^exo
12-apr 6585/11 mix API+Na2HPO4 7H2O
17.12.2012 12:29:07
Integral -606.86 mJ
normalized -120.60 Jg^-1
Onset 49.85 °C
Peak 52.78 °C
Left Limit 43.25 °C
Right Limit 57.95 °C
Na 2HPO4 7H2O, 5.0320 mg
Integral -2007.81 mJ
normalized -399.01 Jg^-1
Onset 106.12 °C
Peak 110.04 °C
Left Limit 80.89 °C
Right 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
5
Wg^-1
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
mix API +
Na2HPO4 7H2O,
2.6820 mg
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
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
STAR^e SW 12.00

FIG. 23

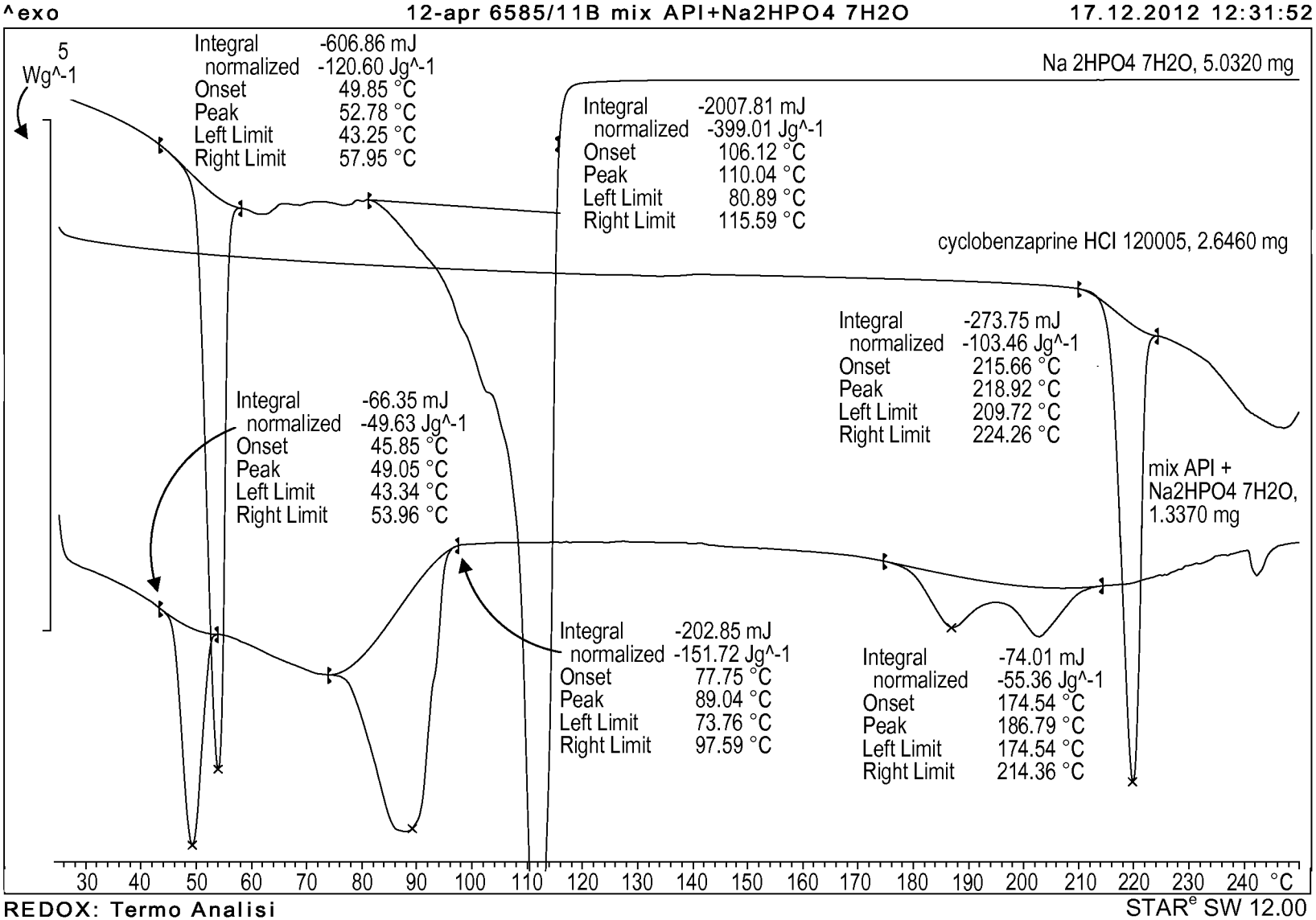

^exo
12-apr 6585/11B mix API+Na2HPO4 7H2O
17.12.2012 12:31:52
5
Wg^-1
Integral -606.86 mJ
normalized -120.60 Jg^-1
Onset 49.85 °C
Peak 52.78 °C
Left Limit 43.25 °C
Right Limit 57.95 °C
Na 2HPO4 7H2O, 5.0320 mg
Integral -2007.81 mJ
normalized -399.01 Jg^-1
Onset 106.12 °C
Peak 110.04 °C
Left Limit 80.89 °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
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
mix API + Na2HPO4 7H2O, 1.3370 mg
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

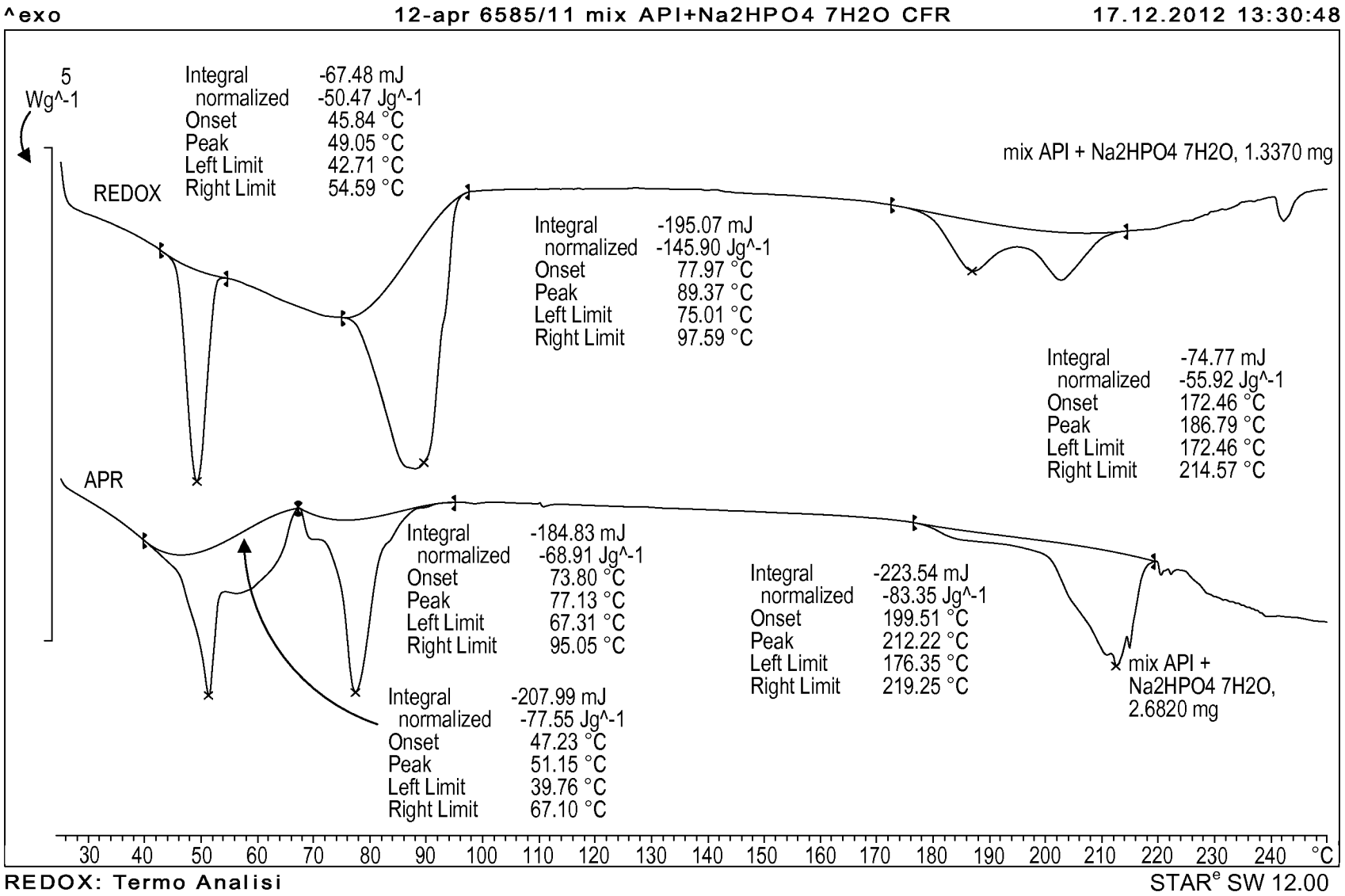

^exo
12-apr 6585/11 mix API+Na2HPO4 7H2O CFR
17.12.2012 13:30:48
5
Wg^-1
REDOX
Integral -67.48 mJ
normalized -50.47 Jg^-1
Onset 45.84 °C
Peak 49.05 °C
Left Limit 42.71 °C
Right Limit 54.59 °C
mix API + Na2HPO4 7H2O, 1.3370 mg
Integral -195.07 mJ
normalized -145.90 Jg^-1
Onset 77.97 °C
Peak 89.37 °C
Left 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
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
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

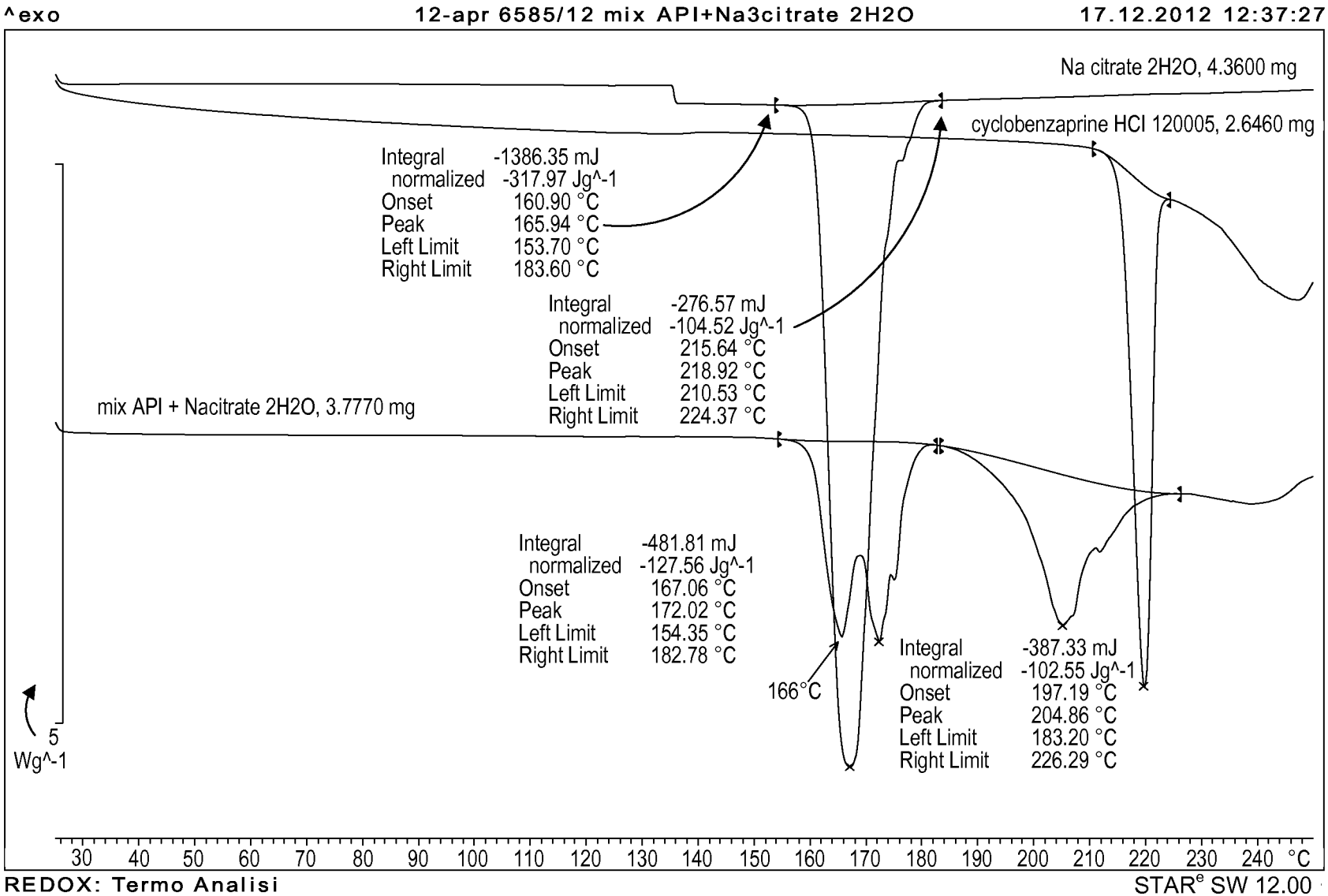

^exo
12-apr 6585/12 mix API+Na3citrate 2H2O
17.12.2012 12:37:27
Na citrate 2H2O, 4.3600 mg
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -1386.35 mJ
normalized -317.97 Jg^-1
Onset 160.90 °C
Peak 165.94 °C
Left Limit 153.70 °C
Right Limit 183.60 °C
Integral -276.57 mJ
normalized -104.52 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 210.53 °C
Right Limit 224.37 °C
mix API + Nacitrate 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. 26

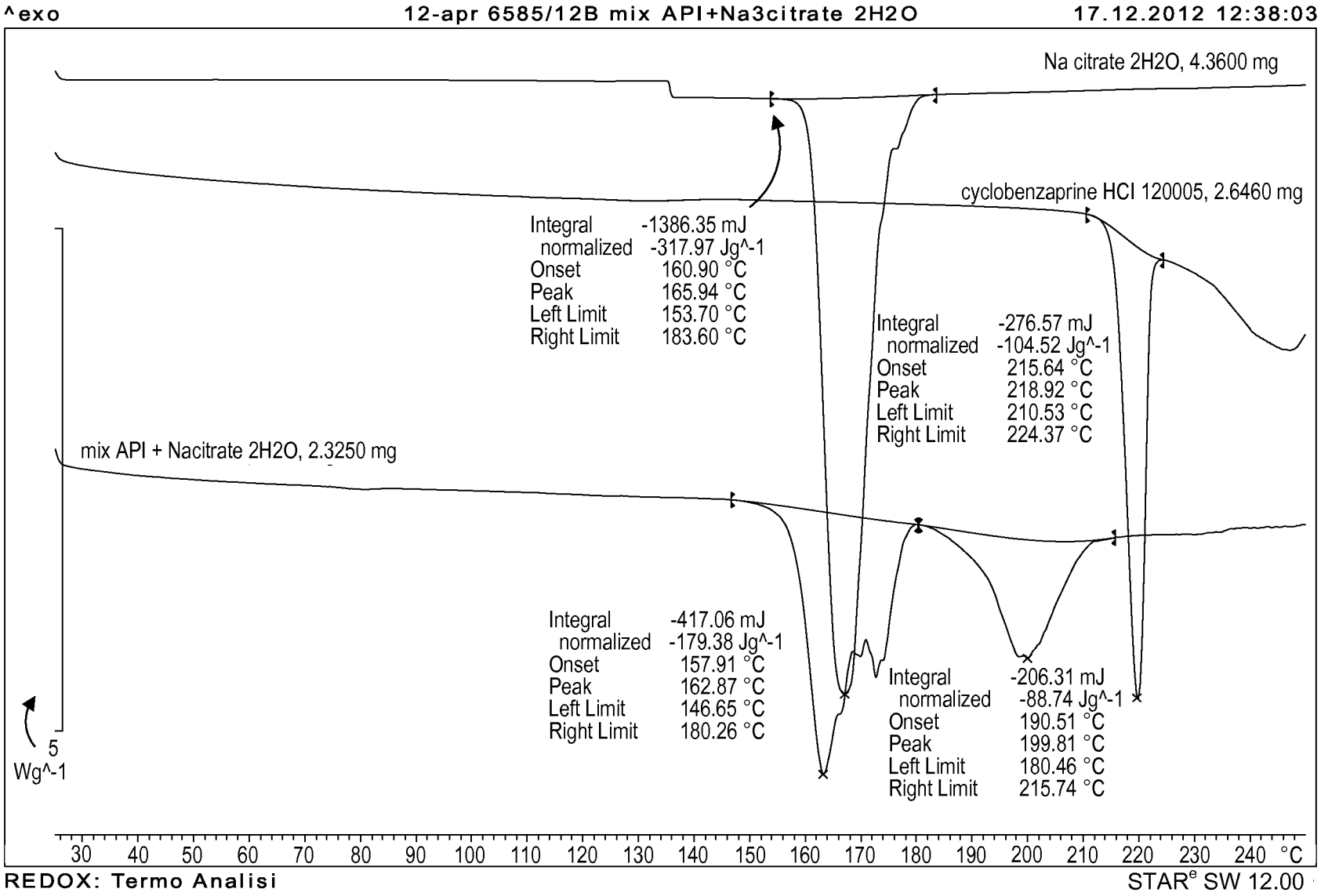

^exo
12-apr 6585/12B mix API+Na3citrate 2H2O
17.12.2012 12:38:03
Na citrate 2H2O, 4.3600 mg
cyclobenzaprine HCl 120005, 2.6460 mg
mix API + Nacitrate 2H2O, 2.3250 mg
Integral -1386.35 mJ
normalized -317.97 Jg^-1
Onset 160.90 °C
Peak 165.94 °C
Left Limit 153.70 °C
Right Limit 183.60 °C
Integral -276.57 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

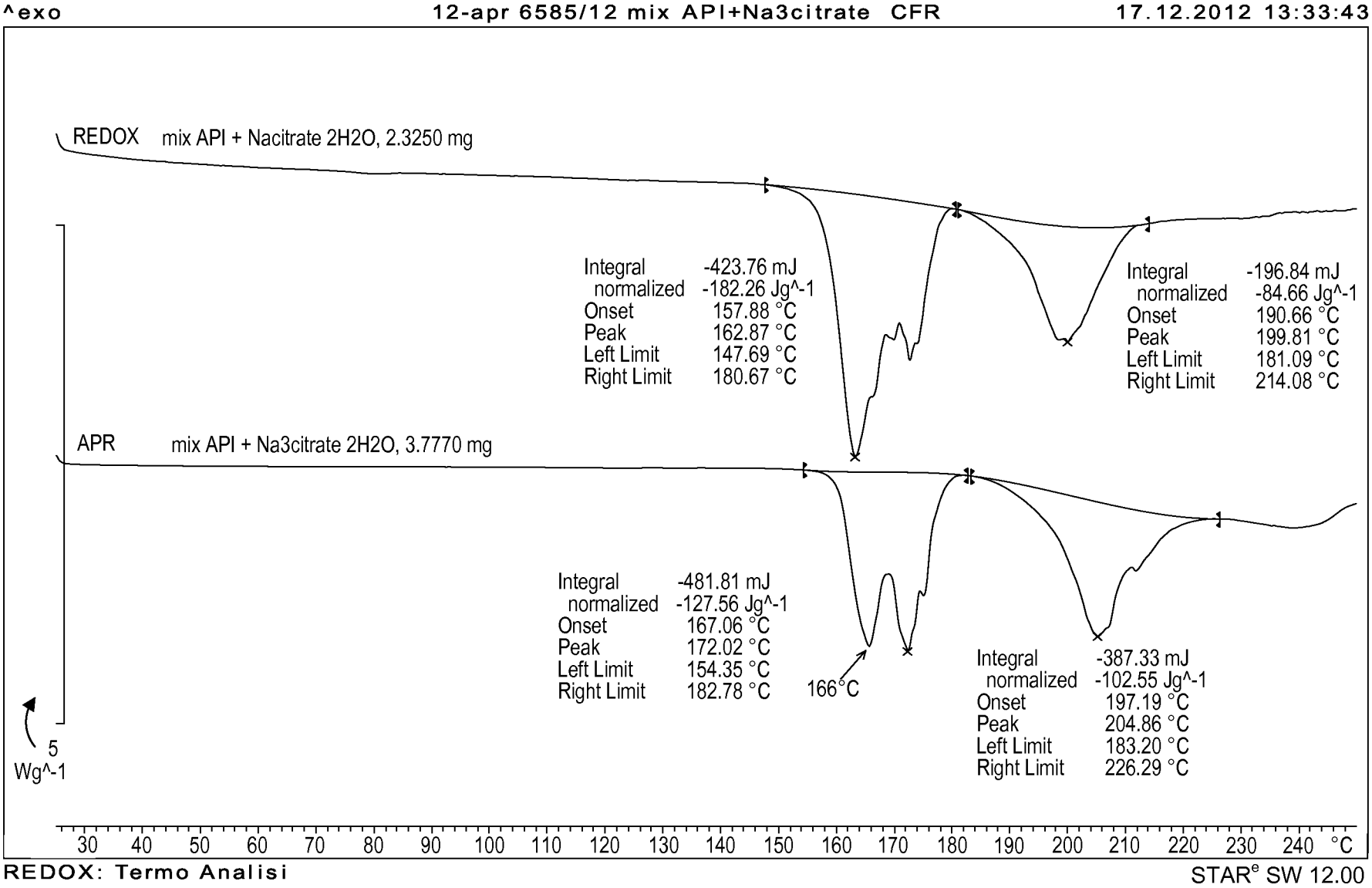

^exo
12-apr 6585/12 mix API+Na3citrate CFR
17.12.2012 13:33:43
REDOX mix API + Nacitrate 2H2O, 2.3250 mg
Integral -423.76 mJ
normalized -182.26 Jg^-1
Onset 157.88 °C
Peak 162.87 °C
Left Limit 147.69 °C
Right Limit 180.67 °C
Integral -196.84 mJ
normalized -84.66 Jg^-1
Onset 190.66 °C
Peak 199.81 °C
Left 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

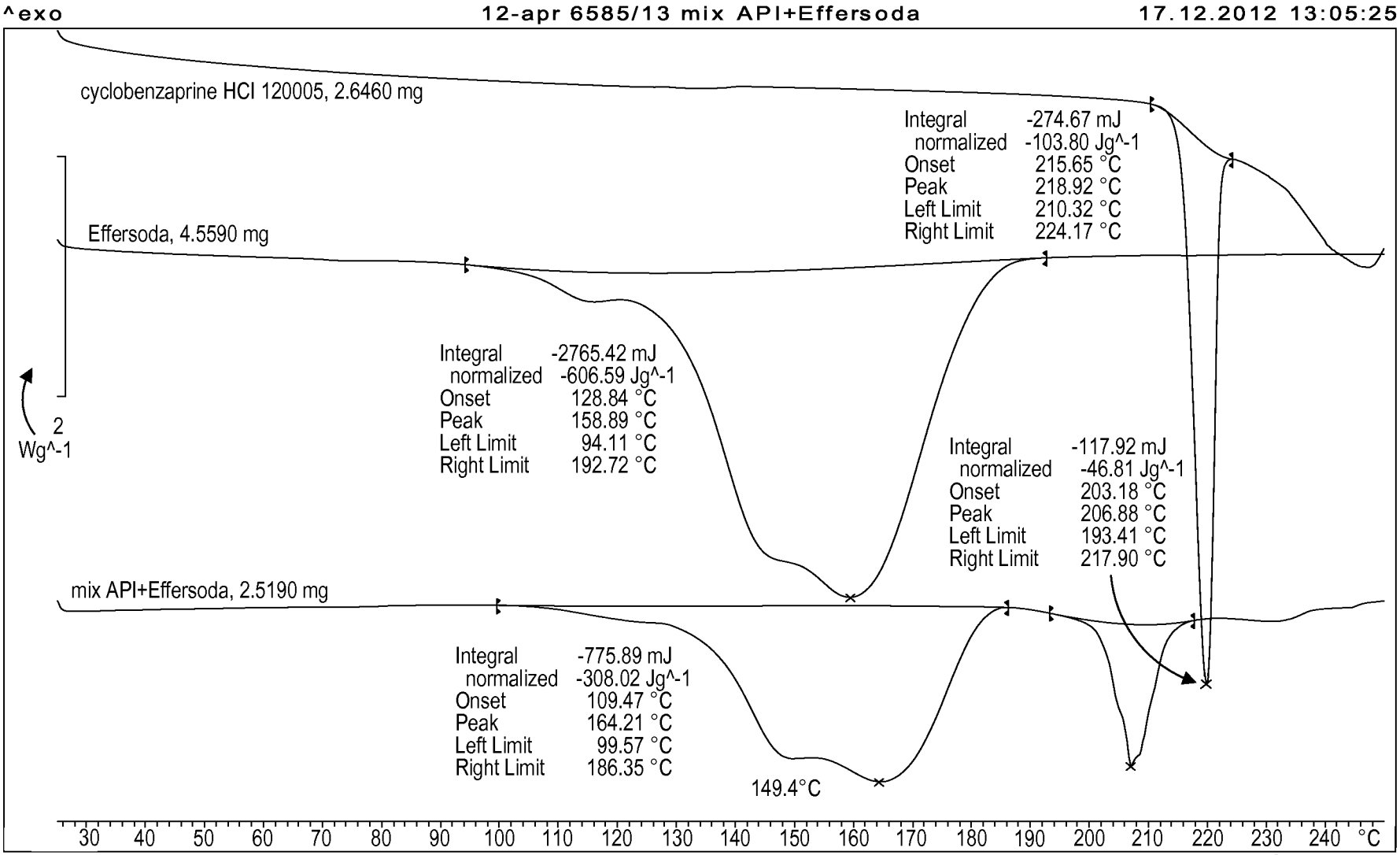

^exo
12-apr 6585/13 mix API+Effersoda
17.12.2012 13:05:25
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -274.67 mJ
normalized -103.80 Jg^-1
Onset 215.65 °C
Peak 218.92 °C
Left Limit 210.32 °C
Right Limit 224.17 °C
Effersoda, 4.5590 mg
Integral -2765.42 mJ
normalized -606.59 Jg^-1
Onset 128.84 °C
Peak 158.89 °C
Left Limit 94.11 °C
Right Limit 192.72 °C
2
Wg^-1
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
mix API+Effersoda, 2.5190 mg
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
STAR^e SW 12.00

FIG. 29

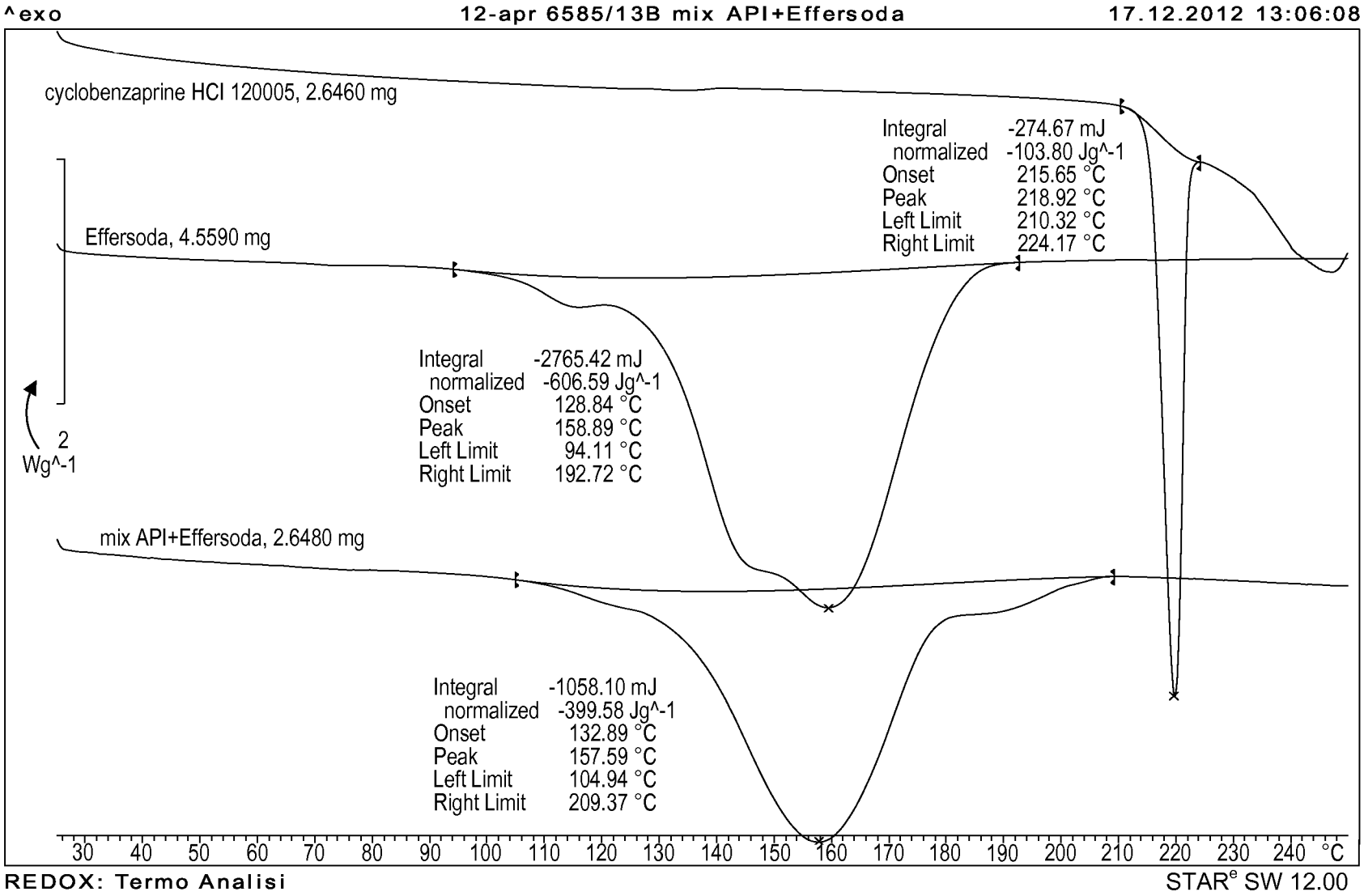

^exo
12-apr 6585/13B mix API+Effersoda
17.12.2012 13:06:08
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -274.67 mJ
normalized -103.80 Jg^-1
Onset 215.65 °C
Peak 218.92 °C
Left Limit 210.32 °C
Right Limit 224.17 °C
Effersoda, 4.5590 mg
Integral -2765.42 mJ
normalized -606.59 Jg^-1
Onset 128.84 °C
Peak 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

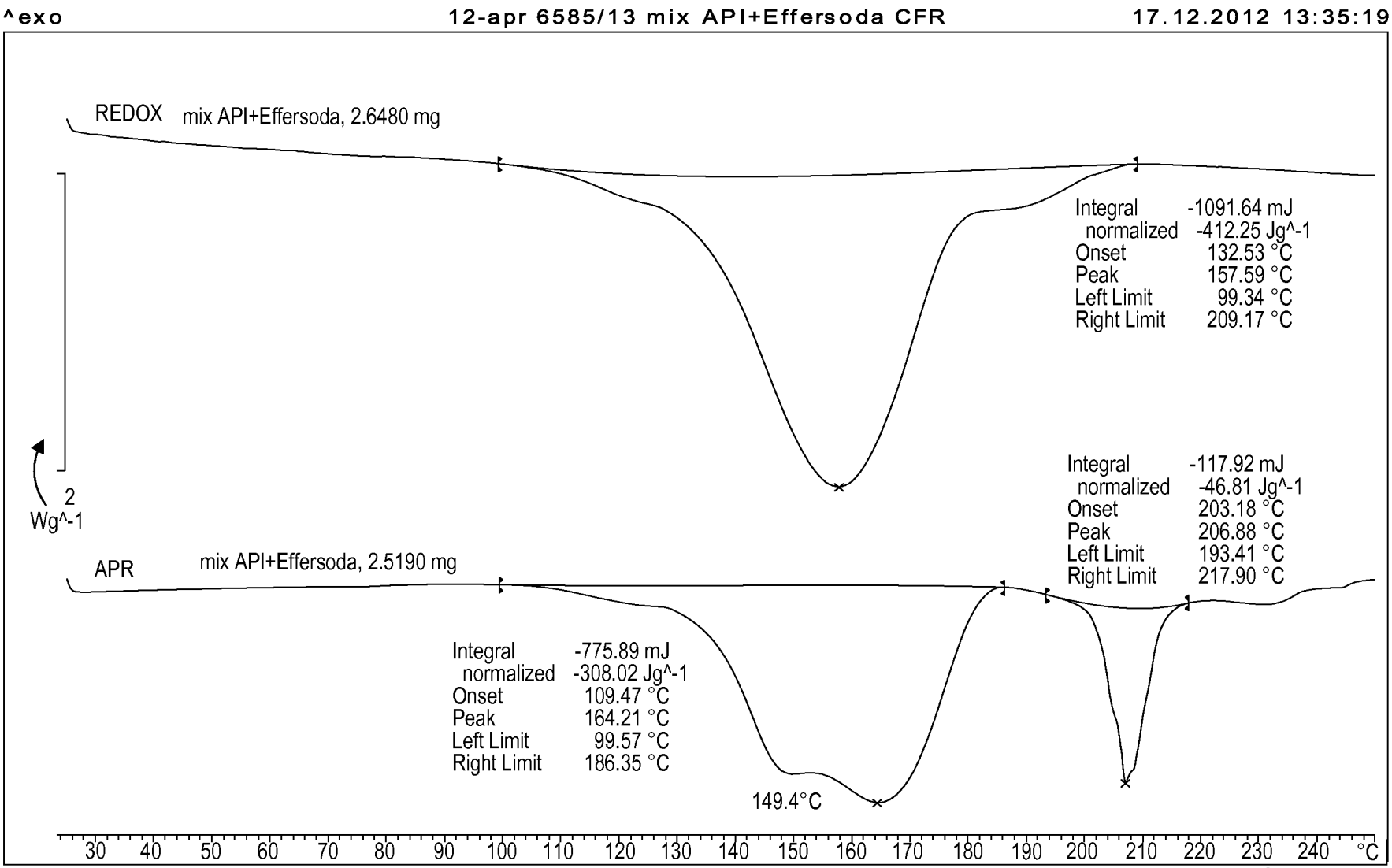

^exo
12-apr 6585/13 mix API+Effersoda CFR
17.12.2012 13:35:19
REDOX mix API+Effersoda, 2.6480 mg
Integral -1091.64 mJ
normalized -412.25 Jg^-1
Onset 132.53 °C
Peak 157.59 °C
Left Limit 99.34 °C
Right Limit 209.17 °C
2
Wg^-1
Integral -117.92 mJ
normalized -46.81 Jg^-1
Onset 203.18 °C
Peak 206.88 °C
Left Limit 193.41 °C
Right Limit 217.90 °C
APR mix API+Effersoda, 2.5190 mg
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
STAR^e SW 12.00

FIG. 31

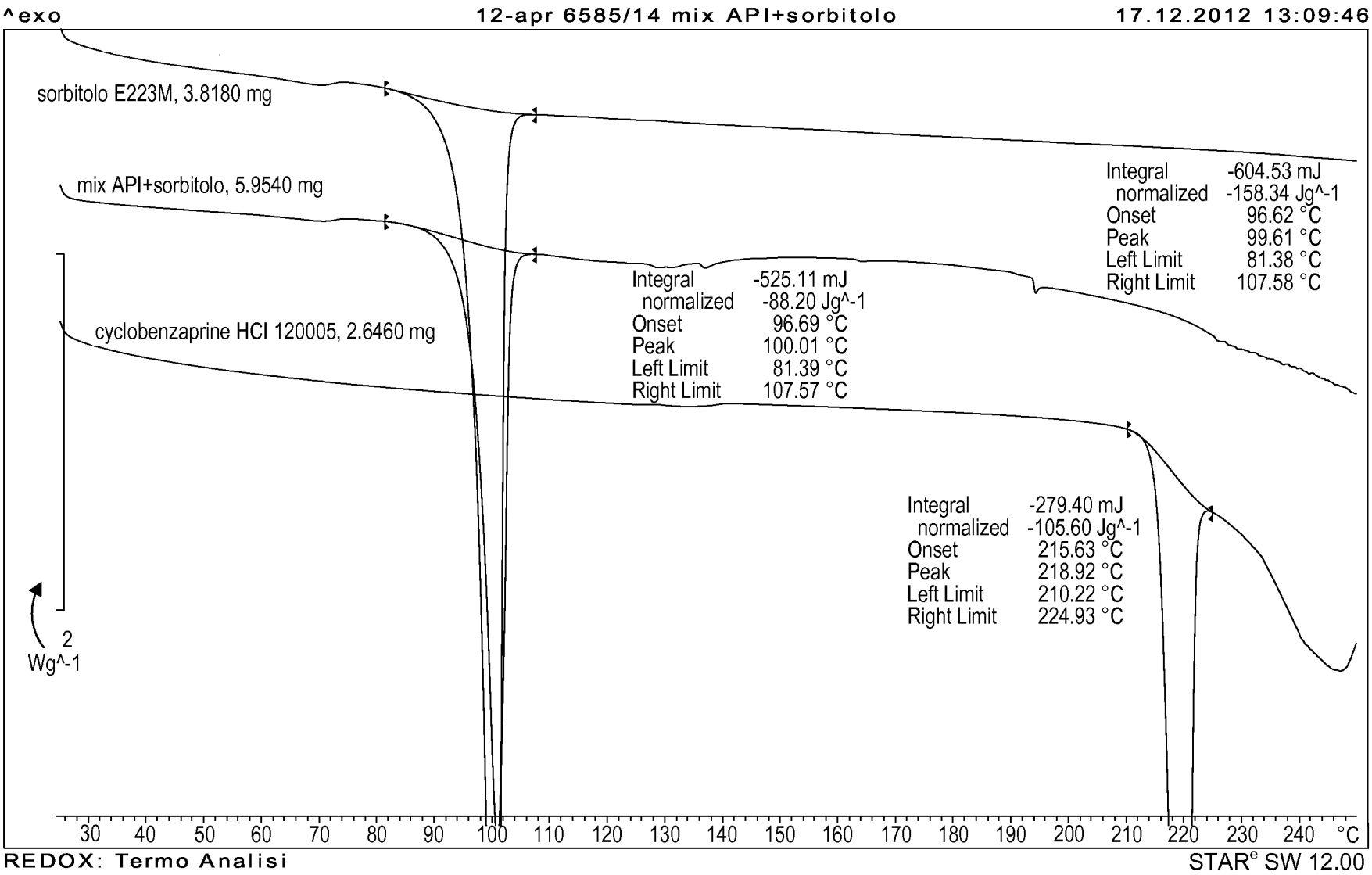

^exo
12-apr 6585/14 mix API+sorbitolo
17.12.2012 13:09:46
sorbitolo E223M, 3.8180 mg
mix API+sorbitolo, 5.9540 mg
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -604.53 mJ
normalized -158.34 Jg^-1
Onset 96.62 °C
Peak 99.61 °C
Left Limit 81.38 °C
Right Limit 107.58 °C
Integral -525.11 mJ
normalized -88.20 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
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
STAR^e SW 12.00

FIG. 32

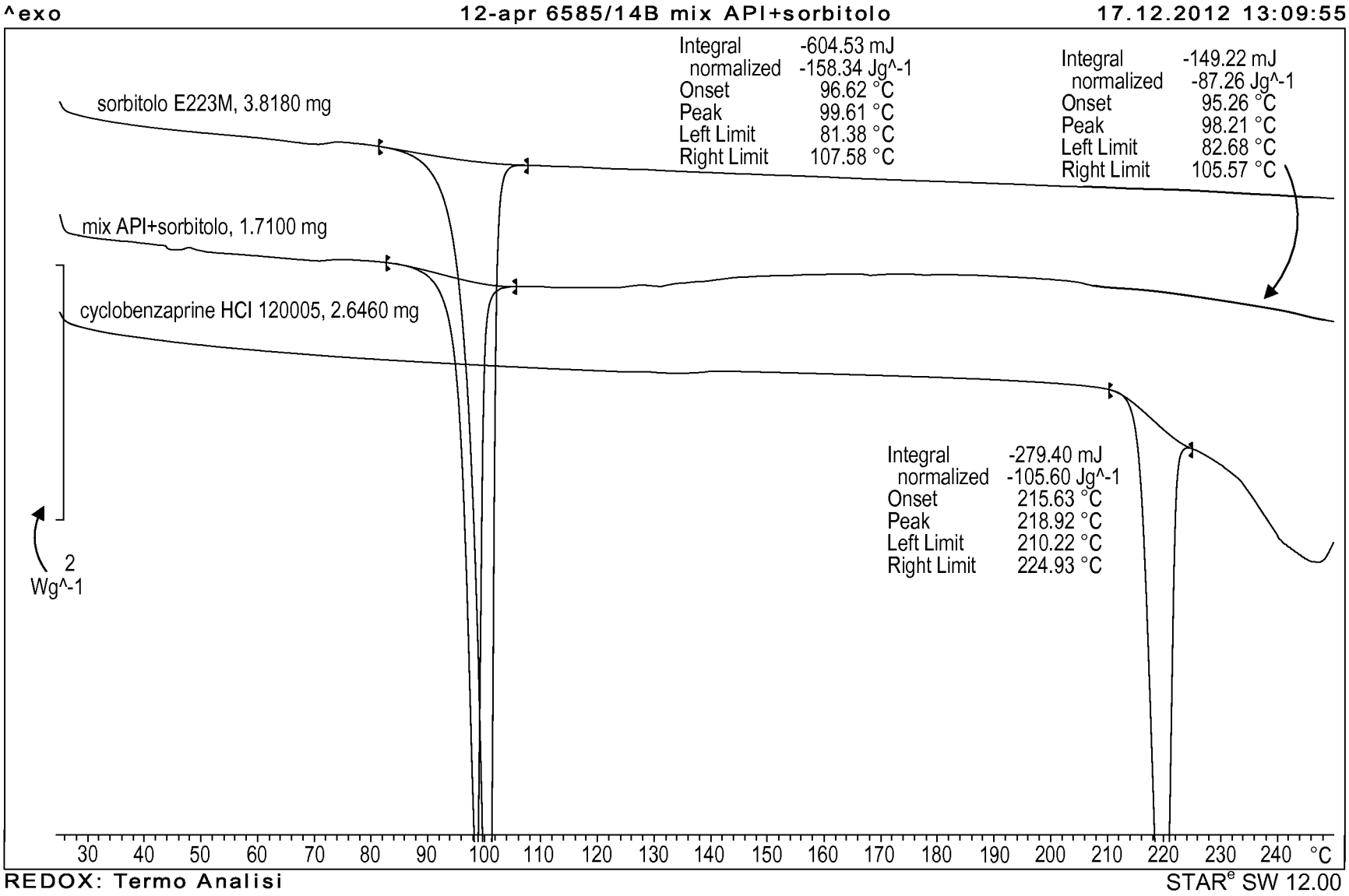

^exo
12-apr 6585/14B mix API+sorbitolo
17.12.2012 13:09:55
Integral -604.53 mJ
normalized -158.34 Jg^-1
Onset 96.62 °C
Peak 99.61 °C
Left Limit 81.38 °C
Right Limit 107.58 °C
Integral -149.22 mJ
normalized -87.26 Jg^-1
Onset 95.26 °C
Peak 98.21 °C
Left Limit 82.68 °C
Right Limit 105.57 °C
sorbitolo E223M, 3.8180 mg
mix API+sorbitolo, 1.7100 mg
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

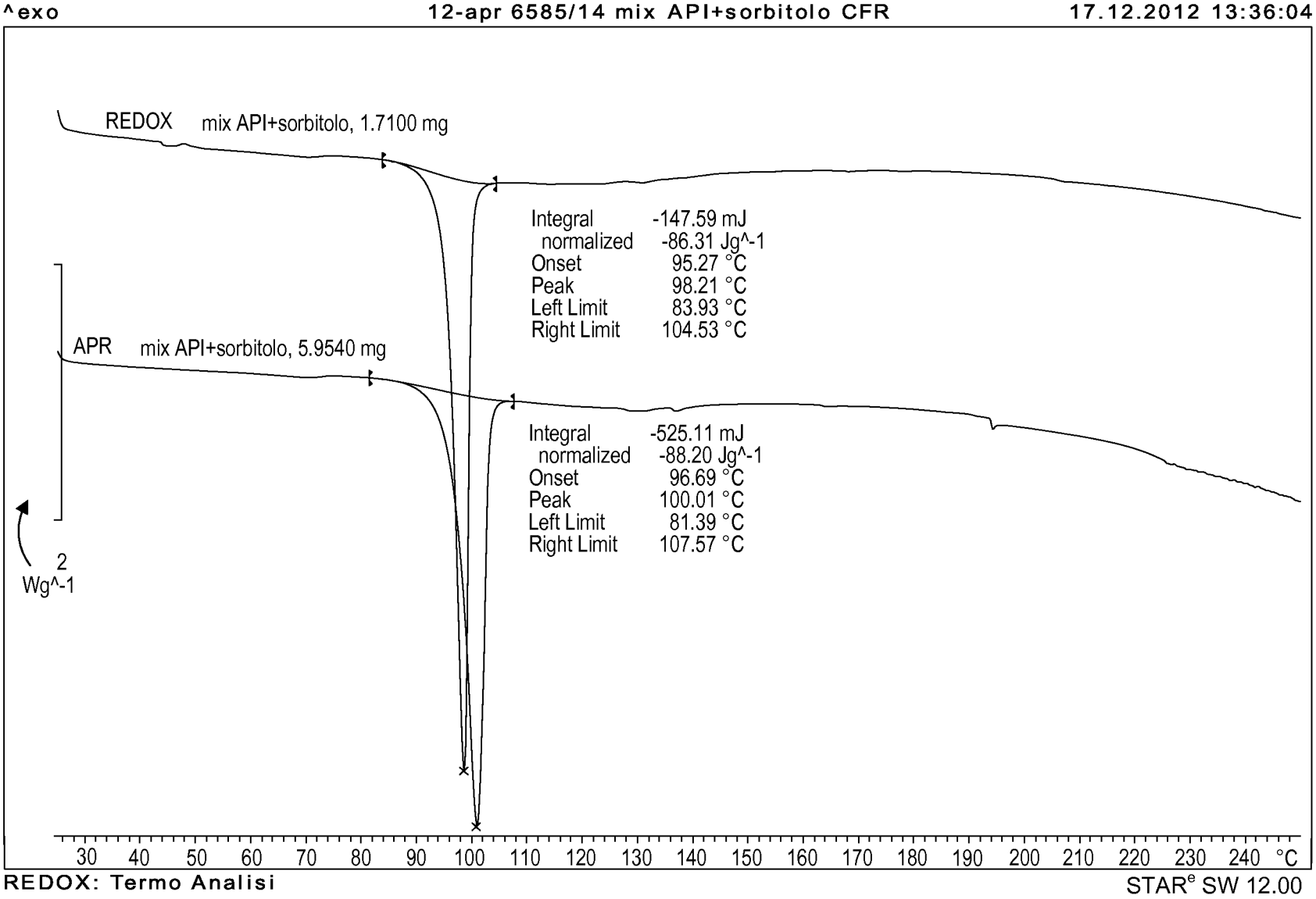

^exo
12-apr 6585/14 mix API+sorbitolo CFR
17.12.2012 13:36:04
REDOX mix API+sorbitolo, 1.7100 mg
Integral -147.59 mJ
normalized -86.31 Jg^-1
Onset 95.27 °C
Peak 98.21 °C
Left Limit 83.93 °C
Right Limit 104.53 °C
APR mix API+sorbitolo, 5.9540 mg
Integral -525.11 mJ
normalized -88.20 Jg^-1
Onset 96.69 °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)

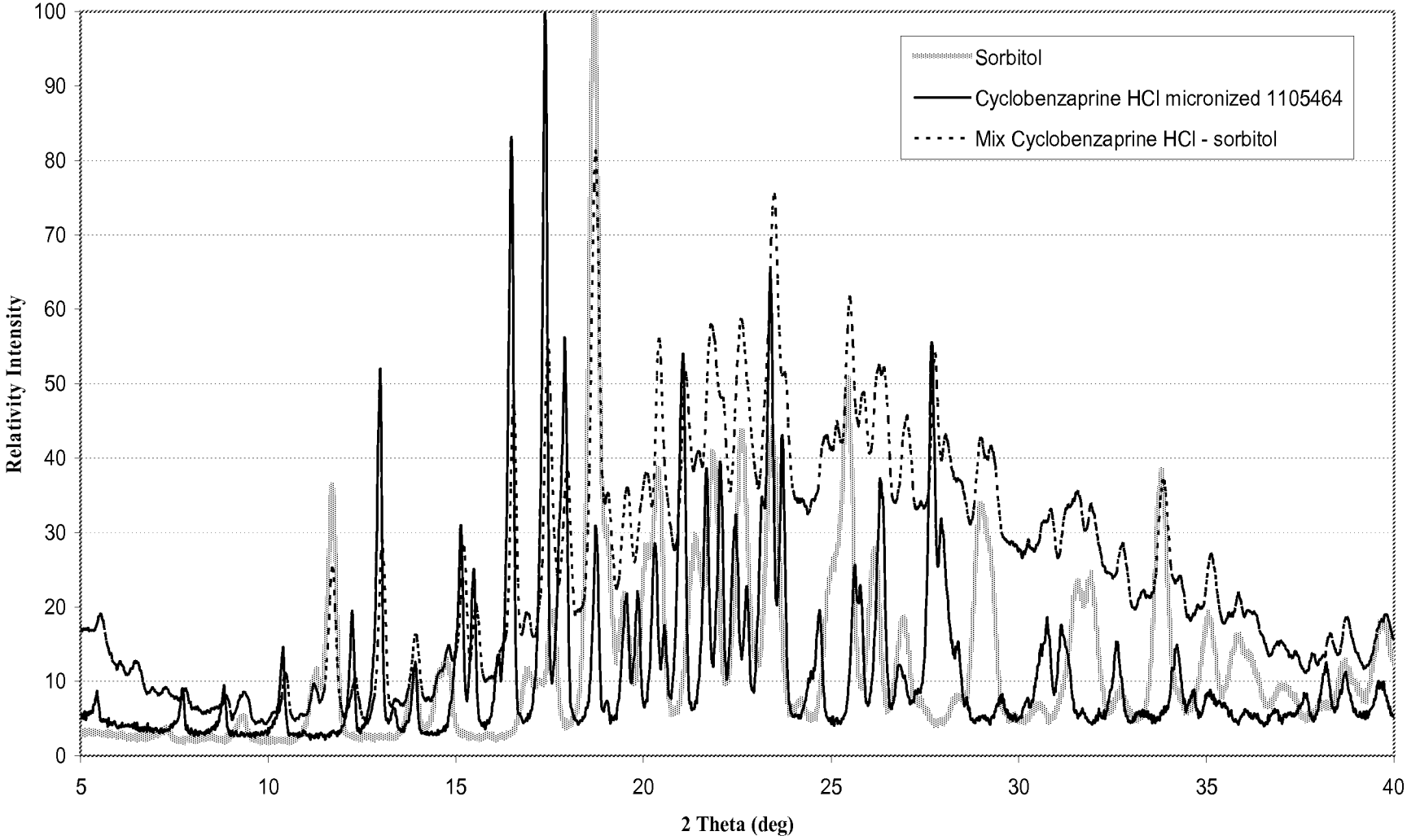



FIG. 35

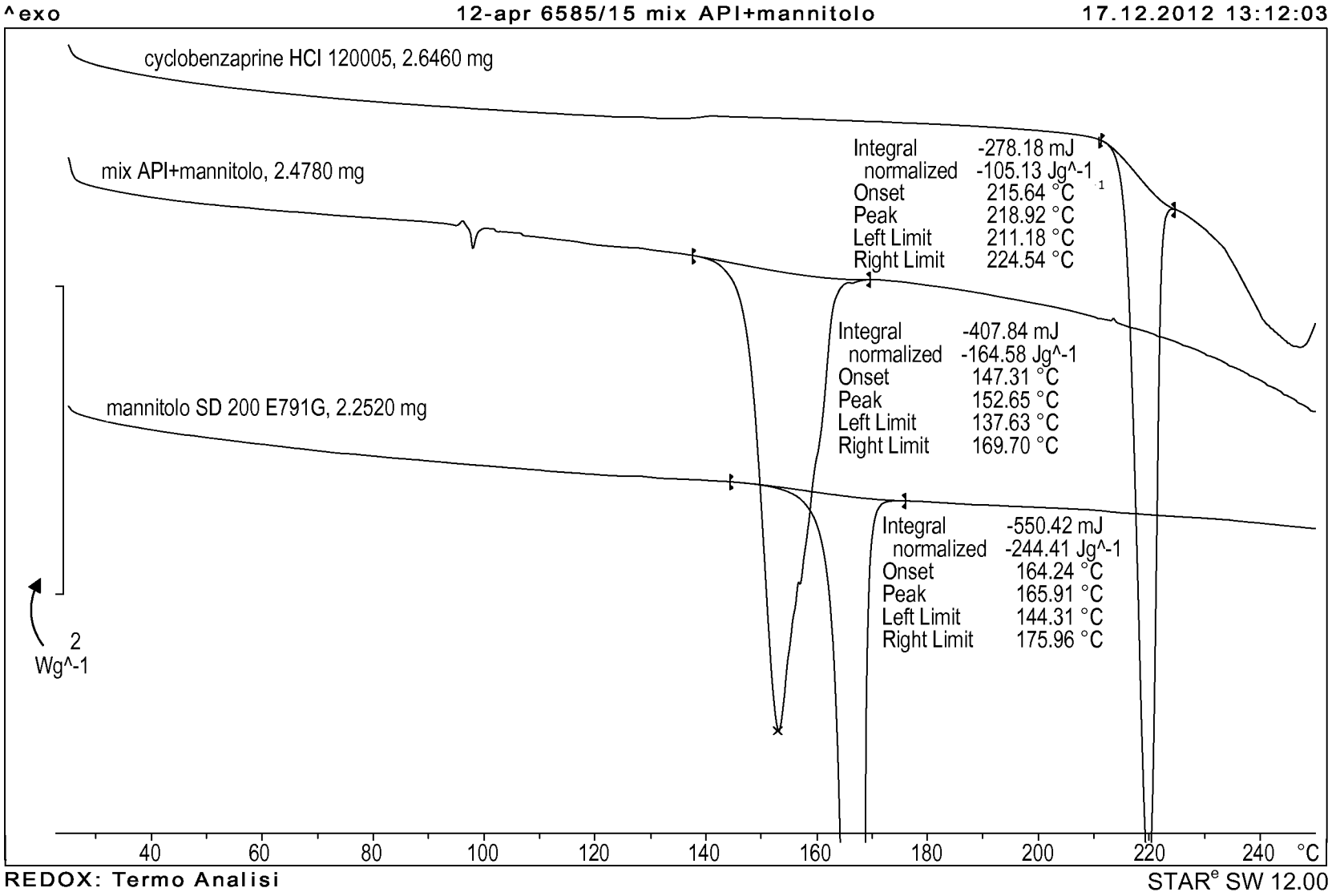

^exo
12-apr 6585/15 mix API+mannitolo
17.12.2012 13:12:03
cyclobenzaprine HCl 120005, 2.6460 mg
mix API+mannitolo, 2.4780 mg
mannitolo SD 200 E791G, 2.2520 mg
Integral -278.18 mJ
normalized -105.13 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 211.18 °C
Right Limit 224.54 °C
Integral -407.84 mJ
normalized -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
STAR^e SW 12.00

FIG. 36

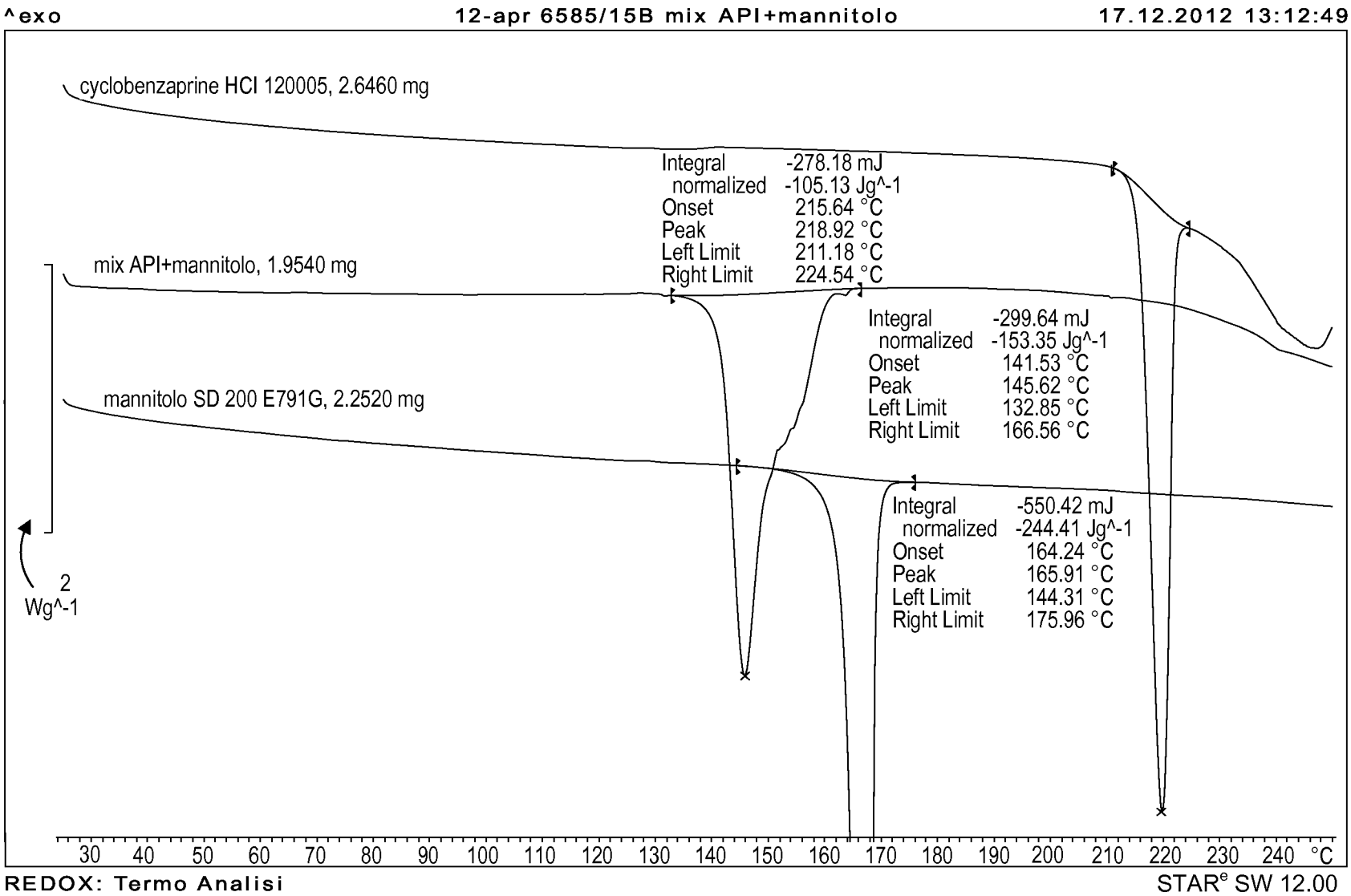

^exo
12-apr 6585/15B mix API+mannitolo
17.12.2012 13:12:49
cyclobenzaprine HCl 120005, 2.6460 mg
Integral -278.18 mJ
normalized -105.13 Jg^-1
Onset 215.64 °C
Peak 218.92 °C
Left Limit 211.18 °C
Right Limit 224.54 °C
mix API+mannitolo, 1.9540 mg
Integral -299.64 mJ
normalized -153.35 Jg^-1
Onset 141.53 °C
Peak 145.62 °C
Left Limit 132.85 °C
Right Limit 166.56 °C
mannitolo SD 200 E791G, 2.2520 mg
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

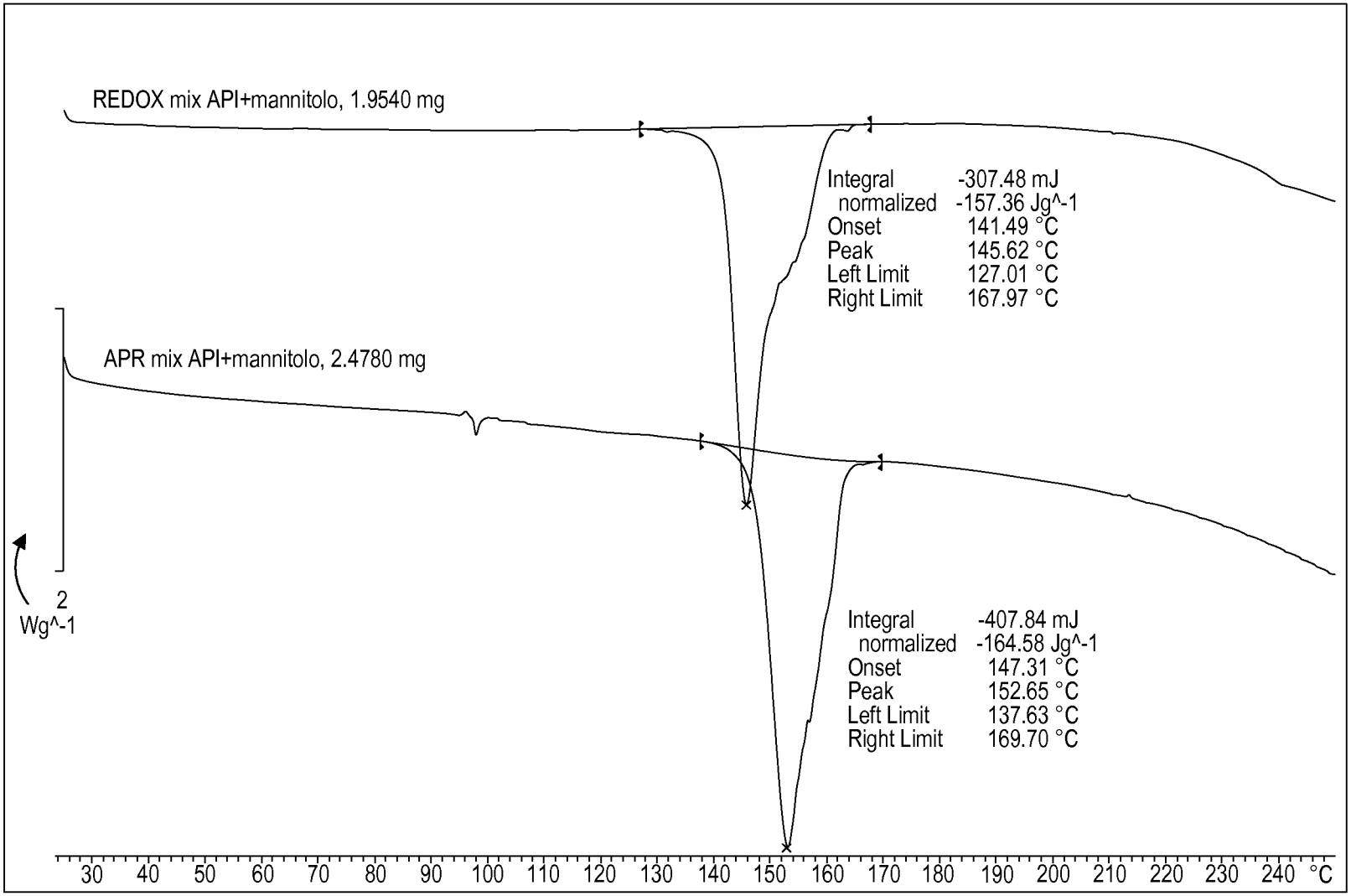

^exo
12-apr 6585/15 mix API+mannitolo CFR
17.12.2012 13:37:02
REDOX mix API+mannitolo, 1.9540 mg
Integral -307.48 mJ
normalized -157.36 Jg^-1
Onset 141.49 °C
Peak 145.62 °C
Left Limit 127.01 °C
Right Limit 167.97 °C
APR mix API+mannitolo, 2.4780 mg
2
Wg^-1
Integral -407.84 mJ
normalized -164.58 Jg^-1
Onset 147.31 °C
Peak 152.65 °C
Left Limit 137.63 °C
Right Limit 169.70 °C
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

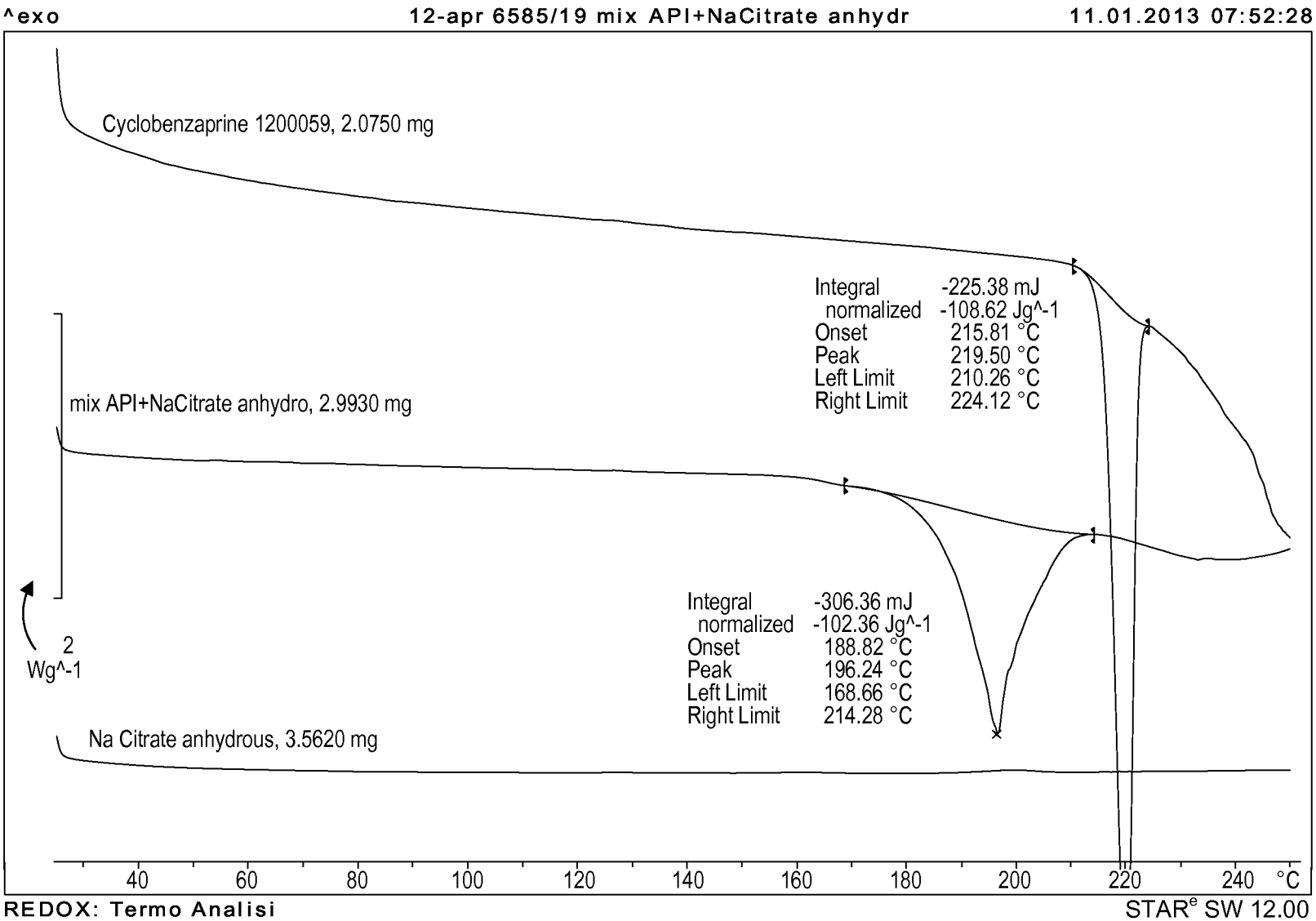

^exo
12-apr 6585/19 mix API+NaCitrate anhydr
11.01.2013 07:52:28
Cyclobenzaprine 1200059, 2.0750 mg
Integral -225.38 mJ
normalized -108.62 Jg^-1
Onset 215.81 °C
Peak 219.50 °C
Left Limit 210.26 °C
Right Limit 224.12 °C
mix API+NaCitrate anhydro, 2.9930 mg
Integral -306.36 mJ
normalized -102.36 Jg^-1
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

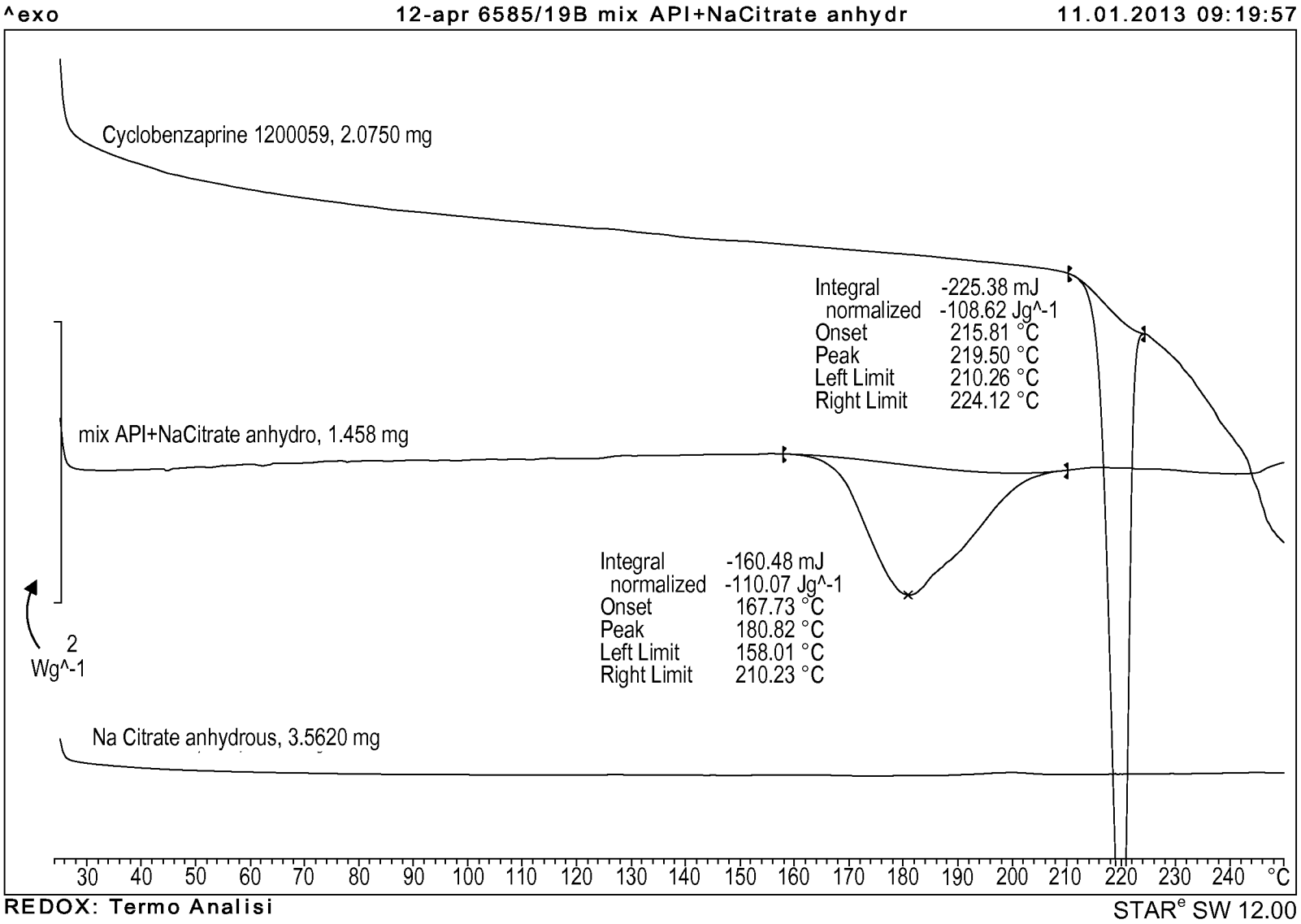

^exo
12-apr 6585/19B mix API+NaCitrate anhydr
11.01.2013 09:19:57
Cyclobenzaprine 1200059, 2.0750 mg
Integral -225.38 mJ
normalized -108.62 Jg^-1
Onset 215.81 °C
Peak 219.50 °C
Left Limit 210.26 °C
Right Limit 224.12 °C
mix API+NaCitrate anhydro, 1.458 mg
Integral -160.48 mJ
normalized -110.07 Jg^-1
Onset 167.73 °C
Peak 180.82 °C
Left Limit 158.01 °C
Right Limit 210.23 °C
2
Wg^-1
Na Citrate anhydrous, 3.5620 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
STAR^e SW 12.00

FIG. 40

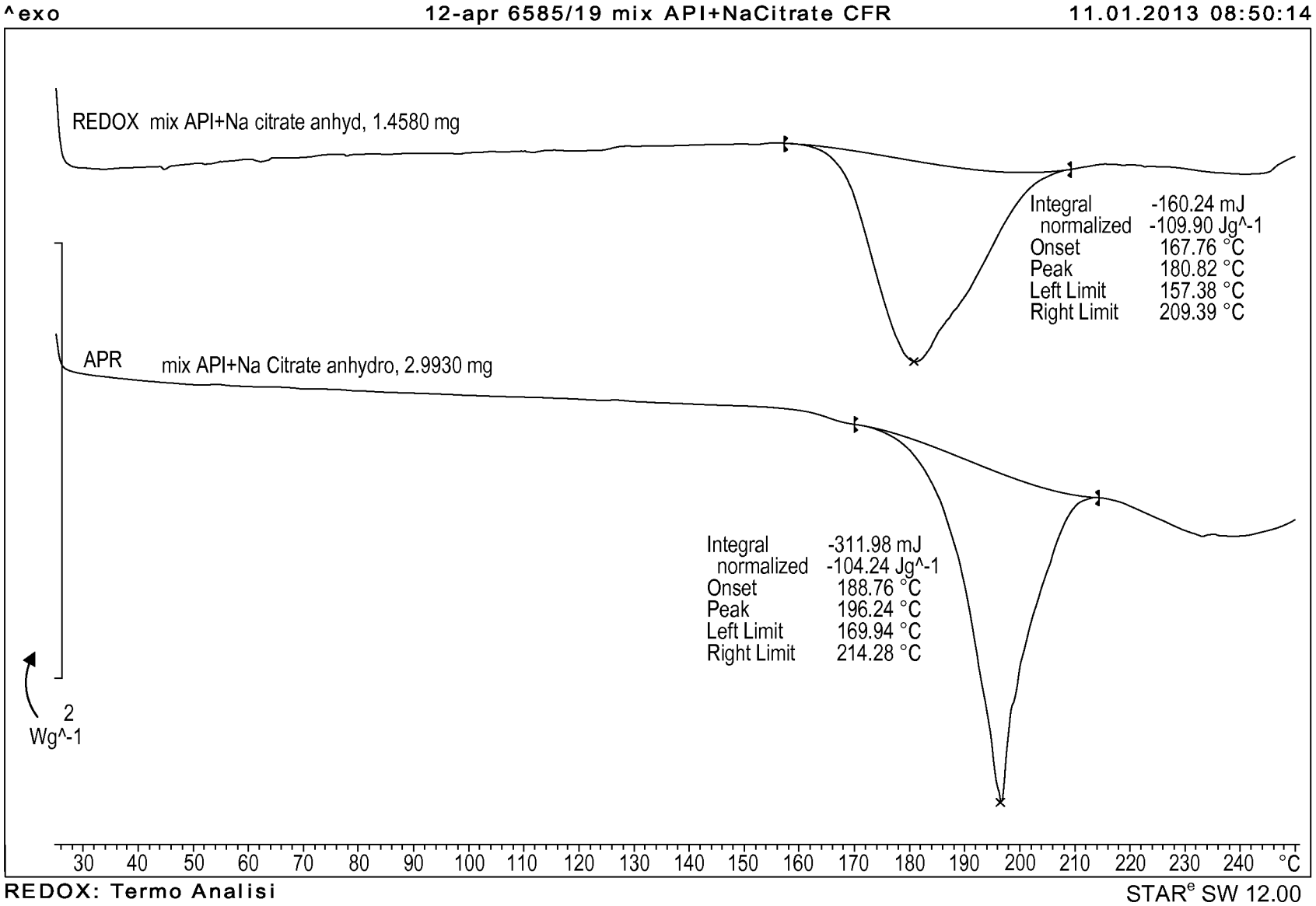

^exo
12-apr 6585/19 mix API+NaCitrate CFR
11.01.2013 08:50:14
REDOX mix API+Na citrate anhyd, 1.4580 mg
Integral -160.24 mJ
normalized -109.90 Jg^-1
Onset 167.76 °C
Peak 180.82 °C
Left Limit 157.38 °C
Right Limit 209.39 °C
APR mix API+Na Citrate anhydro, 2.9930 mg
Integral -311.98 mJ
normalized -104.24 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
STAR^e SW 12.00

FIG. 41

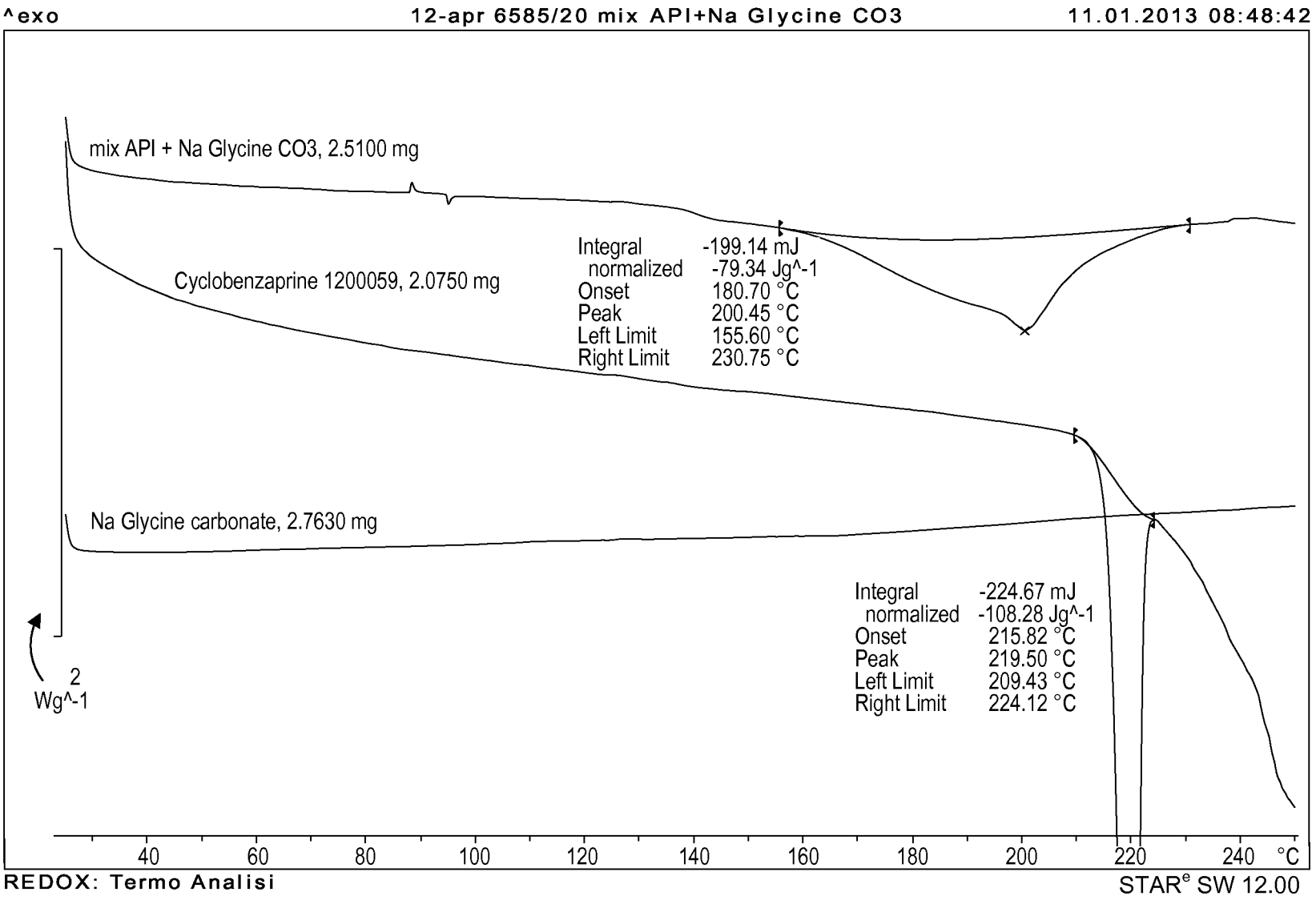

^exo
12-apr 6585/20 mix API+Na Glycine CO3
11.01.2013 08:48:42
mix API + Na Glycine CO3, 2.5100 mg
Cyclobenzaprine 1200059, 2.0750 mg
Integral -199.14 mJ
normalized -79.34 Jg^-1
Onset 180.70 °C
Peak 200.45 °C
Left Limit 155.60 °C
Right Limit 230.75 °C
Na Glycine carbonate, 2.7630 mg
Integral -224.67 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
STAR^e SW 12.00

FIG. 42

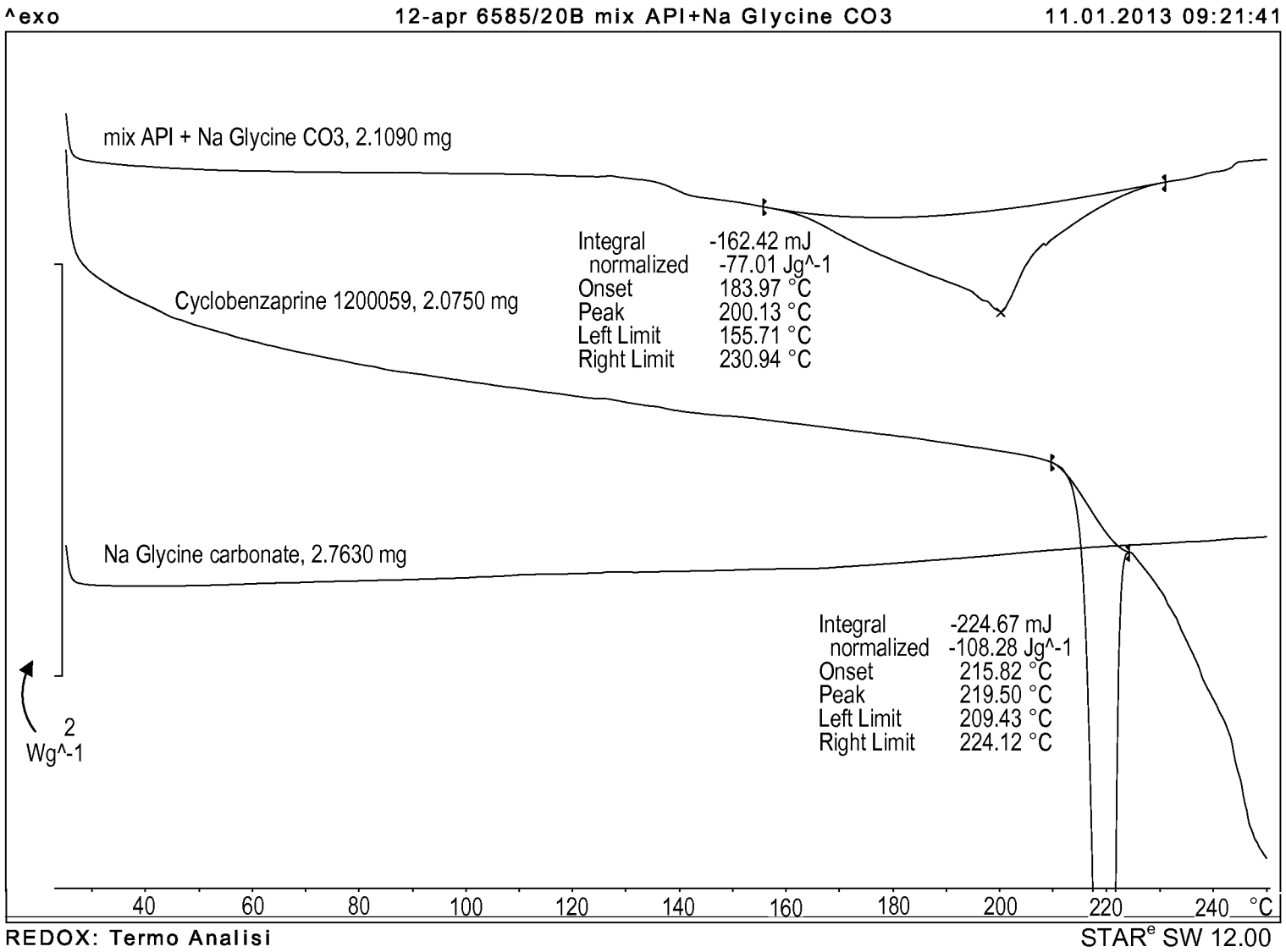

^exo
12-apr 6585/20B mix API+Na Glycine CO3
11.01.2013 09:21:41
mix API + Na Glycine CO3, 2.1090 mg
Integral -162.42 mJ
normalized -77.01 Jg^-1
Onset 183.97 °C
Peak 200.13 °C
Left Limit 155.71 °C
Right Limit 230.94 °C
Cyclobenzaprine 1200059, 2.0750 mg
Na Glycine carbonate, 2.7630 mg
Integral -224.67 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
STAR^e SW 12.00

FIG. 43

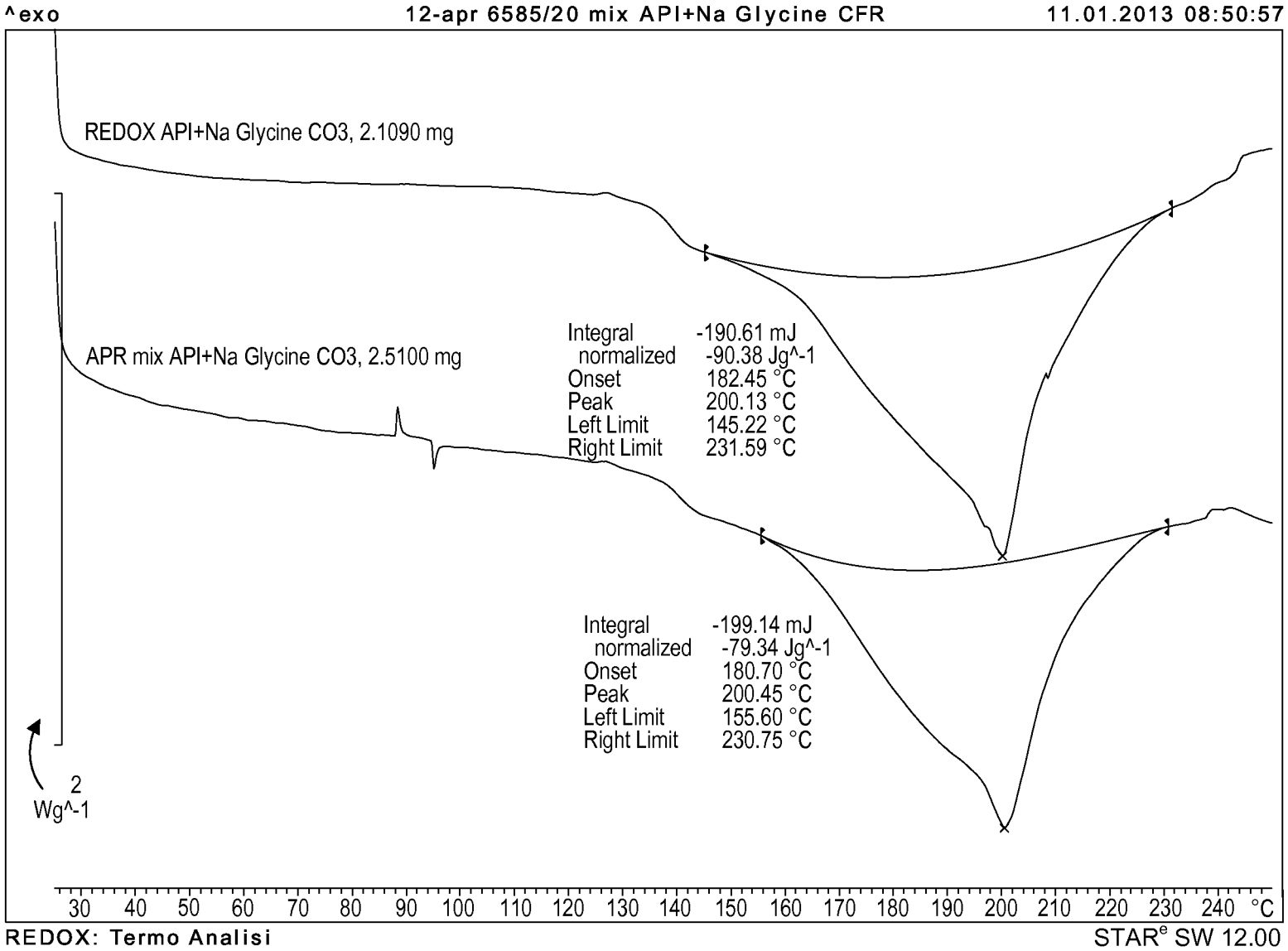

^exo
12-apr 6585/20 mix API+Na Glycine CFR
11.01.2013 08:50:57
REDOX API+Na Glycine CO3, 2.1090 mg
APR mix API+Na Glycine CO3, 2.5100 mg
Integral -190.61 mJ
normalized -90.38 Jg^-1
Onset 182.45 °C
Peak 200.13 °C
Left Limit 145.22 °C
Right Limit 231.59 °C
Integral -199.14 mJ
normalized -79.34 Jg^-1
Onset 180.70 °C
Peak 200.45 °C
Left Limit 155.60 °C
Right Limit 230.75 °C
2
Wg^-1
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. 44

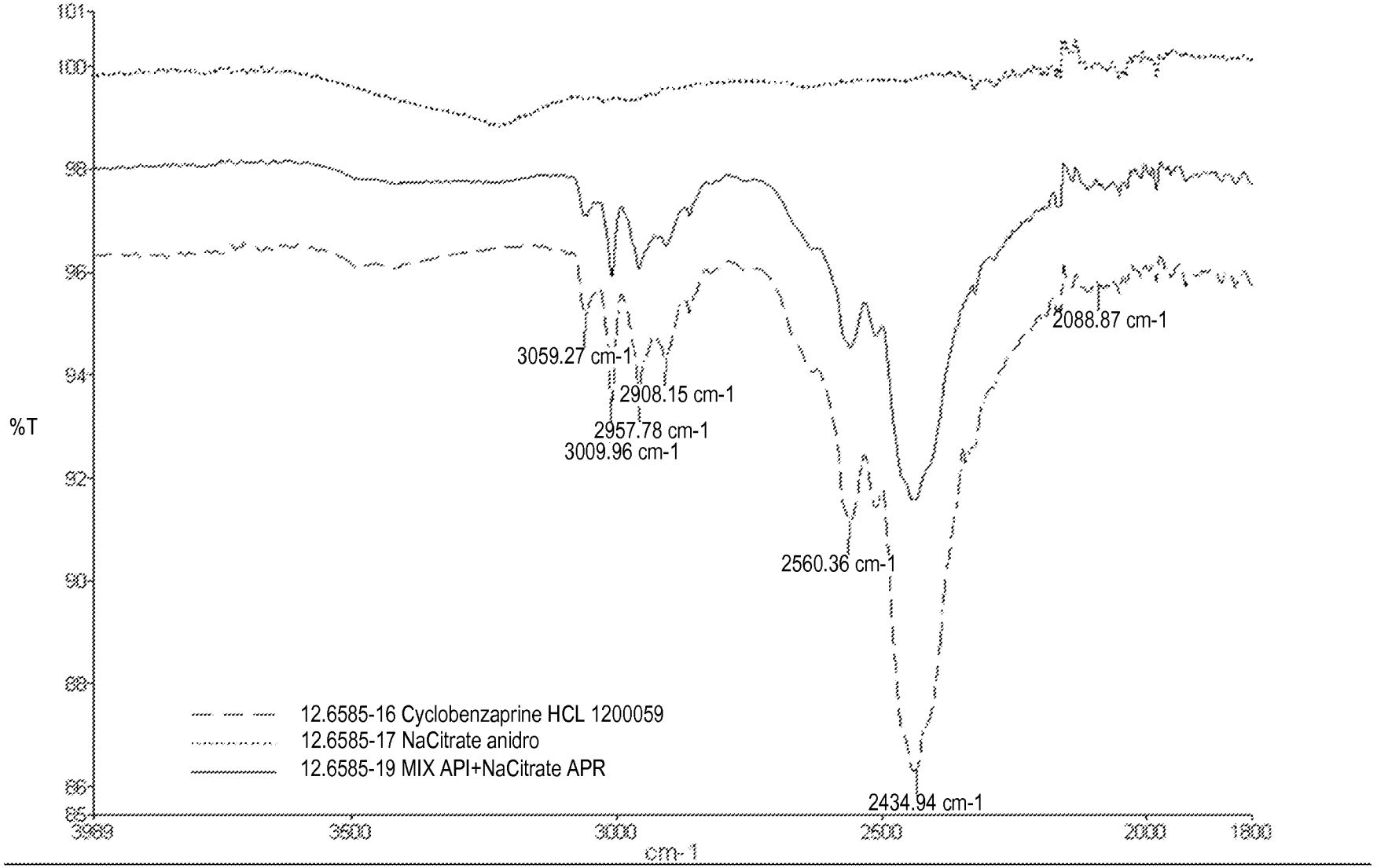

101
100
98
96
94
92
90
88
86
85
%T
3059.27 cm-1
2908.15 cm-1
2957.78 cm-1
3009.96 cm-1
2560.36 cm-1
2088.87 cm-1
2434.94 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-17 NaCitrate anidro
12.6585-19 MIX API+NaCitrate APR
3500
3000
2500
2000
1800
cm-1

FIG. 45

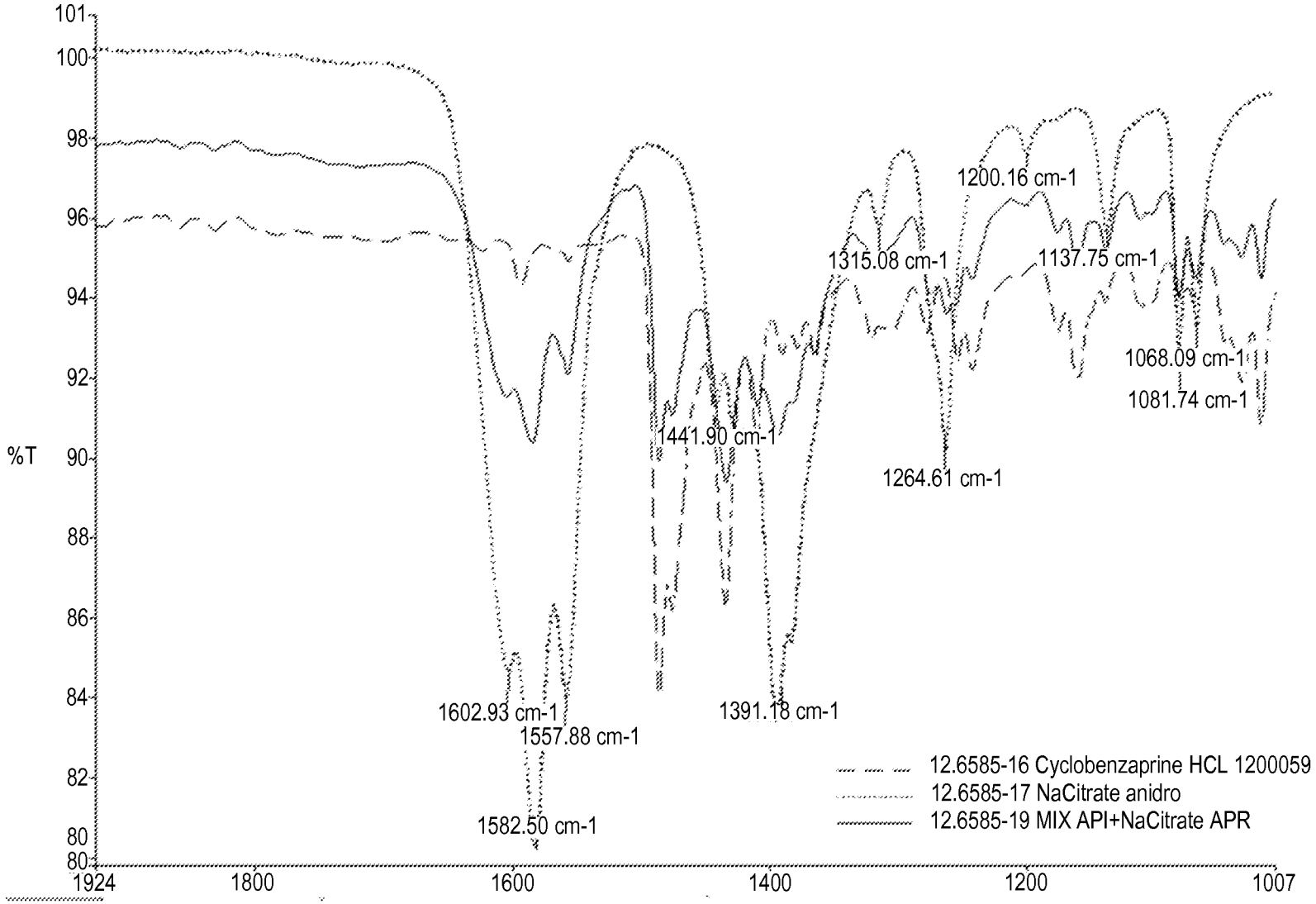

101
100
98
96
94
92
90
88
86
84
82
80
80
%T
1924
1800
1600
1400
1200
1007
1200.16 cm-1
1315.08 cm-1
1137.75 cm-1
1068.09 cm-1
1081.74 cm-1
1441.90 cm-1
1264.61 cm-1
1602.93 cm-1
1557.88 cm-1
1391.18 cm-1
1582.50 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-17 NaCitrate anidro
12.6585-19 MIX API+NaCitrate APR

FIG. 46

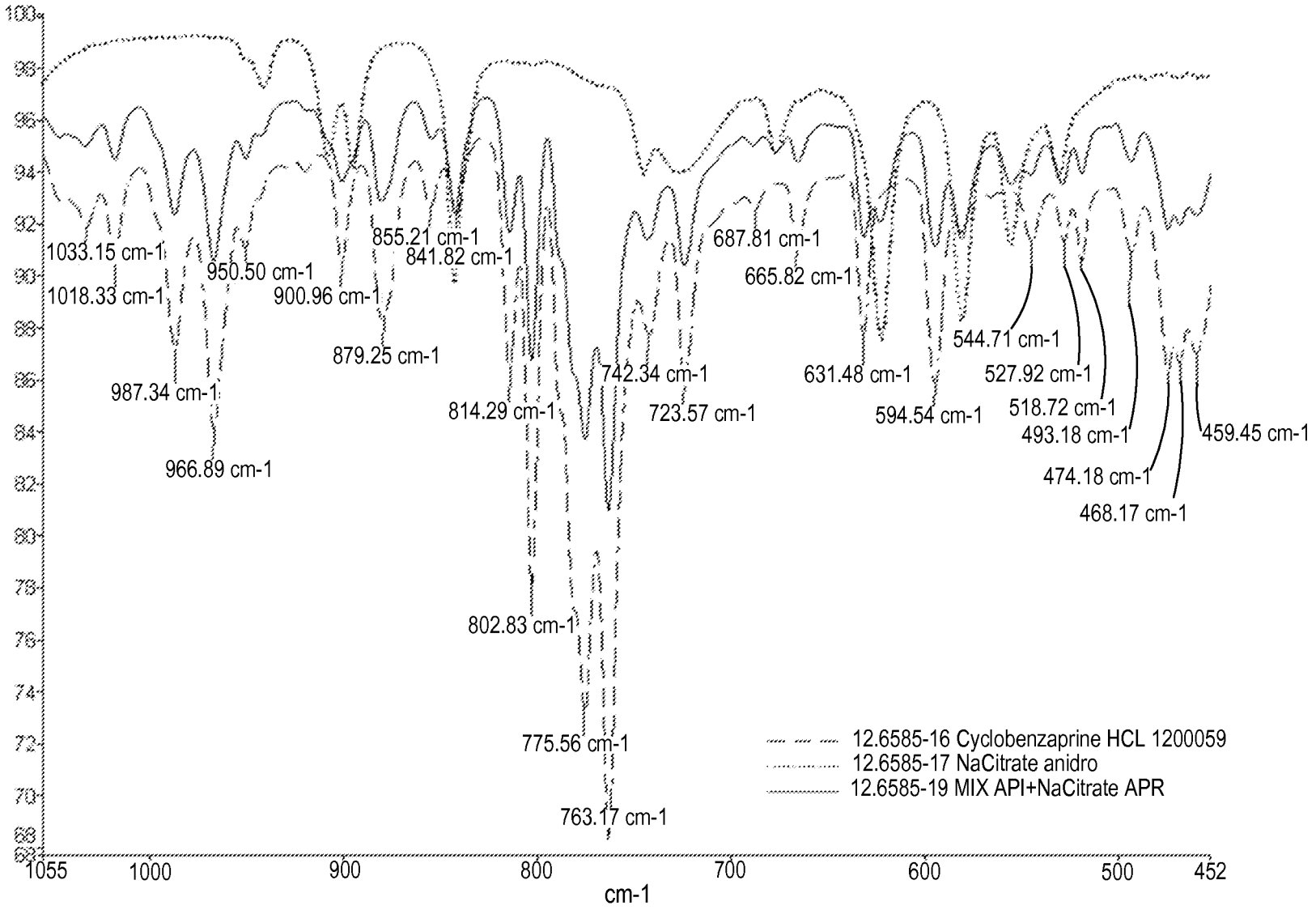

1033.15 cm-1
1018.33 cm-1
950.50 cm-1
987.34 cm-1
966.89 cm-1
900.96 cm-1
879.25 cm-1
855.21 cm-1
841.82 cm-1
814.29 cm-1
802.83 cm-1
775.56 cm-1
763.17 cm-1
742.34 cm-1
723.57 cm-1
687.81 cm-1
665.82 cm-1
631.48 cm-1
594.54 cm-1
544.71 cm-1
527.92 cm-1
518.72 cm-1
493.18 cm-1
474.18 cm-1
468.17 cm-1
459.45 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-17 NaCitrate anidro
12.6585-19 MIX API+NaCitrate APR
100
98
96
94
92
90
88
86
84
82
80
78
76
74
72
70
68
66
1055
1000
900
800
700
600
500
452
cm-1

FIG. 47

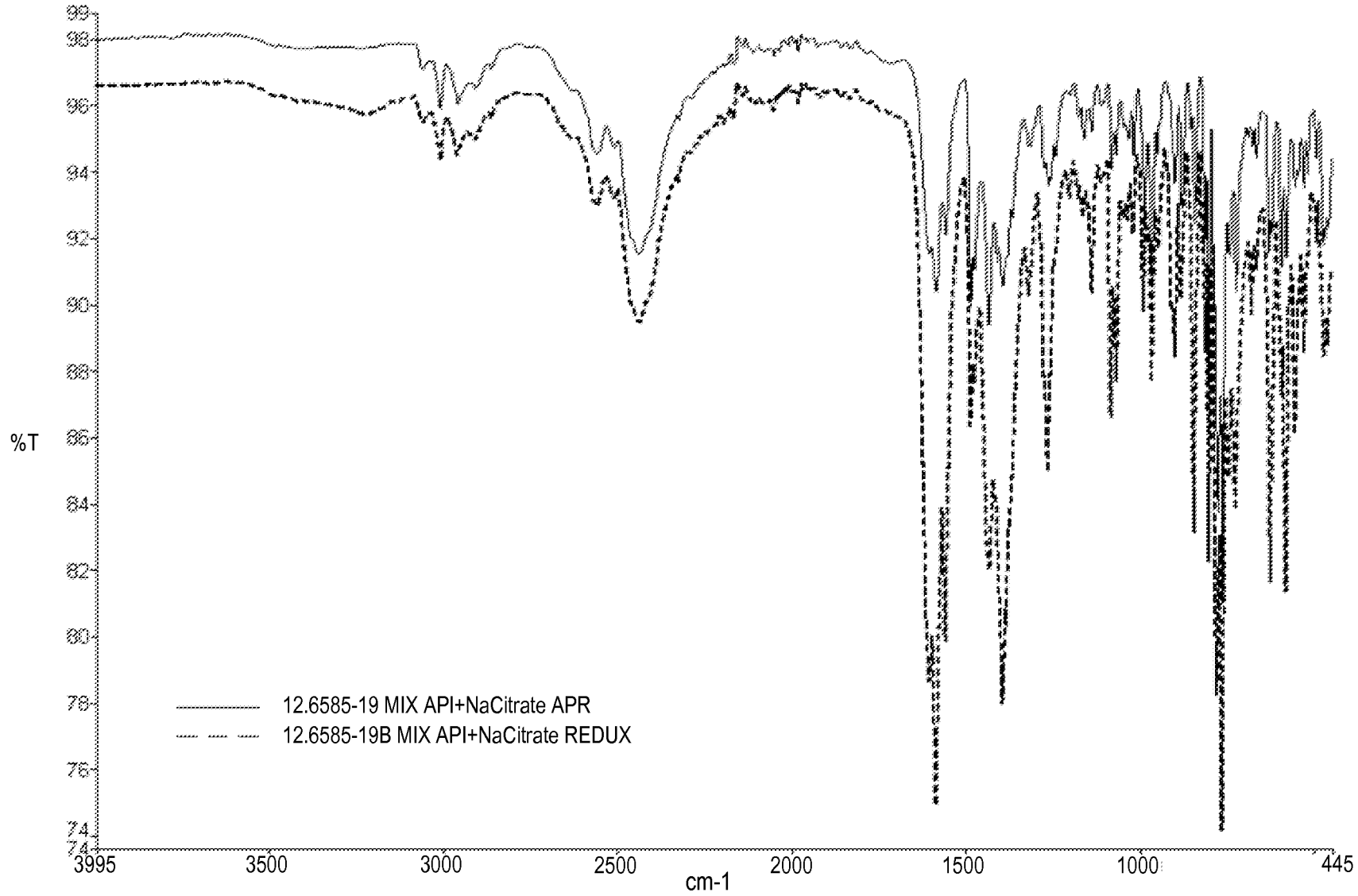

%T
98
96
94
92
90
88
86
84
82
80
78
76
74
74
3995
3500
3000
2500
2000
1500
1000
445
cm-1
12.6585-19 MIX API+NaCitrate APR
12.6585-19B MIX API+NaCitrate REDUX

FIG. 48

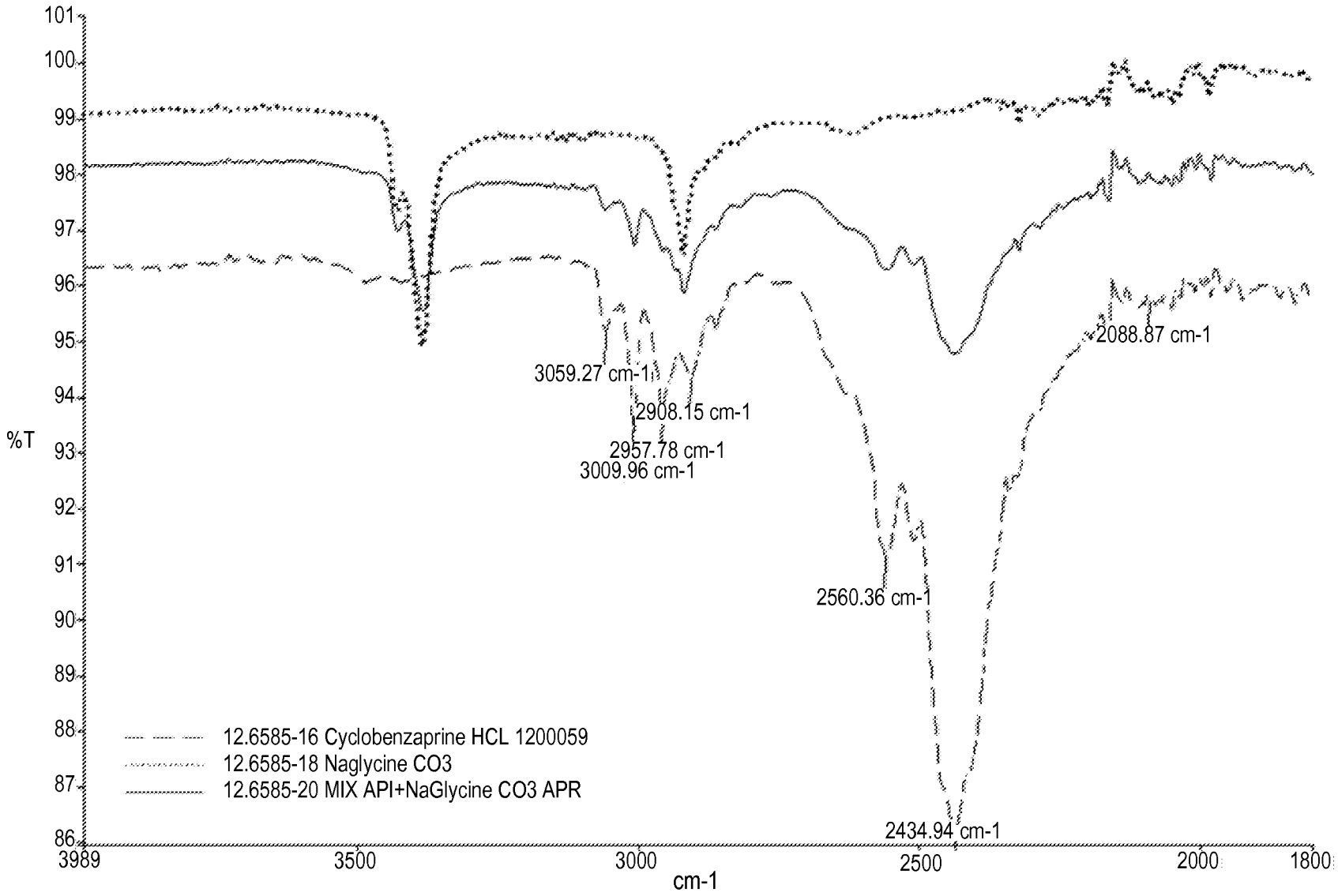

101
100
99
98
97
96
95
94
93
92
91
90
89
88
87
86
%T
3989
3500
3000
2500
2000
1800
cm-1
3059.27 cm-1
2908.15 cm-1
2957.78 cm-1
3009.96 cm-1
2560.36 cm-1
2088.87 cm-1
2434.94 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-18 Naglycine CO3
12.6585-20 MIX API+NaGlycine CO3 APR

FIG. 49

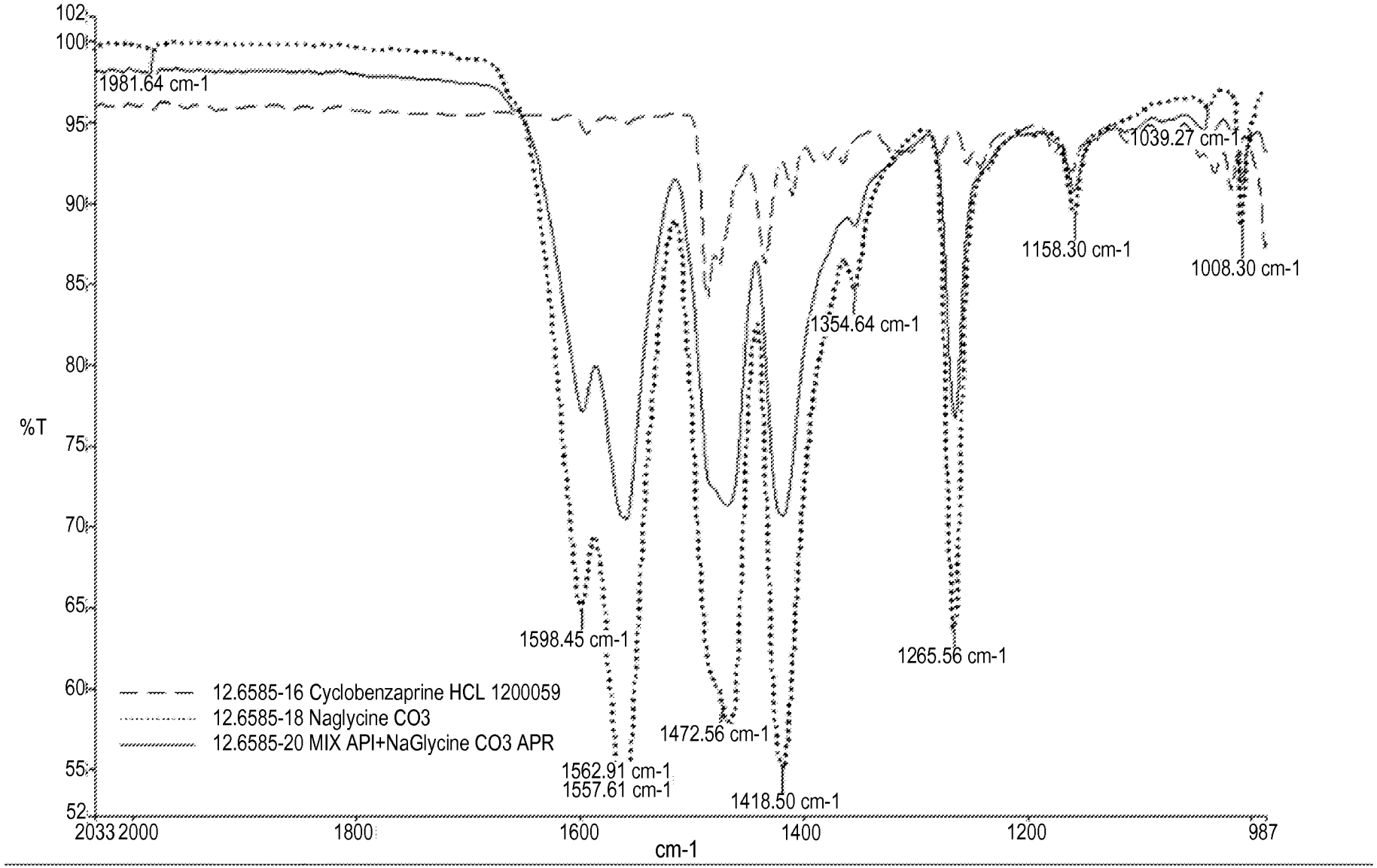

102
100
95
90
85
80
75
70
65
60
55
52
%T
2033 2000
1800
1600
1400
1200
987
cm-1
1981.64 cm-1
1598.45 cm-1
1562.91 cm-1
1557.61 cm-1
1472.56 cm-1
1418.50 cm-1
1354.64 cm-1
1265.56 cm-1
1158.30 cm-1
1039.27 cm-1
1008.30 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-18 Naglycine CO3
12.6585-20 MIX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

FIG. 50

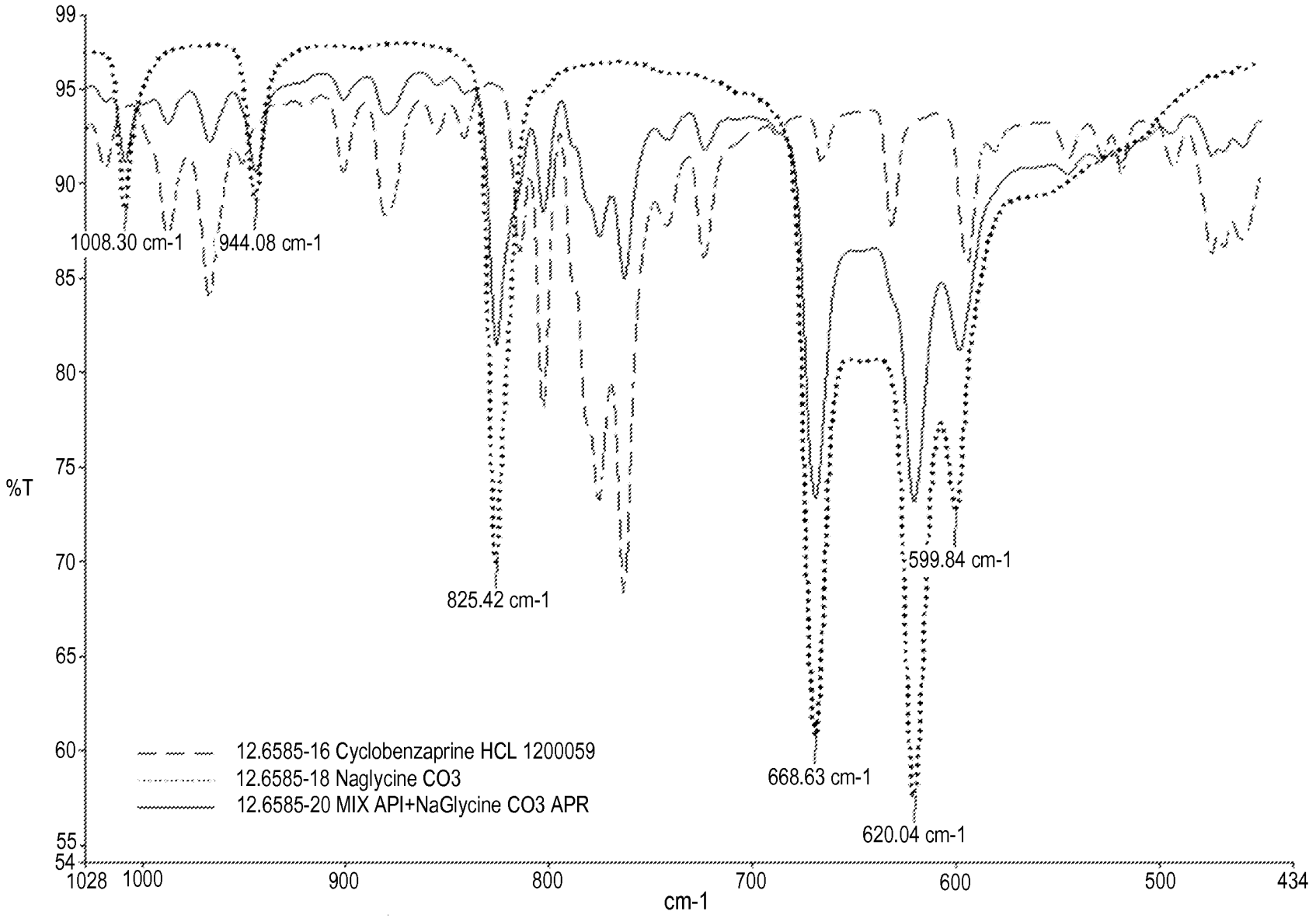

99
95
90
85
80
75
70
65
60
55
54
%T
1008.30 cm-1
944.08 cm-1
825.42 cm-1
668.63 cm-1
620.04 cm-1
599.84 cm-1
12.6585-16 Cyclobenzaprine HCL 1200059
12.6585-18 Naglycine CO3
12.6585-20 MIX API+NaGlycine CO3 APR
1028
1000
900
800
700
600
500
434
cm-1

FIG. 51

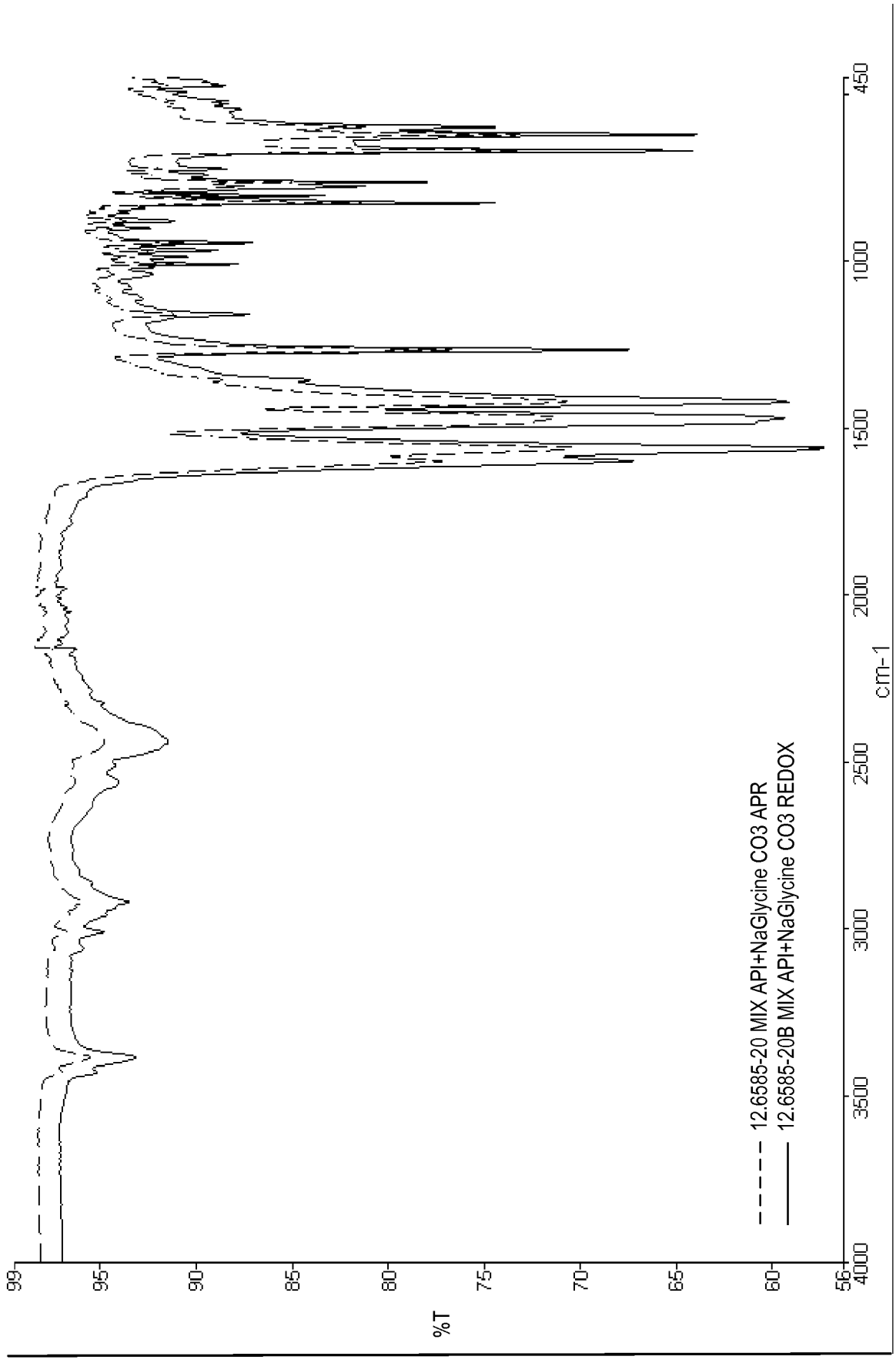

99
95
90
85
80
75
70
65
60
56
%T
4000
3500
3000
2500
2000
1500
1000
450
cm-1
12.6585-20 MIX API+NaGlycine CO3 APR
12.6585-20B MIX API+NaGlycine CO3 REDOX

FIG. 52

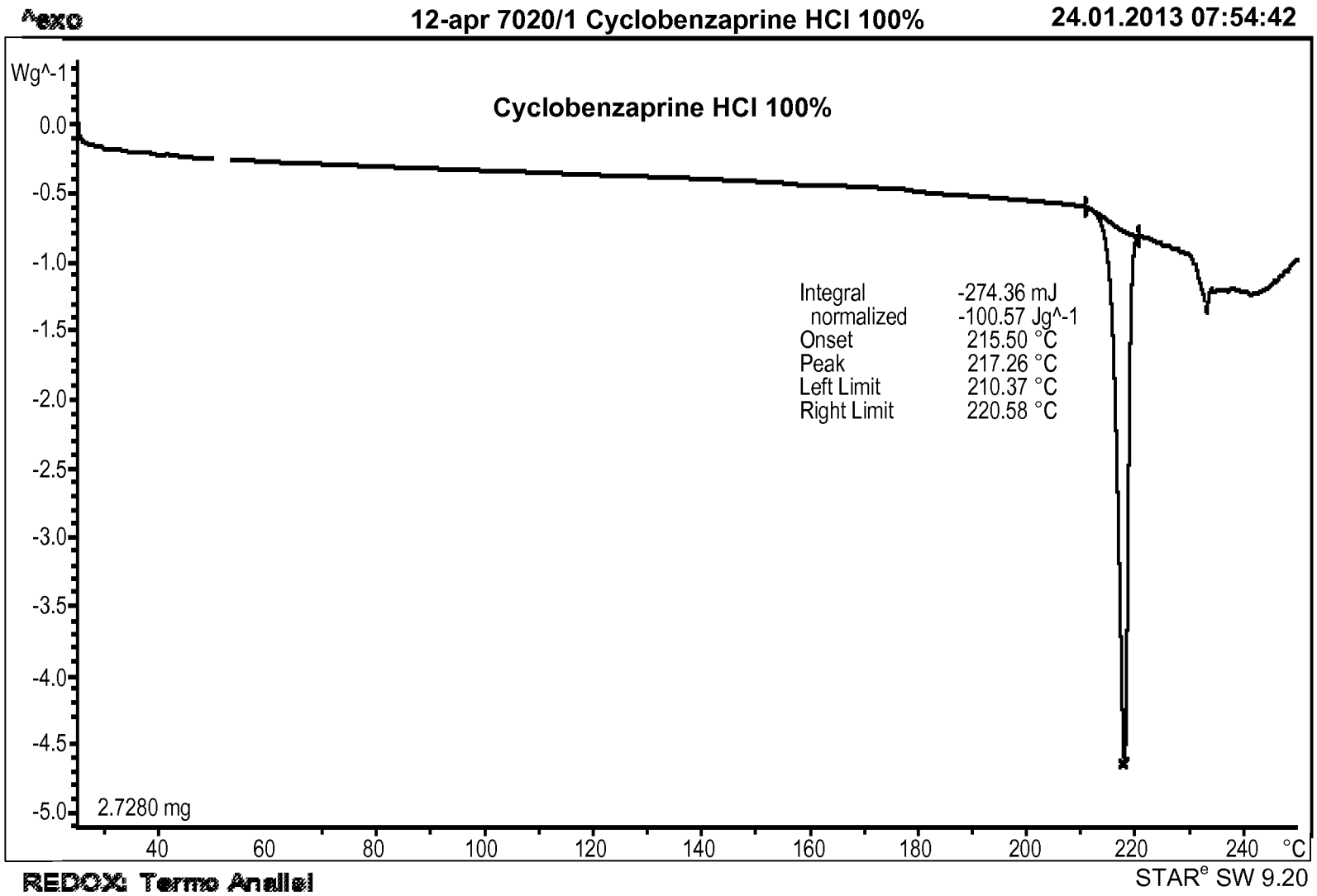

^exo
12-apr 7020/1 Cyclobenzaprine HCl 100%
24.01.2013 07:54:42
Wg^-1
Cyclobenzaprine HCl 100%
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
-4.5
-5.0
Integral -274.36 mJ
normalized -100.57 Jg^-1
Onset 215.50 °C
Peak 217.26 °C
Left Limit 210.37 °C
Right Limit 220.58 °C
2.7280 mg
40
60
80
100
120
140
160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

FIG. 53

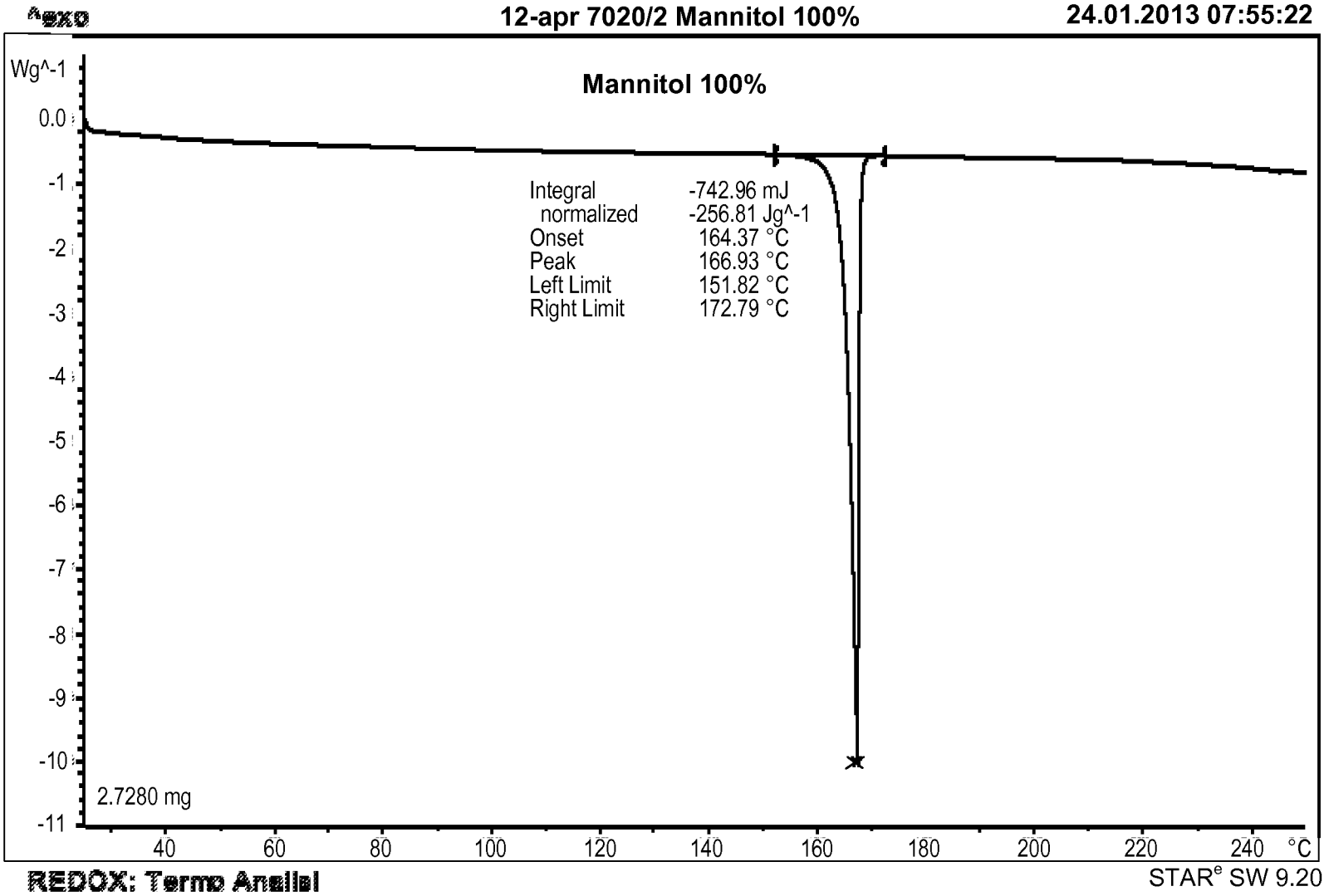

^exo
12-apr 7020/2 Mannitol 100%
24.01.2013 07:55:22
Mannitol 100%
Wg^-1
0.0
-1
-2
-3
-4
-5
-6
-7
-8
-9
-10
-11
Integral -742.96 mJ
normalized -256.81 Jg^-1
Onset 164.37 °C
Peak 166.93 °C
Left Limit 151.82 °C
Right Limit 172.79 °C
2.7280 mg
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi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

FIG. 54

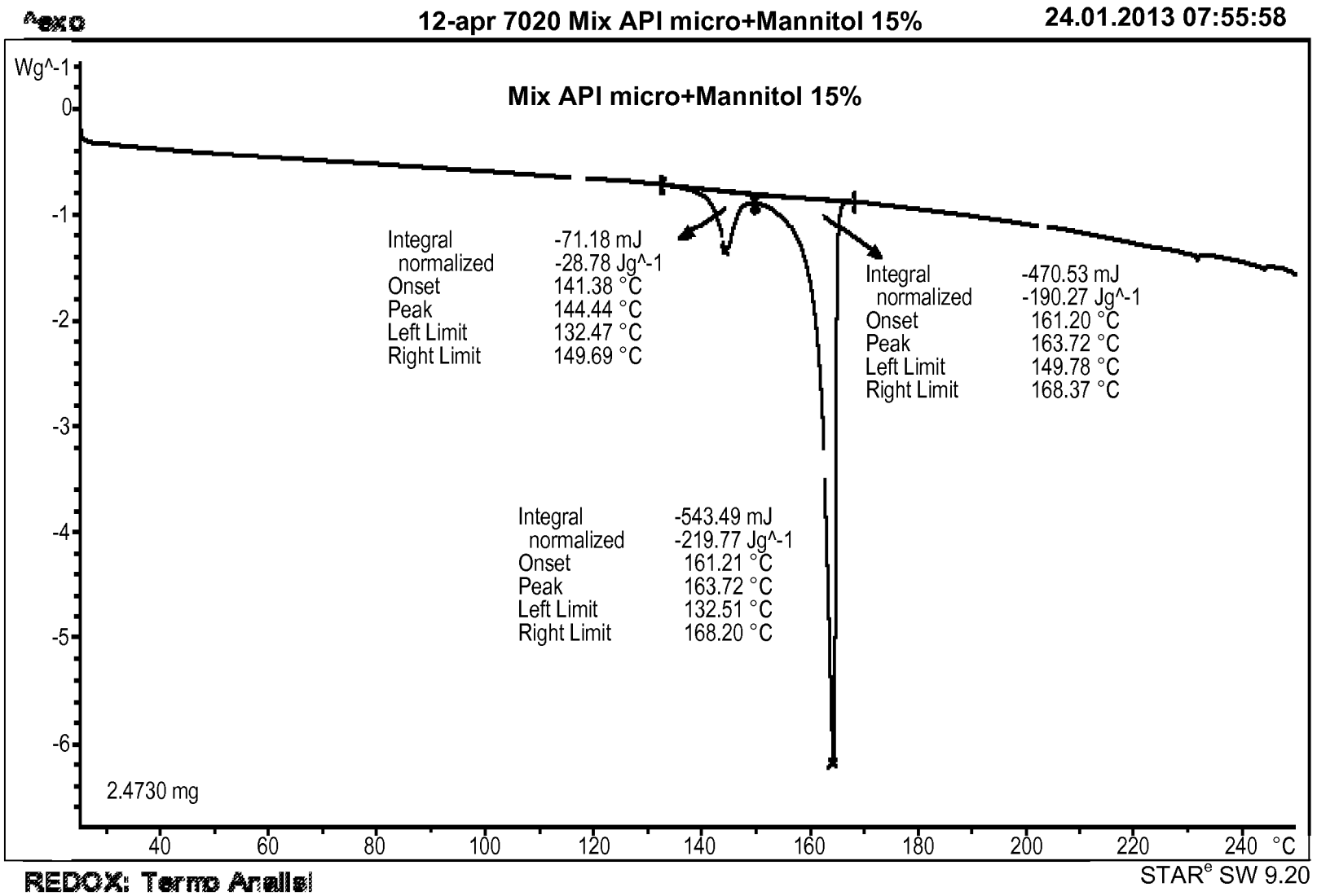

^exo
12-apr 7020 Mix API micro+Mannitol 15%
24.01.2013 07:55:58
Wg^-1
Mix API micro+Mannitol 15%
Integral -71.18 mJ
normalized -28.78 Jg^-1
Onset 141.38 °C
Peak 144.44 °C
Left Limit 132.47 °C
Right Limit 149.69 °C
Integral -470.53 mJ
normalized -190.27 Jg^-1
Onset 161.20 °C
Peak 163.72 °C
Left Limit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

FIG. 55

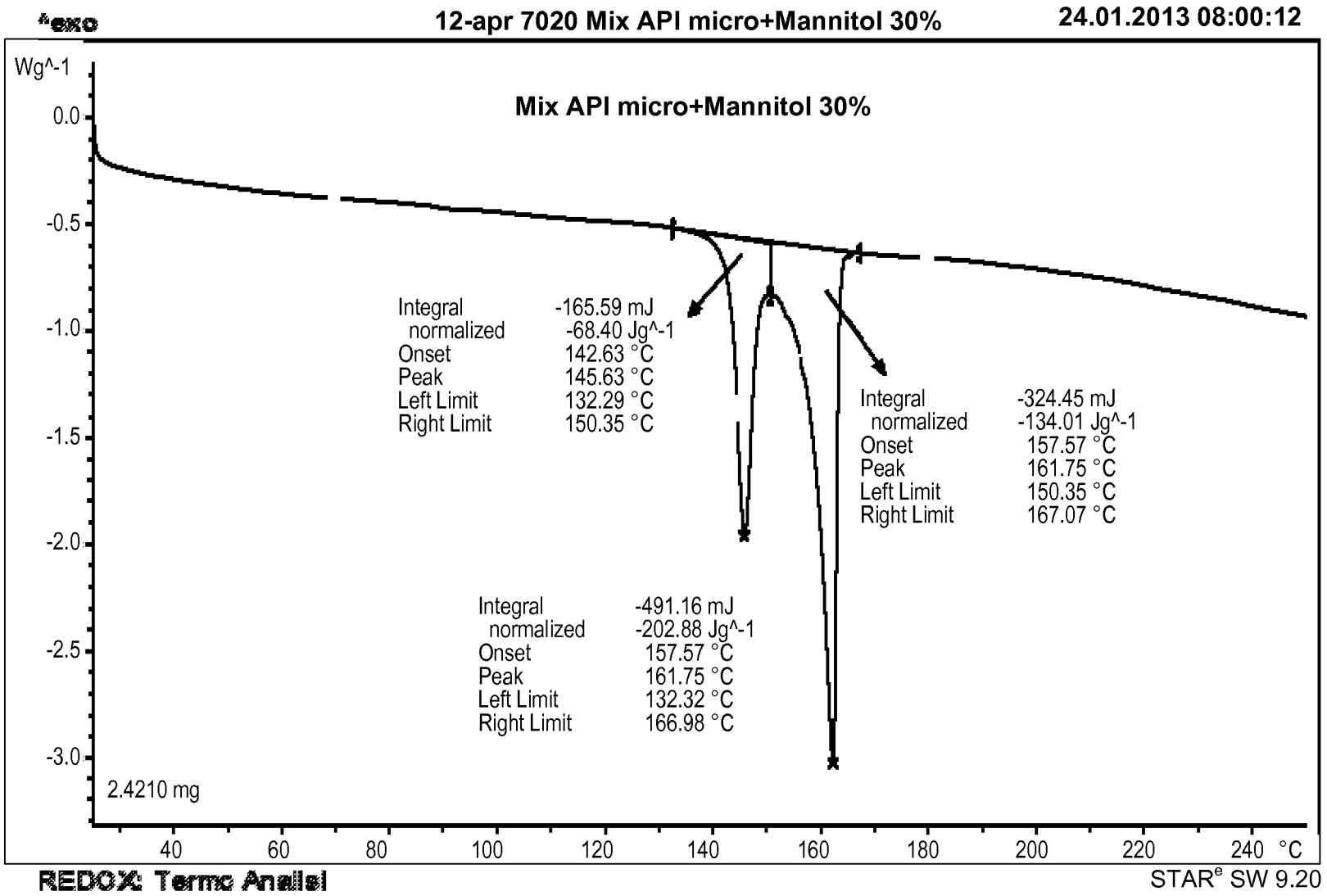

^exo
12-apr 7020 Mix API micro+Mannitol 30%
24.01.2013 08:00:12
Wg^-1
Mix API micro+Mannitol 30%
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
Integral -165.59 mJ
normalized -68.40 Jg^-1
Onset 142.63 °C
Peak 145.63 °C
Left Limit 132.29 °C
Right Limit 150.35 °C
Integral -324.45 mJ
normalized -134.01 Jg^-1
Onset 157.57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

FIG. 56

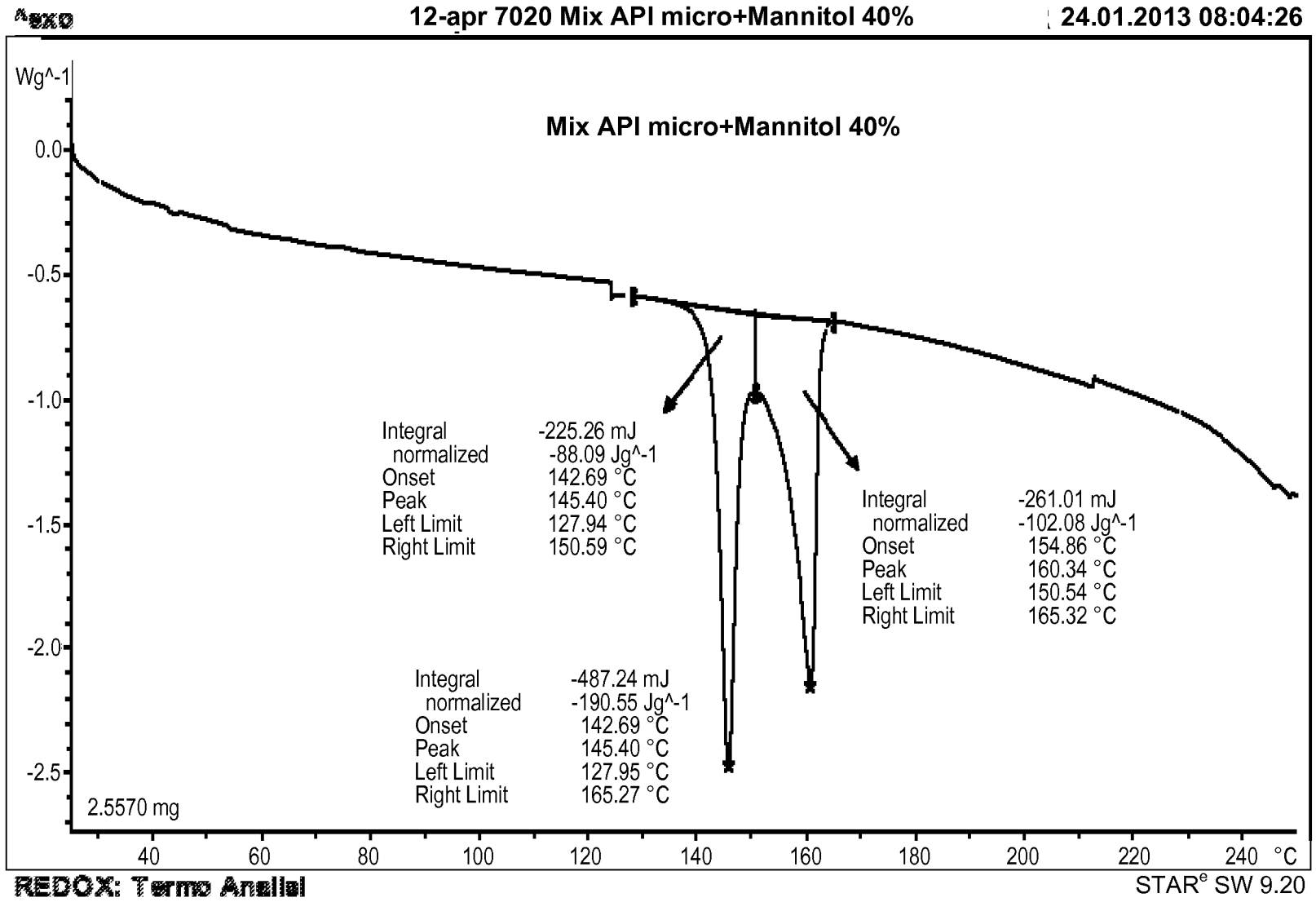

EXO
12-apr 7020 Mix API micro+Mannitol 40%
24.01.2013 08:04:26
Wg^-1
Mix API micro+Mannitol 40%
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
Integral -225.26 mJ
normalized -88.09 Jg^-1
Onset 142.69 °C
Peak 145.40 °C
Left Limit 127.94 °C
Right Limit 150.59 °C
Integral -261.01 mJ
normalized -102.08 Jg^-1
Onset 154.86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

FIG. 57

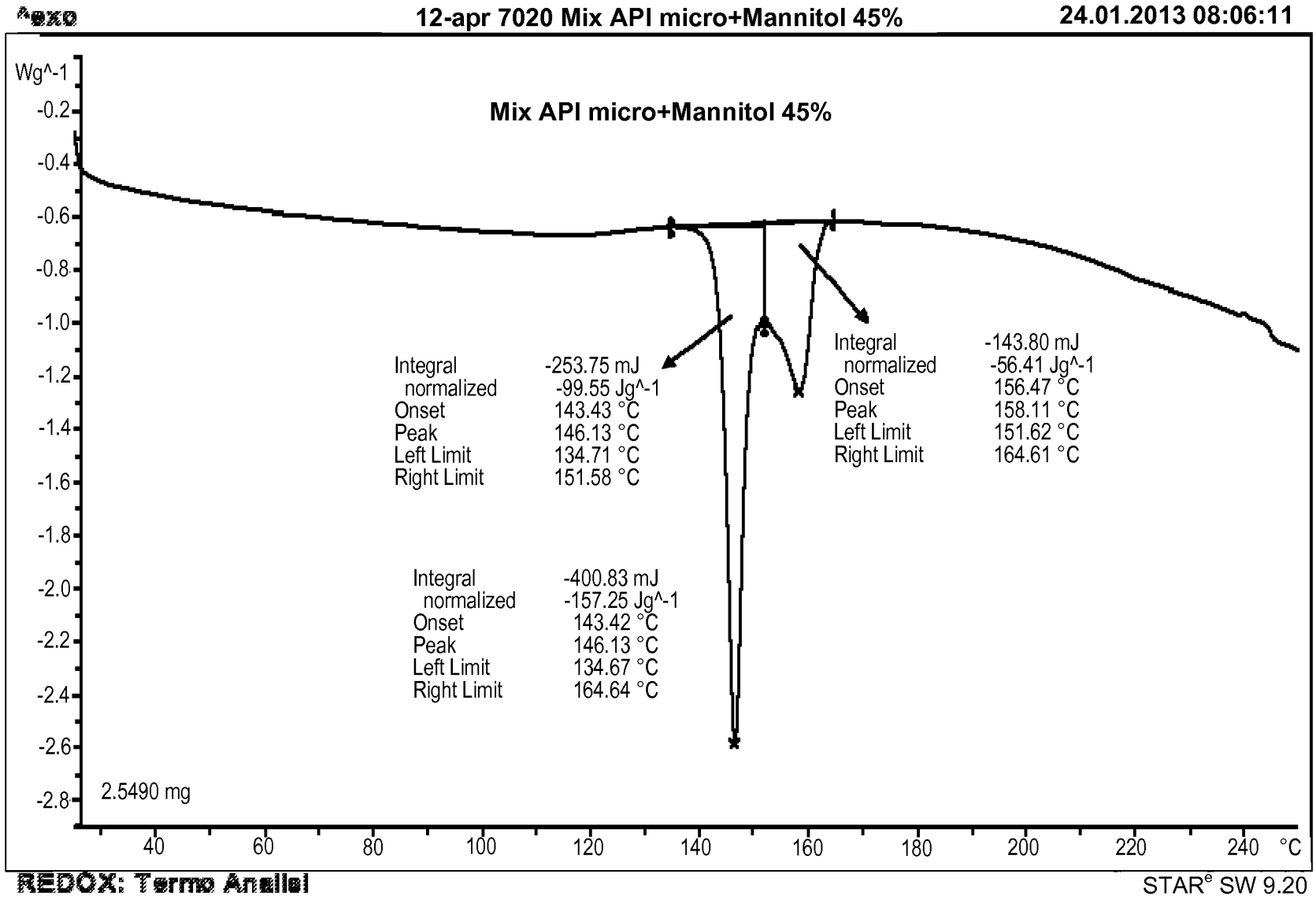

^exo
12-apr 7020 Mix API micro+Mannitol 45%
24.01.2013 08:06:11
Wg^-1
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
-2.0
-2.2
-2.4
-2.6
-2.8
Mix API micro+Mannitol 45%
Integral -253.75 mJ
normalized -99.55 Jg^-1
Onset 143.43 °C
Peak 146.13 °C
Left Limit 134.71 °C
Right Limit 151.58 °C
Integral -143.80 mJ
normalized -56.41 Jg^-1
Onset 156.47 °C
Peak 158.11 °C
Left Limit 151.62 °C
Right Limit 164.61 °C
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
2.5490 mg
40
60
80
100
120
140
160
180
200
220
240
°C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 58

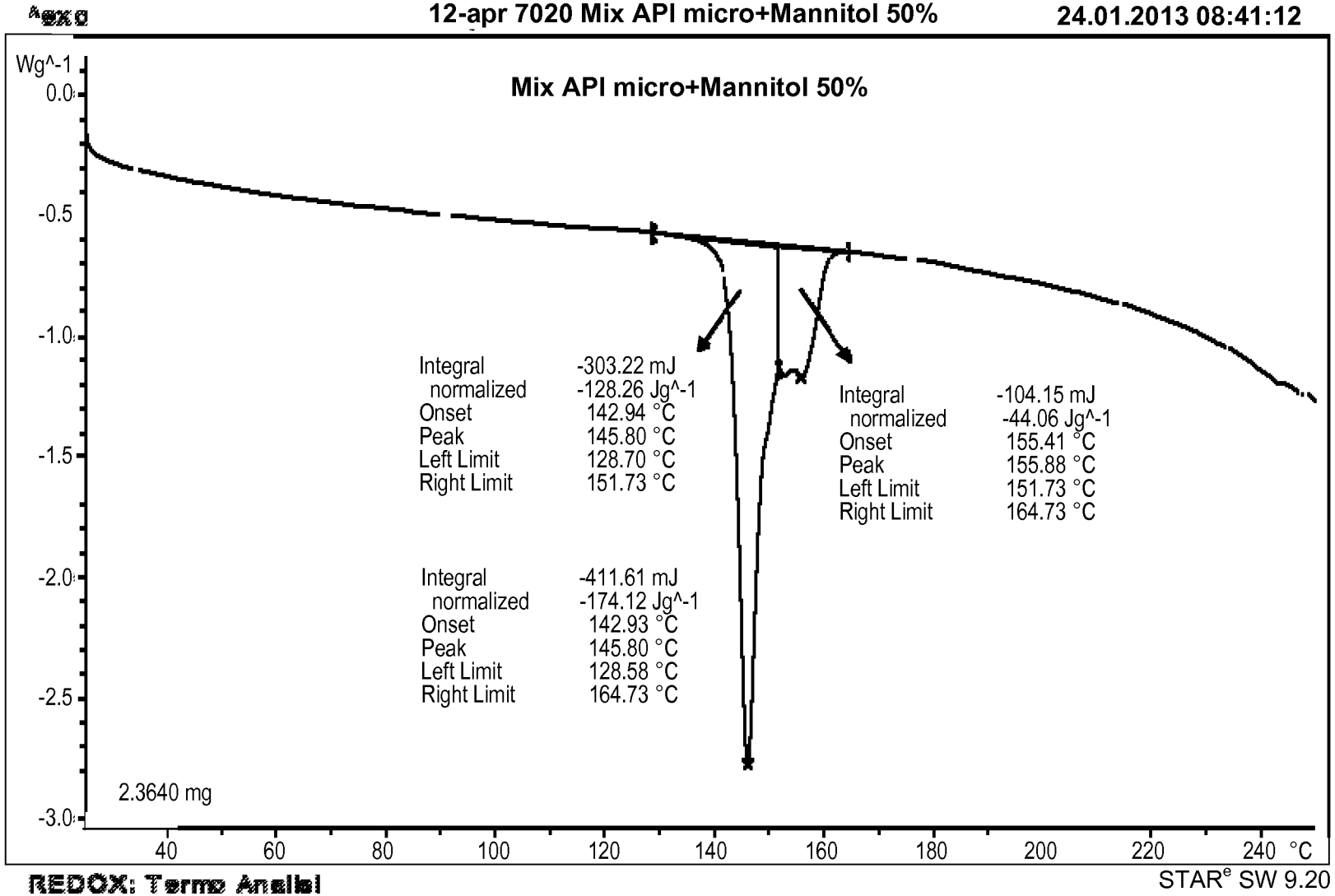

12-apr 7020 Mix API micro+Mannitol 50%
24.01.2013 08:41:12
Mix API micro+Mannitol 50%
Wg^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
Integral -303.22 mJ
normalized -128.26 Jg^-1
Onset 142.94 °C
Peak 145.80 °C
Left Limit 128.70 °C
Right Limit 151.73 °C
Integral -104.15 mJ
normalized -44.06 Jg^-1
Onset 155.41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

FIG. 59

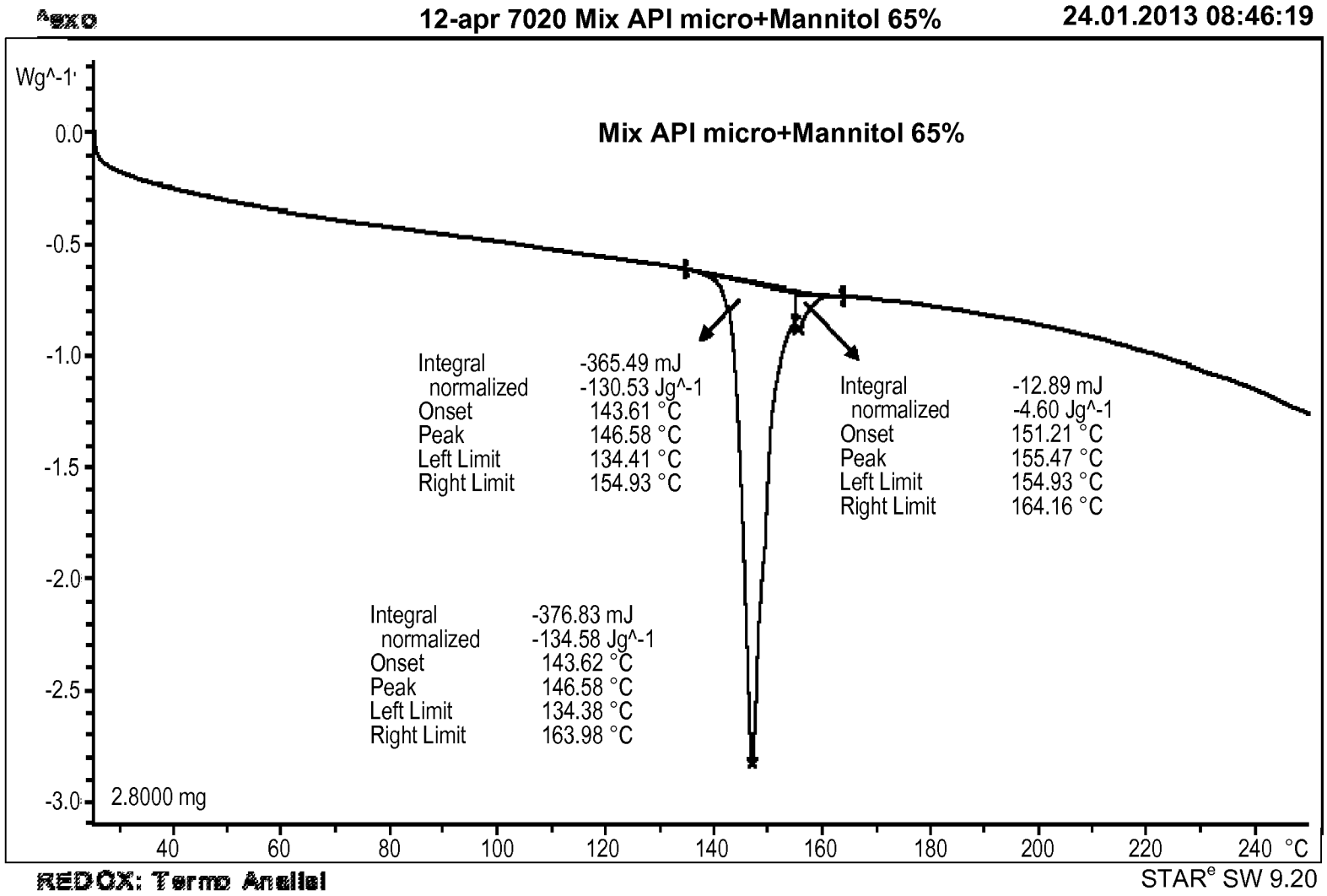

^exo
12-apr 7020 Mix API micro+Mannitol 65%
24.01.2013 08:46:19
Wg^-1
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
Mix API micro+Mannitol 65%
Integral -365.49 mJ
normalized -130.53 Jg^-1
Onset 143.61 °C
Peak 146.58 °C
Left Limit 134.41 °C
Right Limit 154.93 °C
Integral -12.89 mJ
normalized -4.60 Jg^-1
Onset 151.21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

FIG. 60

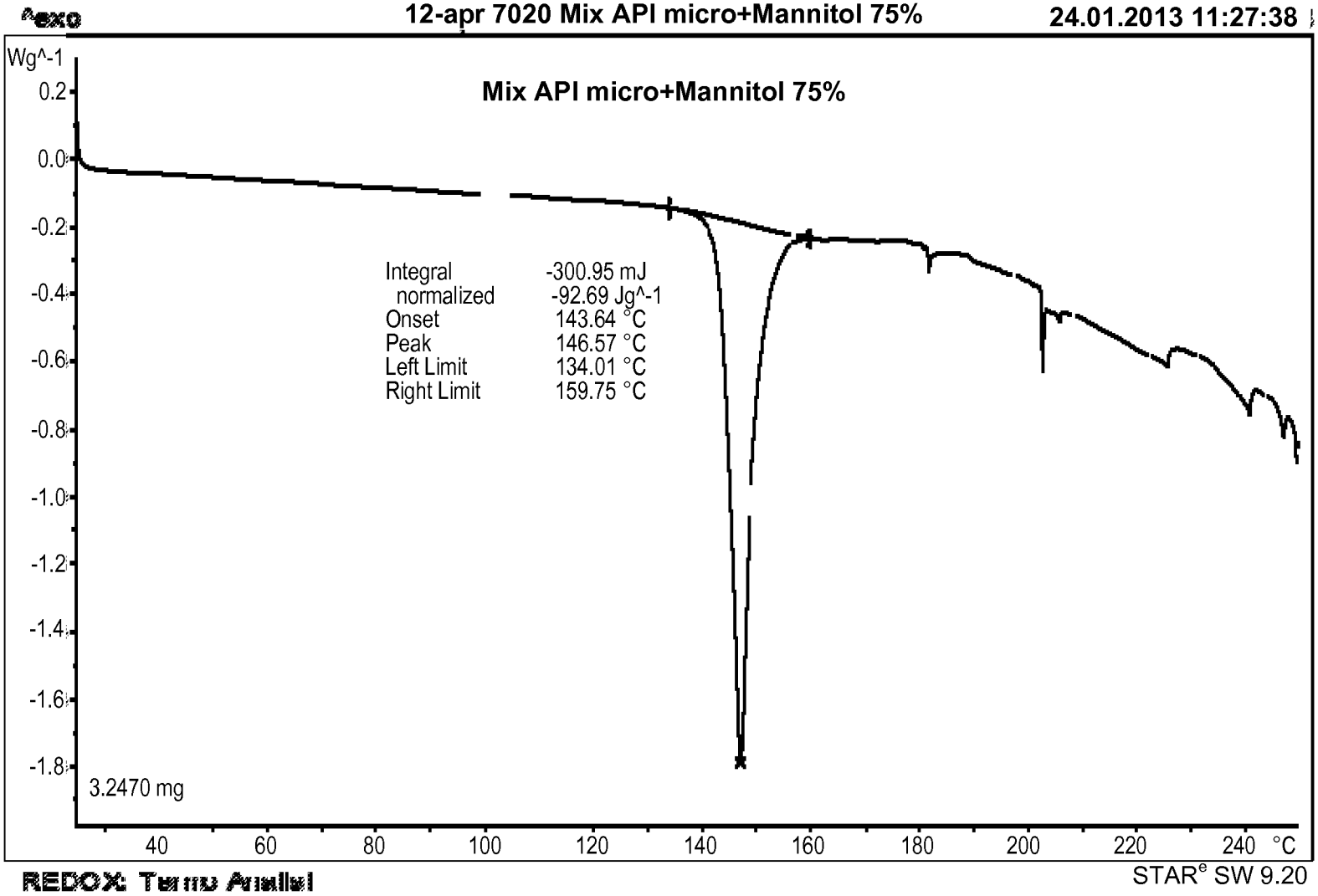

^exo
12-apr 7020 Mix API micro+Mannitol 75%
24.01.2013 11:27:38
Wg^-1
Mix API micro+Mannitol 75%
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
Integral -300.95 mJ
normalized -92.69 Jg^-1
Onset 143.64 °C
Peak 146.57 °C
Left Limit 134.01 °C
Right Limit 159.75 °C
3.2470 mg
40
60
80
100
120
140
160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

FIG. 61

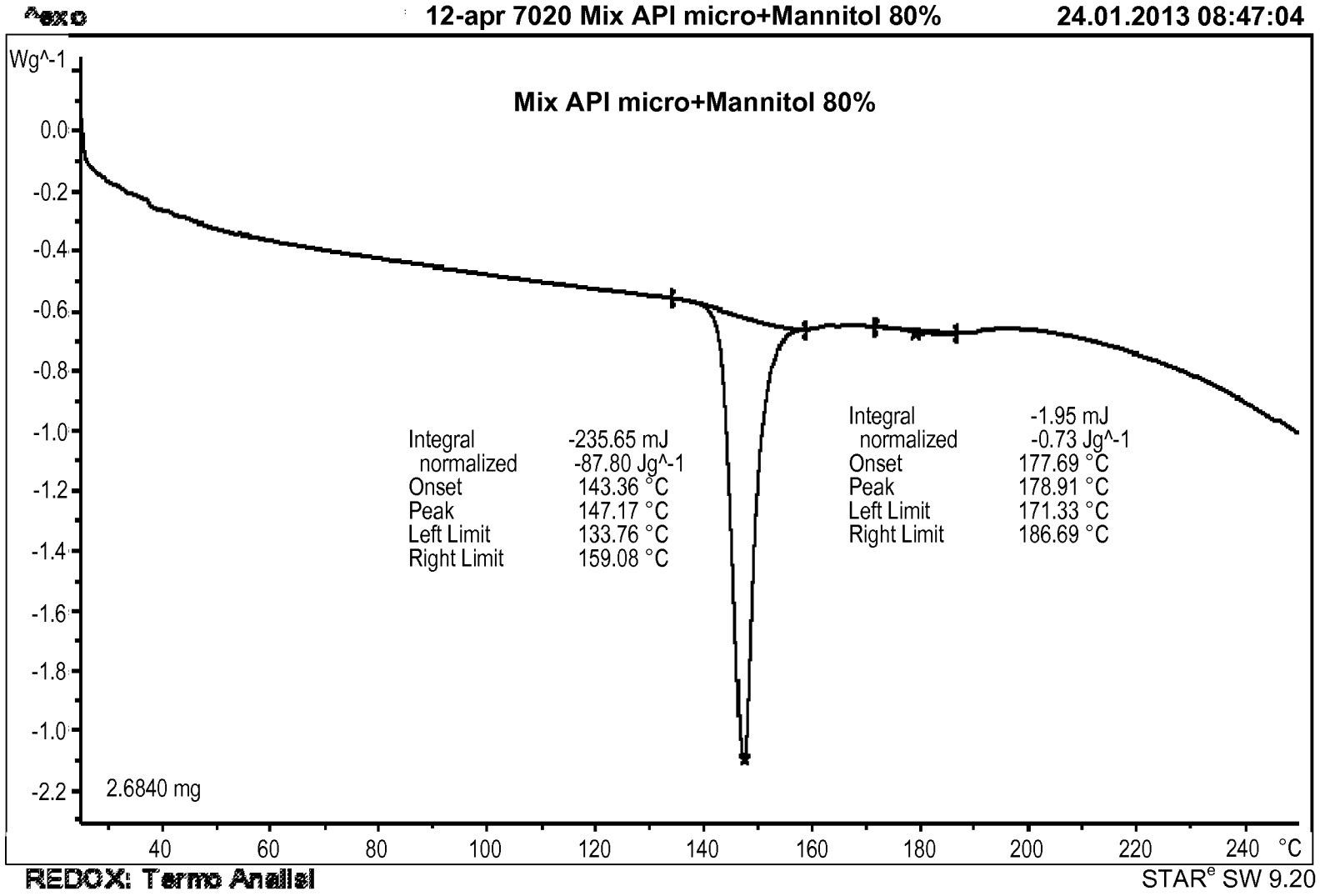

Exo
12-apr 7020 Mix API micro+Mannitol 80%
24.01.2013 08:47:04
Wg^-1
Mix API micro+Mannitol 80%
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
-1.0
-2.2
Integral -235.65 mJ
normalized -87.80 Jg^-1
Onset 143.36 °C
Peak 147.17 °C
Left Limit 133.76 °C
Right Limit 159.08 °C
Integral -1.95 mJ
normalized -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
40
60
80
100
120
140
160
180
200
220
240 °C
REDOX: Termo Analisi
STARe SW 9.20

FIG. 62

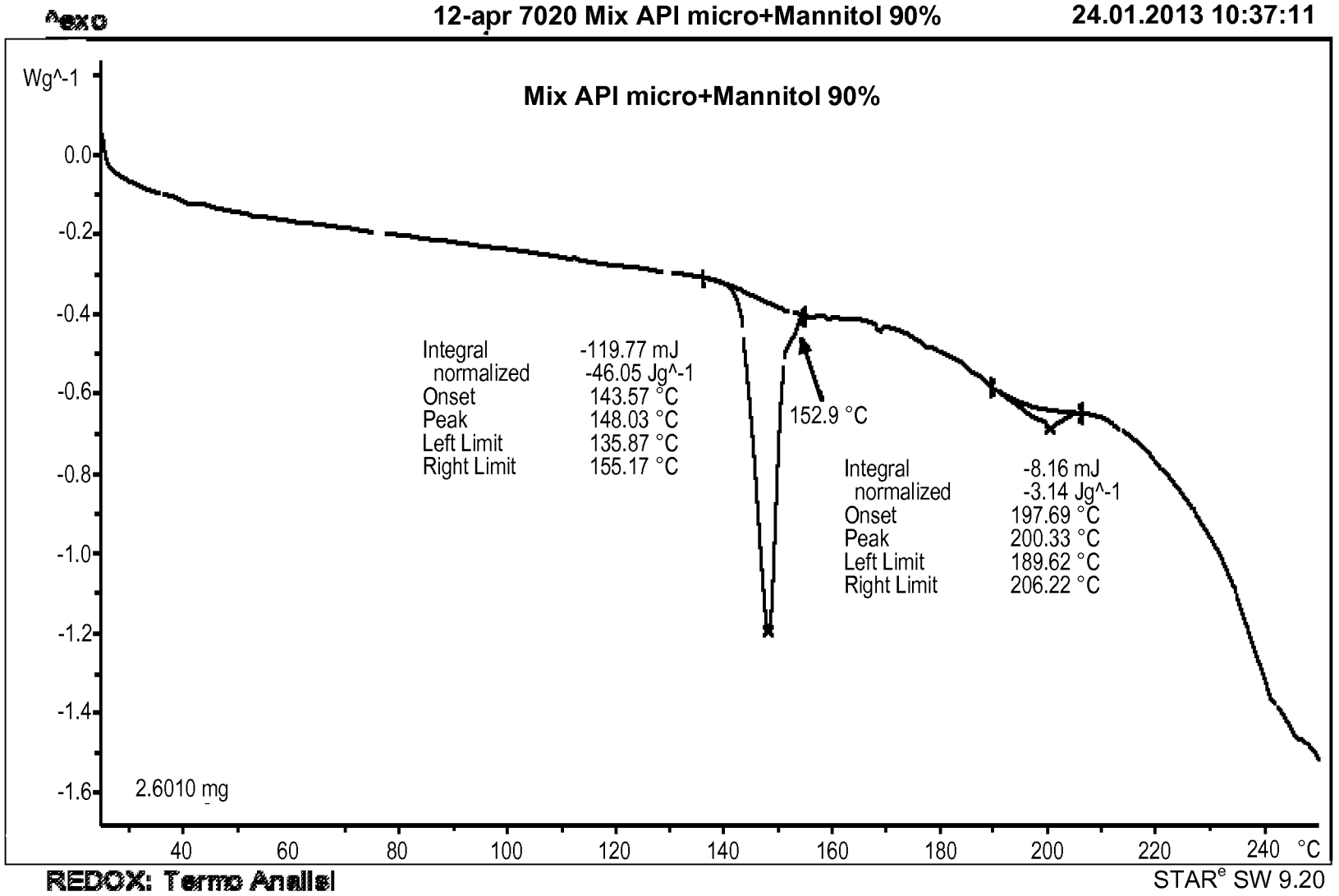

^exo
12-apr 7020 Mix API micro+Mannitol 90%
24.01.2013 10:37:11
Wg^-1
Mix API micro+Mannitol 90%
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
Integral -119.77 mJ
normalized -46.05 Jg^-1
Onset 143.57 °C
Peak 148.03 °C
Left Limit 135.87 °C
Right Limit 155.17 °C
152.9 °C
Integral -8.16 mJ
normalized -3.14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

FIG. 63

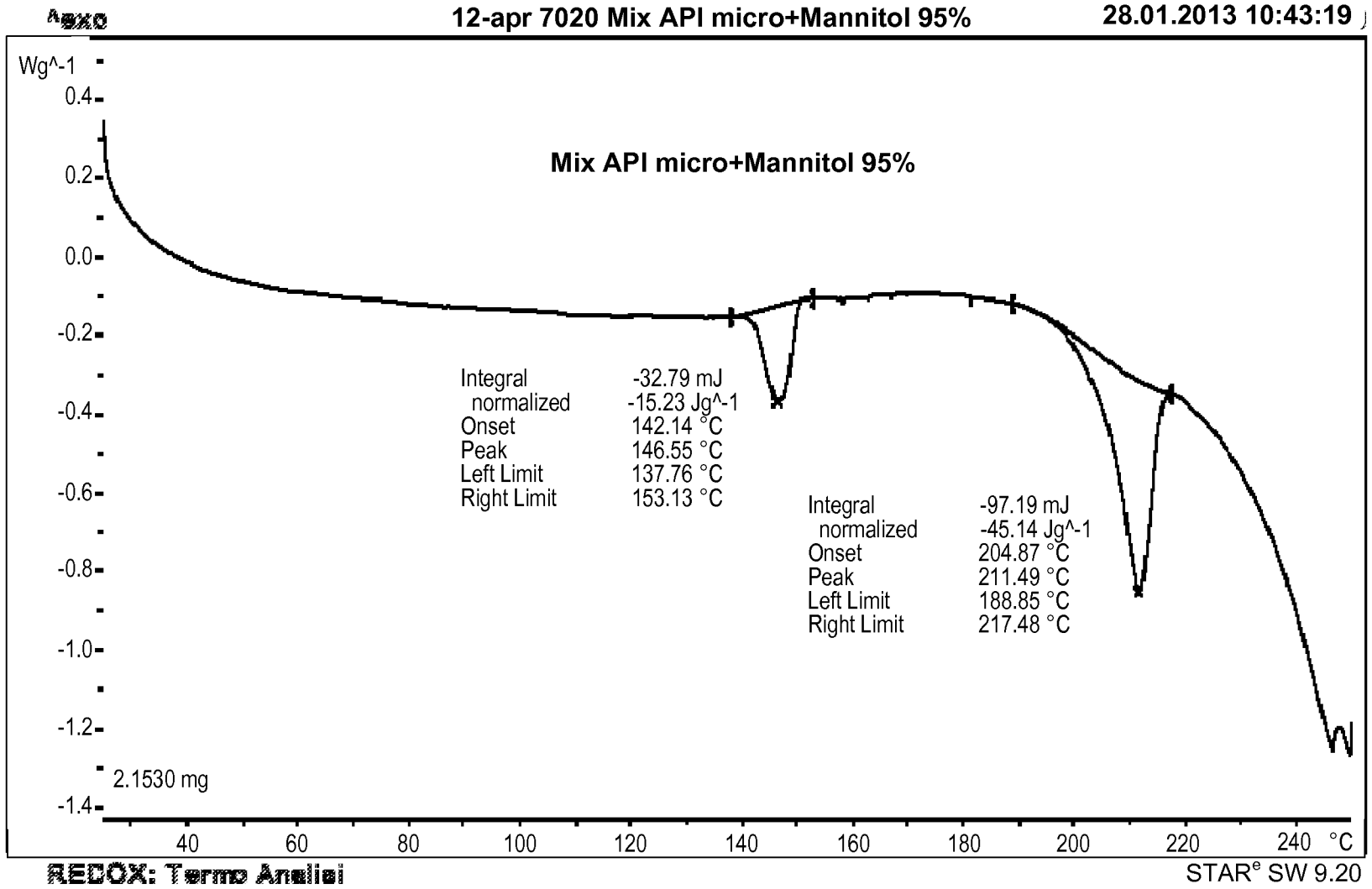

Exo
12-apr 7020 Mix API micro+Mannitol 95%
28.01.2013 10:43:19
Wg^-1
0.4
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
Mix API micro+Mannitol 95%
Integral -32.79 mJ
normalized -15.23 Jg^-1
Onset 142.14 °C
Peak 146.55 °C
Left Limit 137.76 °C
Right Limit 153.13 °C
Integral -97.19 mJ
normalized -45.14 Jg^-1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

FIG. 64

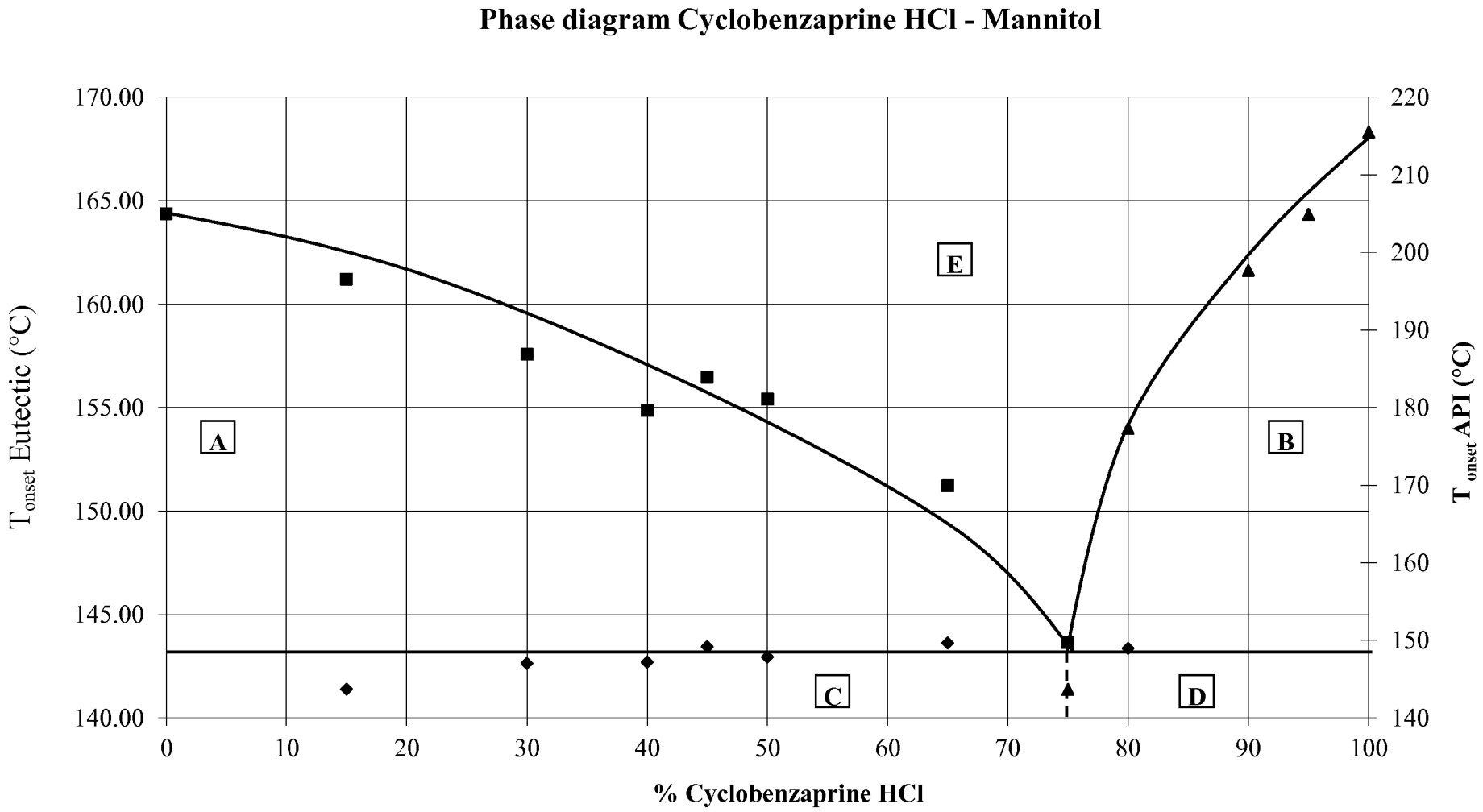

Phase diagram Cyclobenzaprine HCl - Mannitol
170.00
165.00
160.00
155.00
150.00
145.00
140.00
220
210
200
190
180
170
160
150
140
0
10
20
30
40
50
60
70
80
90
100
A
B
C
D
E
T onset Eutectic (°C)
T onset API (°C)
% Cyclobenzaprine HCl

FIG. 65

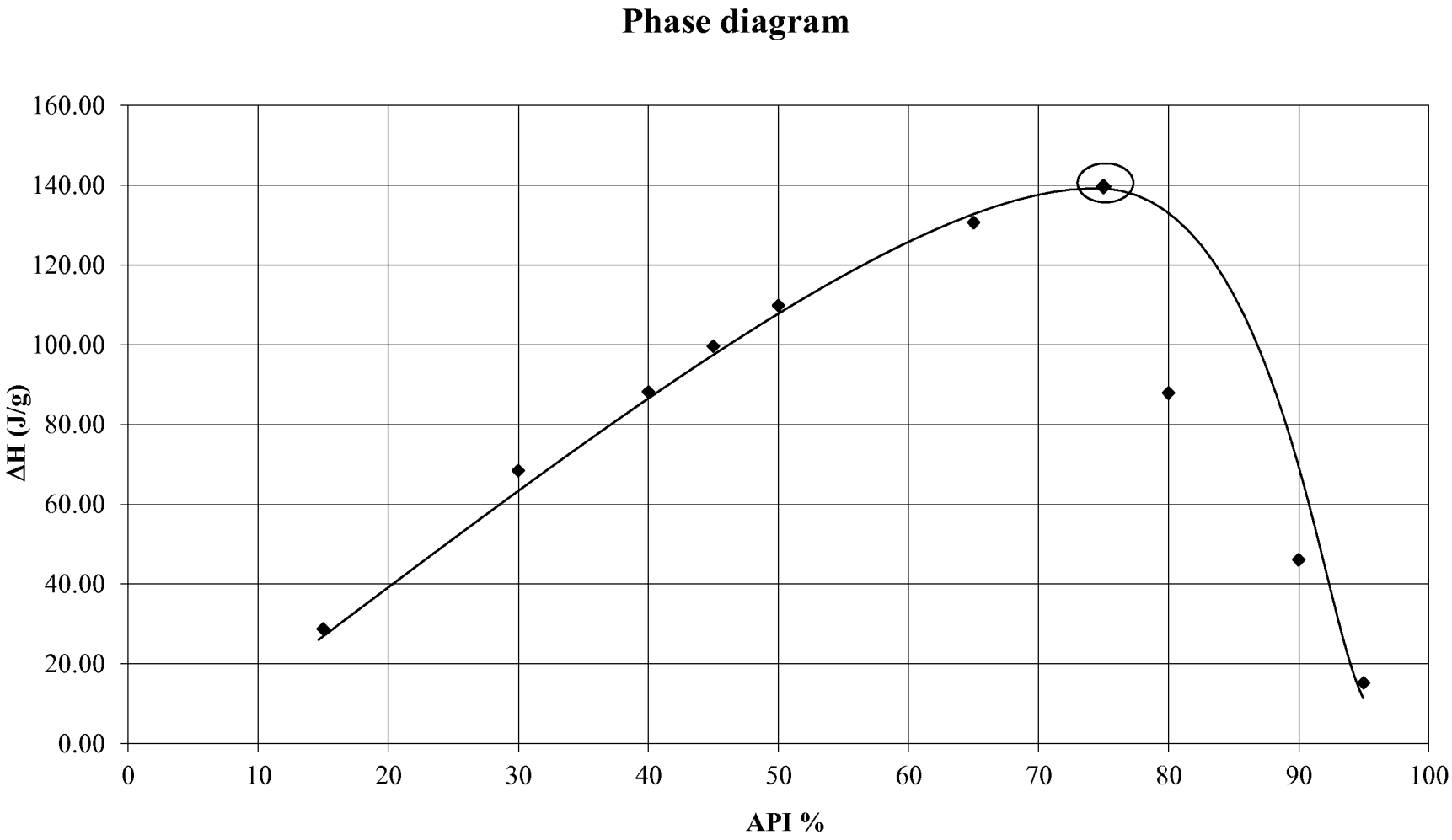

Phase diagram
160.00
140.00
120.00
100.00
80.00
60.00
40.00
20.00
0.00
ΔH (J/g)
0
10
20
30
40
50
60
70
80
90
100
API %

FIG. 66

**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 |

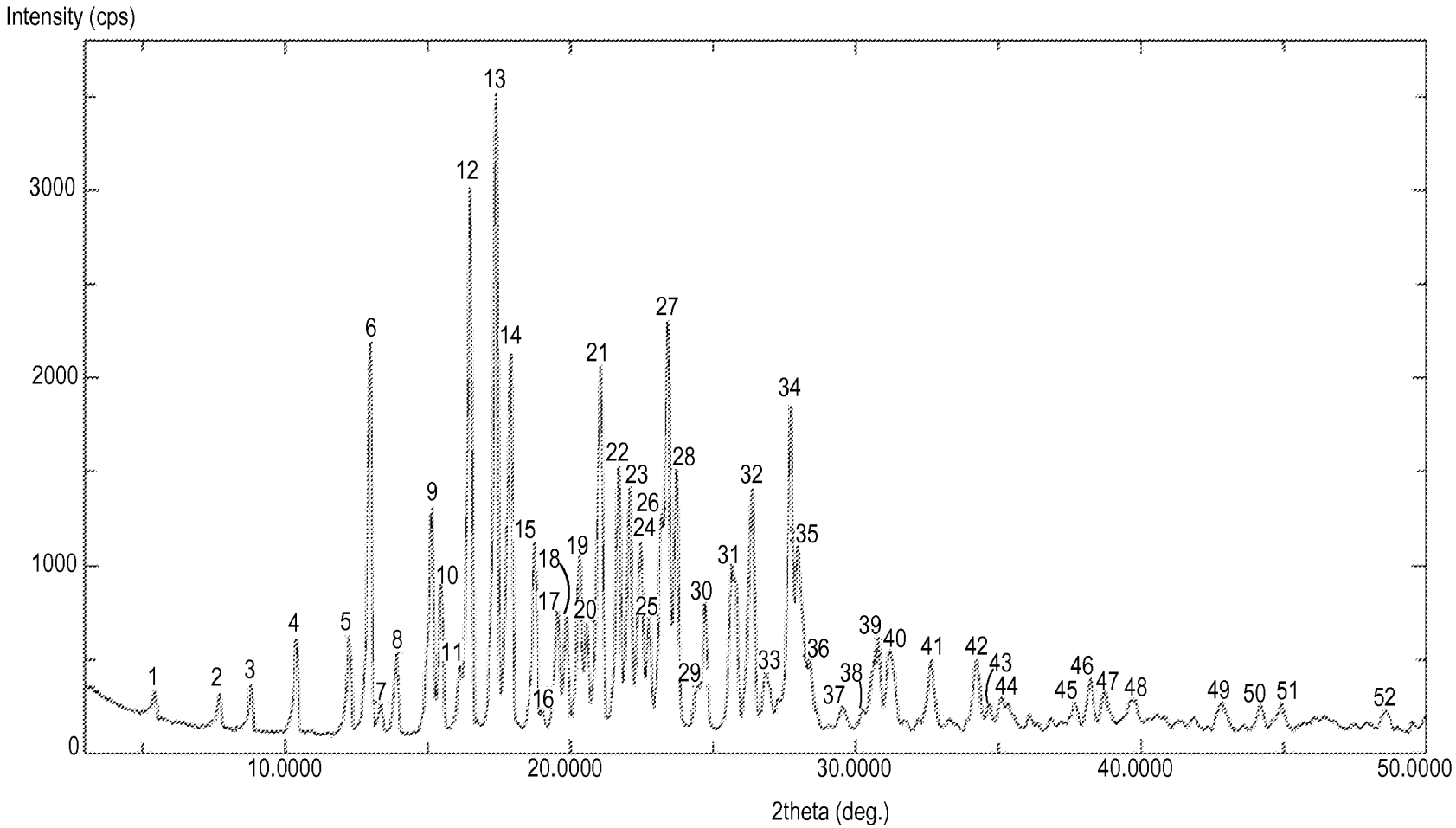



**FIG. 67**

February-06-2013 12:25:16 Page-1

## 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 | 18.760 | 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 | | | | | | |



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 |

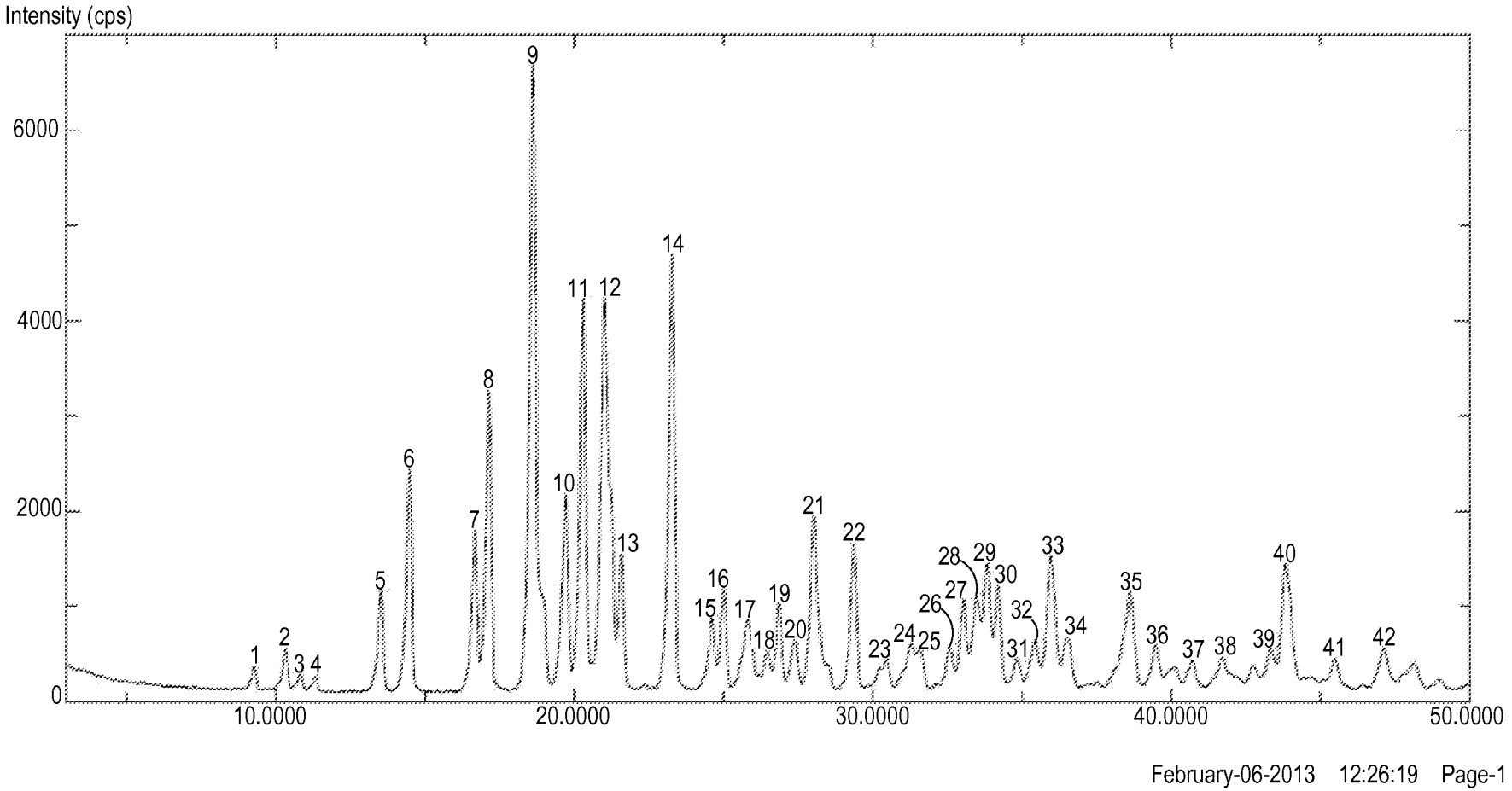



FIG. 69

## Peak Search

Sample : Mannitolo File : Mannitolo.raw Date : January-24-13 12:00:25 Operator : Redox
Comment : FT 0.02 deg-1.0 s Memo : Mannitolo
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 | 16.680 | 0.165 | 5.3106 | 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)

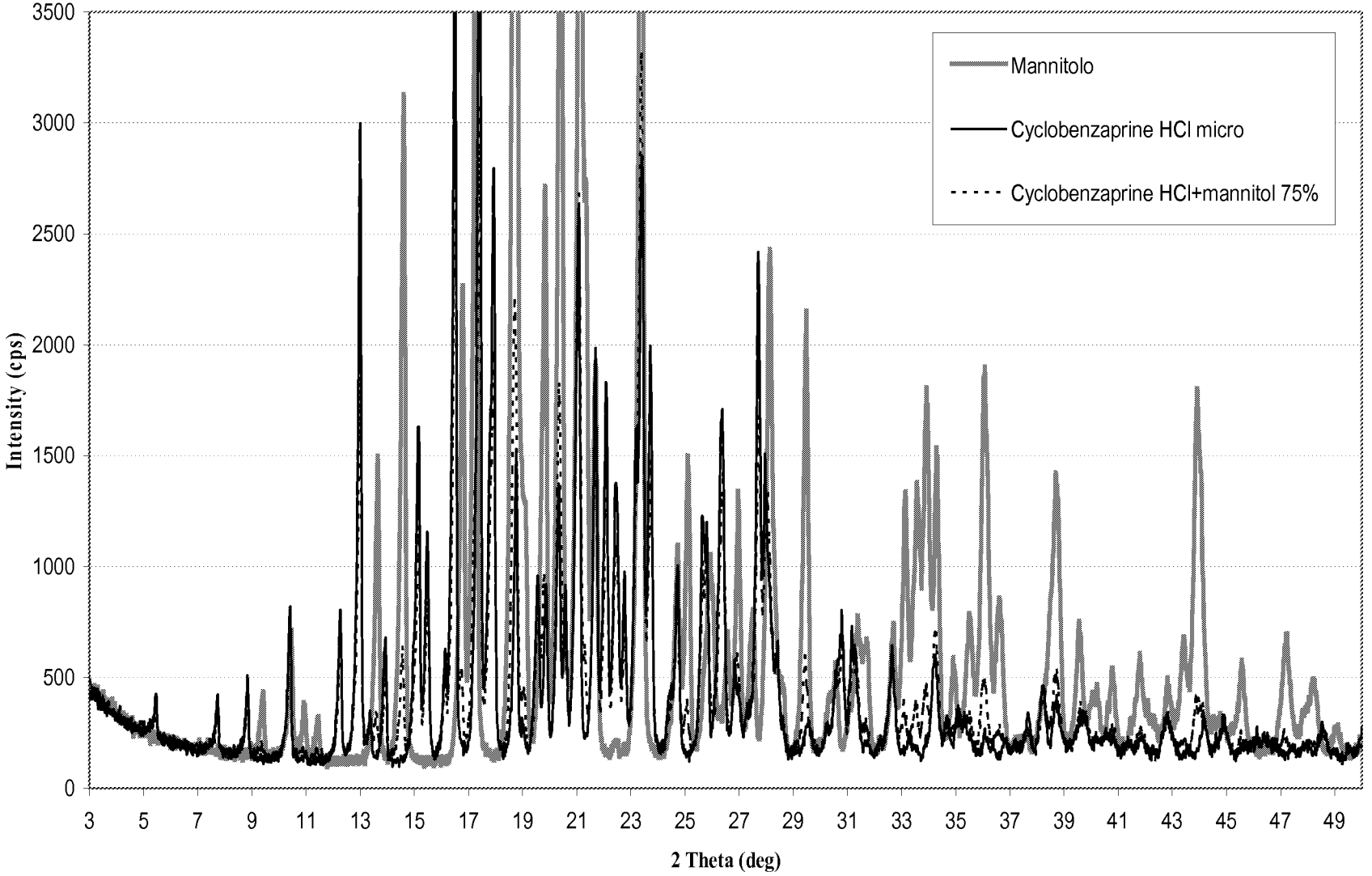



FIG. 71

(Diffrattogramma X-Rays)

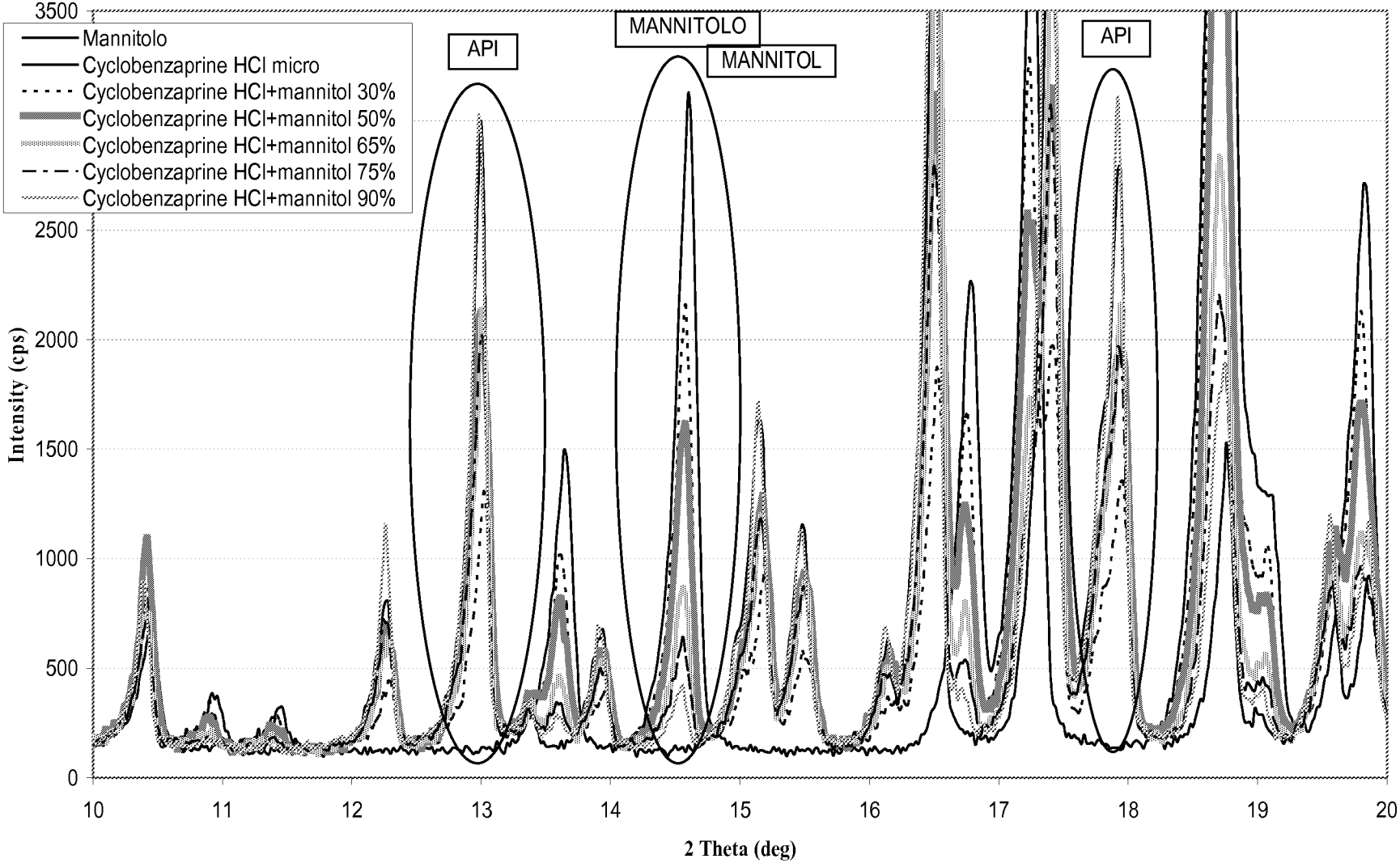



FIG. 72

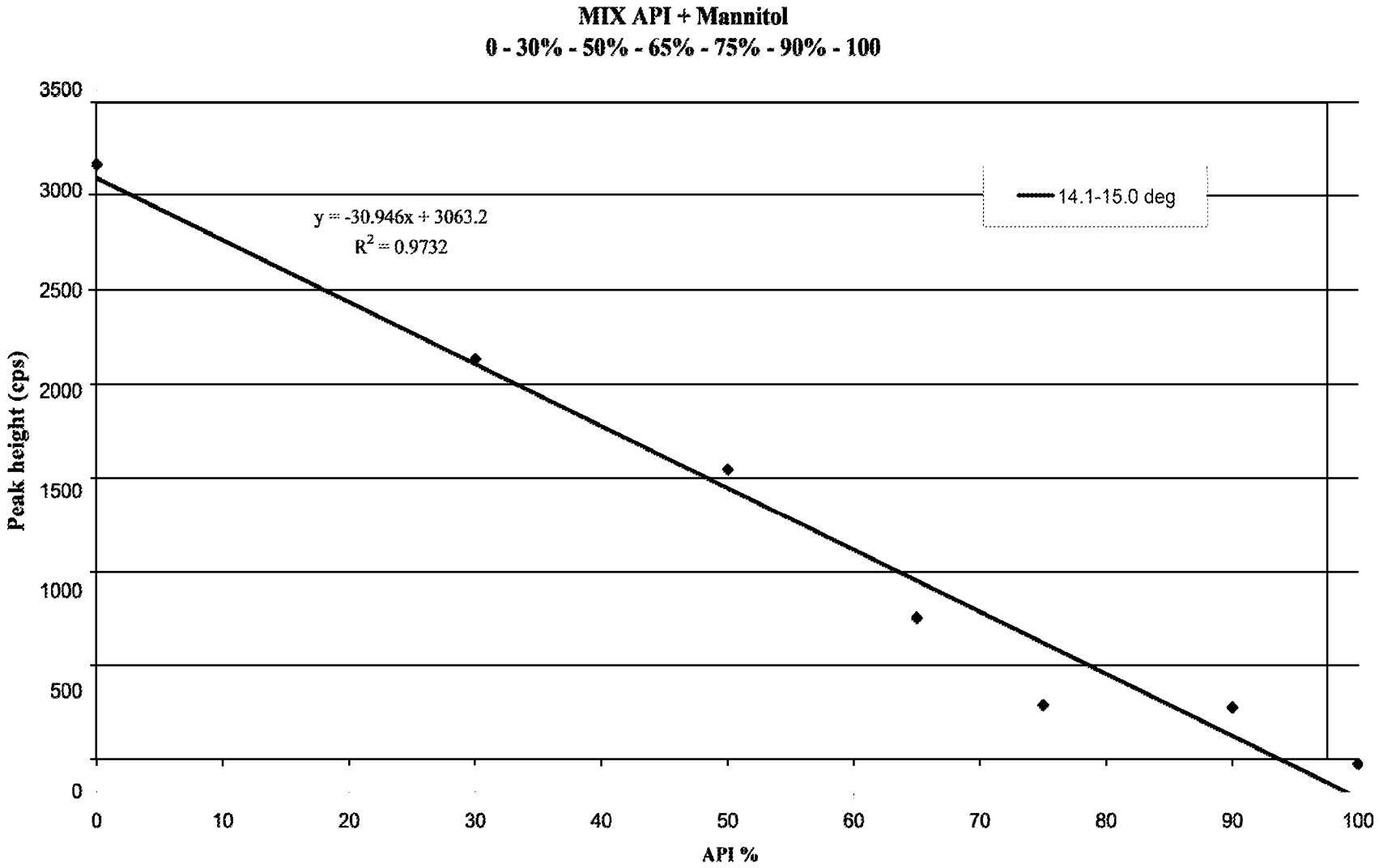

MIX API + Mannitol
0 - 30% - 50% - 65% - 75% - 90% - 100
y = -30.946x + 3063.2
R2 = 0.9732
14.1-15.0 deg
Peak height (cps)
API %
3500
3000
2500
2000
1500
1000
500
0
0
10
20
30
40
50
60
70
80
90
100

FIG. 73

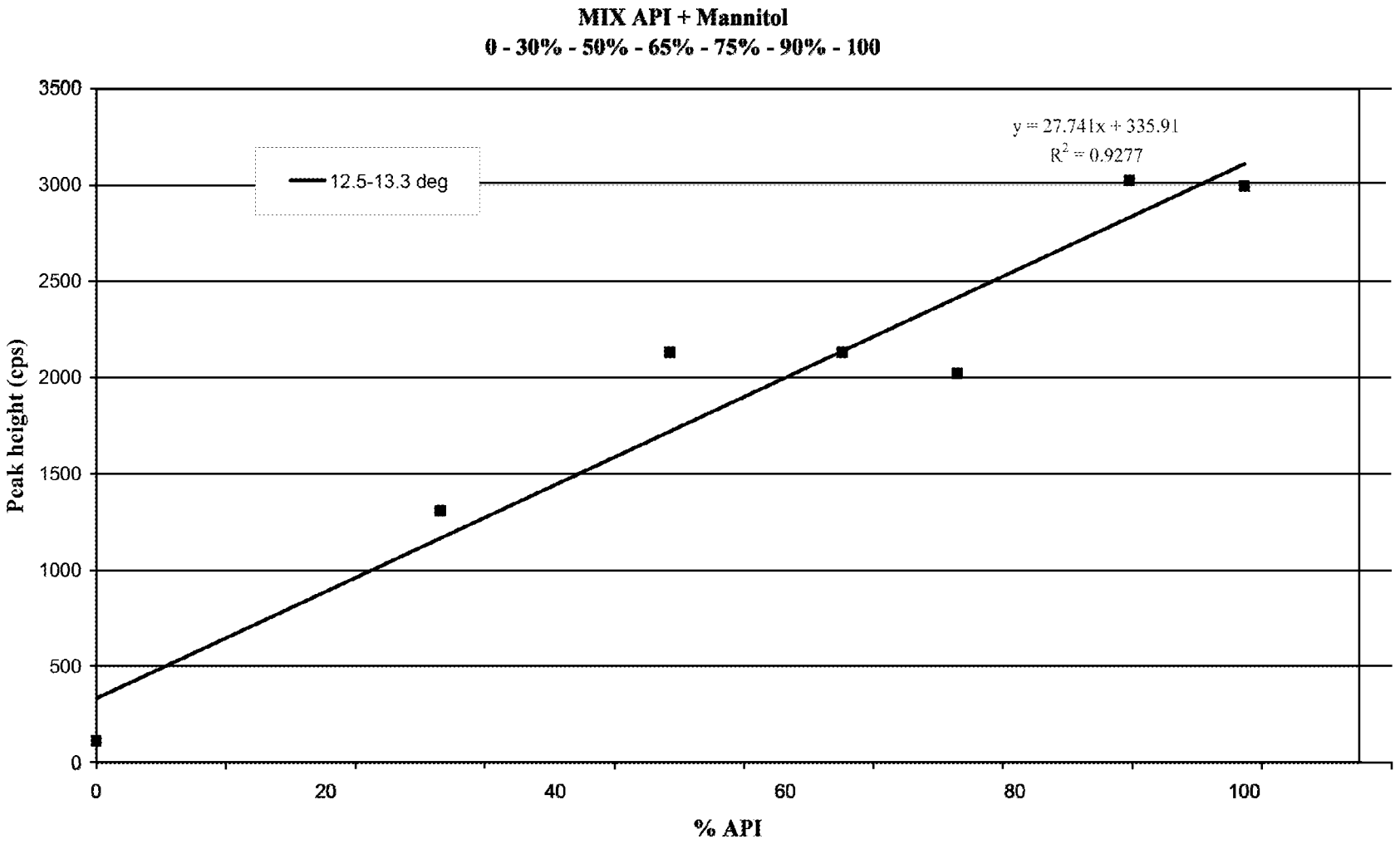

MIX API + Mannitol
0 - 30% - 50% - 65% - 75% - 90% - 100
y = 27.741x + 335.91
R2 = 0.9277
12.5-13.3 deg
Peak height (cps)
3500
3000
2500
2000
1500
1000
500
0
0
20
40
60
80
100
% API

FIG. 74

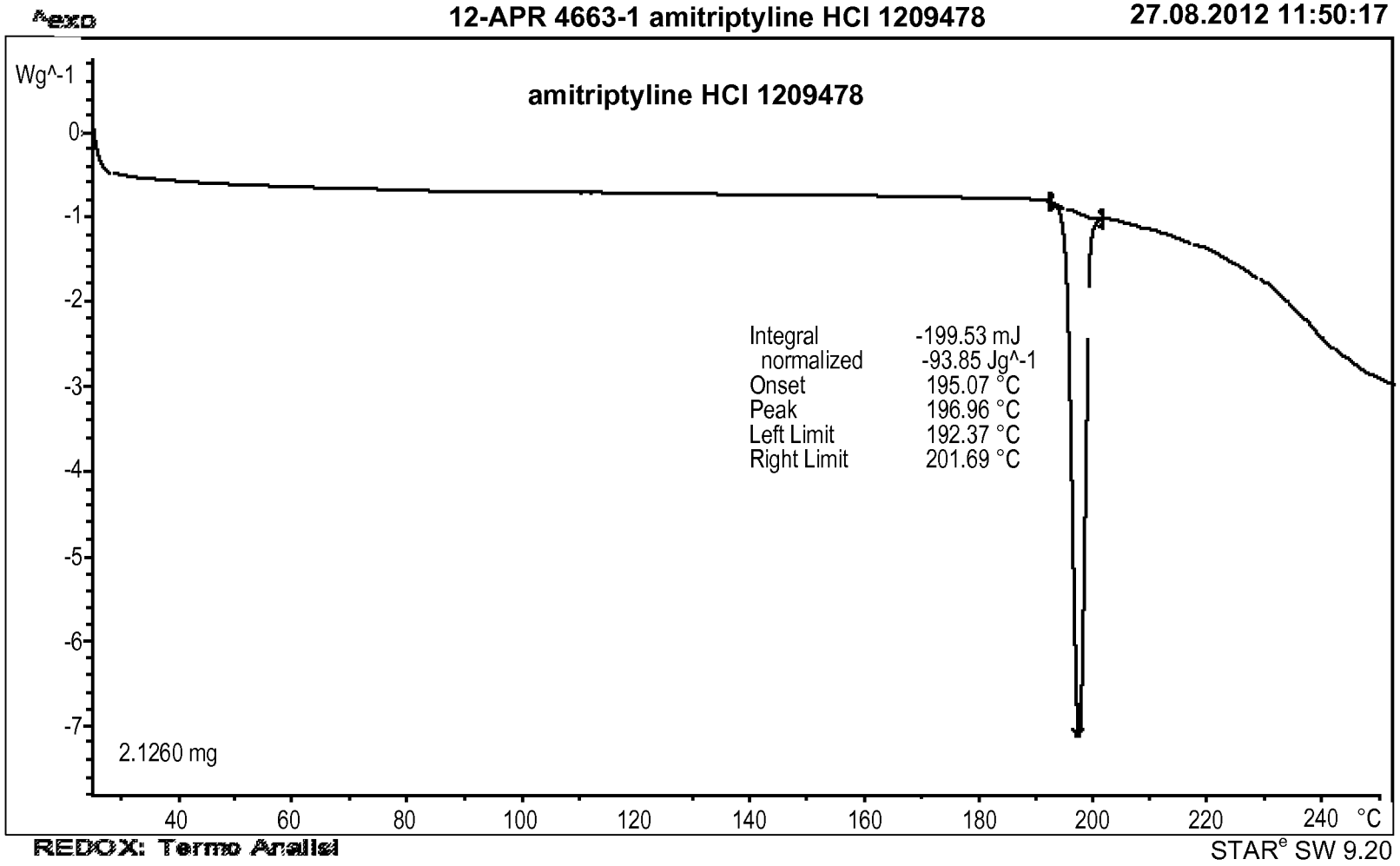

^exo
12-APR 4663-1 amitriptyline HCl 1209478
27.08.2012 11:50:17
Wg^-1
amitriptyline HCl 1209478
0
-1
-2
-3
-4
-5
-6
-7
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.96 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
2.1260 mg
40
60
80
100
120
140
160
180
200
220
240 °C
REDOX: Termo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

FIG. 75

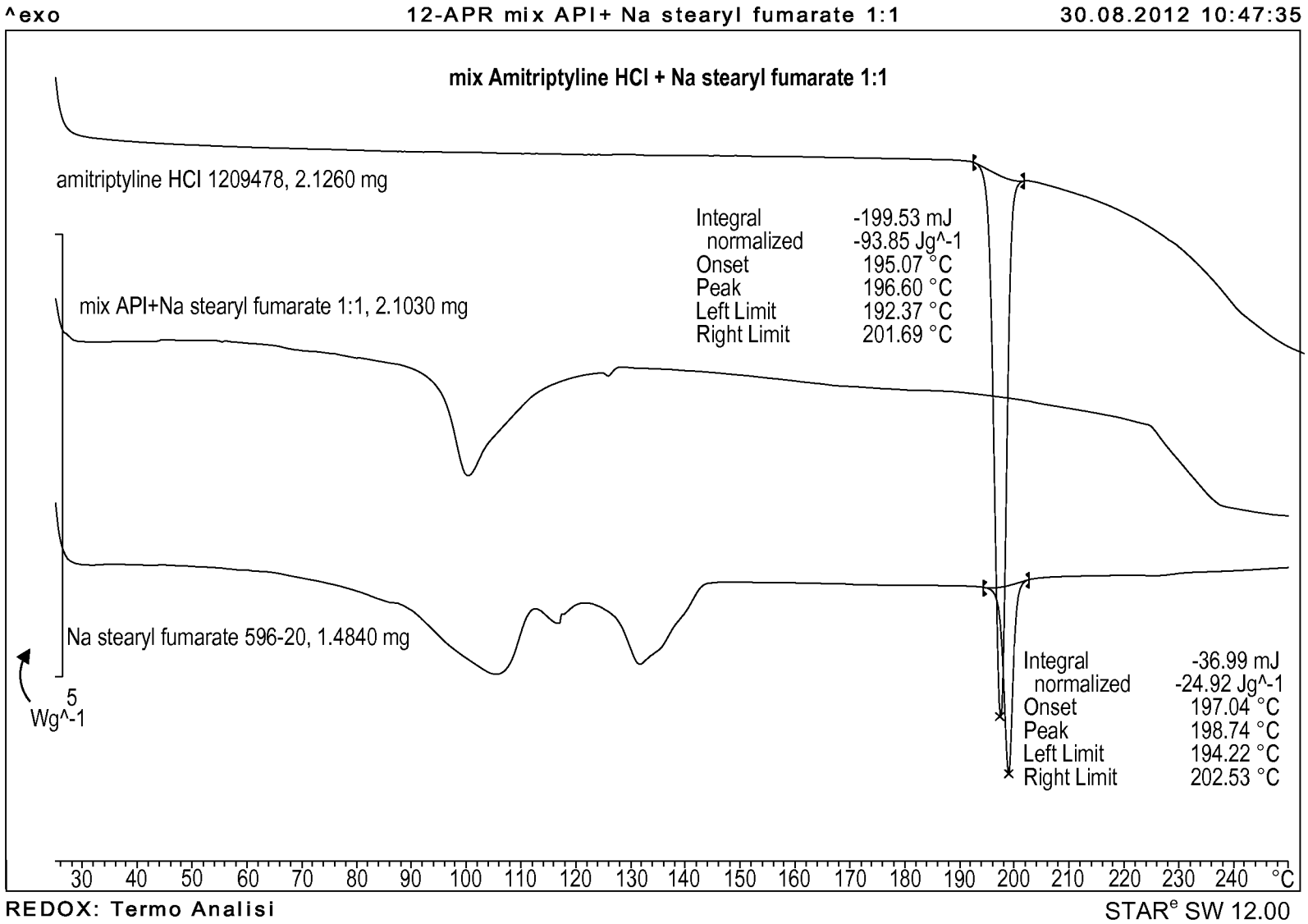

^exo
12-APR mix API+ Na stearyl fumarate 1:1
30.08.2012 10:47:35
mix Amitriptyline HCl + Na stearyl fumarate 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API+Na stearyl fumarate 1:1, 2.1030 mg
Na stearyl fumarate 596-20, 1.4840 mg
5
Wg^-1
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
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
STAR^e SW 12.00

FIG. 76

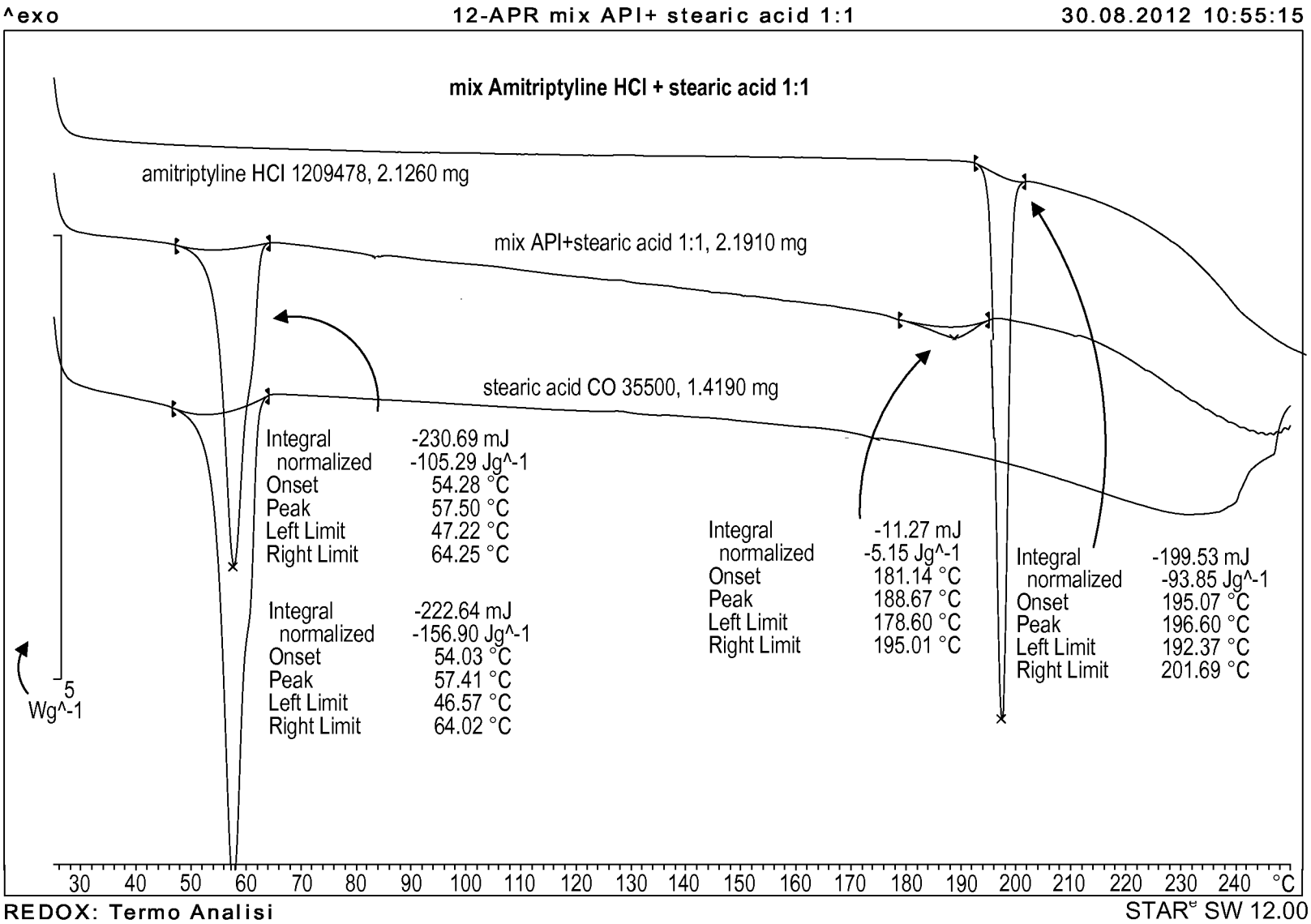

^exo
12-APR mix API+ stearic acid 1:1
30.08.2012 10:55:15
mix Amitriptyline HCl + stearic acid 1:1
amitriptyline HCl 1209478, 2.1260 mg
mix API+stearic acid 1:1, 2.1910 mg
stearic acid CO 35500, 1.4190 mg
Integral -230.69 mJ
normalized -105.29 Jg^-1
Onset 54.28 °C
Peak 57.50 °C
Left Limit 47.22 °C
Right 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

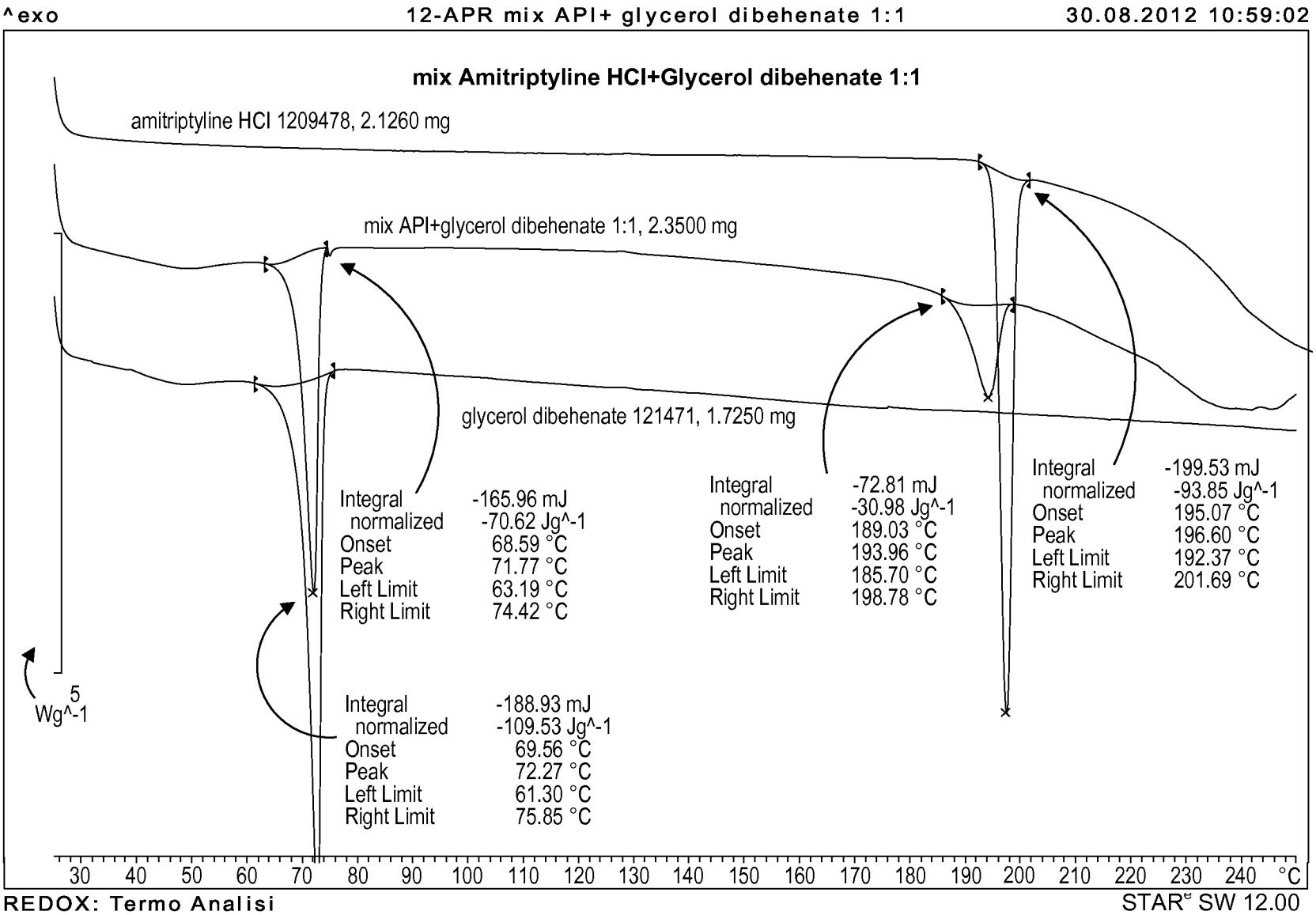

^exo
12-APR mix API+ glycerol dibehenate 1:1
30.08.2012 10:59:02
mix Amitriptyline HCl+Glycerol dibehenate 1:1
amitriptyline HCl 1209478, 2.1260 mg
mix API+glycerol dibehenate 1:1, 2.3500 mg
glycerol dibehenate 121471, 1.7250 mg
Integral -165.96 mJ
normalized -70.62 Jg^-1
Onset 68.59 °C
Peak 71.77 °C
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
5
Wg^-1
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
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
STAR^e SW 12.00

FIG. 78

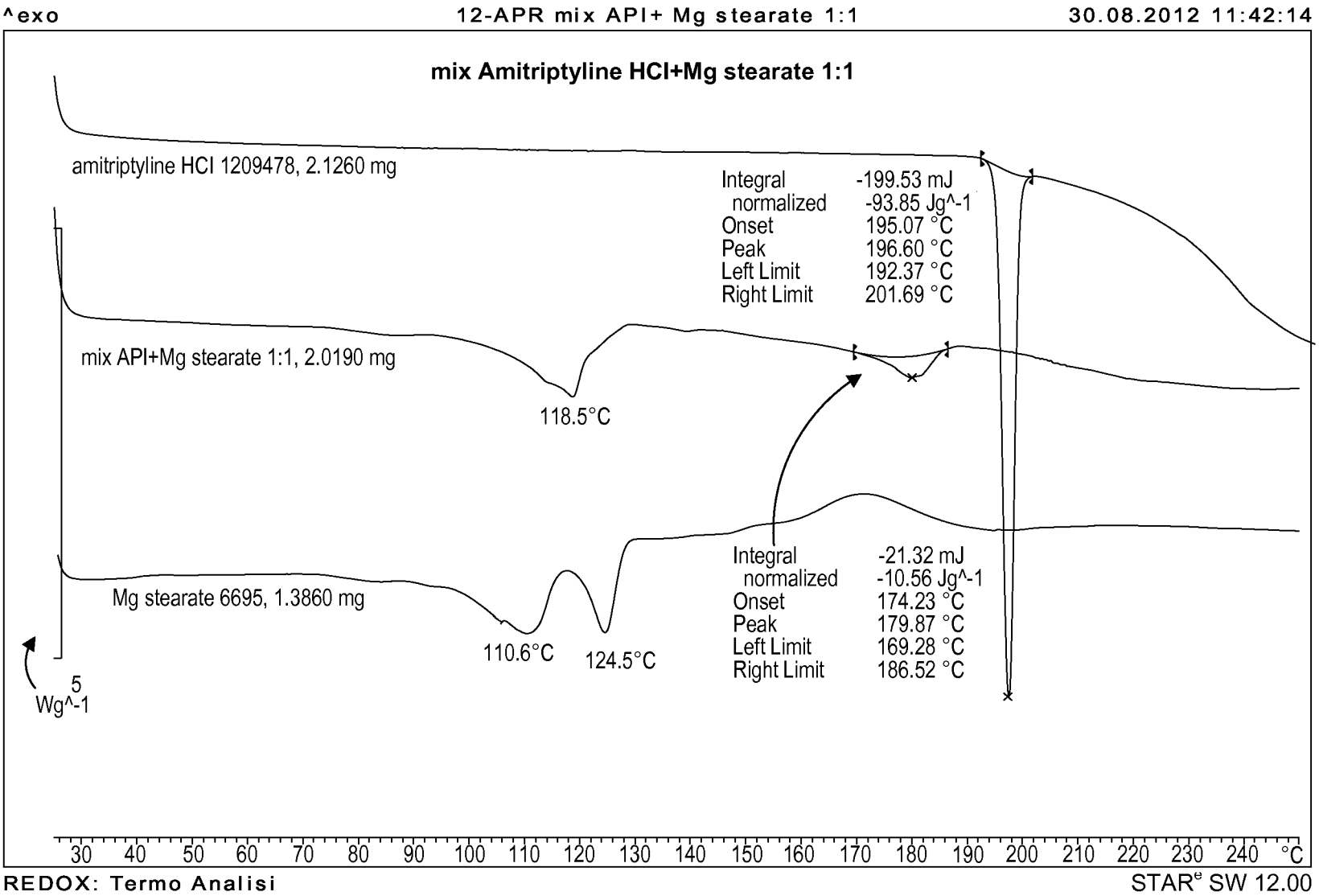

^exo
12-APR mix API+ Mg stearate 1:1
30.08.2012 11:42:14
mix Amitriptyline HCl+Mg stearate 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API+Mg stearate 1:1, 2.0190 mg
118.5°C
Mg stearate 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
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. 79

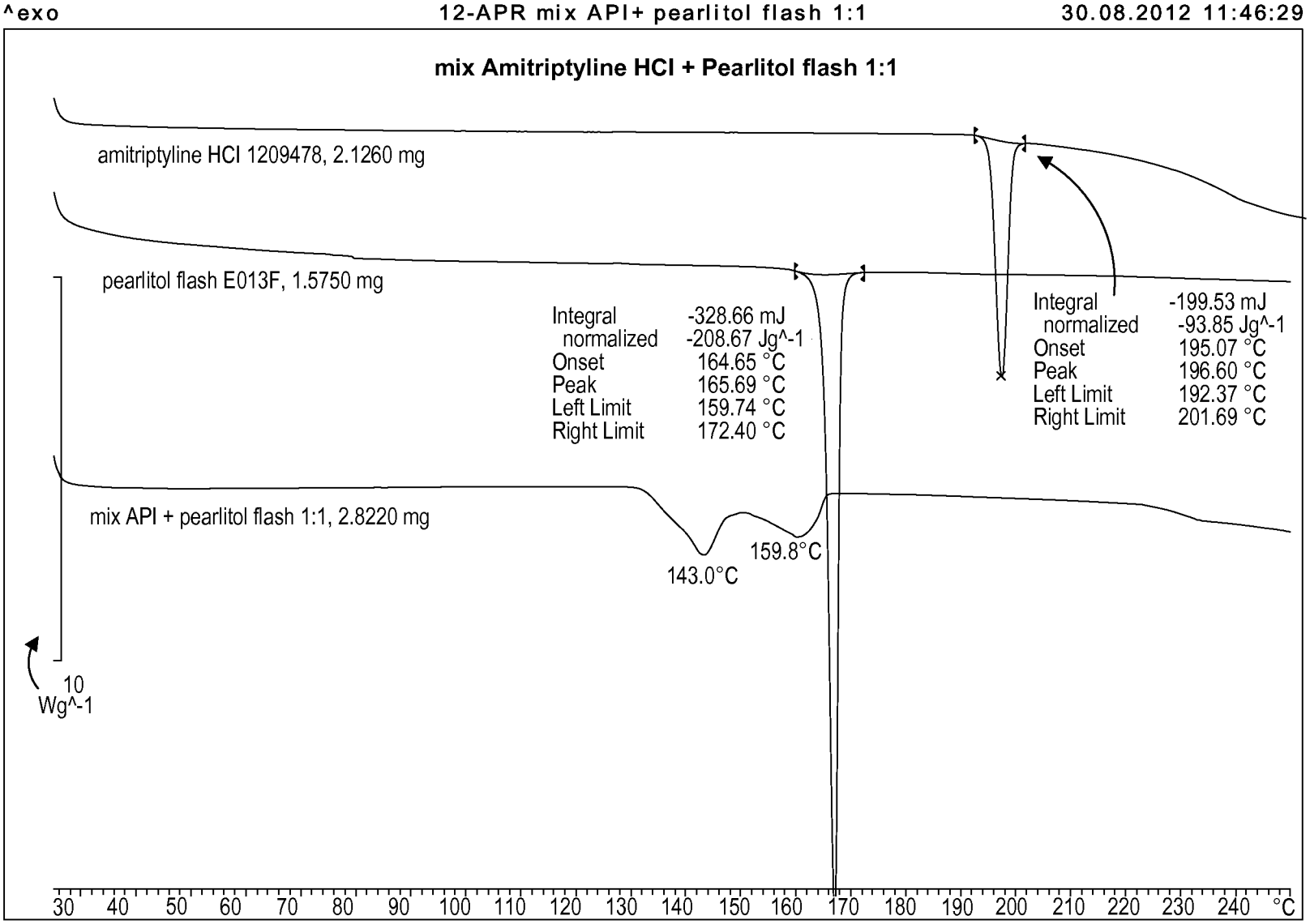

^exo
12-APR mix API+ pearlitol flash 1:1
30.08.2012 11:46:29
mix Amitriptyline HCl + Pearlitol flash 1:1
amitriptyline HCl 1209478, 2.1260 mg
pearlitol flash E013F, 1.5750 mg
Integral -328.66 mJ
normalized -208.67 Jg^-1
Onset 164.65 °C
Peak 165.69 °C
Left Limit 159.74 °C
Right Limit 172.40 °C
Integral -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 + pearlitol flash 1:1, 2.8220 mg
143.0°C
159.8°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
STAR^e SW 12.00

FIG. 80

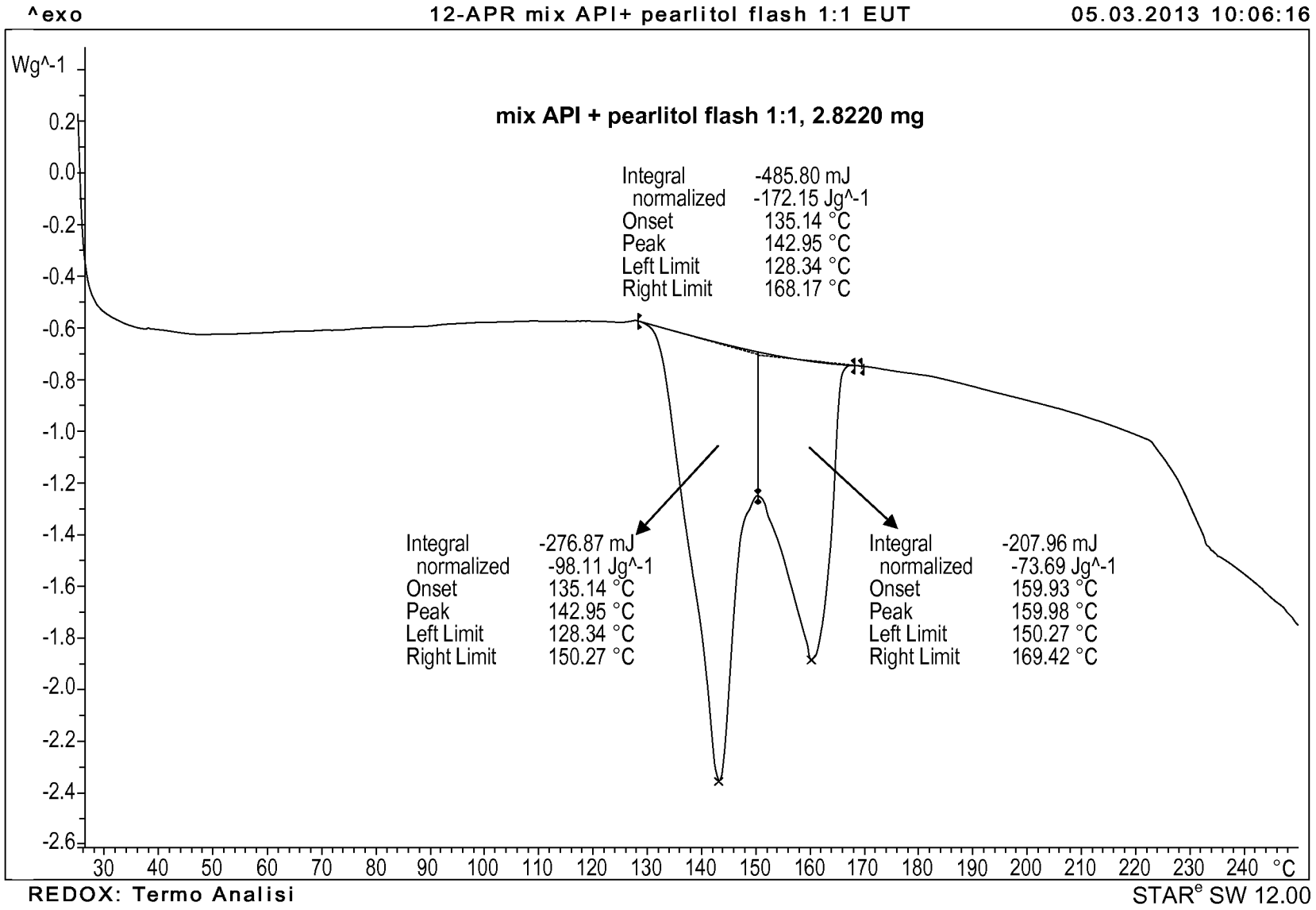

^exo
12-APR mix API+ pearlitol flash 1:1 EUT
05.03.2013 10:06:16
Wg^-1
mix API + pearlitol flash 1:1, 2.8220 mg
Integral -485.80 mJ
normalized -172.15 Jg^-1
Onset 135.14 °C
Peak 142.95 °C
Left Limit 128.34 °C
Right Limit 168.17 °C
Integral -276.87 mJ
normalized -98.11 Jg^-1
Onset 135.14 °C
Peak 142.95 °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
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
STAR^e SW 12.00

FIG. 81

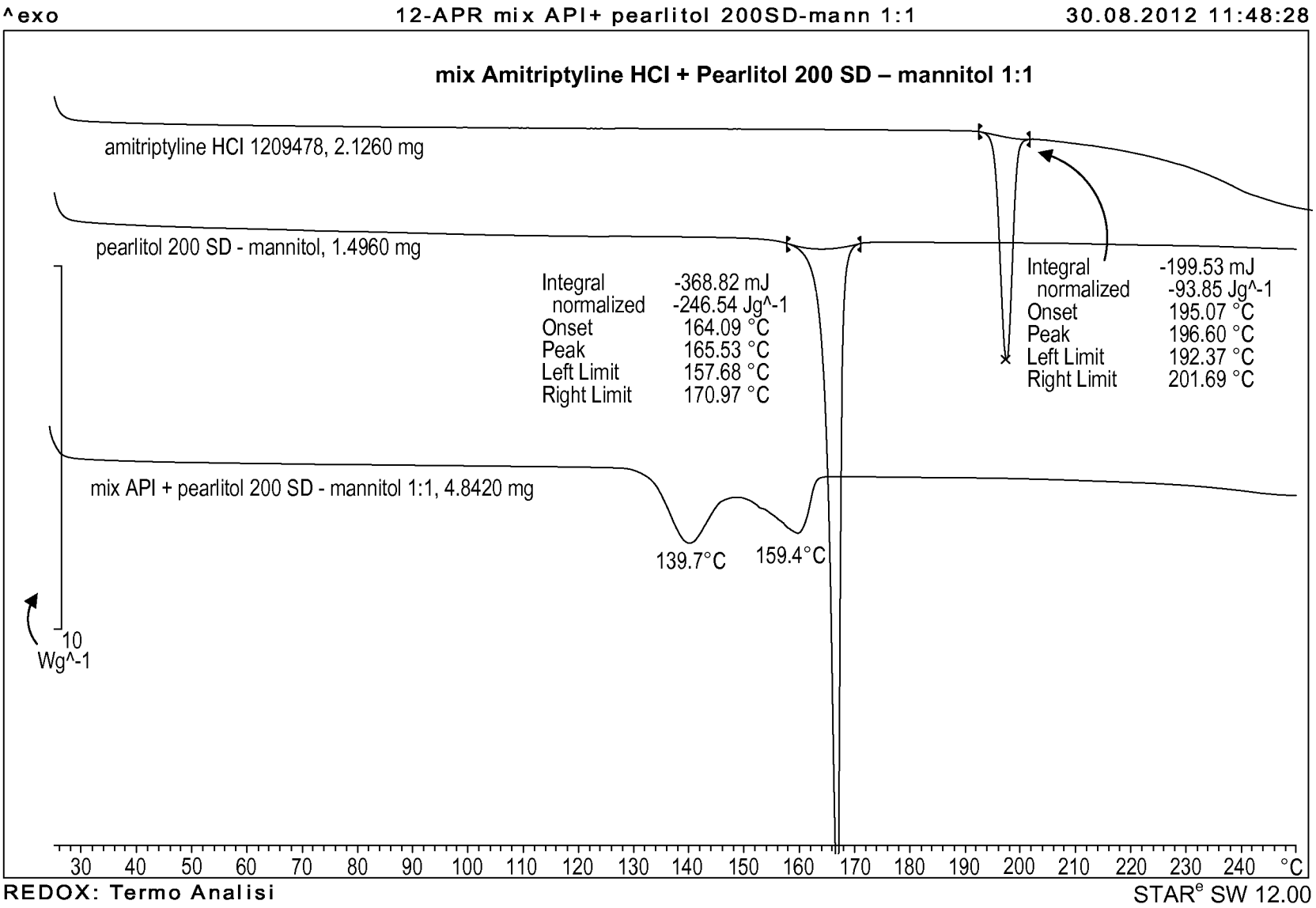

^exo
12-APR mix API+ pearlitol 200SD-mann 1:1
30.08.2012 11:48:28
mix Amitriptyline HCl + Pearlitol 200 SD – mannitol 1:1
amitriptyline HCl 1209478, 2.1260 mg
pearlitol 200 SD - mannitol, 1.4960 mg
Integral -368.82 mJ
normalized -246.54 Jg^-1
Onset 164.09 °C
Peak 165.53 °C
Left Limit 157.68 °C
Right 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
mix API + pearlitol 200 SD - mannitol 1:1, 4.8420 mg
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
STAR^e SW 12.00

FIG. 82

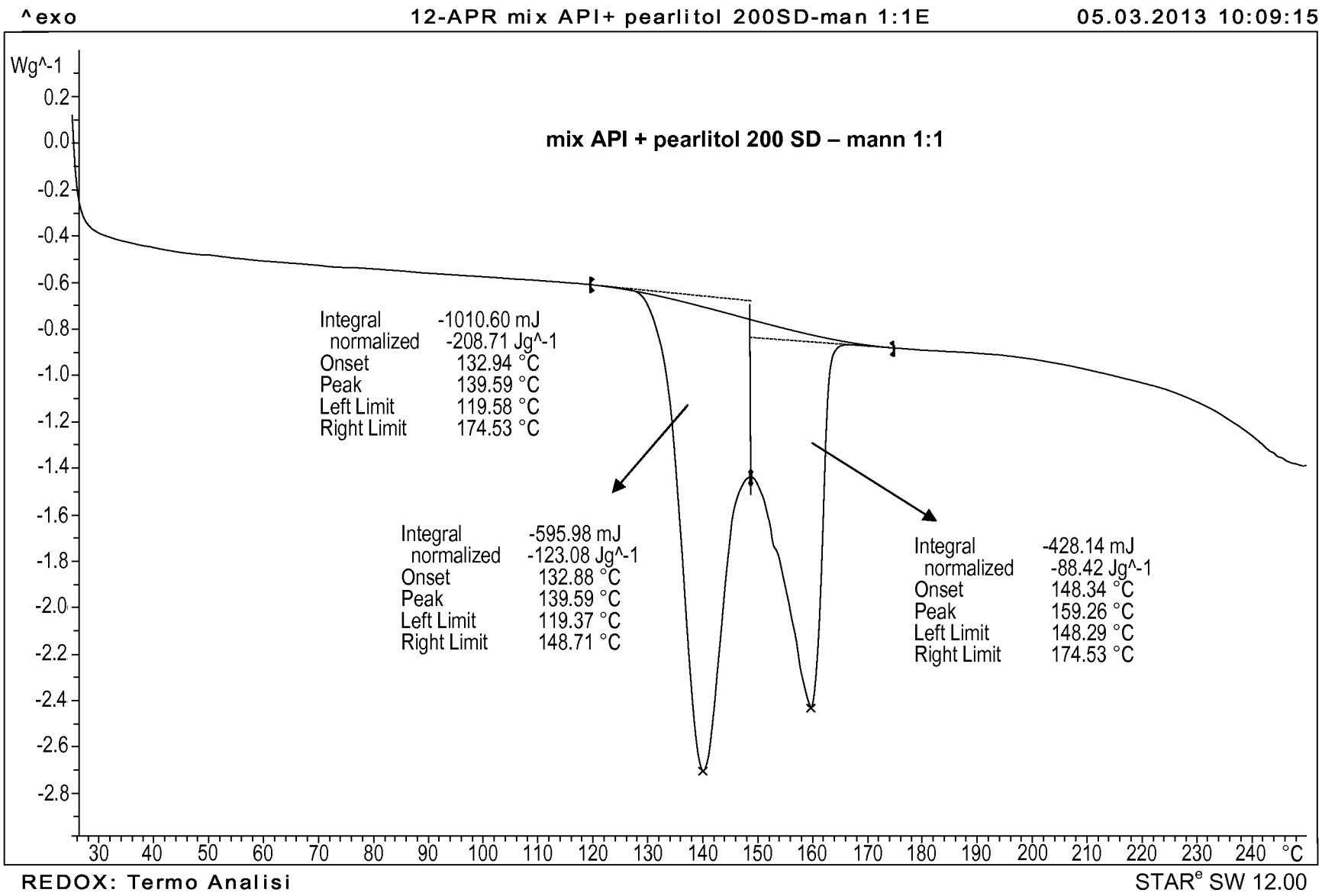

^exo
12-APR mix API+ pearlitol 200SD-man 1:1E
05.03.2013 10:09:15
Wg^-1
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
-2.0
-2.2
-2.4
-2.6
-2.8
mix API + pearlitol 200 SD – mann 1:1
Integral -1010.60 mJ
normalized -208.71 Jg^-1
Onset 132.94 °C
Peak 139.59 °C
Left Limit 119.58 °C
Right Limit 174.53 °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
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
STAR^e SW 12.00

FIG. 83

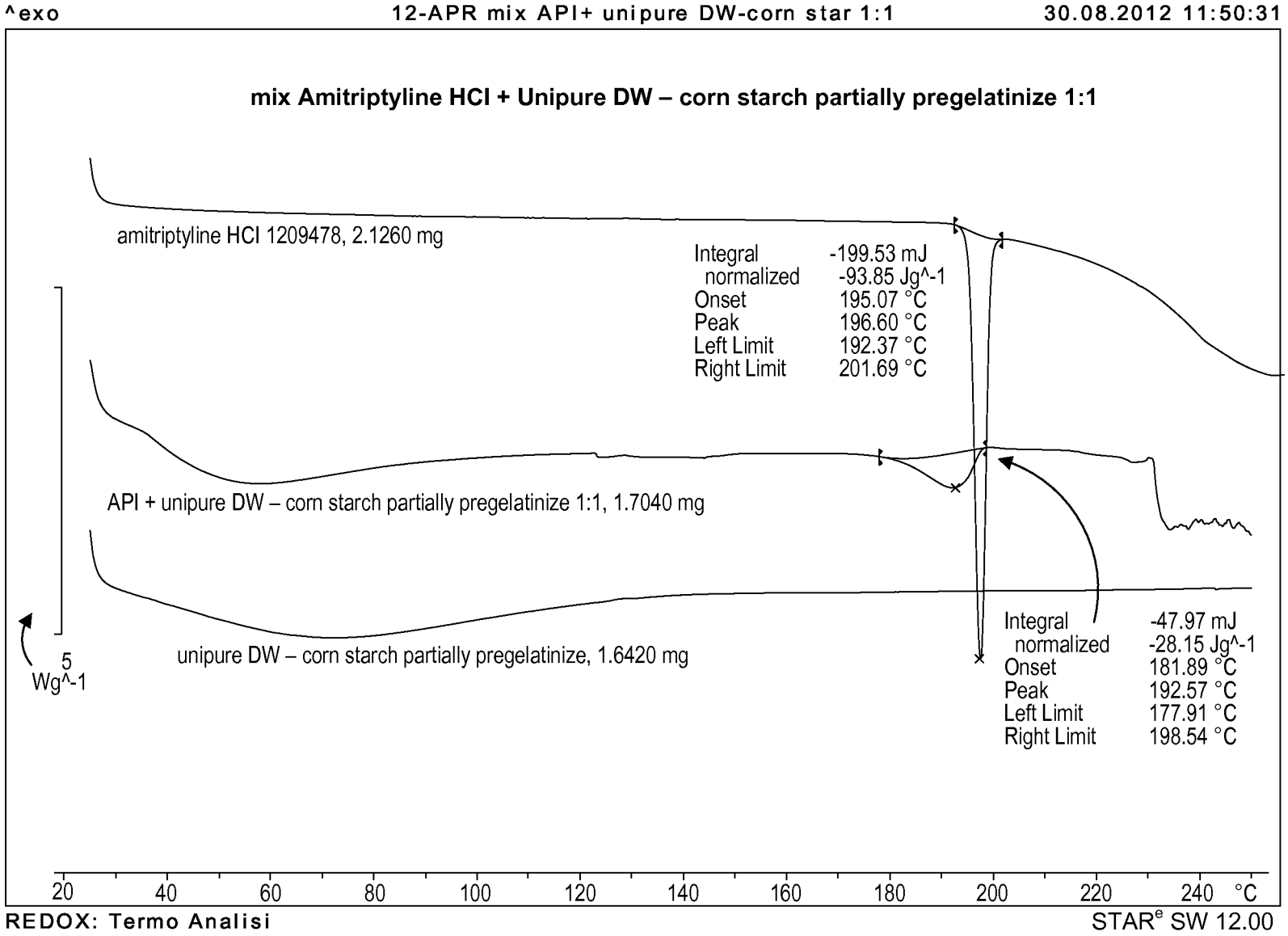

^exo
12-APR mix API+ unipure DW-corn star 1:1
30.08.2012 11:50:31
mix Amitriptyline HCl + Unipure DW – corn starch partially pregelatinize 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
API + 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

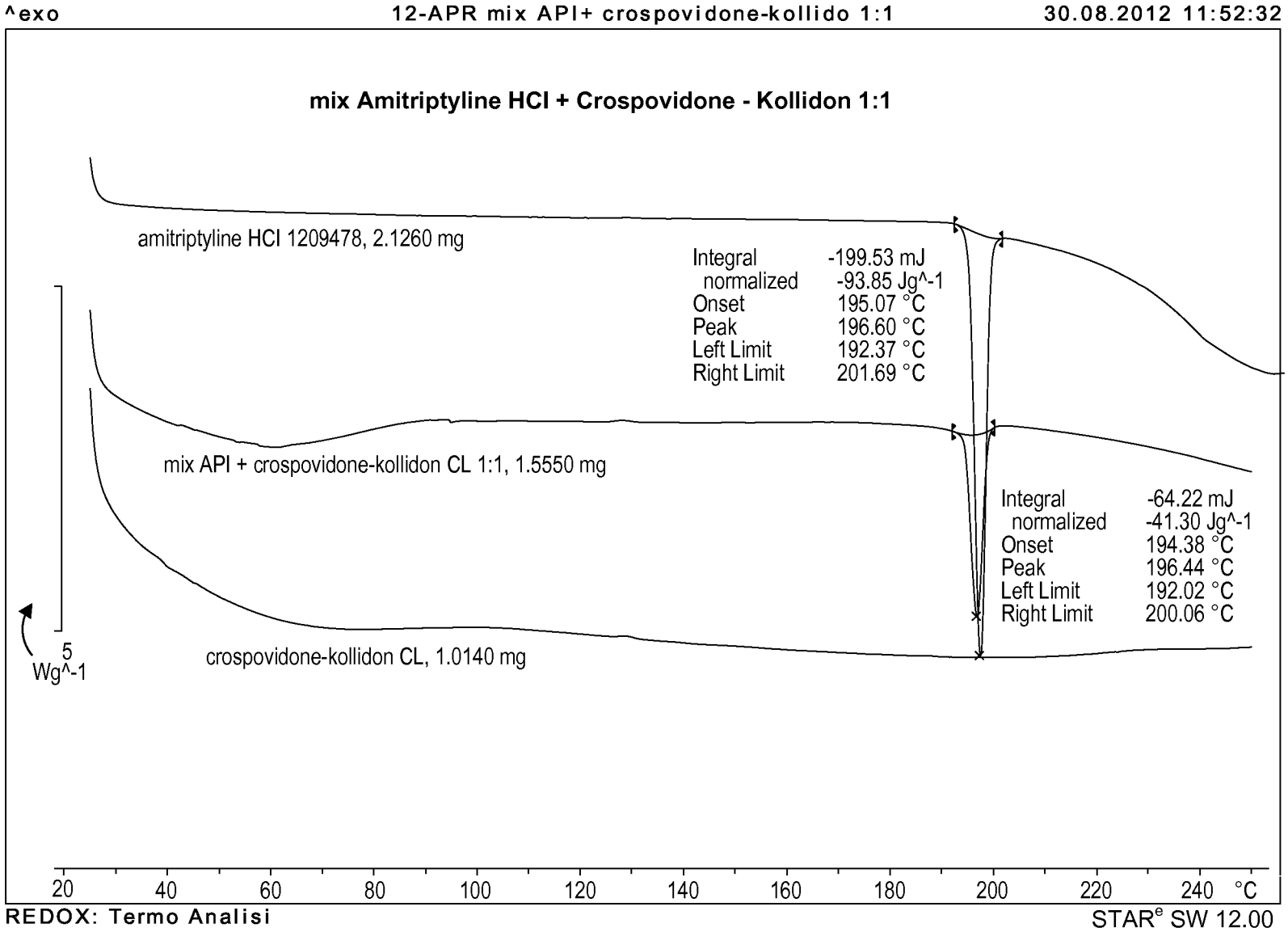

^exo
12-APR mix API+ crospovidone-kollido 1:1
30.08.2012 11:52:32
mix Amitriptyline HCl + Crospovidone - Kollidon 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + crospovidone-kollidon 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
STAR^e SW 12.00

FIG. 85

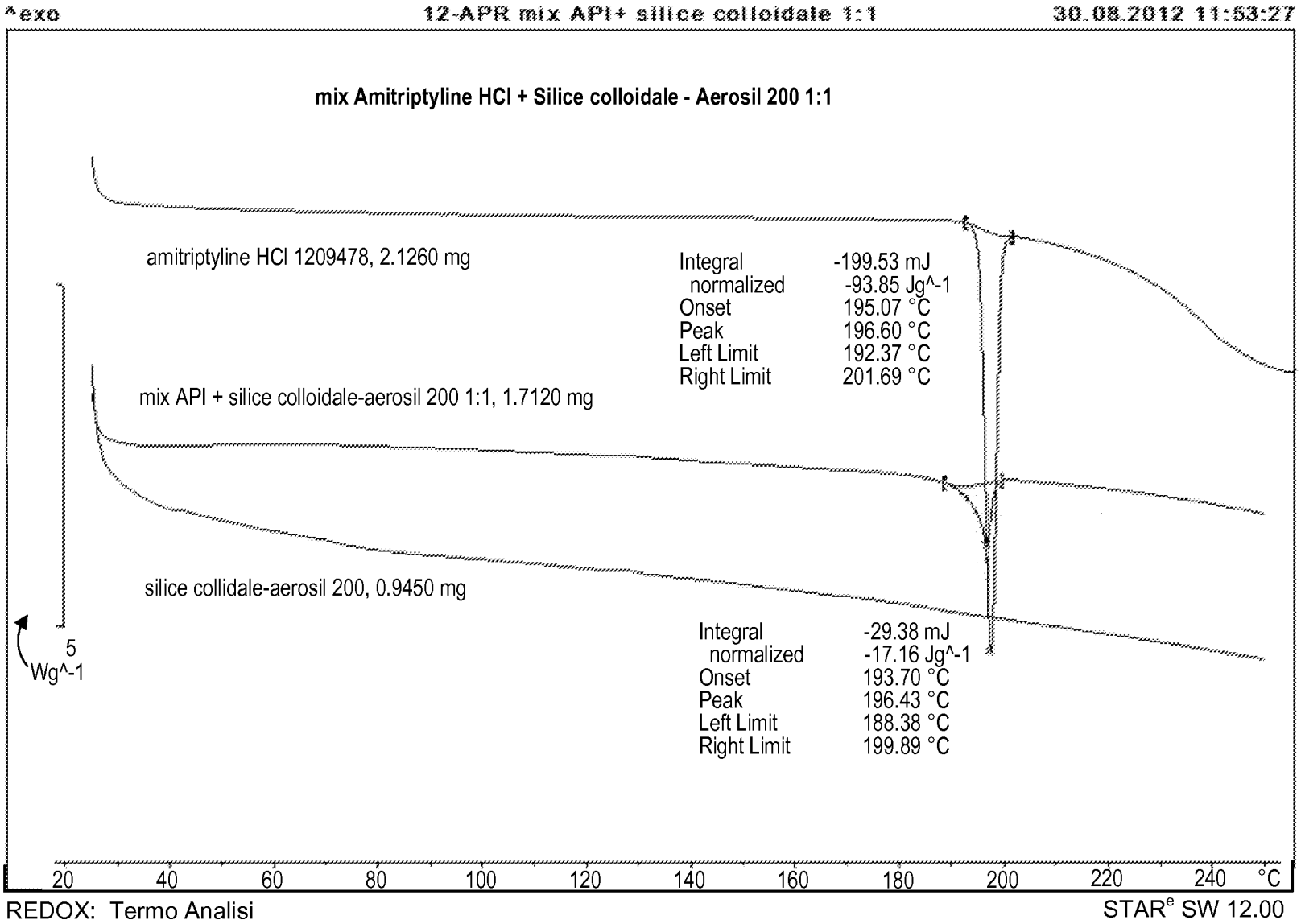

^exo
12-APR mix API+ silice colloidale 1:1
30.08.2012 11:53:27
mix Amitriptyline HCl + Silice colloidale - Aerosil 200 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + silice colloidale-aerosil 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
STAR^e SW 12.00

FIG. 86

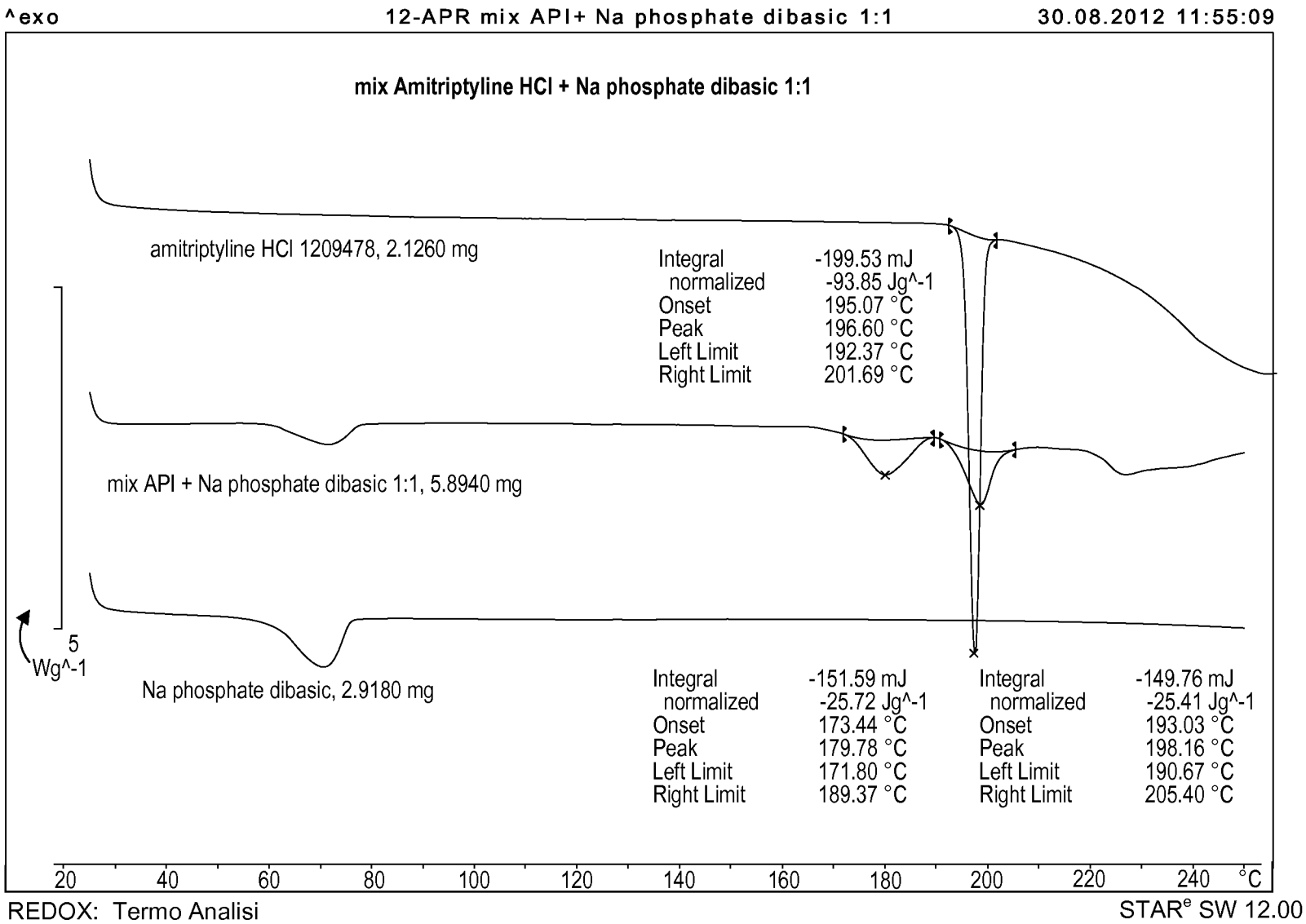

^exo
12-APR mix API+ Na phosphate dibasic 1:1
30.08.2012 11:55:09
mix Amitriptyline HCl + Na phosphate dibasic 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + Na phosphate dibasic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

FIG. 87

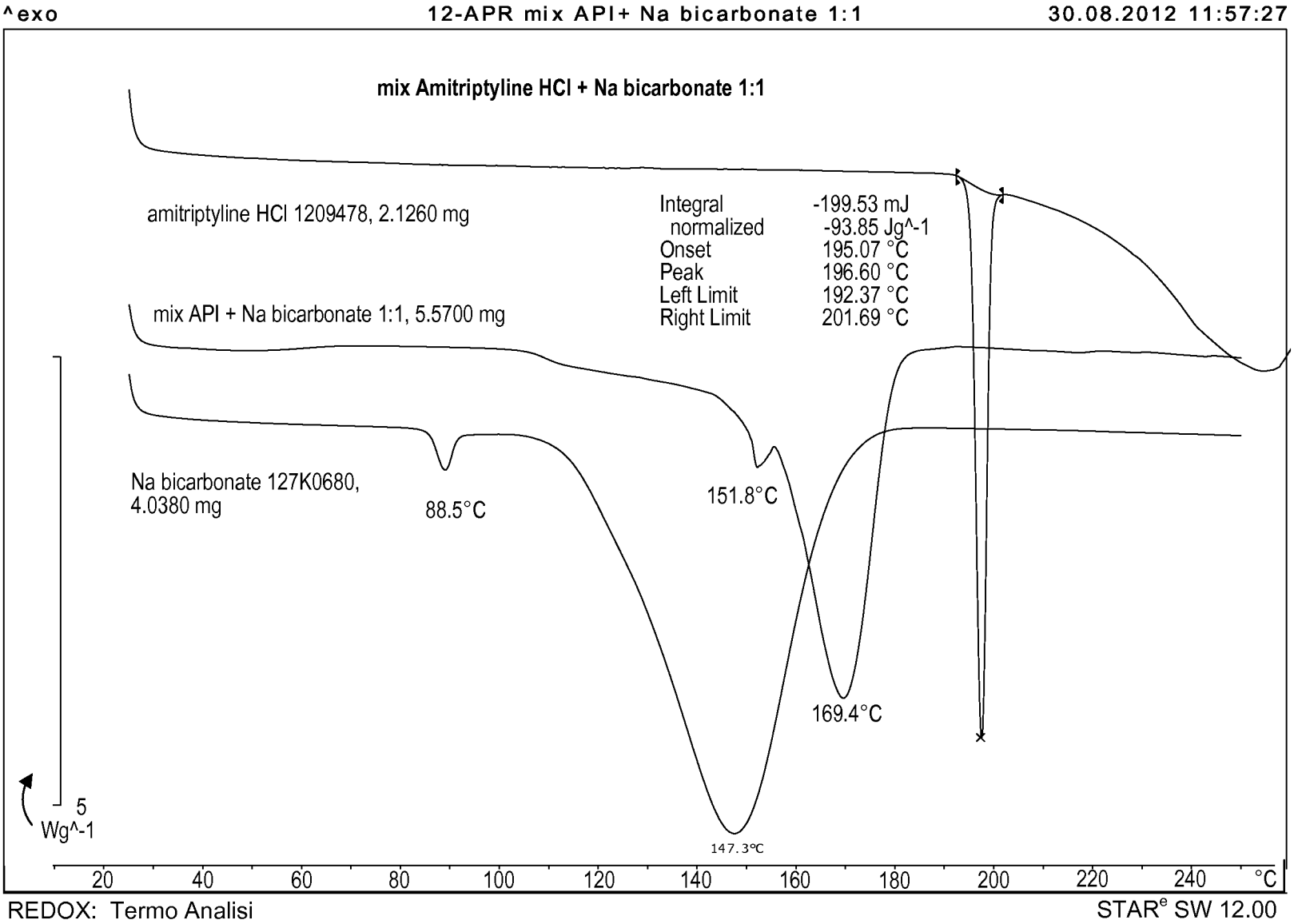

^exo
12-APR mix API+ Na bicarbonate 1:1
30.08.2012 11:57:27
mix Amitriptyline HCl + Na bicarbonate 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + Na bicarbonate 1:1, 5.5700 mg
Na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

FIG. 88

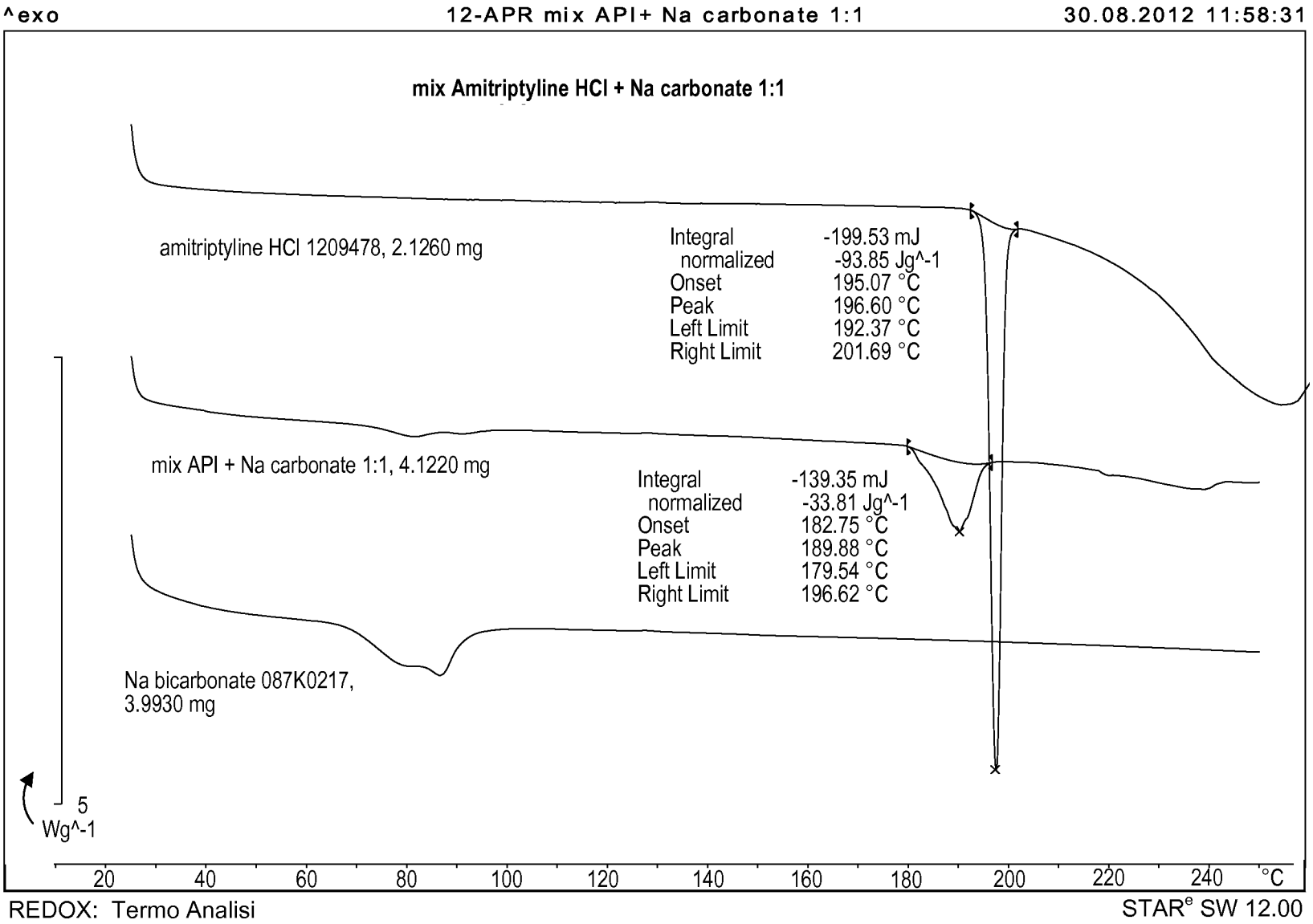

^exo
12-APR mix API+ Na carbonate 1:1
30.08.2012 11:58:31
mix Amitriptyline HCl + Na carbonate 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
mix API + Na carbonate 1:1, 4.1220 mg
Integral -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

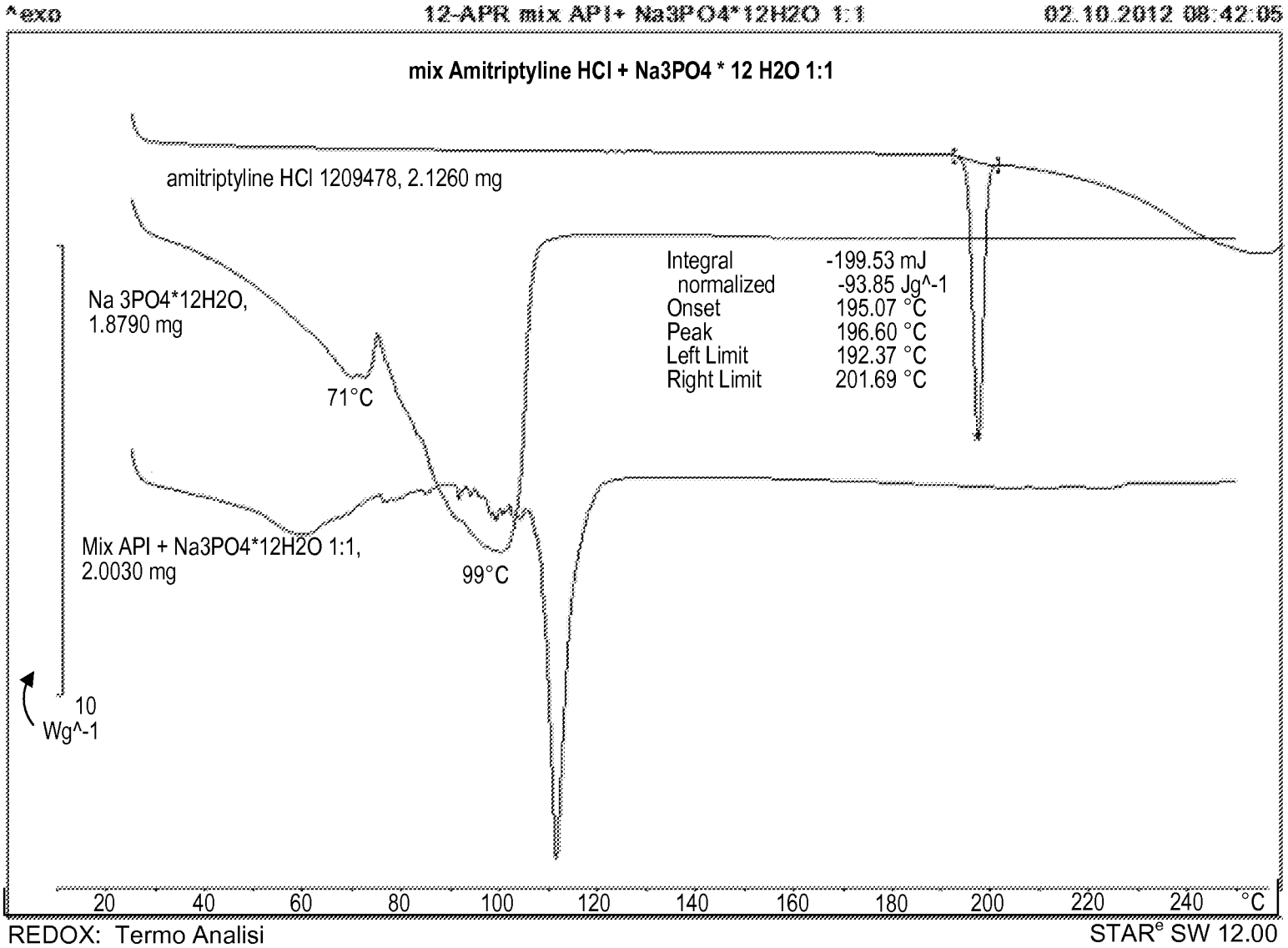

^exo
12-APR mix API+ Na3PO4*12H2O 1:1
02.10.2012 08:42:05
mix Amitriptyline HCl + Na3PO4 * 12 H2O 1:1
amitriptyline HCl 1209478, 2.1260 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
Na 3PO4*12H2O, 1.8790 mg
71°C
Mix API + Na3PO4*12H2O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

FIG. 90

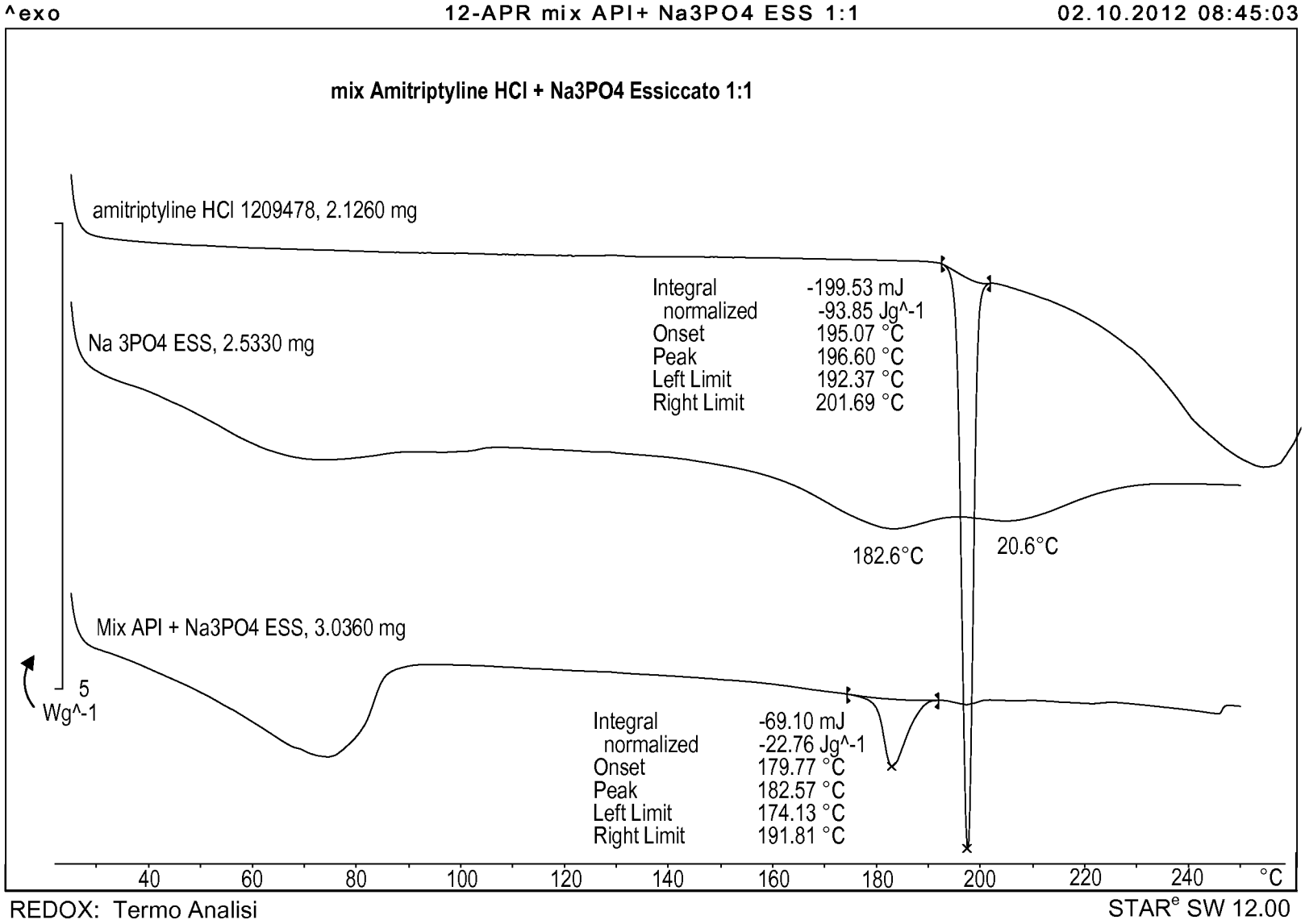

^exo
12-APR mix API+ Na3PO4 ESS 1:1
02.10.2012 08:45:03
mix Amitriptyline HCl + Na3PO4 Essiccato 1:1
amitriptyline HCl 1209478, 2.1260 mg
Na 3PO4 ESS, 2.5330 mg
Mix API + Na3PO4 ESS, 3.0360 mg
Integral -199.53 mJ
normalized -93.85 Jg^-1
Onset 195.07 °C
Peak 196.60 °C
Left Limit 192.37 °C
Right Limit 201.69 °C
182.6°C
20.6°C
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
STAR^e SW 12.00

FIG. 91

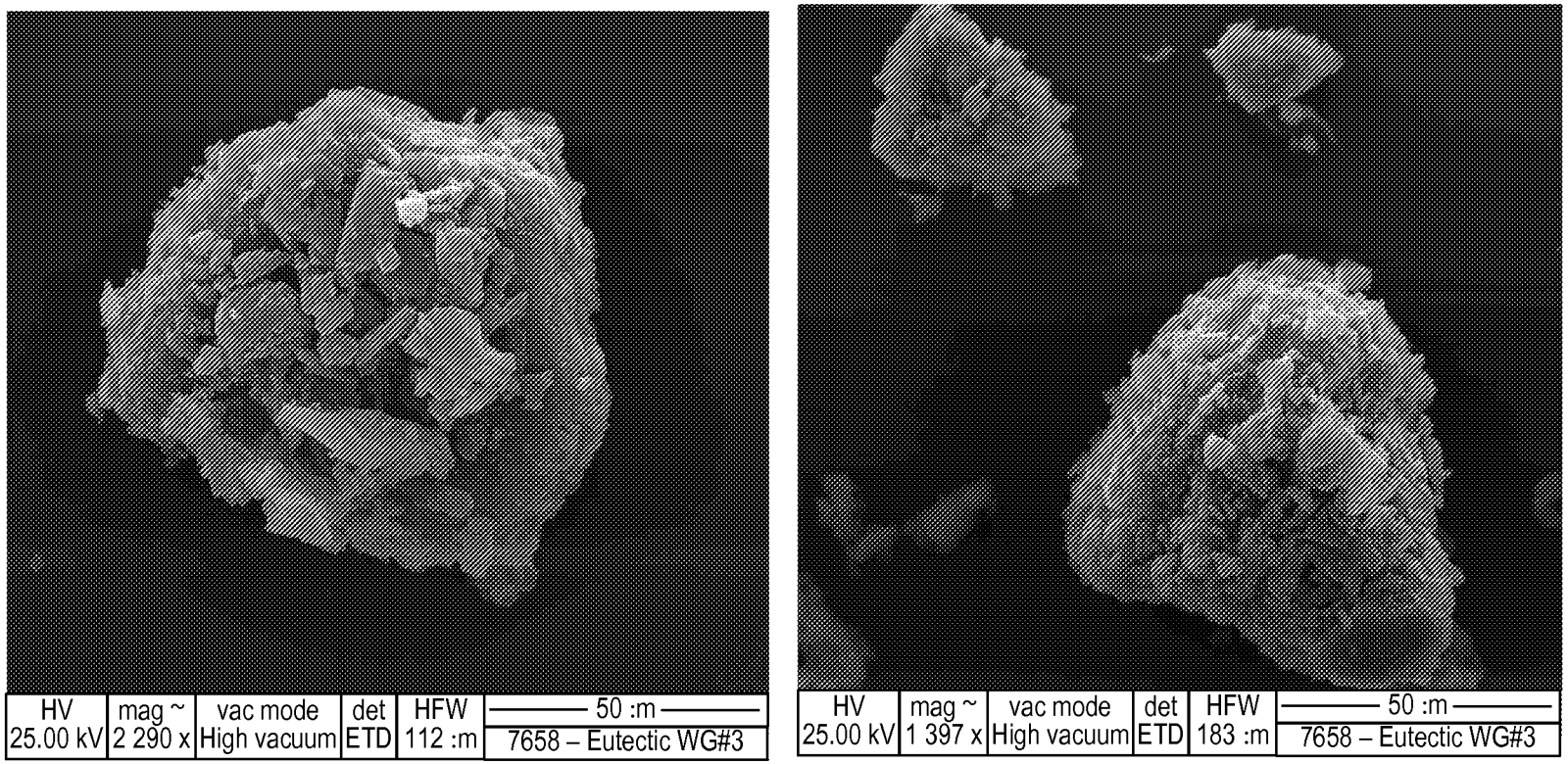

HV
25.00 kV
mag ~
2 290 x
vac mode
High vacuum
det
ETD
HFW
112 :m
50 :m
7658 – Eutectic WG#3
HV
25.00 kV
mag ~
1 397 x
vac mode
High vacuum
det
ETD
HFW
183 :m
50 :m
7658 – Eutectic WG#3

FIG. 92

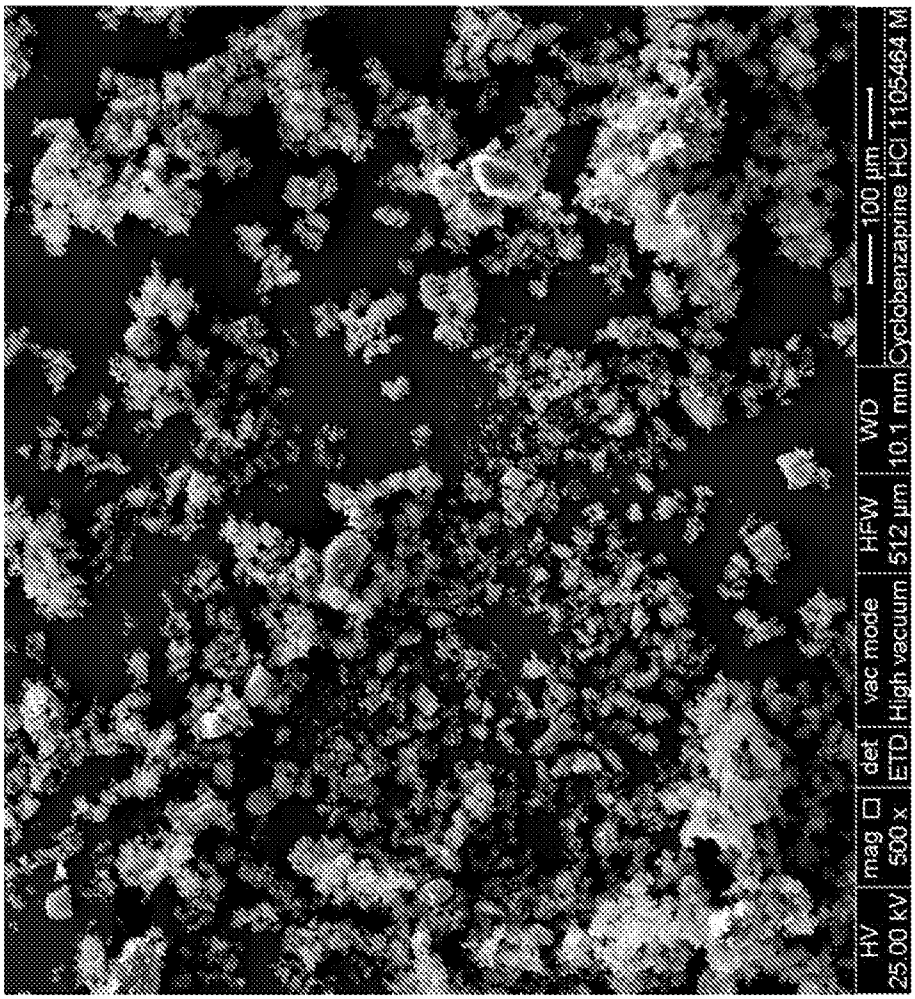

HV
25.00 kV
mag
500 x
det
ETD
vac mode
High vacuum
HFW
512 µm
WD
10.1 mm
100 µm
Cyclobenzaprine HCl 1105464 M

FIG. 93

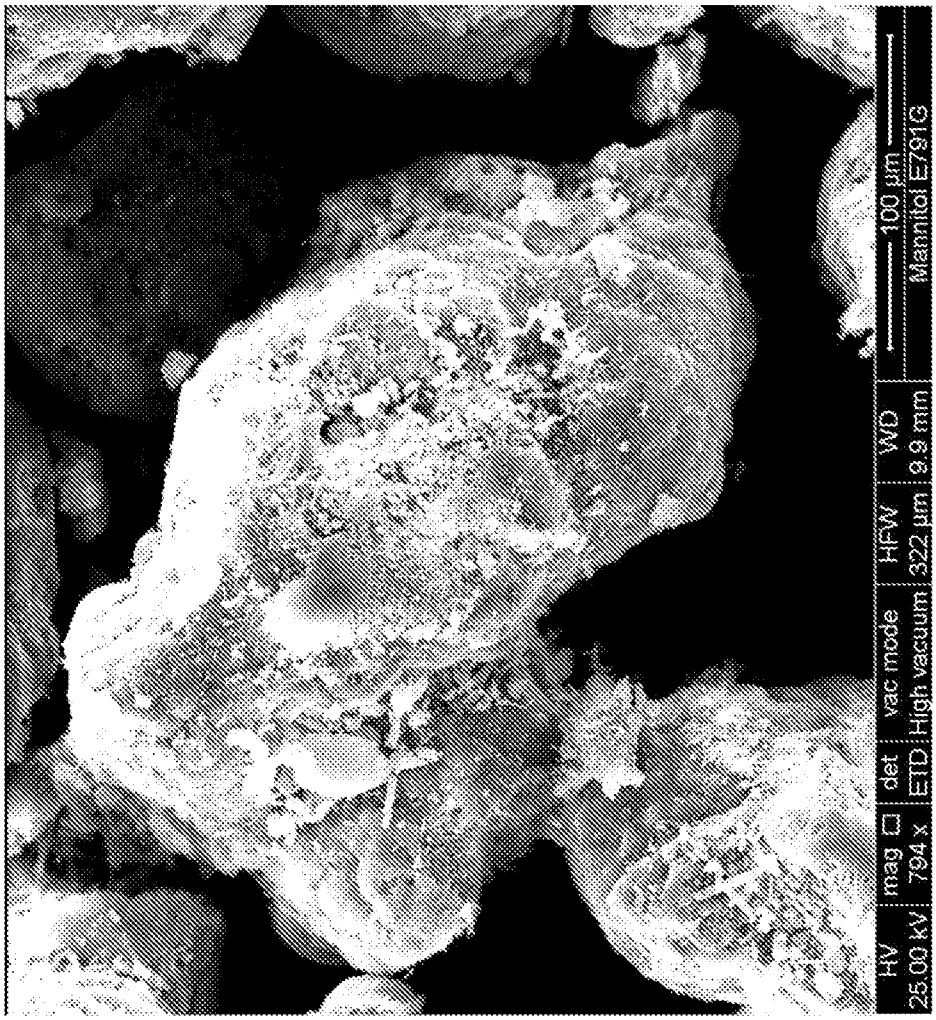

HV
25.00 kV
mag
794 x
det
ETD
vac mode
High vacuum
HFW
322 µm
WD
8.9 mm
100 µm
Mannitol E791G

FIG. 94

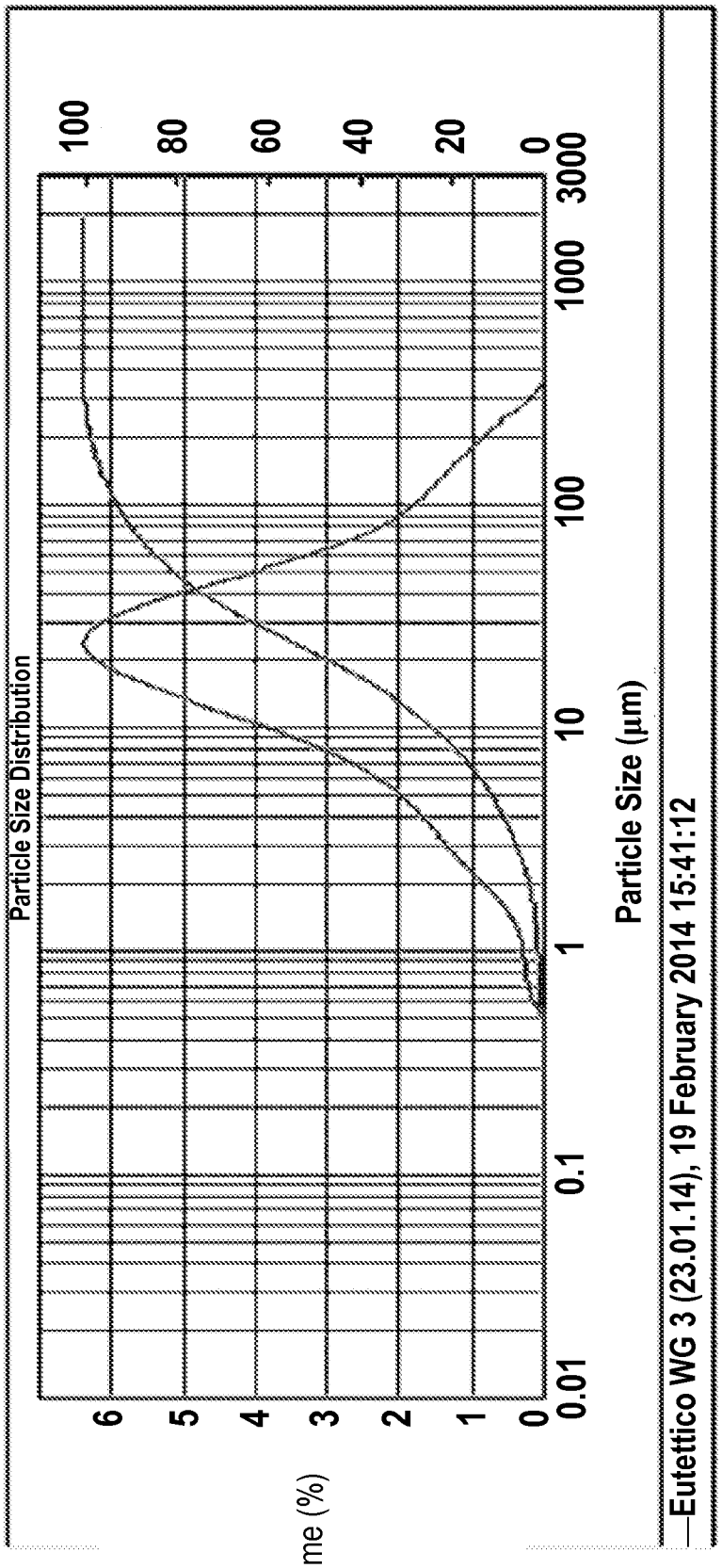

Particle Size Distribution
Volume (%)
0
1
2
3
4
5
6
0.01
0.1
1
10
100
1000
3000
Particle Size (µm)
0
20
40
60
80
100
—Eutettico WG 3 (23.01.14), 19 February 2014 15:41:12

FIG. 95

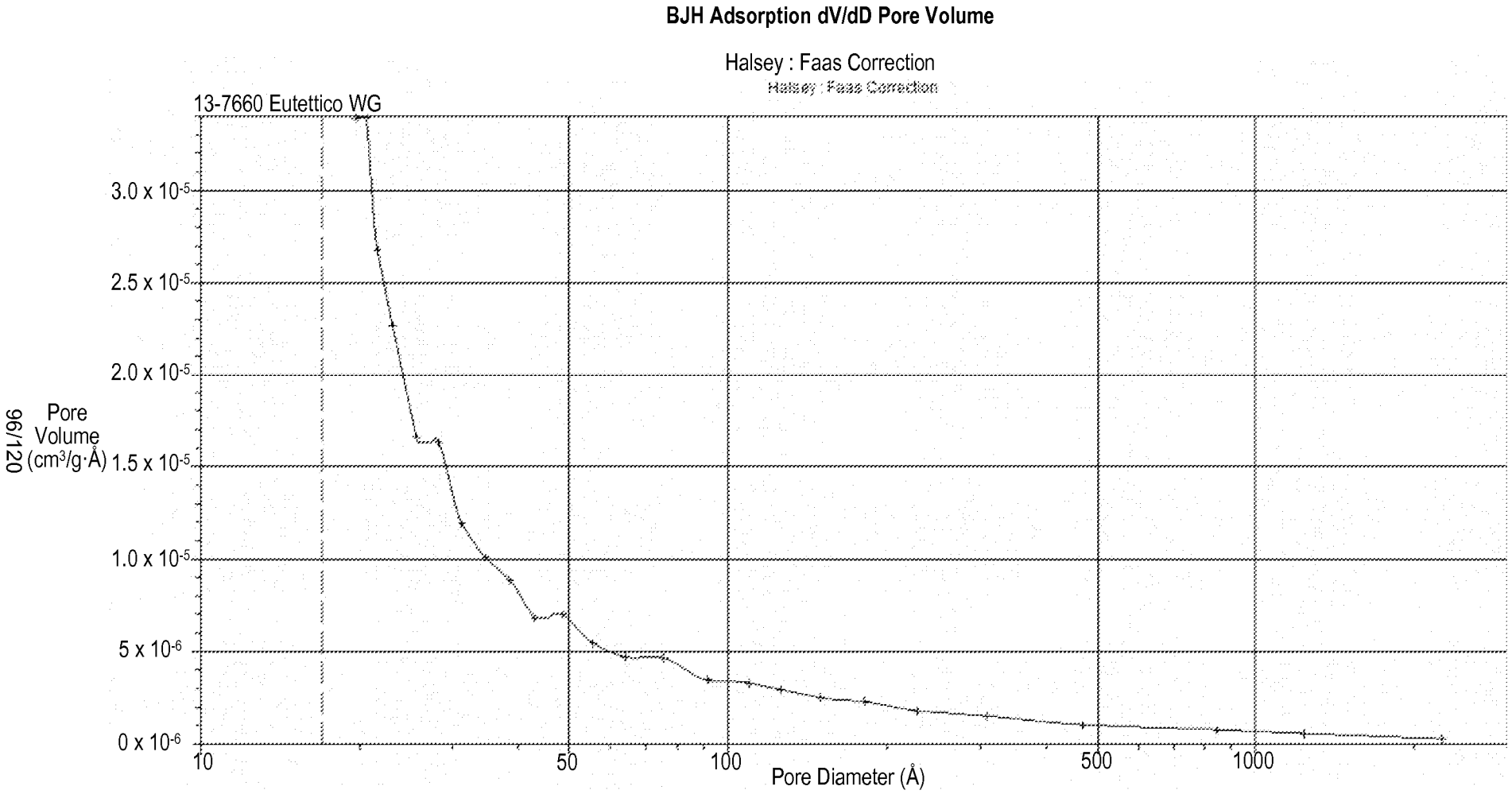

BJH Adsorption dV/dD Pore Volume
Halsey : Faas Correction
13-7660 Eutettico WG
3.0 x 10-5
2.5 x 10-5
2.0 x 10-5
1.5 x 10-5
1.0 x 10-5
5 x 10-6
0 x 10-6
Pore Volume (cm3/g·Å)
10
50
100
500
1000
Pore Diameter (Å)



FIG. 96

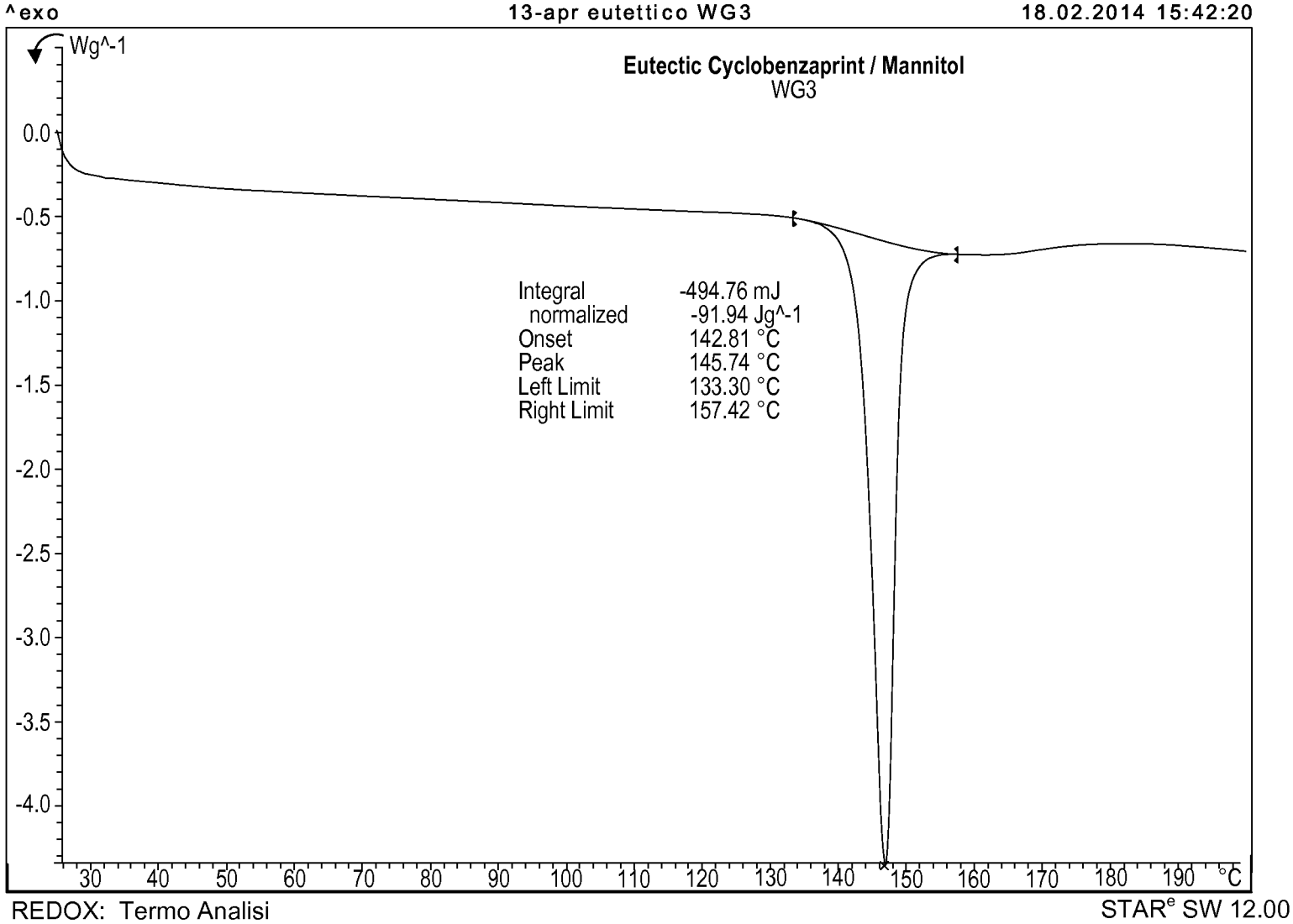

^exo
13-apr eutettico WG3
18.02.2014 15:42:20
Wg^-1
Eutectic Cyclobenzaprint / Mannitol
WG3
0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
Integral -494.76 mJ
normalized -91.94 Jg^-1
Onset 142.81 °C
Peak 145.74 °C
Left Limit 133.30 °C
Right Limit 157.42 °C
30 40 50 60 70 80 90 100 110 120 130 140 150 160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

FIG. 97

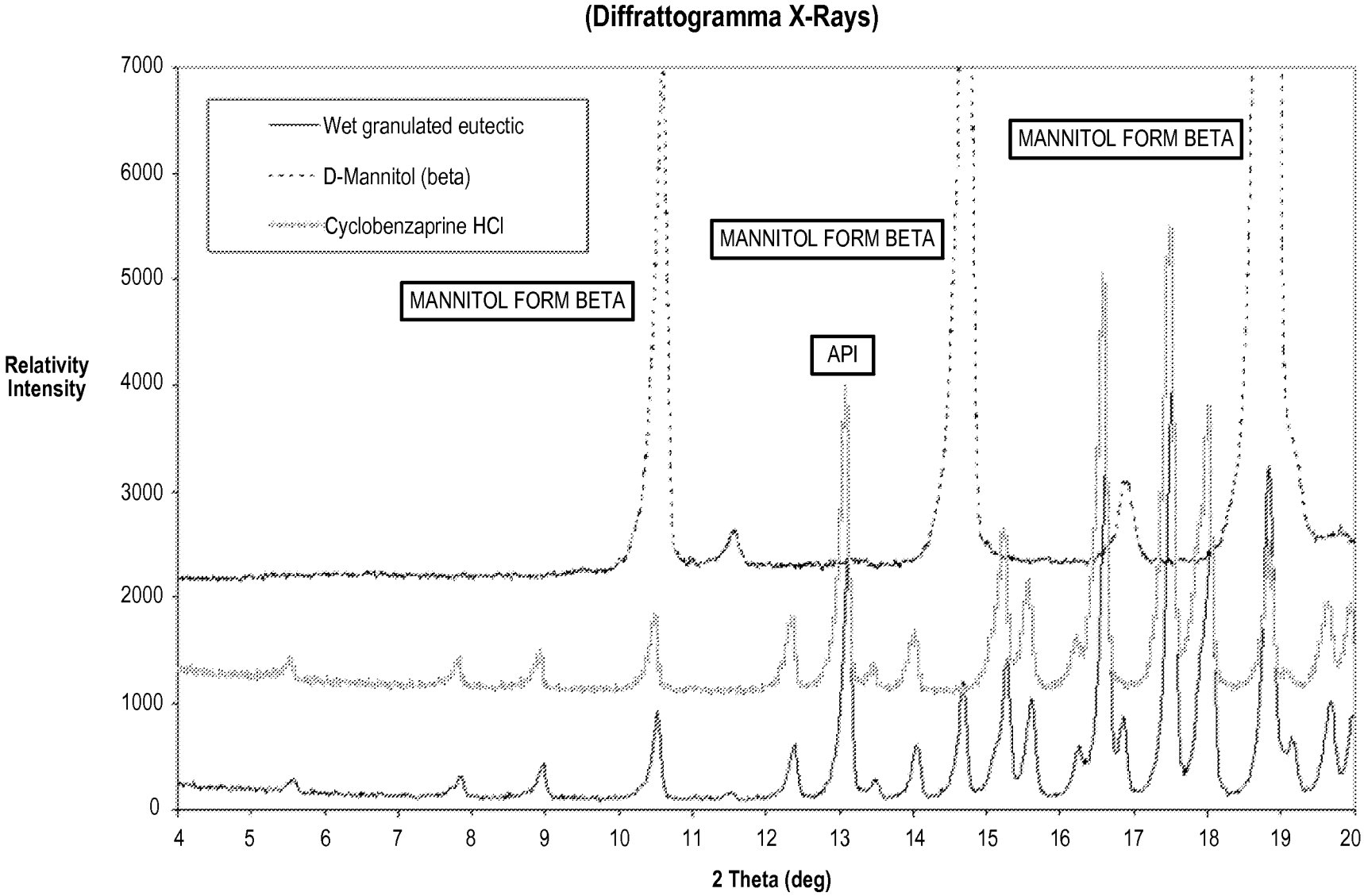

(Diffrattogramma X-Rays)
Wet granulated eutectic
D-Mannitol (beta)
Cyclobenzaprine HCl
MANNITOL FORM BETA
MANNITOL FORM BETA
API
MANNITOL FORM BETA
Relativity Intensity
7000
6000
5000
4000
3000
2000
1000
0
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
2 Theta (deg)

FIG. 98

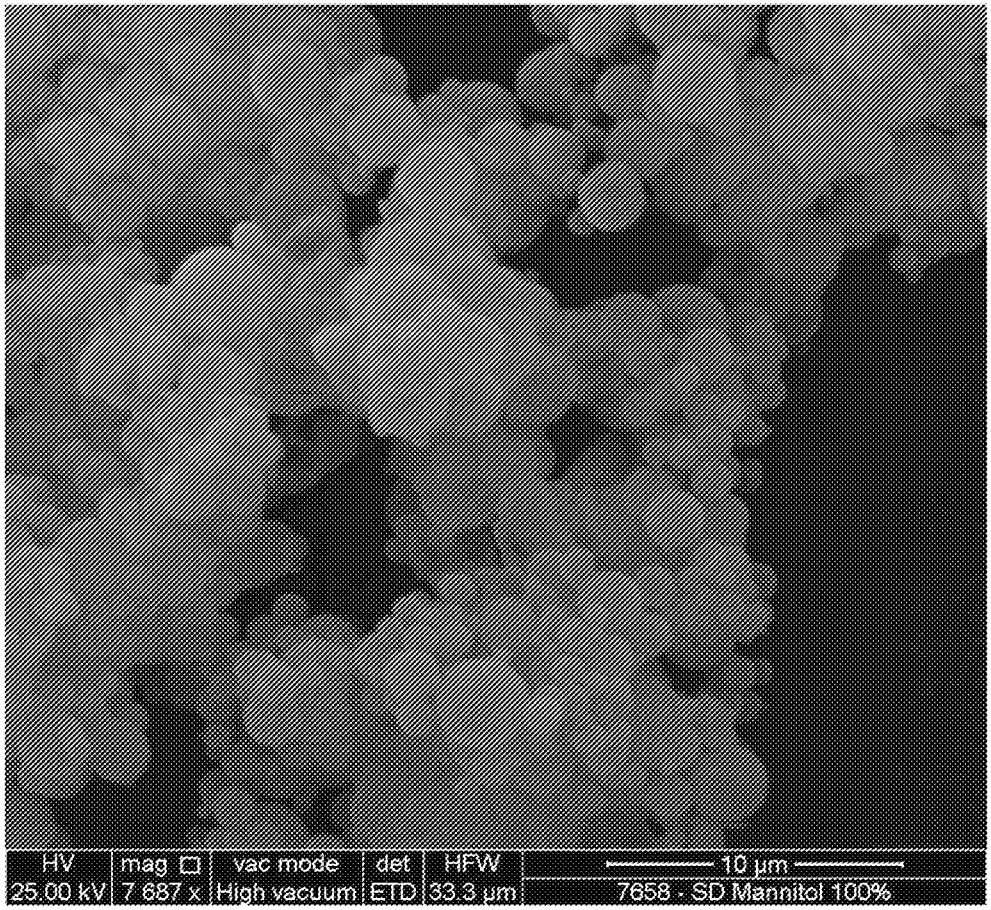

HV
25.00 kV
mag
7 687 x
vac mode
High vacuum
det
ETD
HFW
33.3 µm
10 µm
7658 - SD Mannitol 100%

FIG. 99

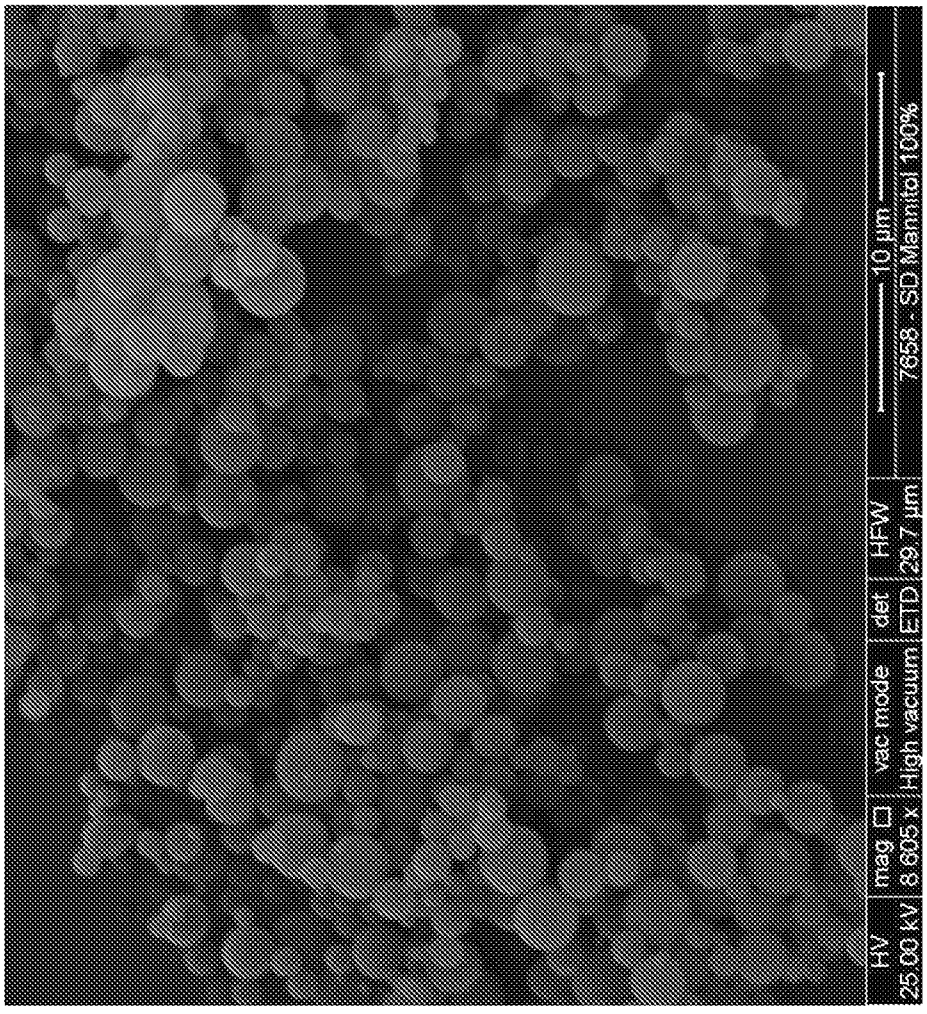

HV
25.00 kV
mag
8 605 x
vac mode
High vacuum
det
ETD
HFW
29.7 µm
10 µm
7658 - SD Mannitol 100%

FIG. 100

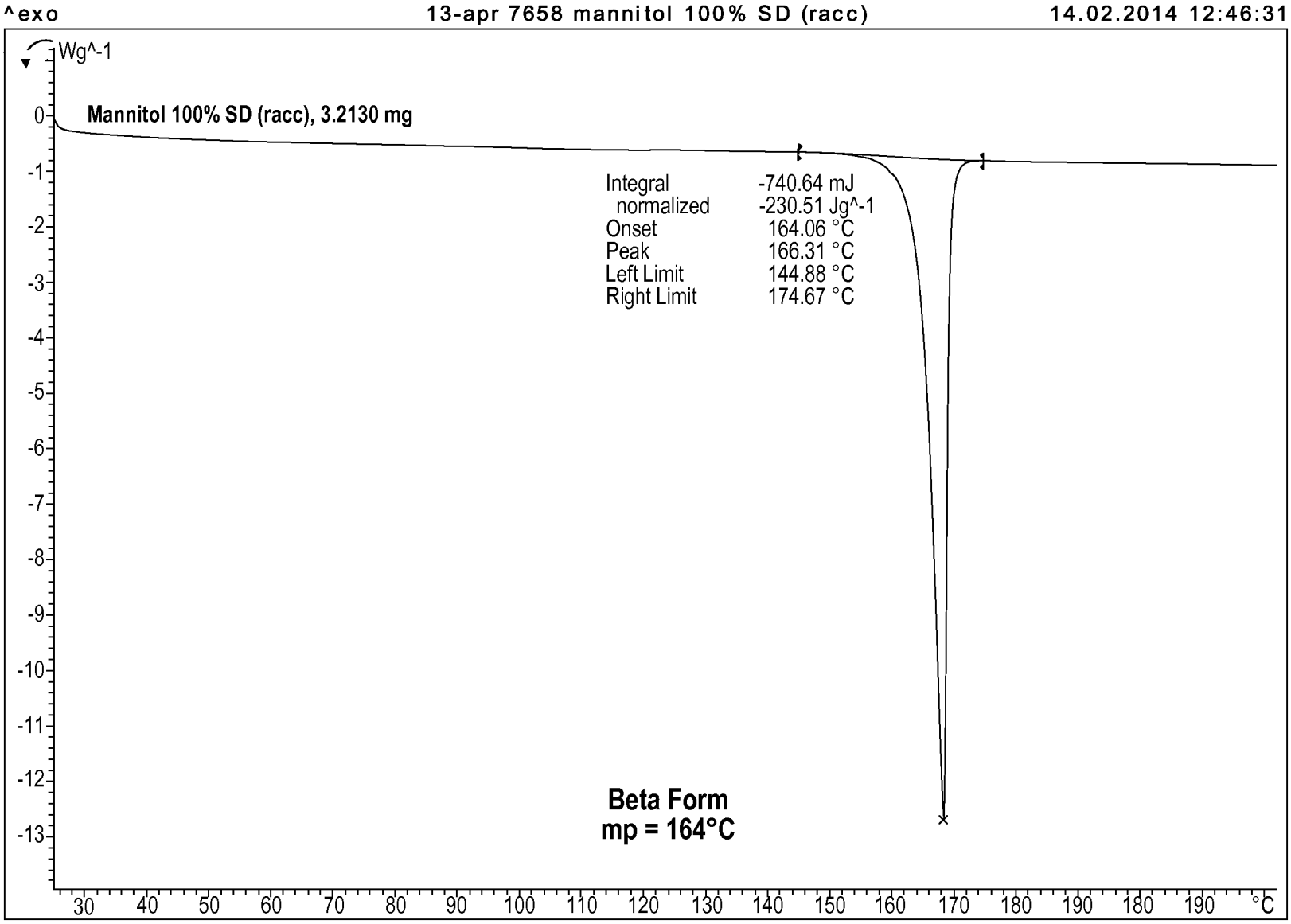

^exo
13-apr 7658 mannitol 100% SD (racc)
14.02.2014 12:46:31
Wg^-1
Mannitol 100% SD (racc), 3.2130 mg
Integral -740.64 mJ
normalized -230.51 Jg^-1
Onset 164.06 °C
Peak 166.31 °C
Left Limit 144.88 °C
Right Limit 174.67 °C
Beta Form
mp = 164°C
°C
REDOX: Termo Analisi
STAR^e SW 12.00

**FIG. 101**

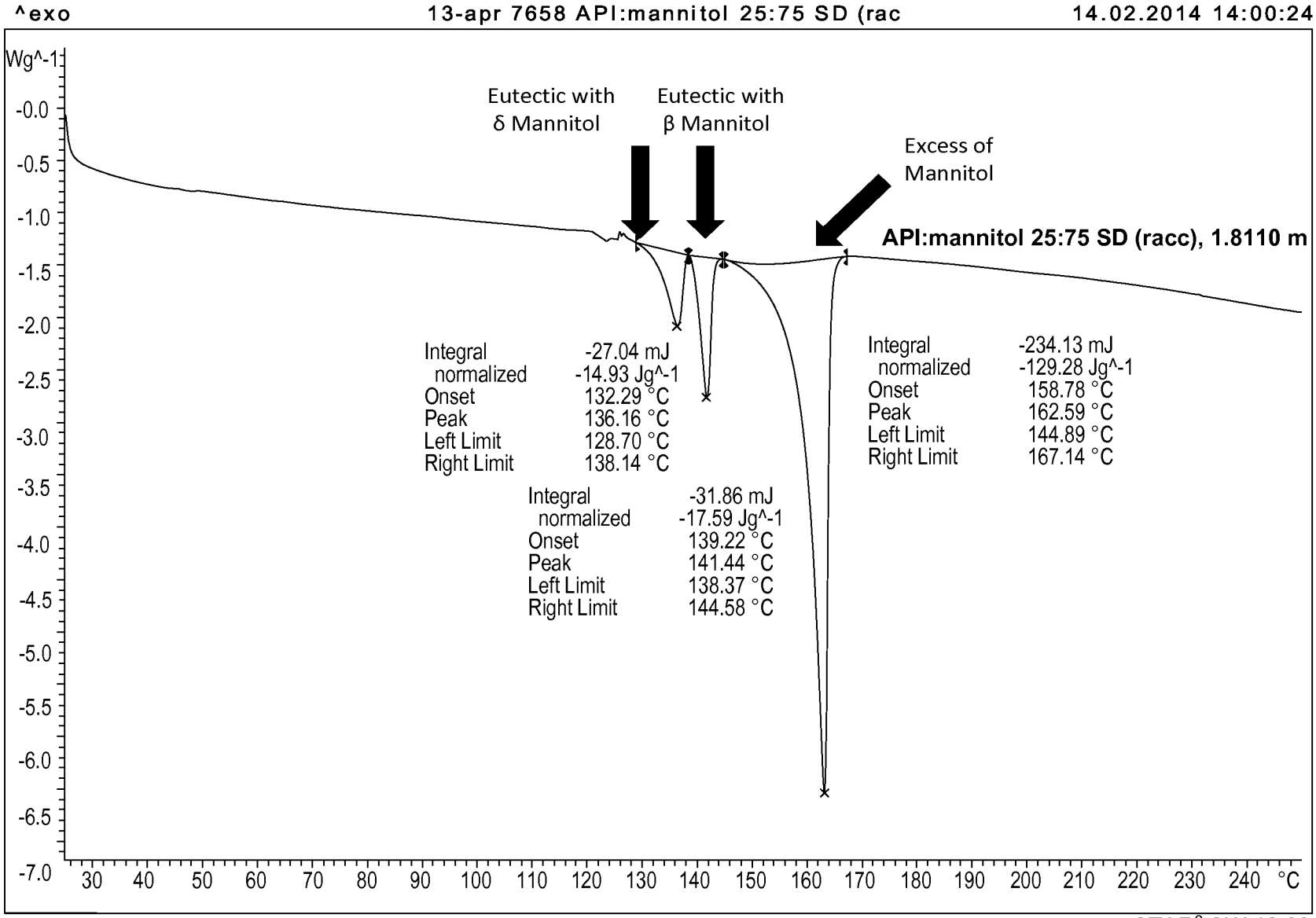

^exo
13-apr 7658 API:mannitol 25:75 SD (rac
14.02.2014 14:00:24
Wg^-1
-0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
-4.5
-5.0
-5.5
-6.0
-6.5
-7.0
30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 °C
Eutectic with δ Mannitol
Eutectic with β Mannitol
Excess of Mannitol
API:mannitol 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

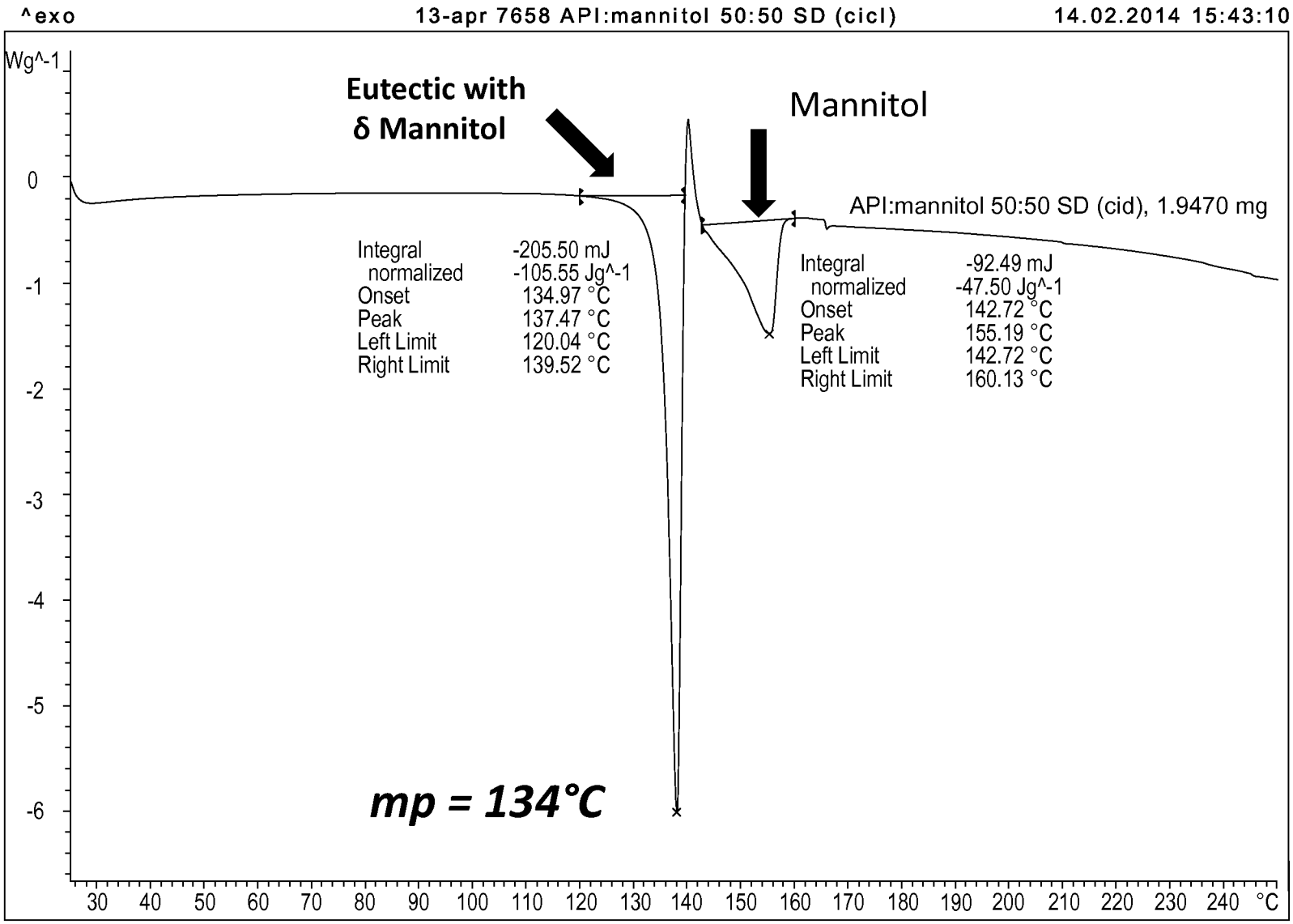

^exo
13-apr 7658 API:mannitol 50:50 SD (cicl)
14.02.2014 15:43:10
Wg^-1
Eutectic with
δ Mannitol
Mannitol
API:mannitol 50:50 SD (cid), 1.9470 mg
Integral -205.50 mJ
normalized -105.55 Jg^-1
Onset 134.97 °C
Peak 137.47 °C
Left Limit 120.04 °C
Right Limit 139.52 °C
Integral -92.49 mJ
normalized -47.50 Jg^-1
Onset 142.72 °C
Peak 155.19 °C
Left Limit 142.72 °C
Right Limit 160.13 °C
mp = 134°C
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
STAR^e SW 12.00

FIG. 103

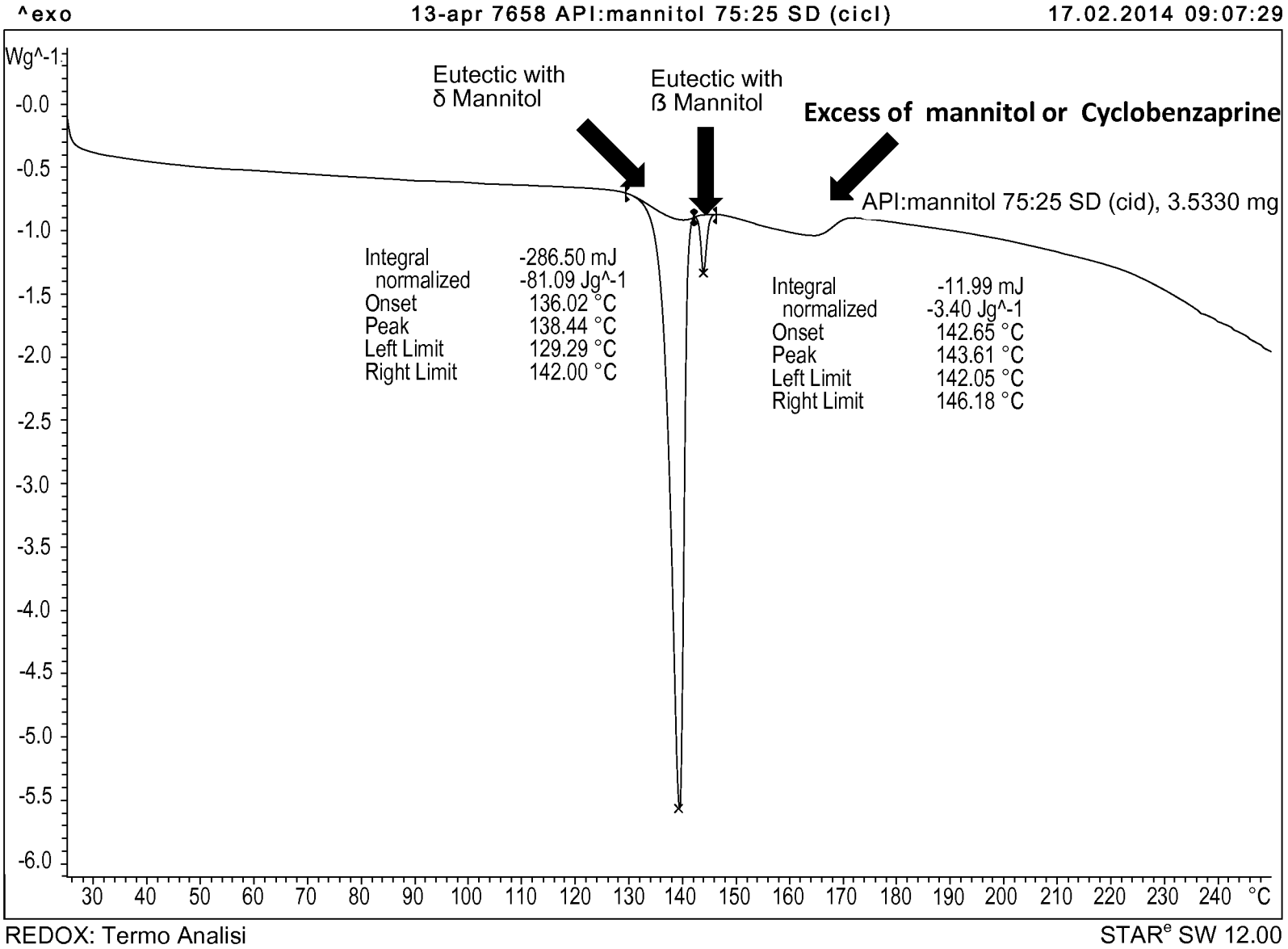

^exo
13-apr 7658 API:mannitol 75:25 SD (cicl)
17.02.2014 09:07:29
Wg^-1
-0.0
-0.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
-4.0
-4.5
-5.0
-5.5
-6.0
Eutectic with δ Mannitol
Eutectic with ß Mannitol
Excess of mannitol or Cyclobenzaprine
API:mannitol 75:25 SD (cid), 3.5330 mg
Integral -286.50 mJ
normalized -81.09 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
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. 104

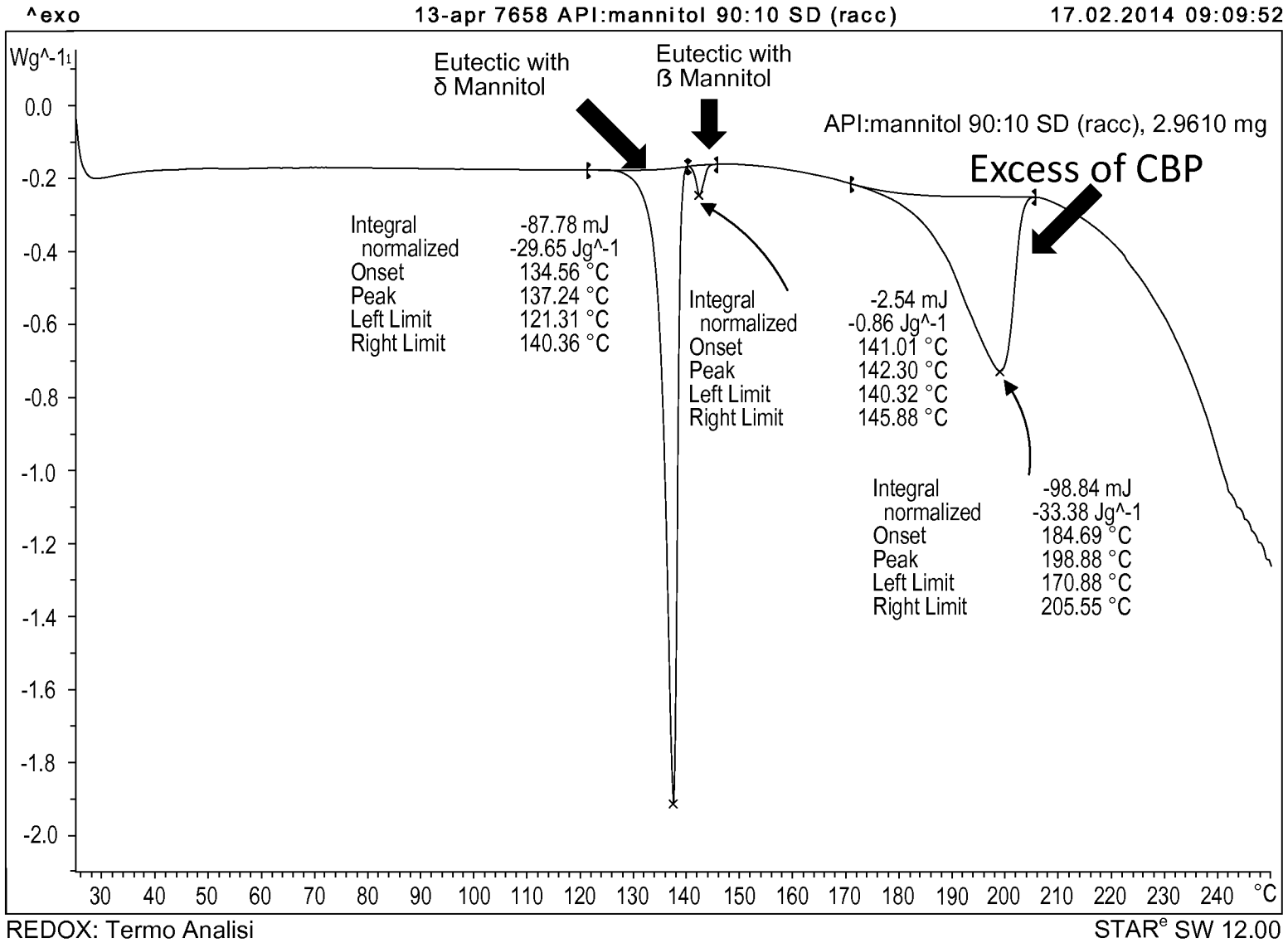

^exo
13-apr 7658 API:mannitol 90:10 SD (racc)
17.02.2014 09:09:52
Wg^-1
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
-1.4
-1.6
-1.8
-2.0
Eutectic with δ Mannitol
Eutectic with ß Mannitol
API:mannitol 90:10 SD (racc), 2.9610 mg
Excess of CBP
Integral -87.78 mJ
normalized -29.65 Jg^-1
Onset 134.56 °C
Peak 137.24 °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
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. 105

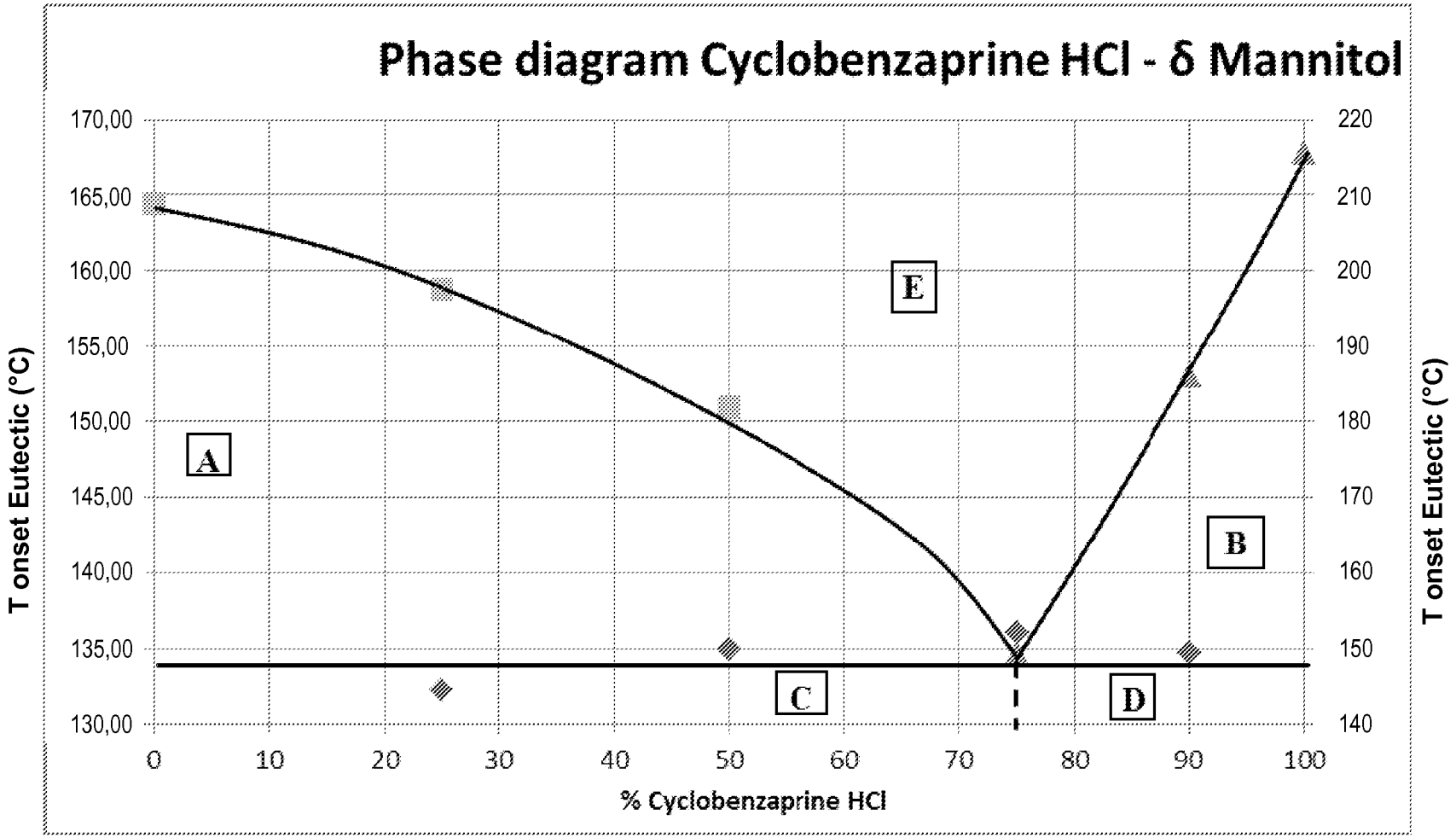

Phase diagram Cyclobenzaprine HCl - δ Mannitol
T onset Eutectic (°C)
T onset Eutectic (°C)
% Cyclobenzaprine HCl
170,00
165,00
160,00
155,00
150,00
145,00
140,00
135,00
130,00
220
210
200
190
180
170
160
150
140
0
10
20
30
40
50
60
70
80
90
100
A
B
C
D
E

FIG. 106

**(Diffrattogramma X-Rays)**

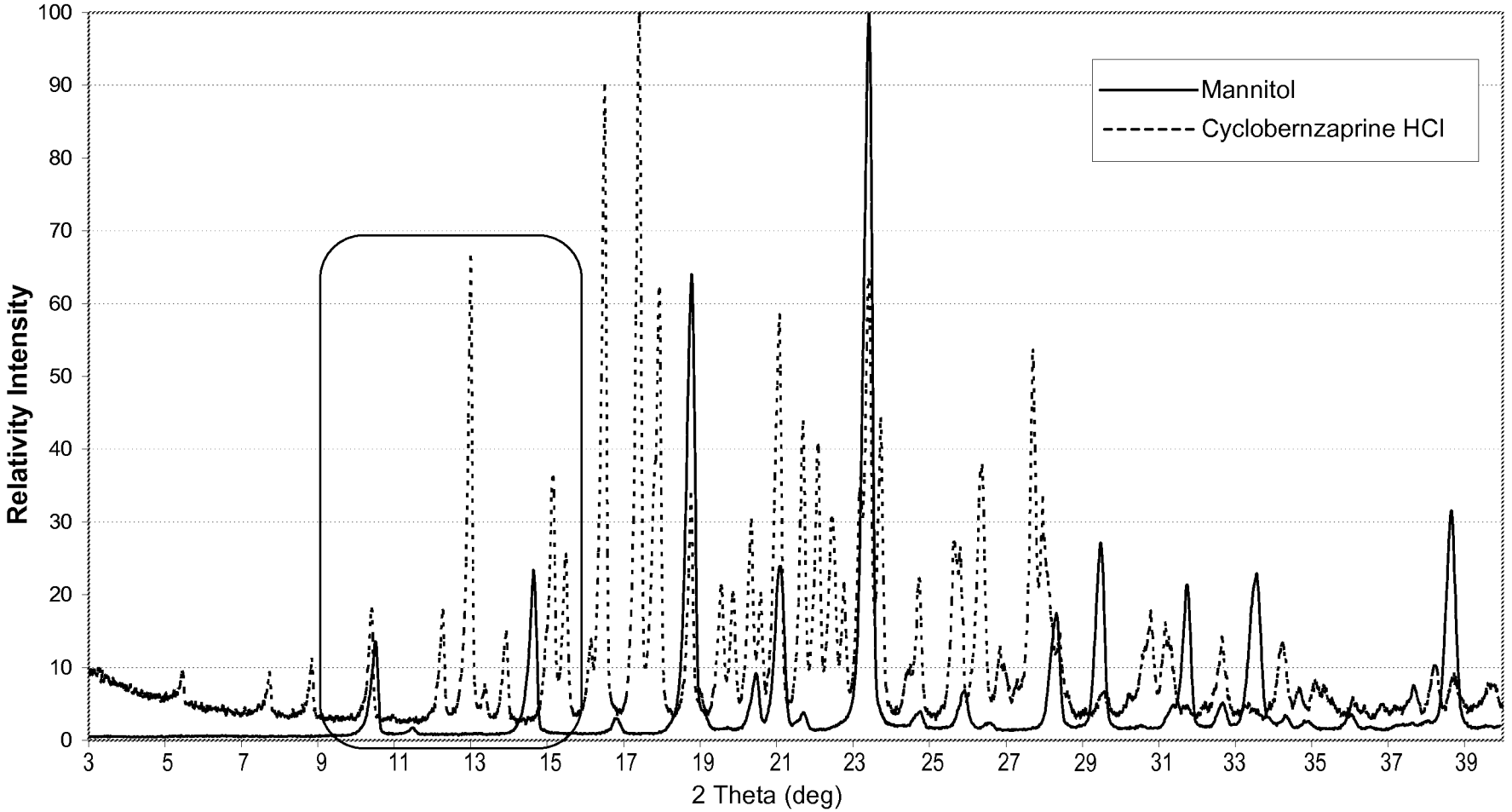



**FIG. 107**

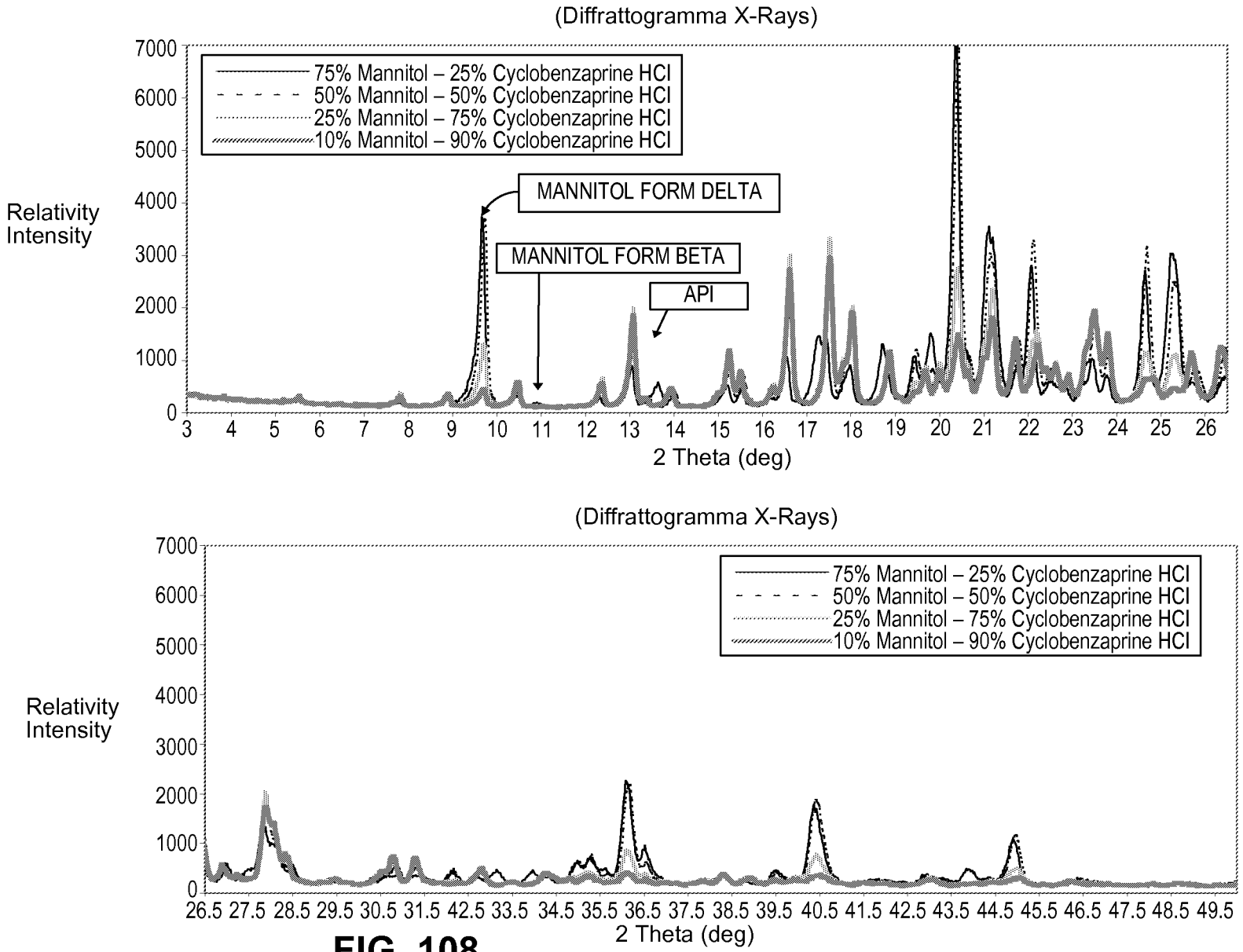

(Diffrattogramma X-Rays)
Relativity Intensity
7000
6000
5000
4000
3000
2000
1000
0
75% Mannitol – 25% Cyclobenzaprine HCl
50% Mannitol – 50% Cyclobenzaprine HCl
25% Mannitol – 75% Cyclobenzaprine HCl
10% Mannitol – 90% Cyclobenzaprine HCl
MANNITOL FORM DELTA
MANNITOL FORM BETA
API
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26
2 Theta (deg)
(Diffrattogramma X-Rays)
Relativity Intensity
7000
6000
5000
4000
3000
2000
1000
0
75% Mannitol – 25% Cyclobenzaprine HCl
50% Mannitol – 50% Cyclobenzaprine HCl
25% Mannitol – 75% Cyclobenzaprine HCl
10% Mannitol – 90% Cyclobenzaprine HCl
26.5 27.5 28.5 29.5 30.5 31.5 42.5 33.5 34.5 35.5 36.5 37.5 38.5 39.5 40.5 41.5 42.5 43.5 44.5 45.5 46.5 47.5 48.5 49.5
2 Theta (deg)

**FIG. 108**

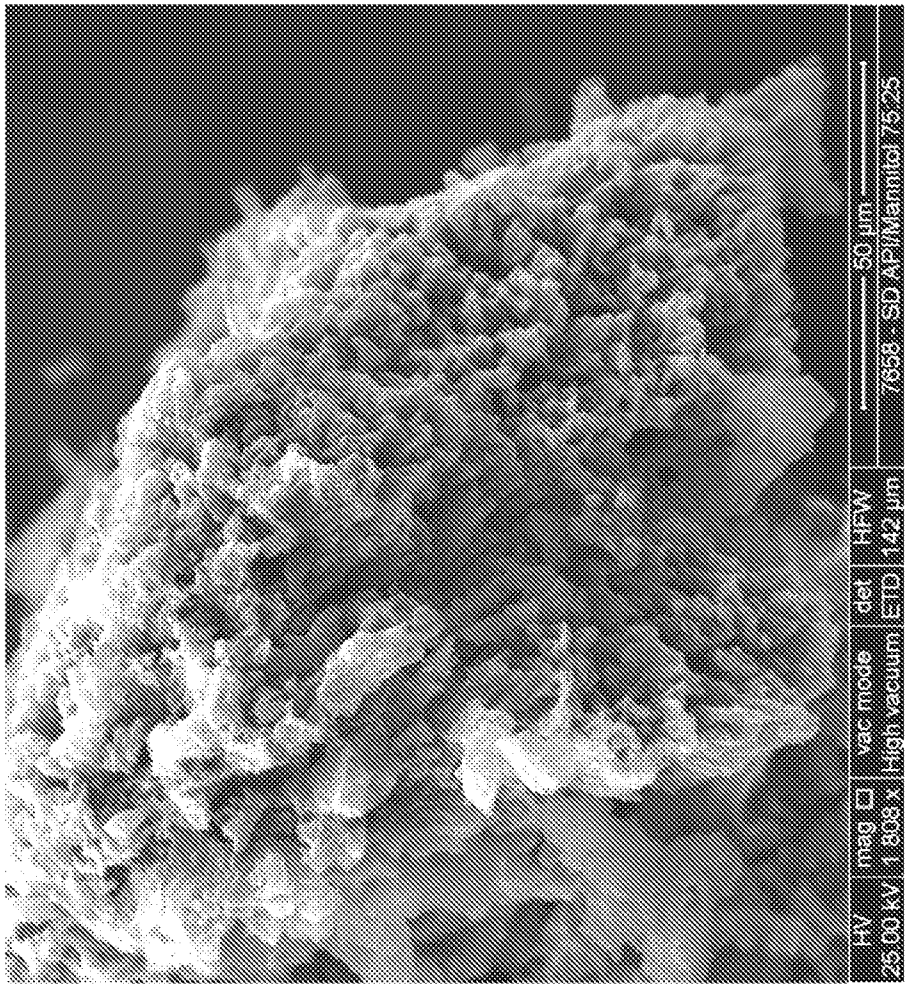

HV
25.00 kV
mag
1 898 x
xtr mode
high vacuum
det
ETD
HFW
142 µm
50 µm
7652 SD API/Mamilol 75:25

FIG. 109

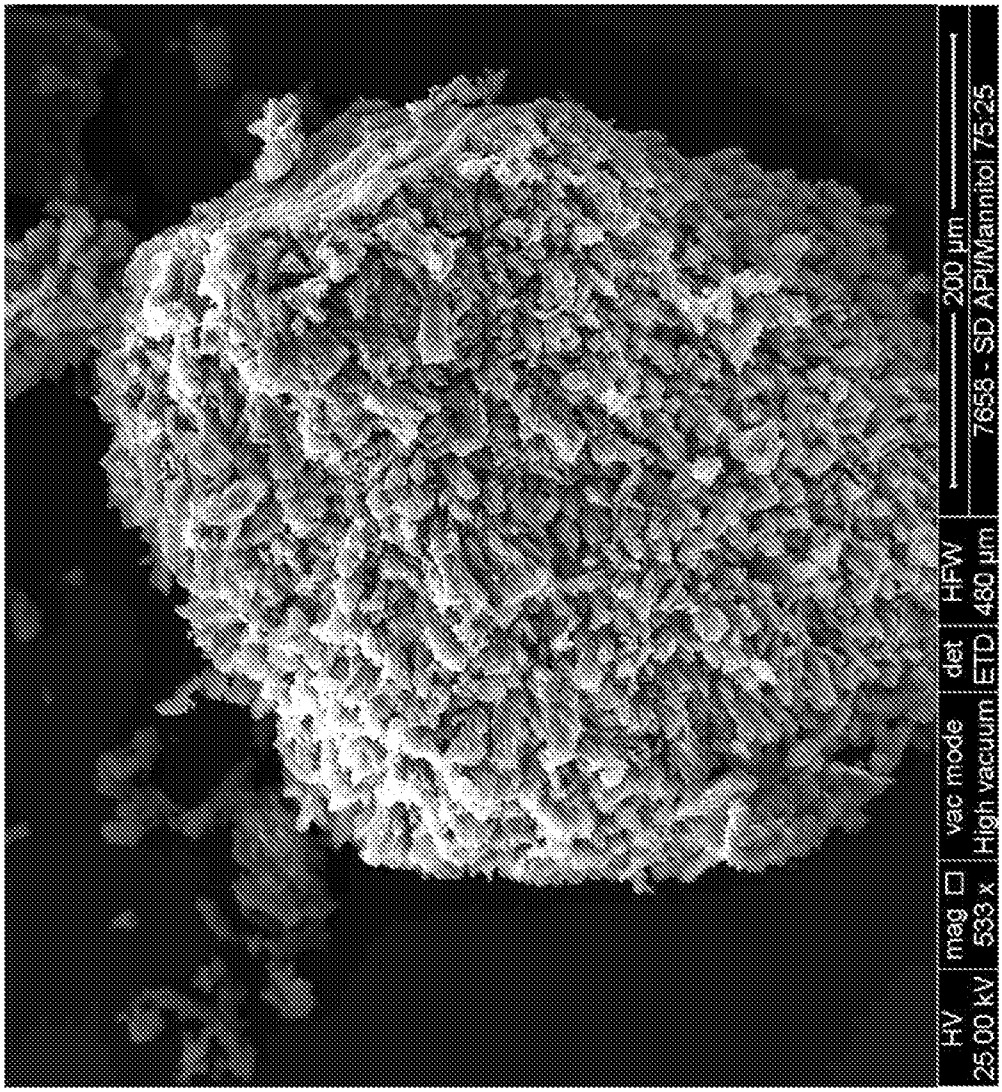

HV
25.00 kV
mag
533 x
vac mode
High vacuum
det
ETD
HFW
480 µm
200 µm
7658 - SD API/Mannitol 75:25

FIG. 110

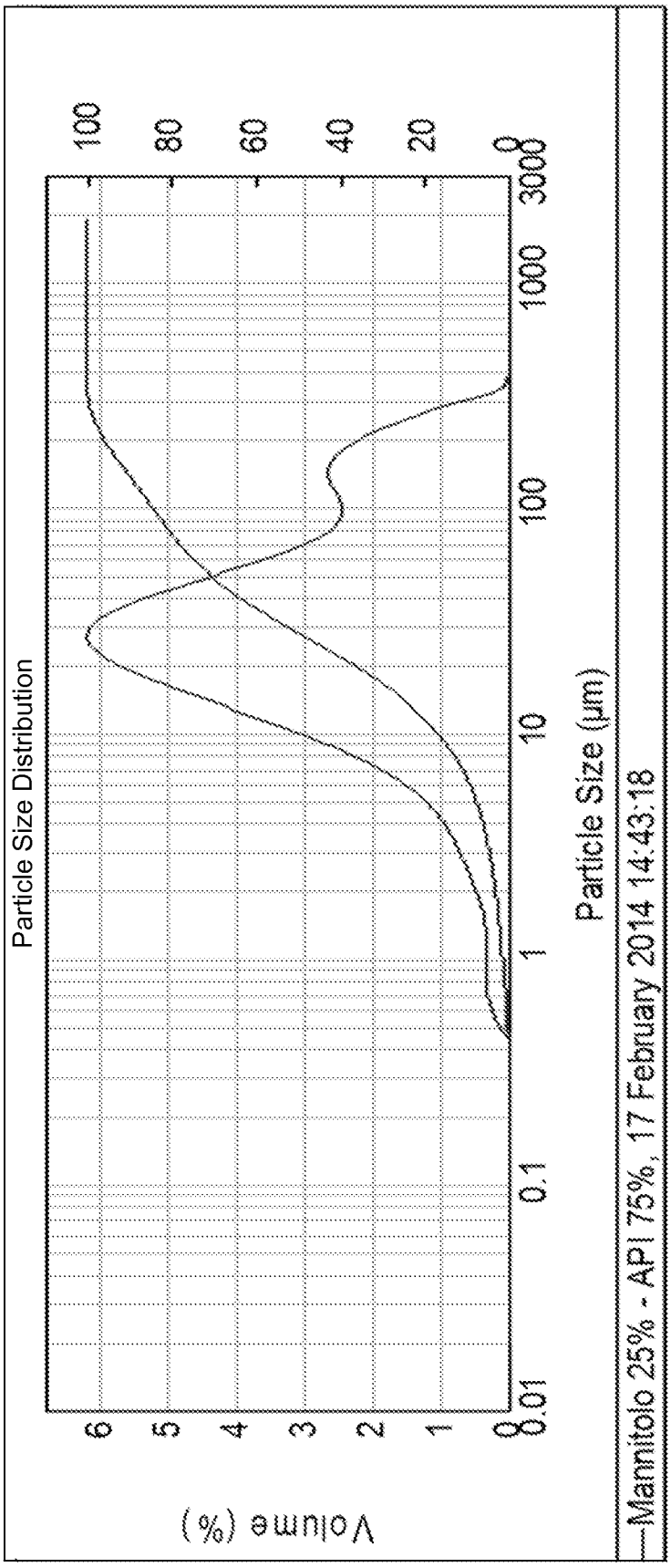

Particle Size Distribution
Volume (%)
Particle Size (µm)
Mannitolo 25% - API 75%, 17 February 2014 14:43:18

FIG. 111

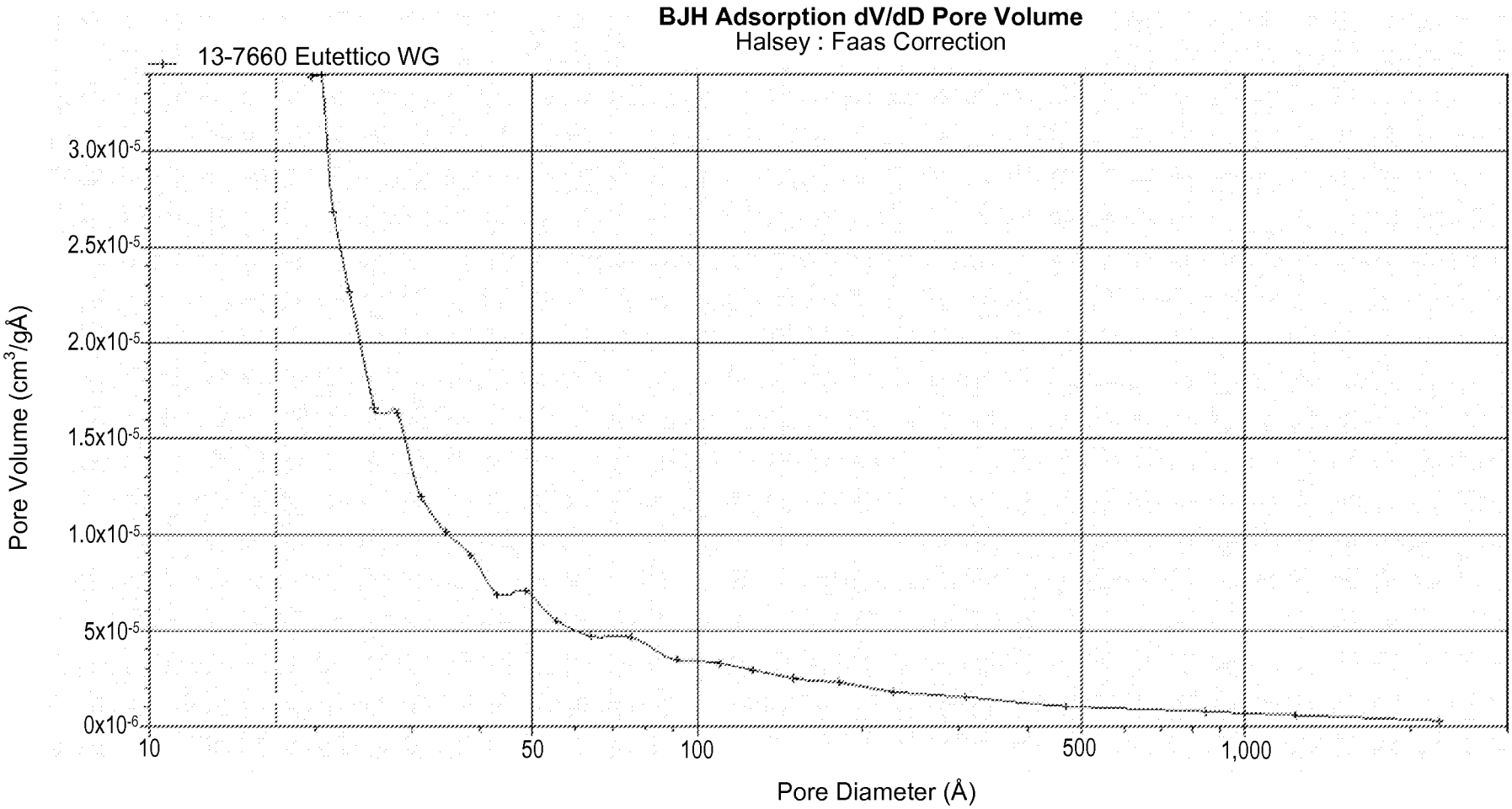

BJH Adsorption dV/dD Pore Volume
Halsey : Faas Correction
13-7660 Eutettico WG
3.0x10-5
2.5x10-5
2.0x10-5
1.5x10-5
1.0x10-5
5x10-5
0x10-6
Pore Volume (cm3/gÅ)
10
50
100
500
1,000
Pore Diameter (Å)

FIG. 112

**(Diffrattogramma X-Rays)**

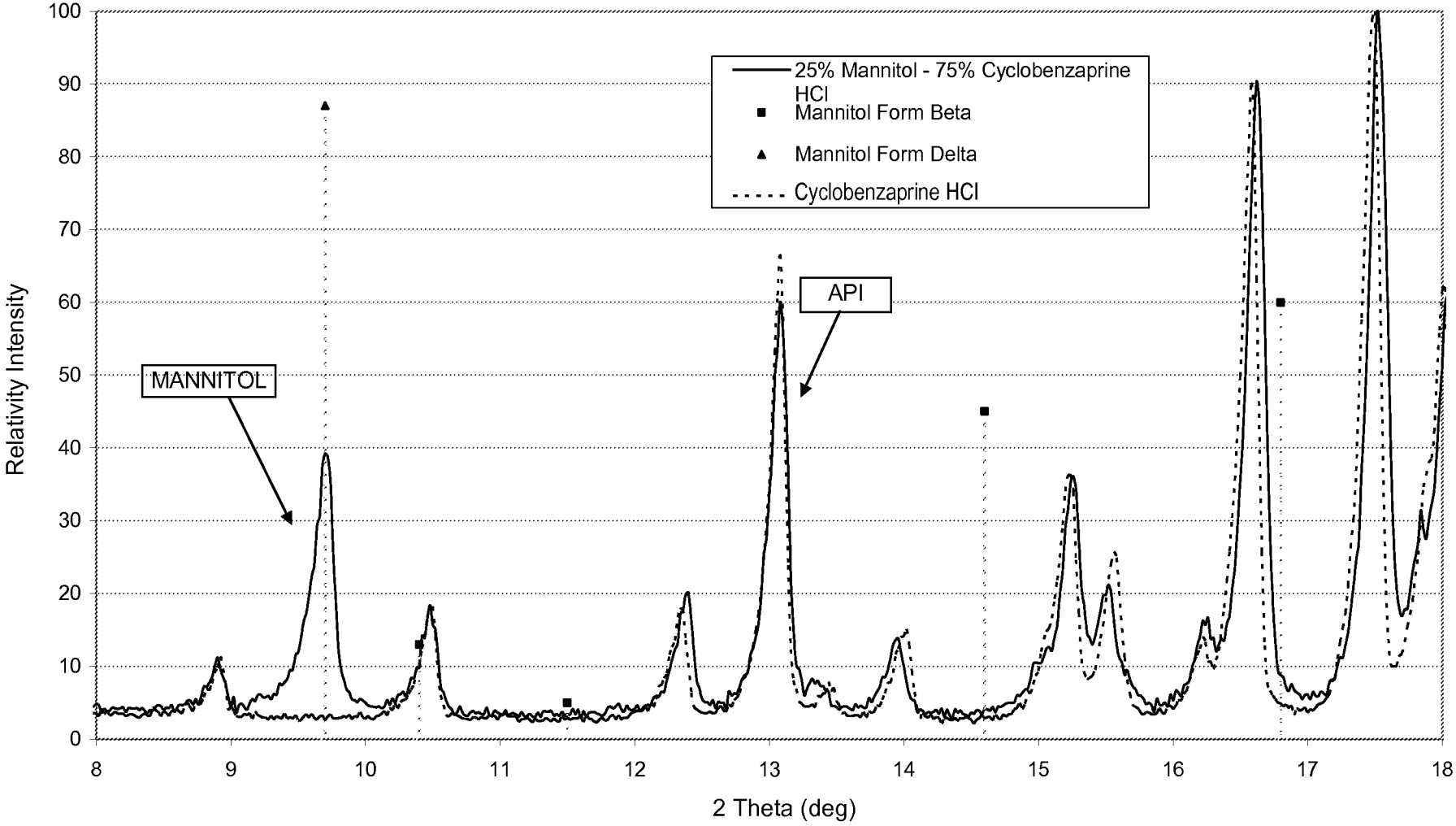



**FIG. 113**

**(Diffrattogramma X-Rays)**

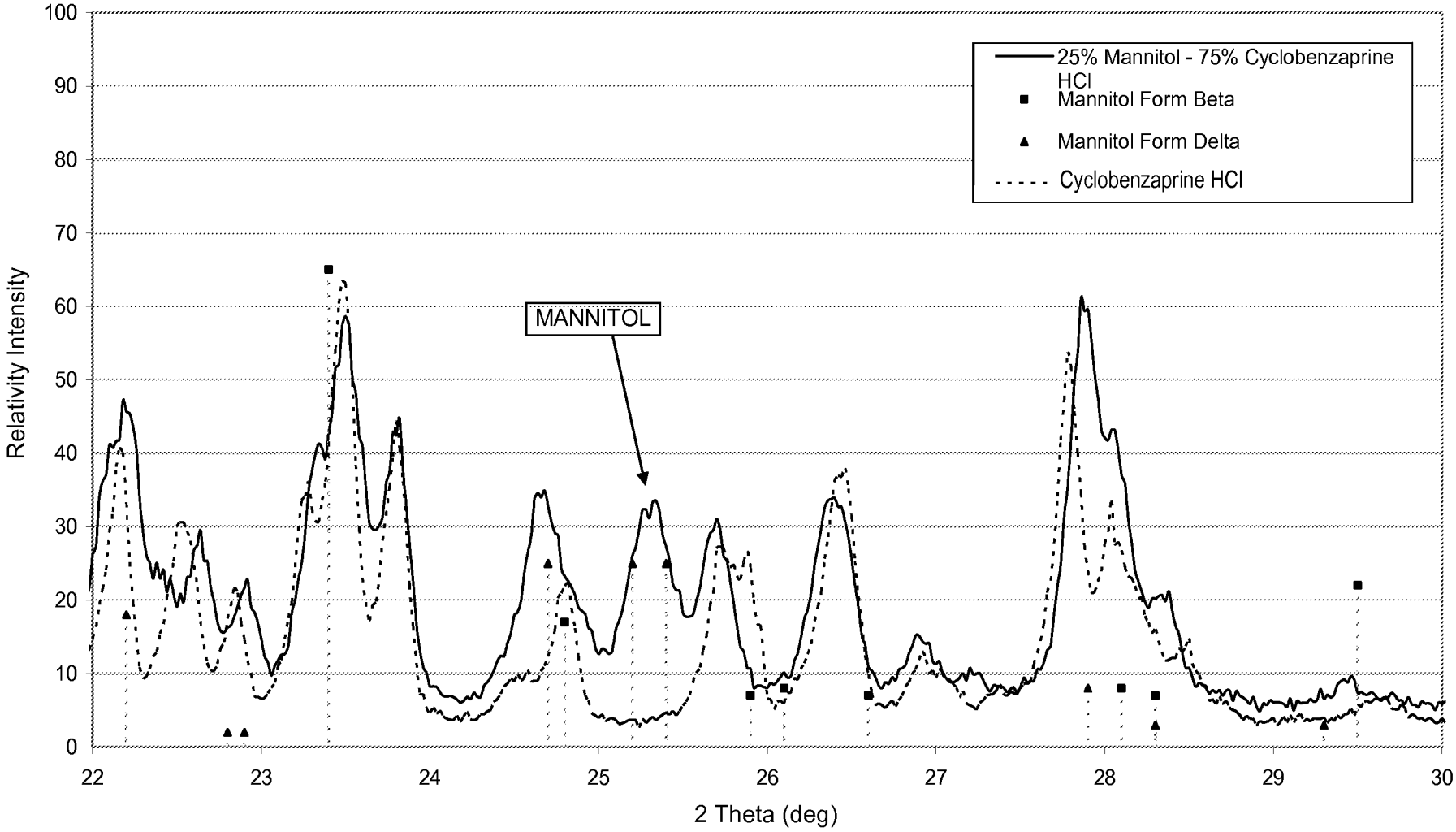



**FIG. 114**

**(Diffrattogramma X-Rays)**

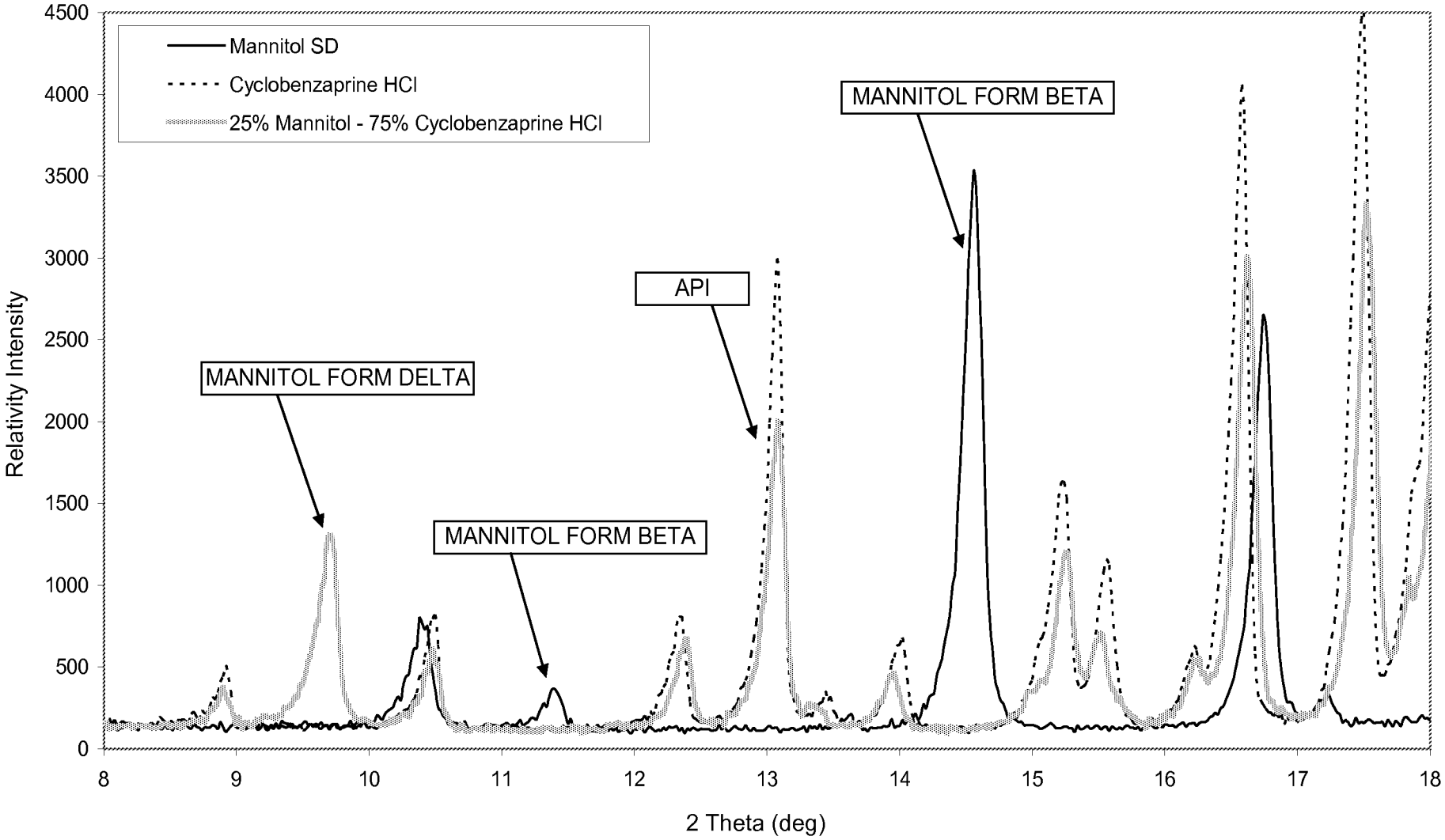



**FIG. 115**

**(Diffrattogramma X-Rays)**

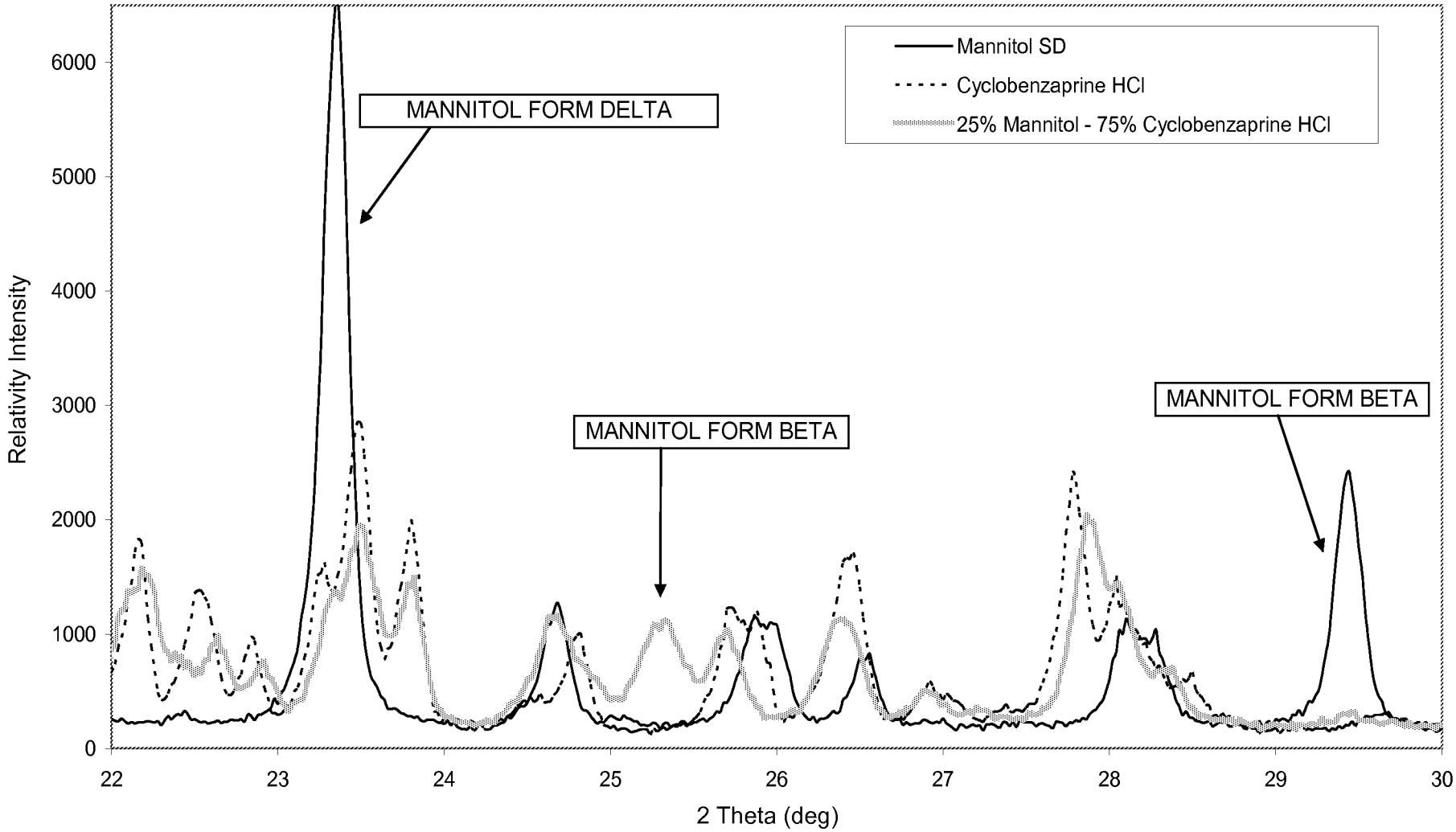



**FIG. 116**

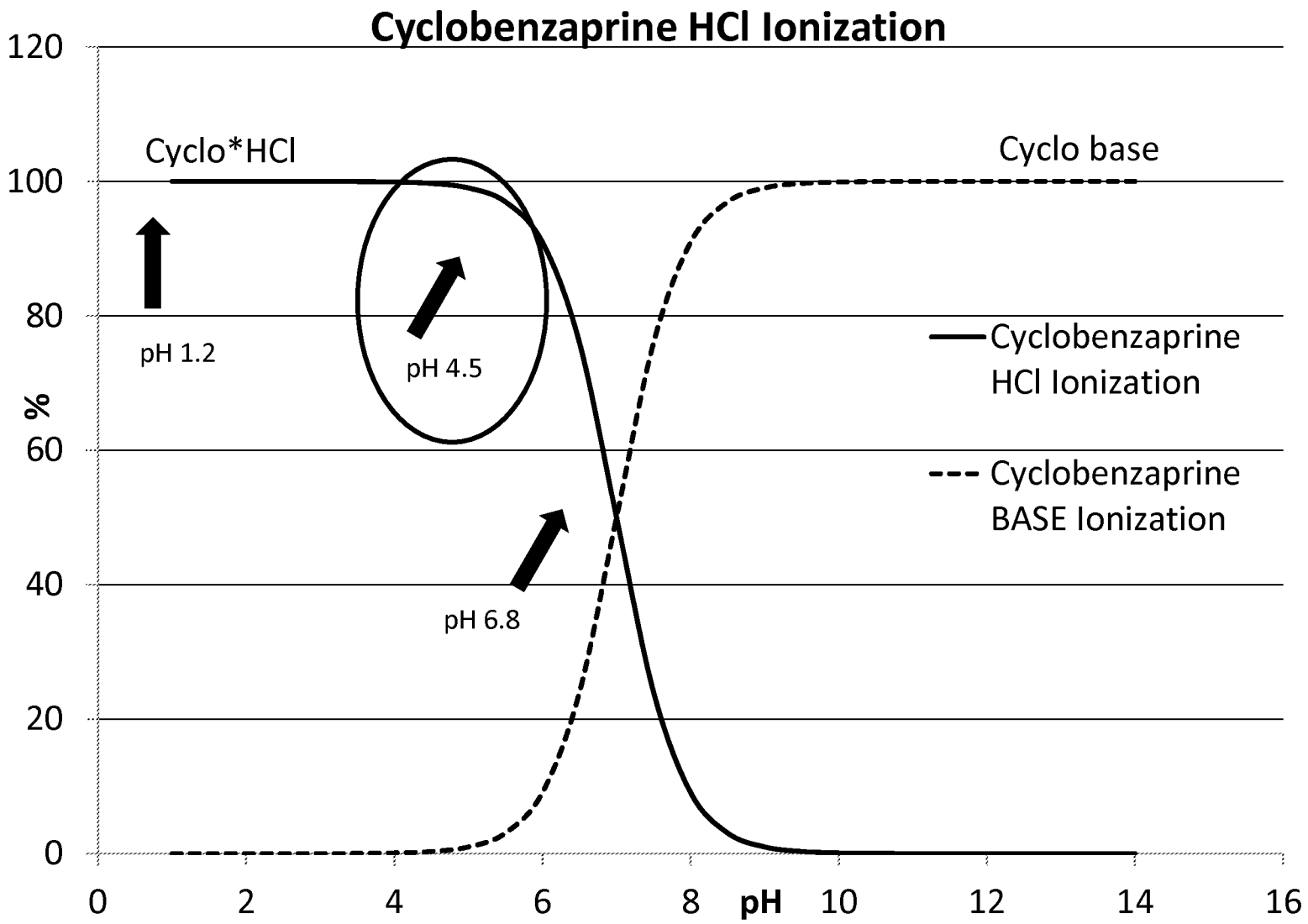

Cyclobenzaprine HCl Ionization
120
100
80
60
40
20
0
%
Cyclo*HCl
Cyclo base
pH 1.2
pH 4.5
pH 6.8
Cyclobenzaprine HCl Ionization
Cyclobenzaprine BASE Ionization
0
2
4
6
8
pH
10
12
14
16

FIG. 117

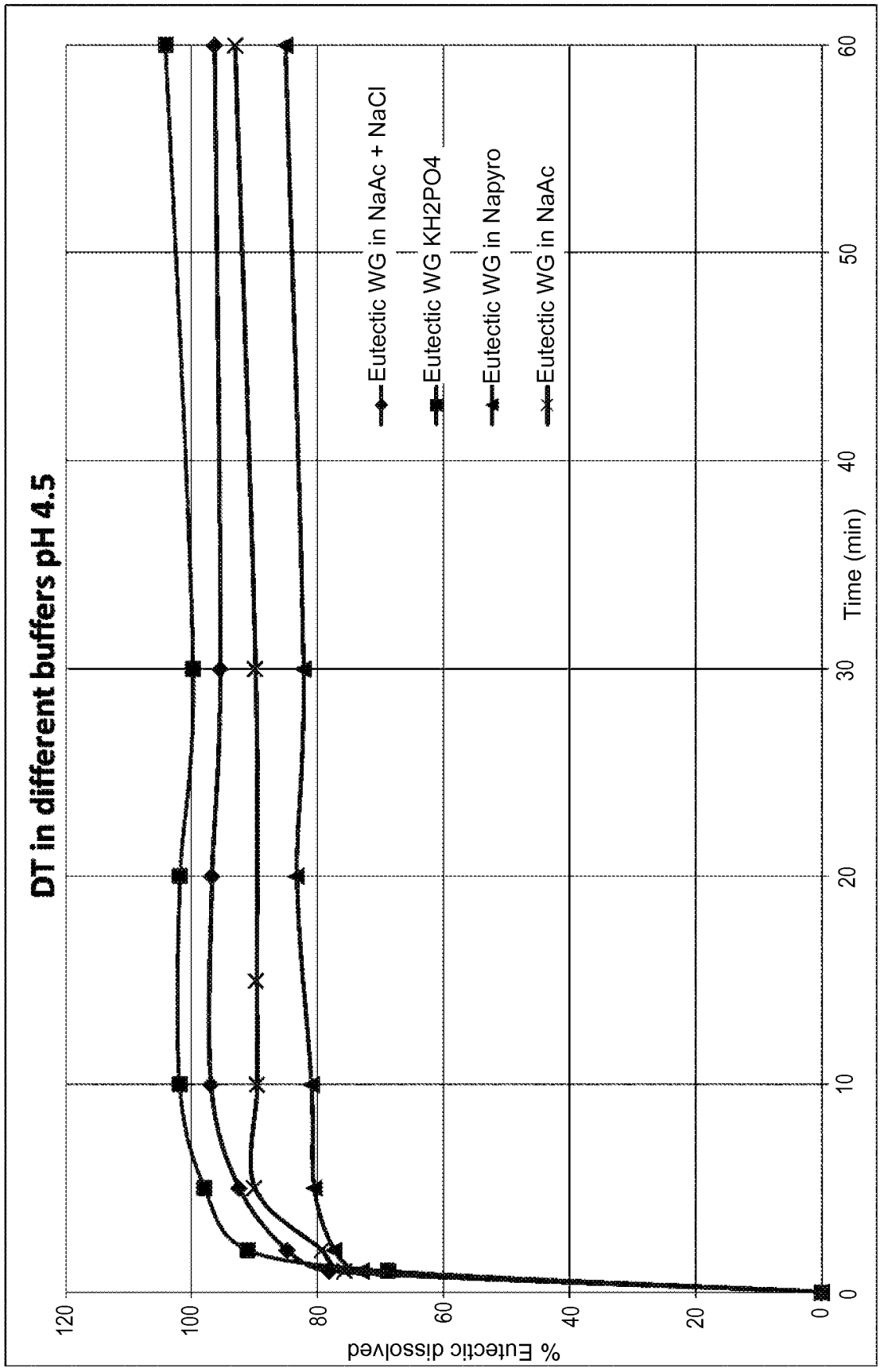

DT in different buffers pH 4.5
% Eutectic dissolved
Time (min)
Eutectic WG in NaAc + NaCl
Eutectic WG KH2PO4
Eutectic WG in Napyro
Eutectic WG in NaAc
0
20
40
60
80
100
120
0
10
20
30
40
50
60

FIG. 118

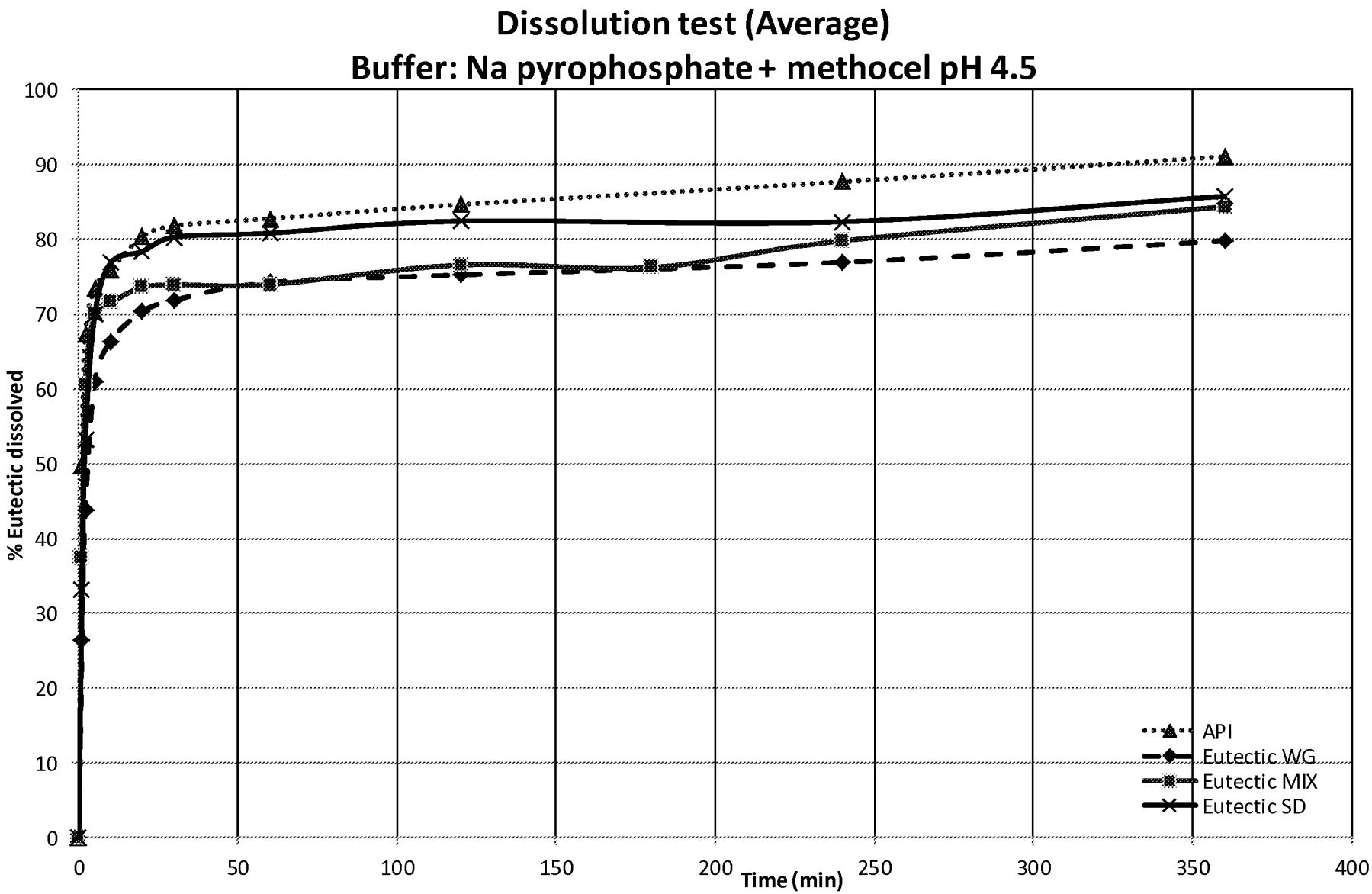

Dissolution test (Average)
Buffer: Na pyrophosphate + methocel pH 4.5
% Eutectic dissolved
Time (min)
0
10
20
30
40
50
60
70
80
90
100
0
50
100
150
200
250
300
350
400
API
Eutectic WG
Eutectic MIX
Eutectic SD

FIG. 119

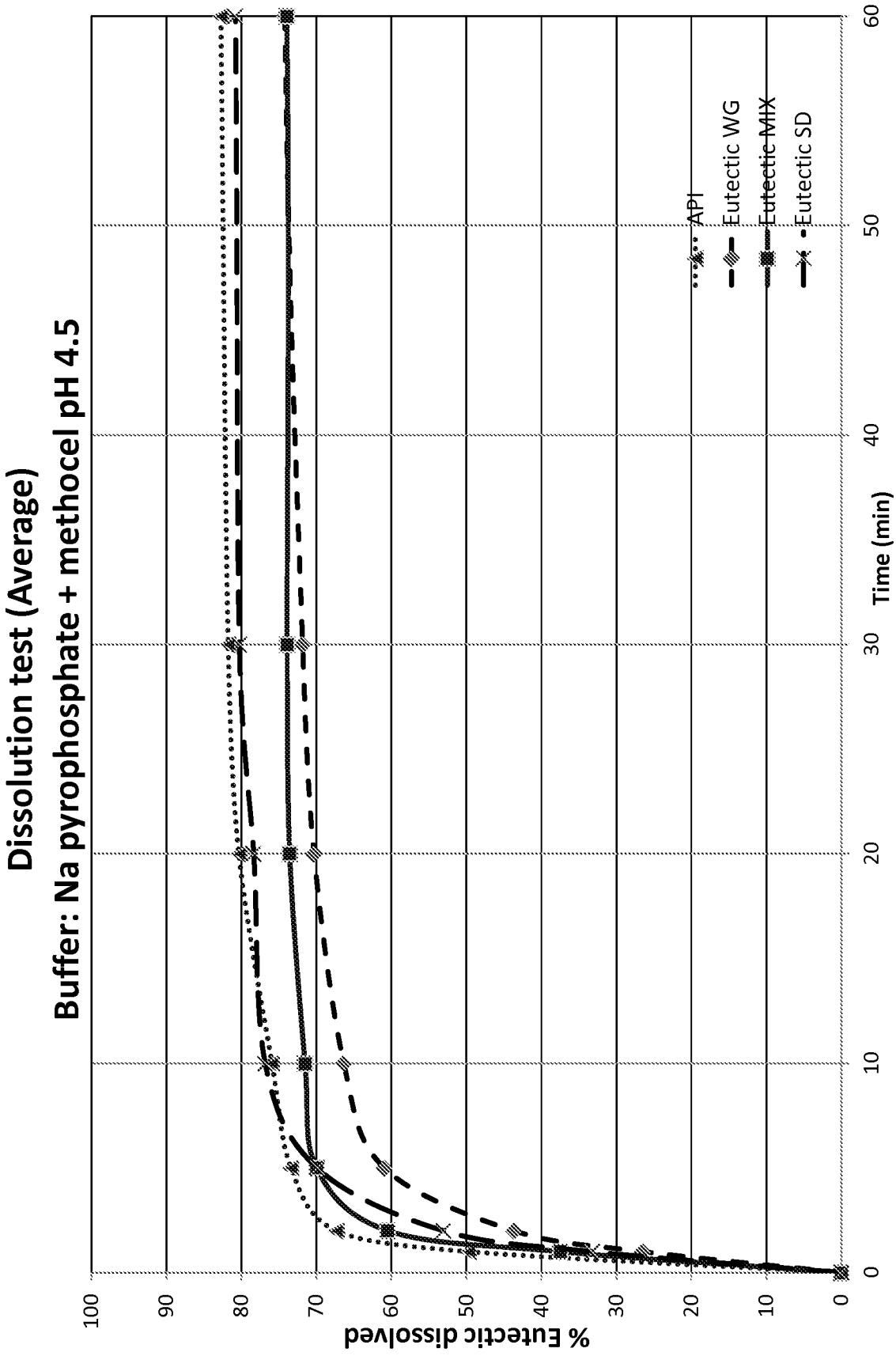

Dissolution test (Average)
Buffer: Na pyrophosphate + methocel pH 4.5
% Eutectic dissolved
Time (min)
0
10
20
30
40
50
60
70
80
90
100
API
Eutectic WG
Eutectic MIX
Eutectic SD

FIG. 120