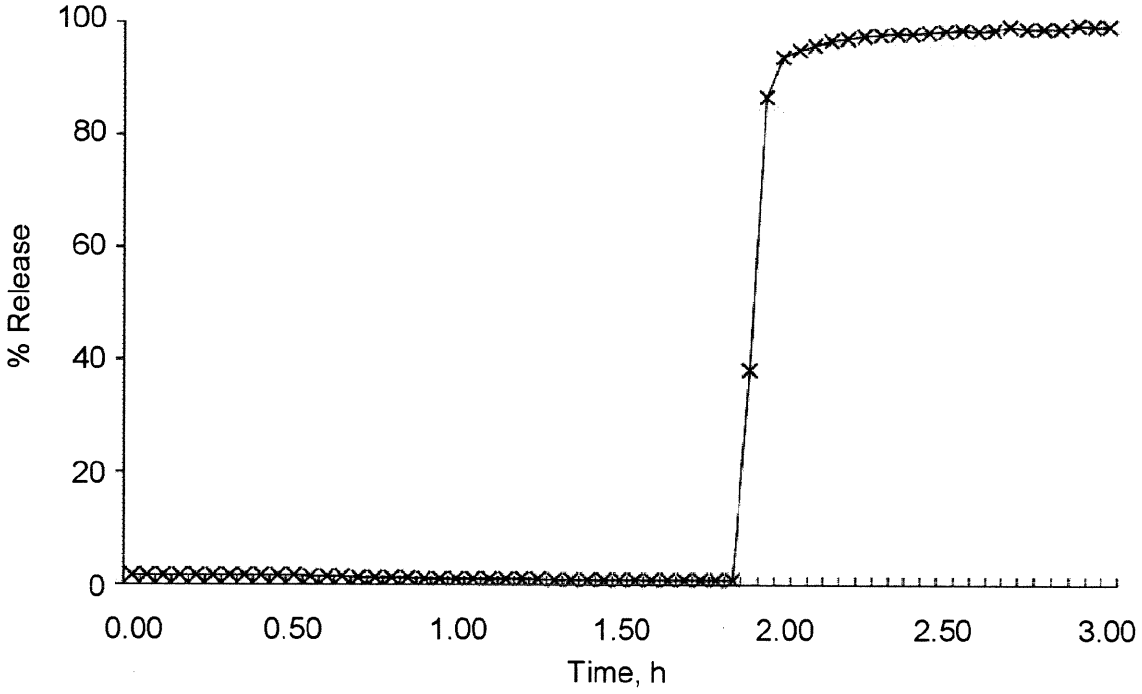



FIG. 1

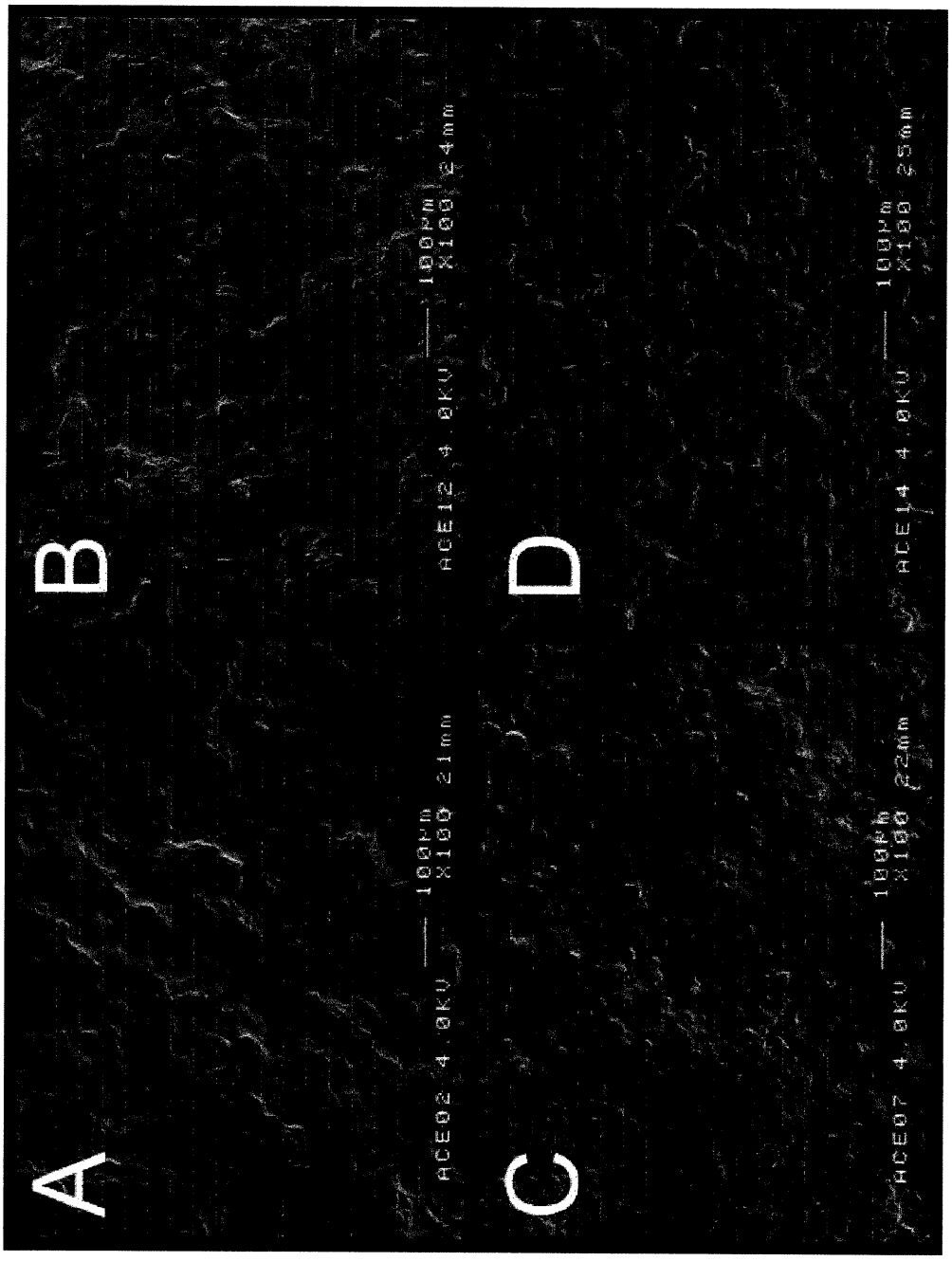

A
ACE02 4.0KV 100μm X100 21mm
B
ACE12 4.0KV 100μm X100 24mm
C
ACE07 4.0KV 100μm X100 22mm
D
ACE14 4.0KV 100μm X100 25mm

FIG. 2

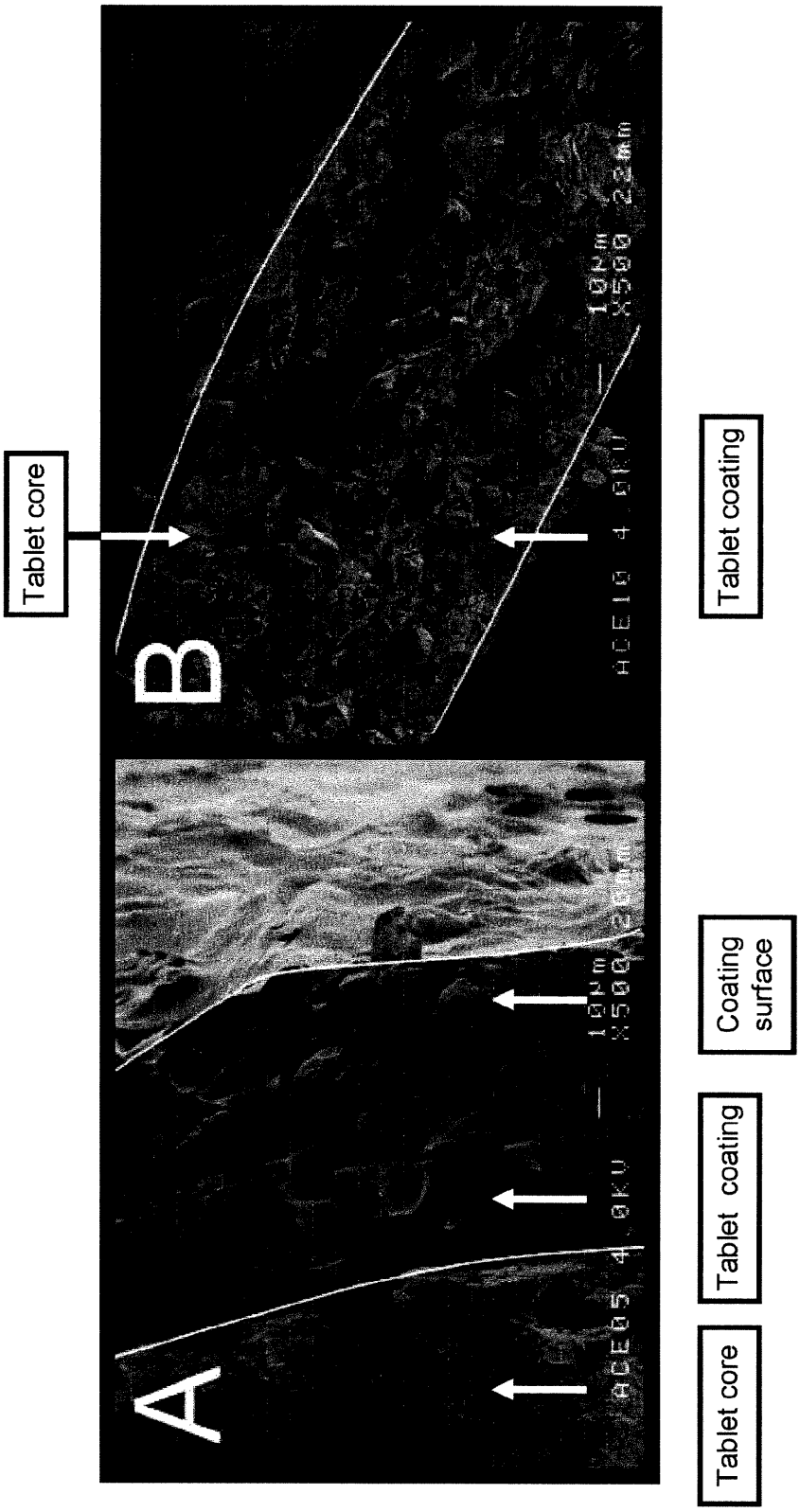

A
B
Tablet core
Tablet coating
Coating surface
Tablet coating
Tablet core

FIG. 3

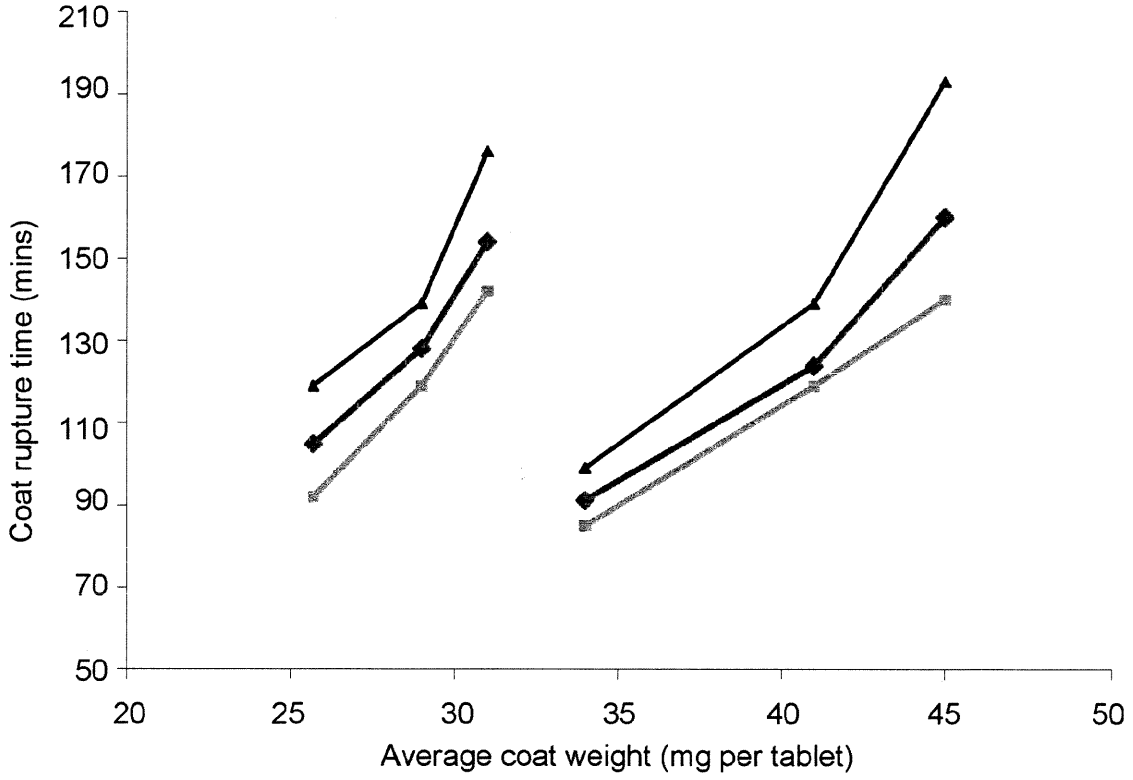

210
190
170
150
130
110
90
70
50
Coat rupture time (mins)
20
25
30
35
40
45
50
Average coat weight (mg per tablet)

FIG. 4

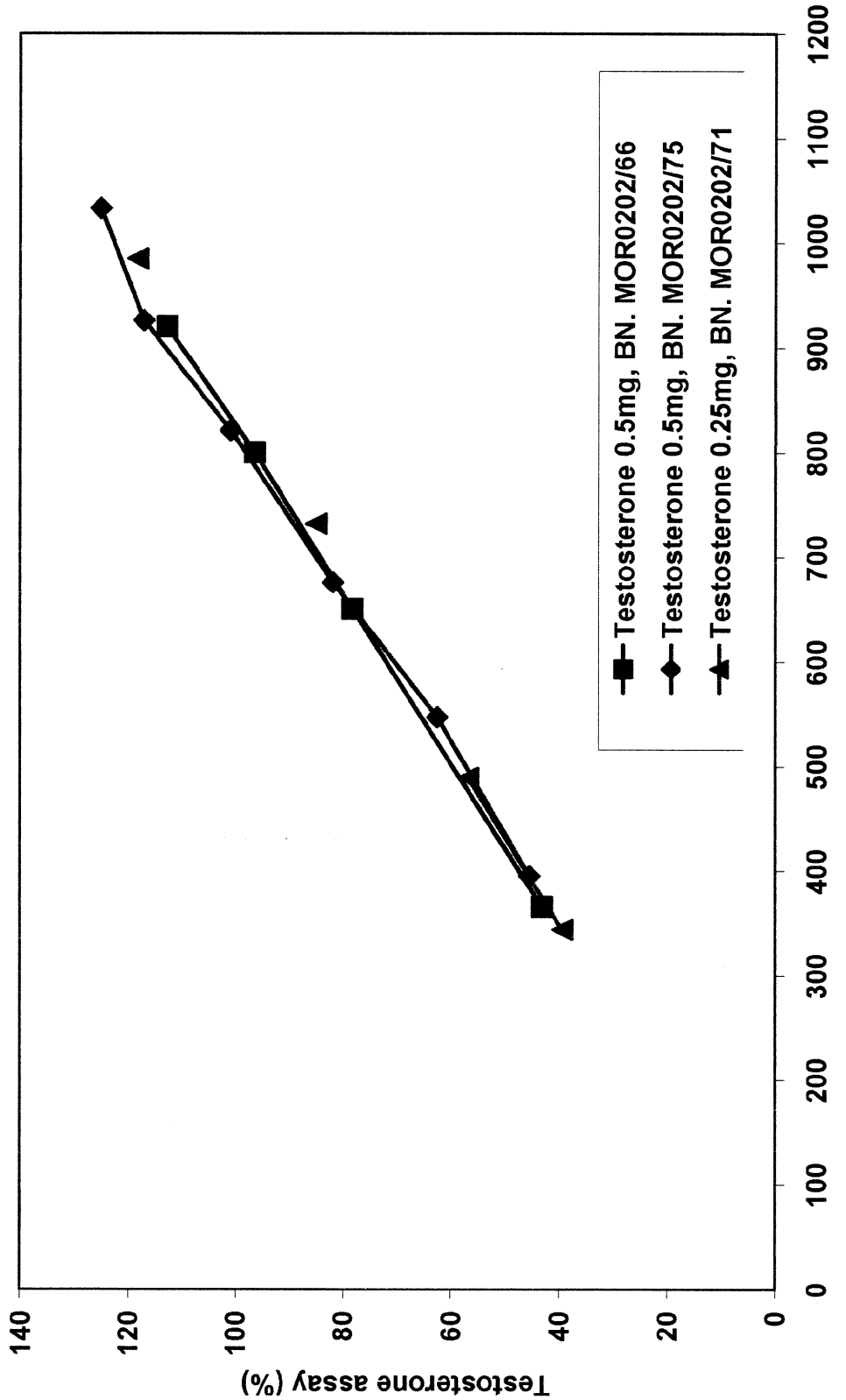

Testosterone assay (%)
0
20
40
60
80
100
120
140
0
100
200
300
400
500
600
700
800
900
1000
1100
1200
Weight of solution sprayed (g)
Testosterone 0.5mg, BN. MOR0202/66
Testosterone 0.5mg, BN. MOR0202/75
Testosterone 0.25mg, BN. MOR0202/71

FIG. 5

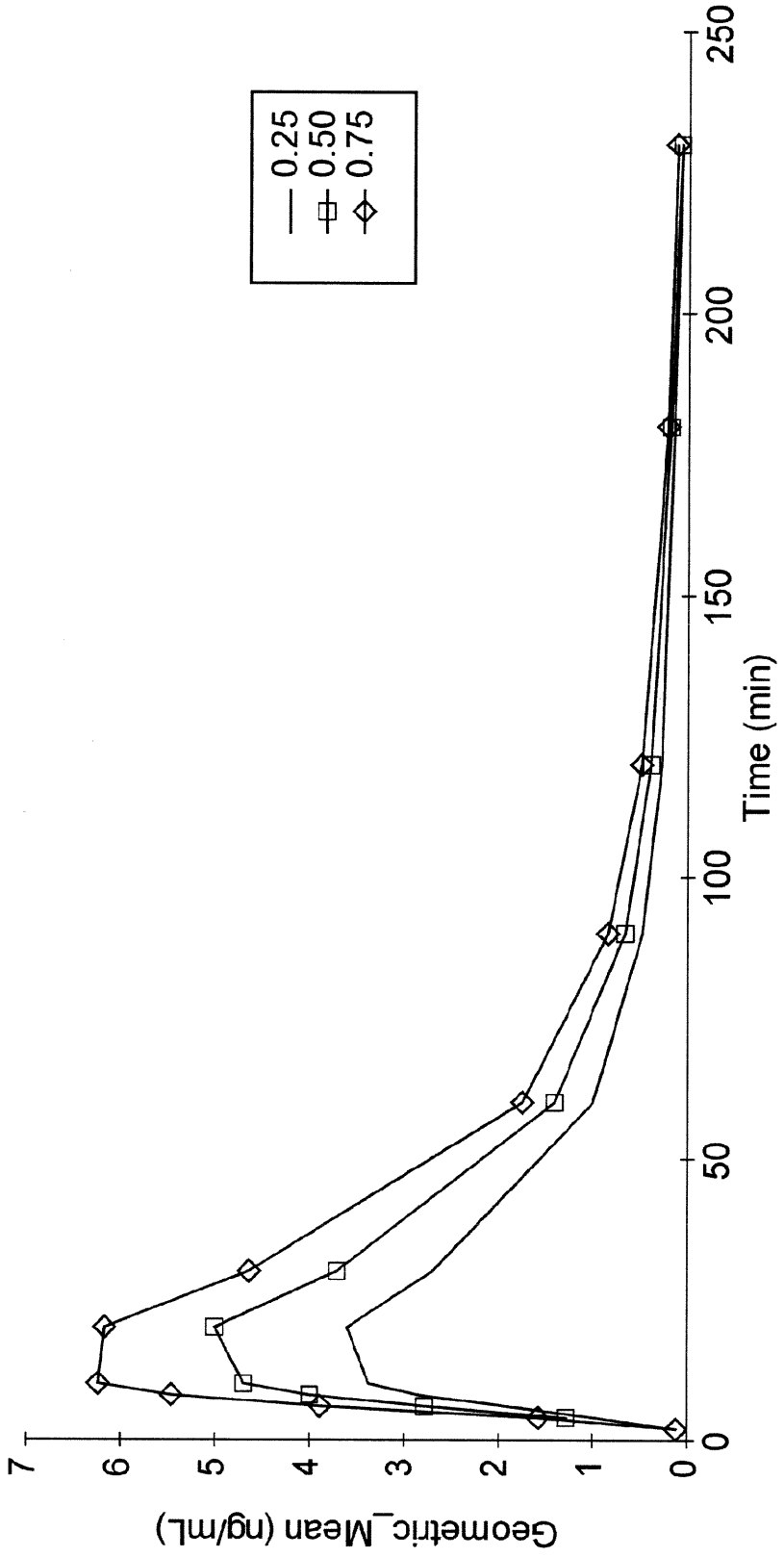

0.25
0.50
0.75
Geometric_Mean (ng/mL)
Time (min)
0
1
2
3
4
5
6
7
0
50
100
150
200
250

FIG. 6

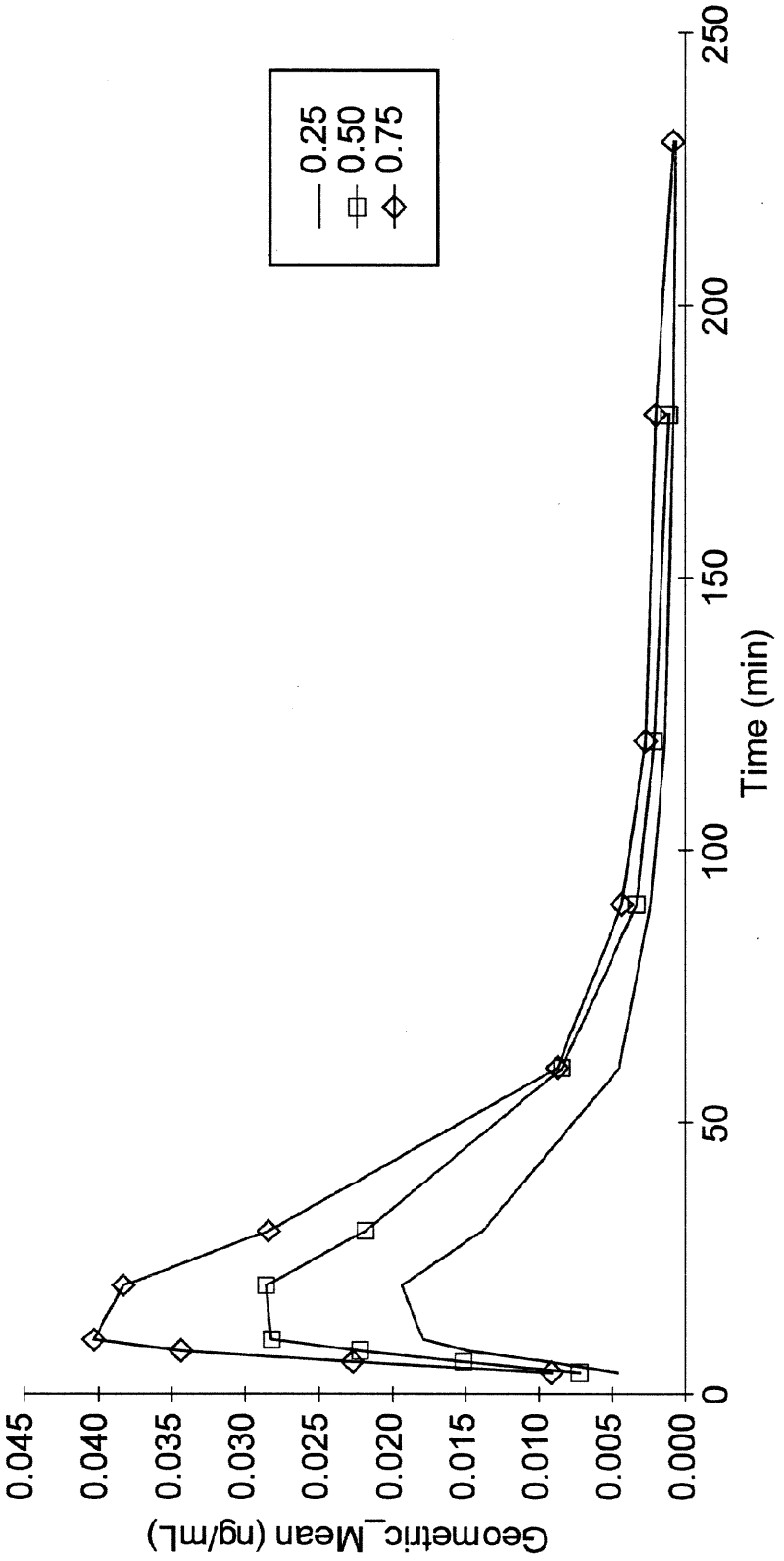

0.25
0.50
0.75
Geometric_Mean (ng/mL)
0.045
0.040
0.035
0.030
0.025
0.020
0.015
0.010
0.005
0.000
0
50
100
150
200
250
Time (min)

FIG. 7

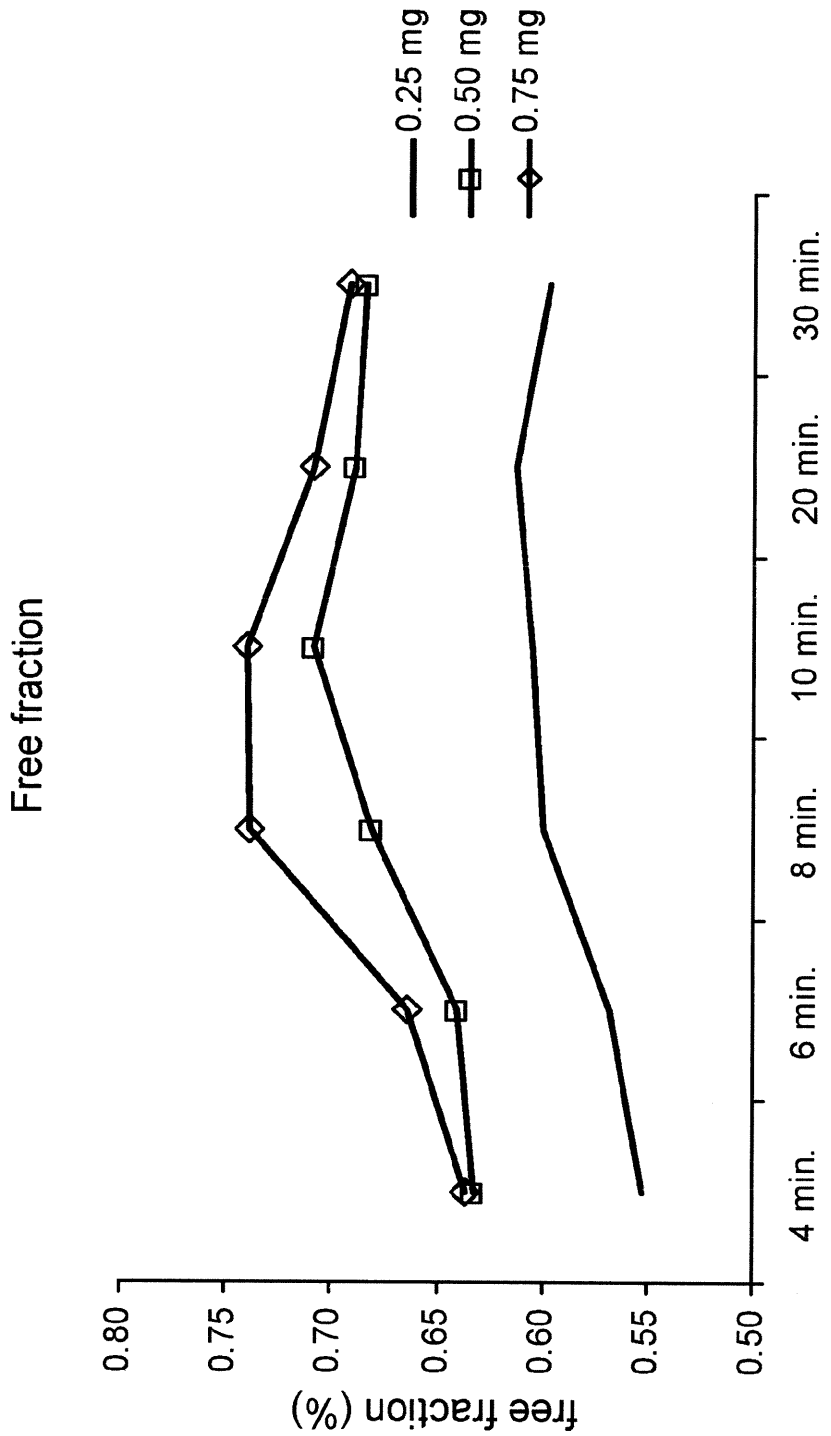

Free fraction
0.25 mg
0.50 mg
0.75 mg
free fraction (%)
0.80
0.75
0.70
0.65
0.60
0.55
0.50
4 min.
6 min.
8 min.
10 min.
20 min.
30 min.
time

FIG. 8

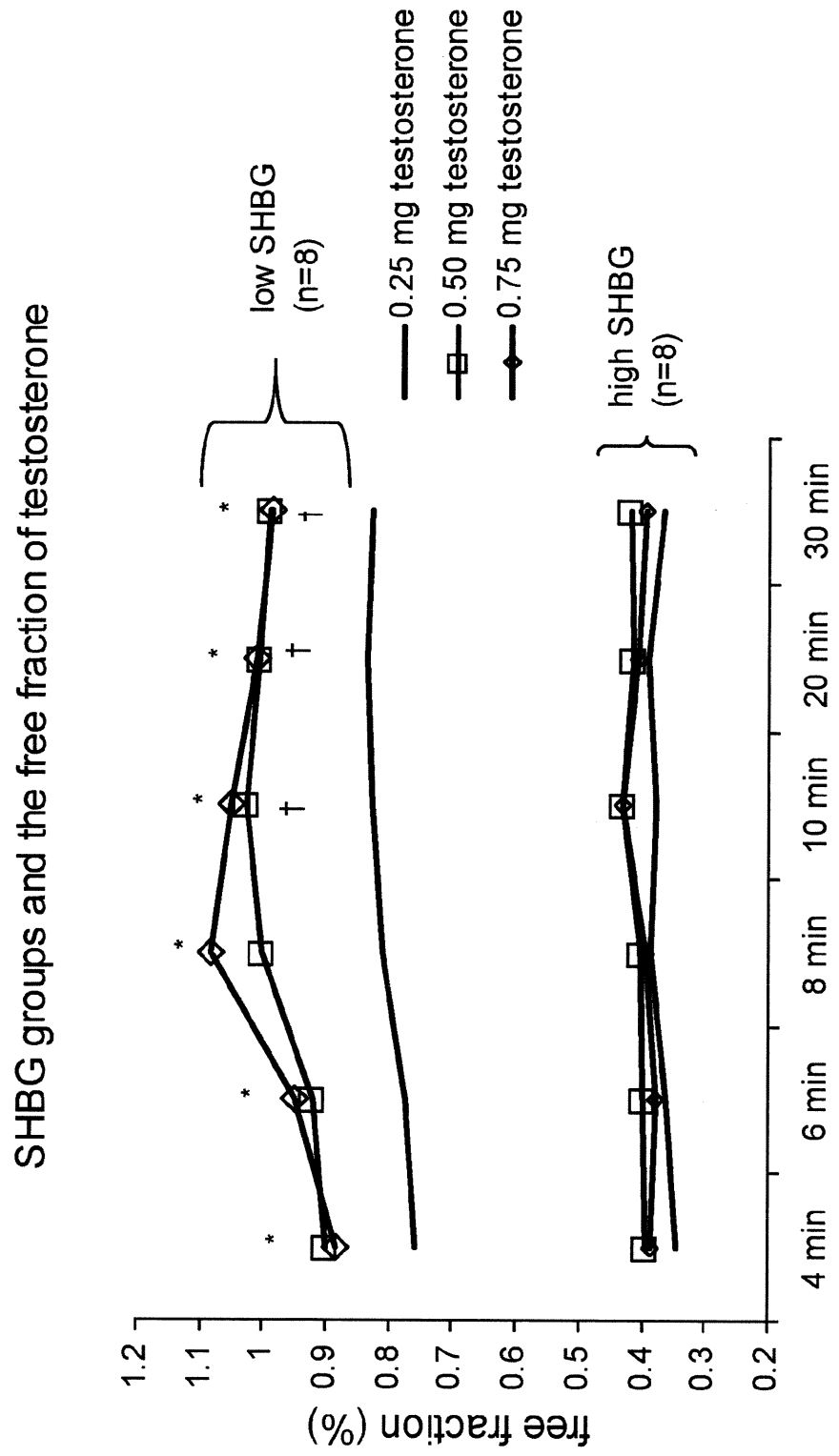

SHBG groups and the free fraction of testosterone
low SHBG
(n=8)
high SHBG
(n=8)
0.25 mg testosterone
0.50 mg testosterone
0.75 mg testosterone
free fraction (%)
1.2
1.1
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
4 min
6 min
8 min
10 min
20 min
30 min
time

FIG. 9

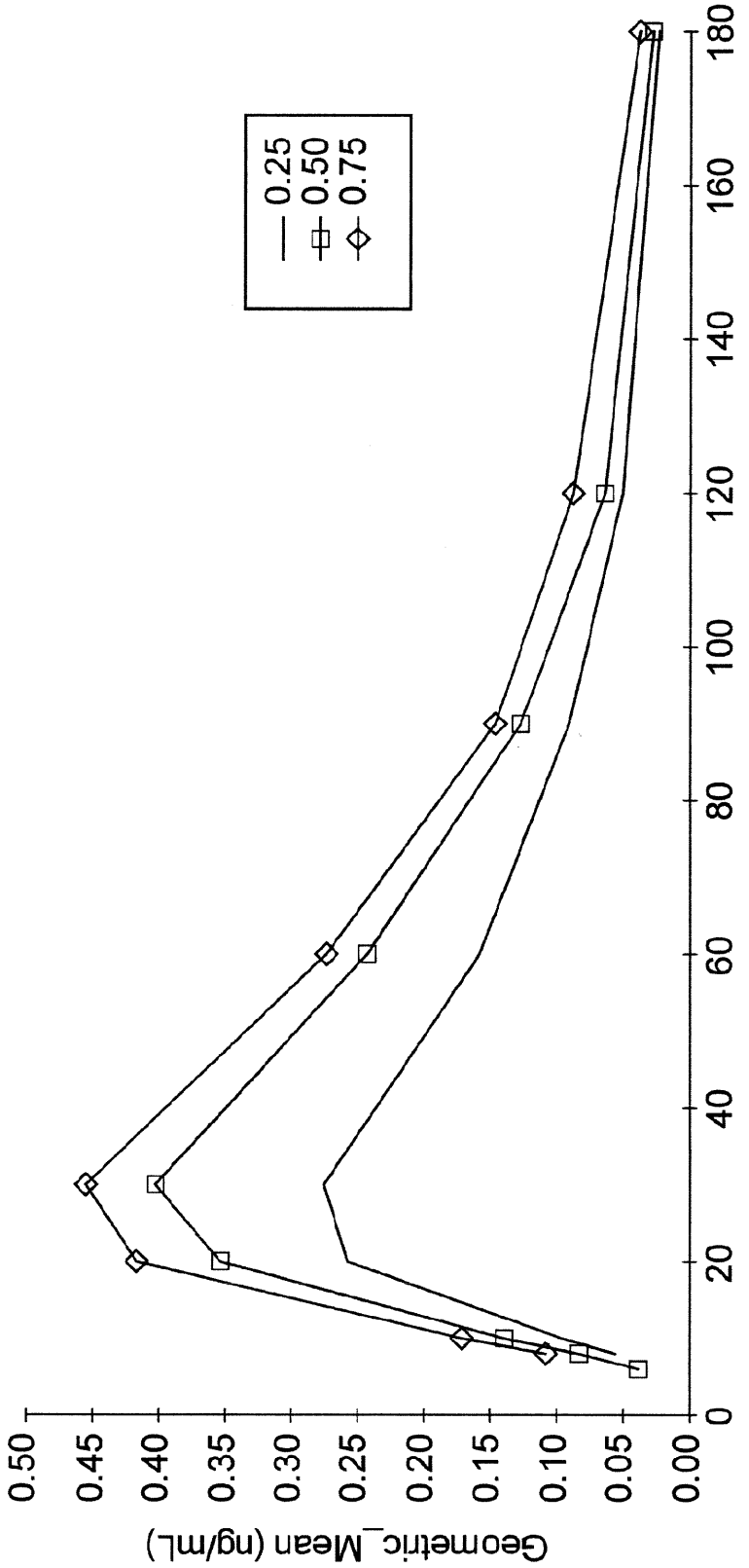
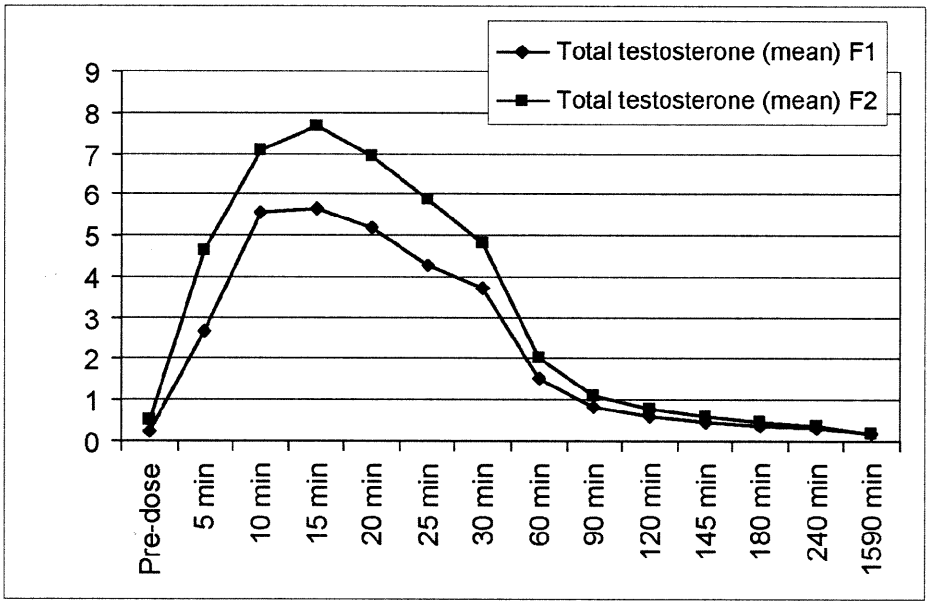

0.25
0.50
0.75
Geometric_Mean (ng/mL)
0.00
0.05
0.10
0.15
0.20
0.25
0.30
0.35
0.40
0.45
0.50
0
20
40
60
80
100
120
140
160
180
Time (min)

FIG. 10

A


Total testosterone (mean) F1
Total testosterone (mean) F2
9
8
7
6
5
4
3
2
1
0
Pre-dose
5 min
10 min
15 min
20 min
25 min
30 min
60 min
90 min
120 min
145 min
180 min
240 min
1590 min

B

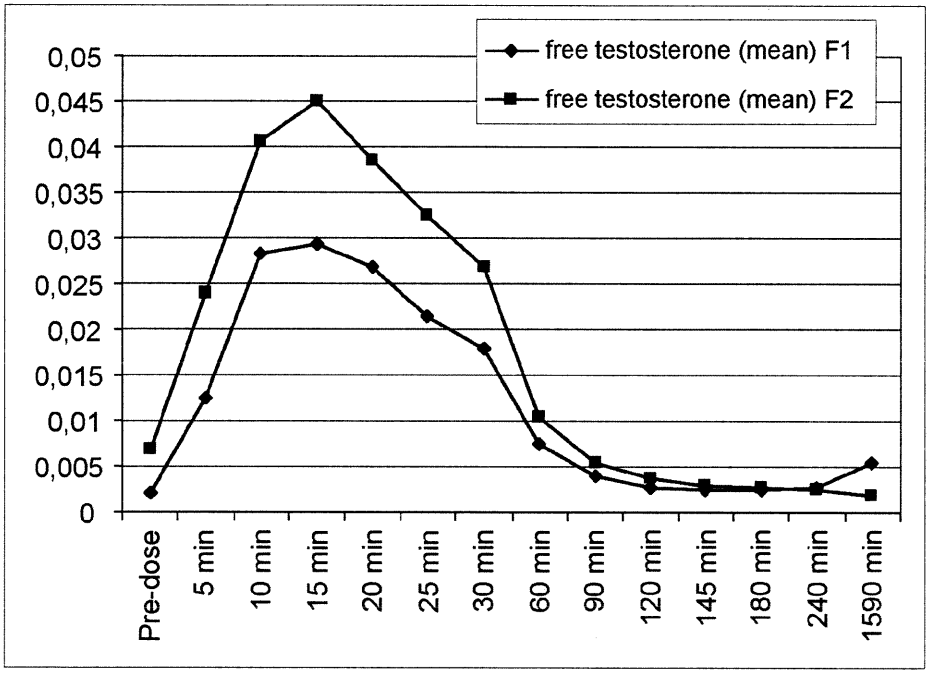

free testosterone (mean) F1
free testosterone (mean) F2
0,05
0,045
0,04
0,035
0,03
0,025
0,02
0,015
0,01
0,005
0
Pre-dose
5 min
10 min
15 min
20 min
25 min
30 min
60 min
90 min
120 min
145 min
180 min
240 min
1590 min

FIG. 11

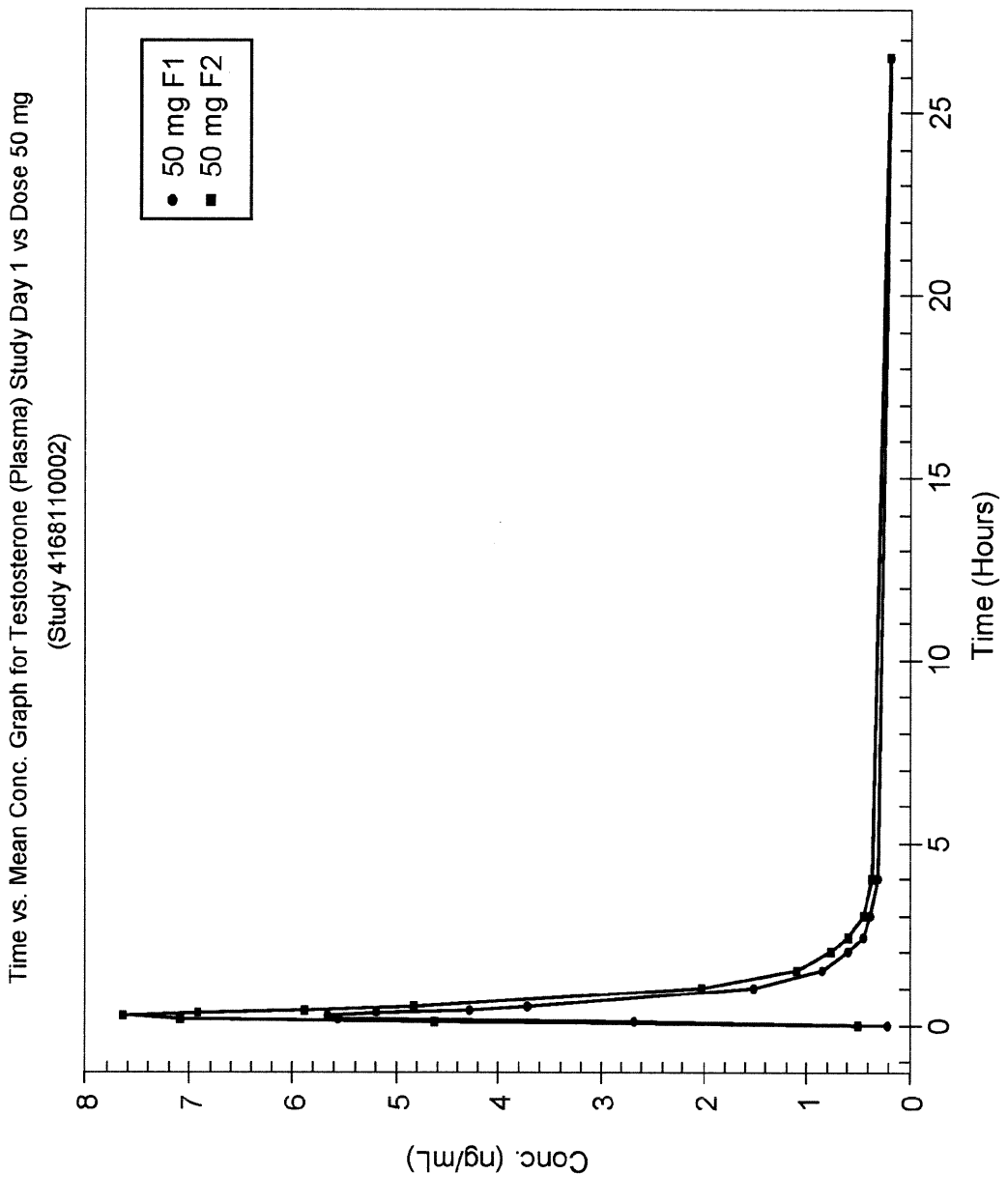

Time vs. Mean Conc. Graph for Testosterone (Plasma) Study Day 1 vs Dose 50 mg
(Study 4168110002)
50 mg F1
50 mg F2
Conc. (ng/mL)
0
1
2
3
4
5
6
7
8
0
5
10
15
20
25
Time (Hours)

FIG. 12

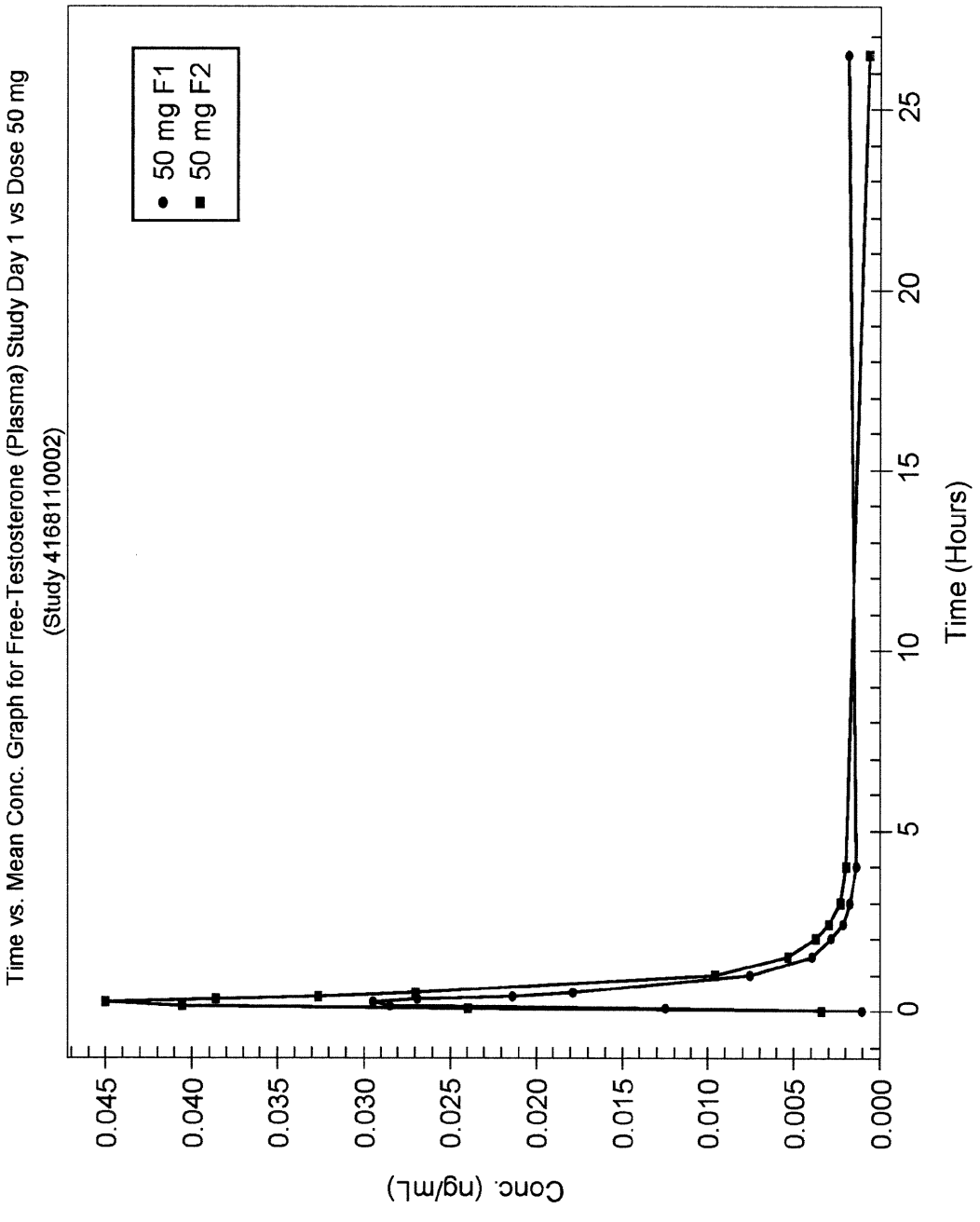

Time vs. Mean Conc. Graph for Free-Testosterone (Plasma) Study Day 1 vs Dose 50 mg
(Study 4168110002)
50 mg F1
50 mg F2
Conc. (ng/mL)
0.045
0.040
0.035
0.030
0.025
0.020
0.015
0.010
0.005
0.000
0
5
10
15
20
25
Time (Hours)

FIG. 13

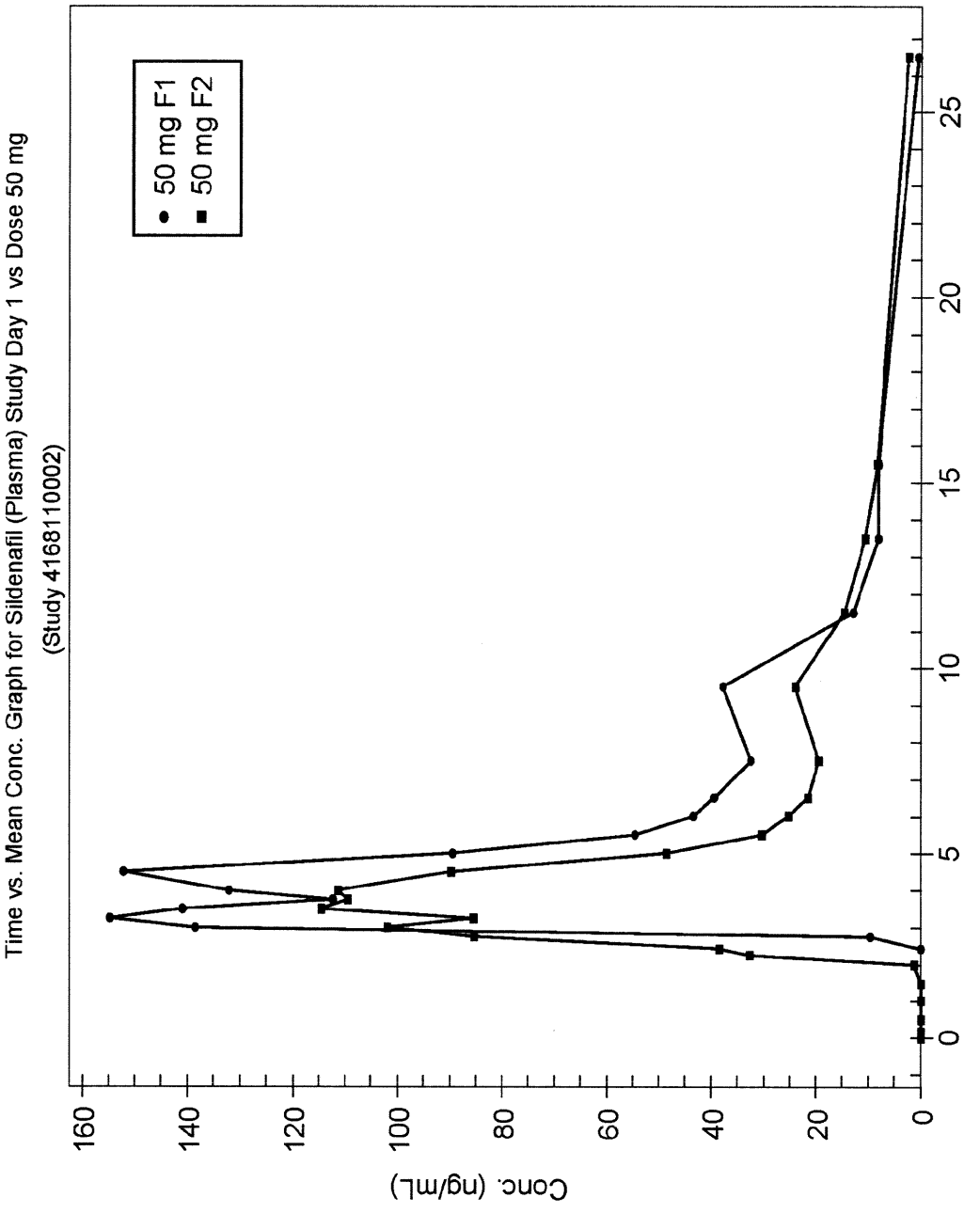

Time vs. Mean Conc. Graph for Sildenafil (Plasma) Study Day 1 vs Dose 50 mg
(Study 4168110002)
50 mg F1
50 mg F2
Conc. (ng/mL)
0
20
40
60
80
100
120
140
160
Time (Hours)
0
5
10
15
20
25

FIG. 14

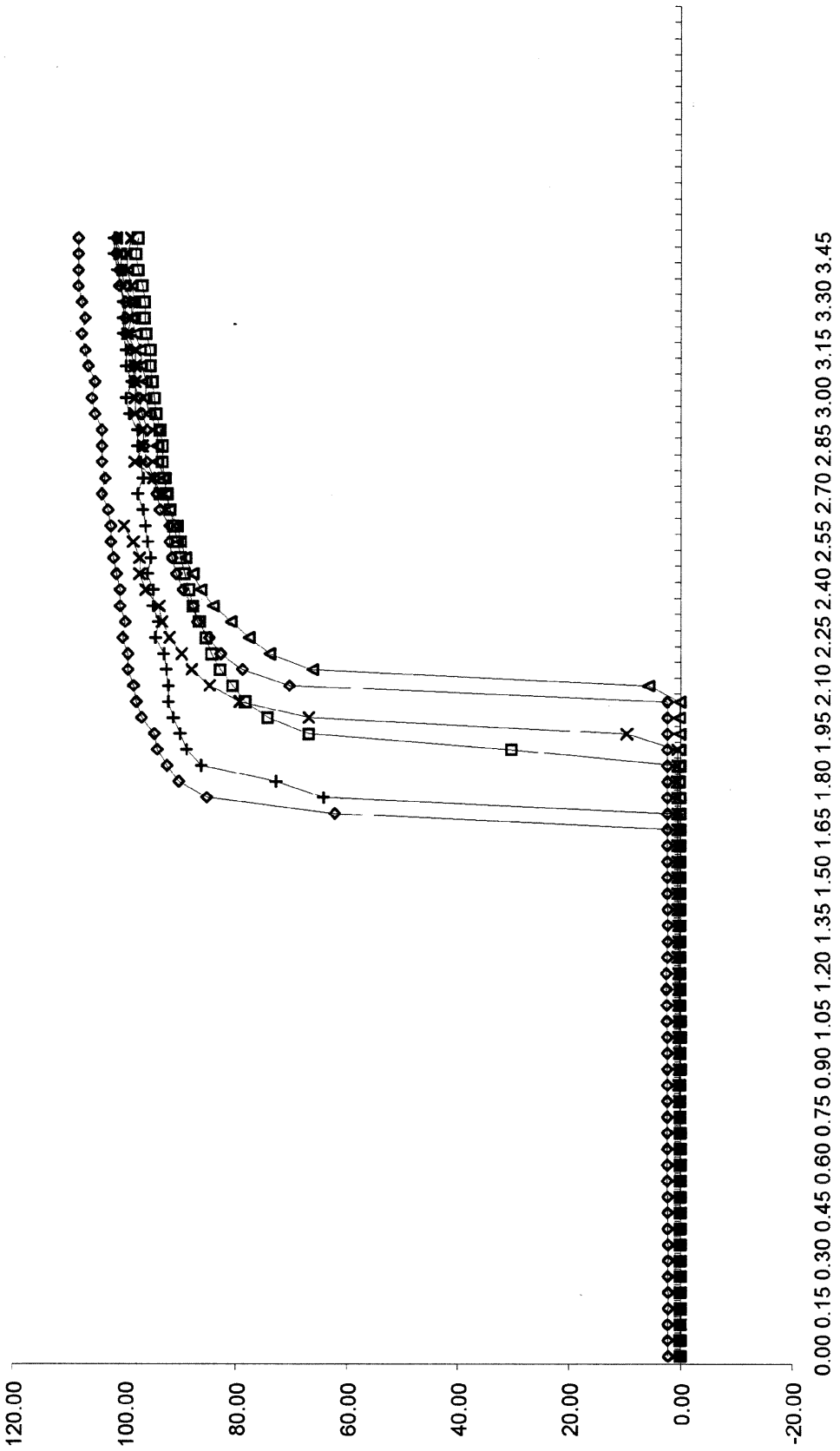

120.00
100.00
80.00
60.00
40.00
20.00
0.00
-20.00
0.00 0.15 0.30 0.45 0.60 0.75 0.90 1.05 1.20 1.35 1.50 1.65 1.80 1.95 2.10 2.25 2.40 2.55 2.70 2.85 3.00 3.15 3.30 3.45

FIG. 15

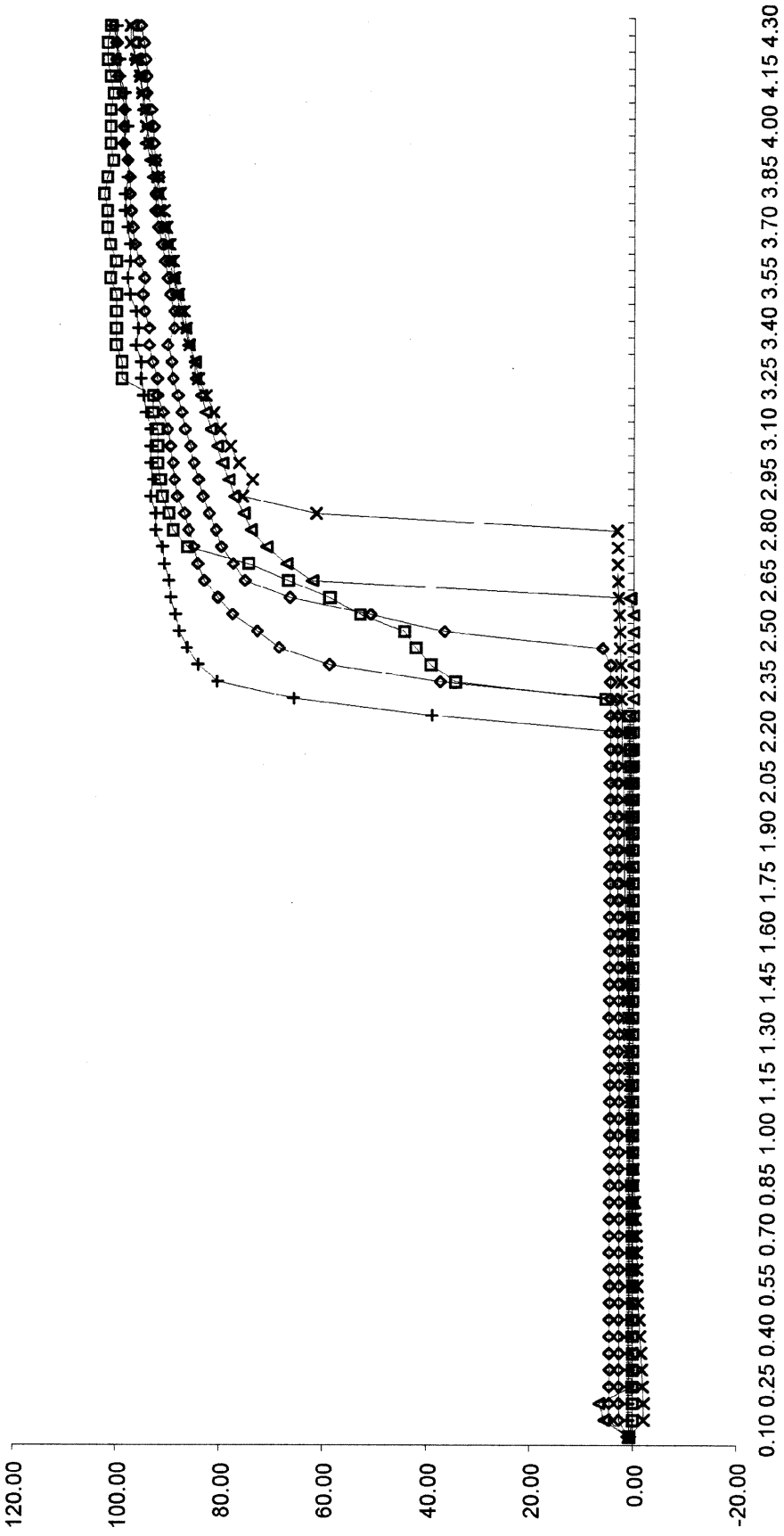

120.00
100.00
80.00
60.00
40.00
20.00
0.00
-20.00
0.10 0.25 0.40 0.55 0.70 0.85 1.00 1.15 1.30 1.45 1.60 1.75 1.90 2.05 2.20 2.35 2.50 2.65 2.80 2.95 3.10 3.25 3.40 3.55 3.70 3.85 4.00 4.15 4.30

FIG. 16