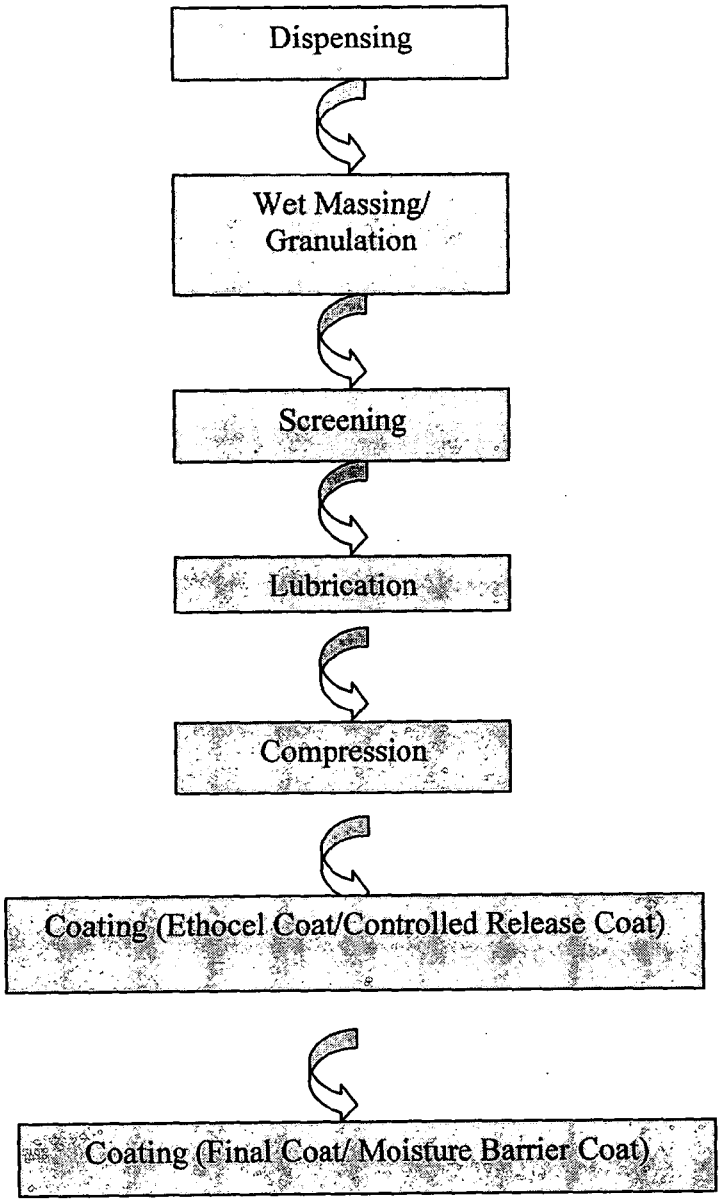

Dispensing
Wet Massing/ Granulation
Screening
Lubrication
Compression
Coating (Ethocel Coat/Controlled Release Coat)
Coating (Final Coat/ Moisture Barrier Coat)

Figure 1

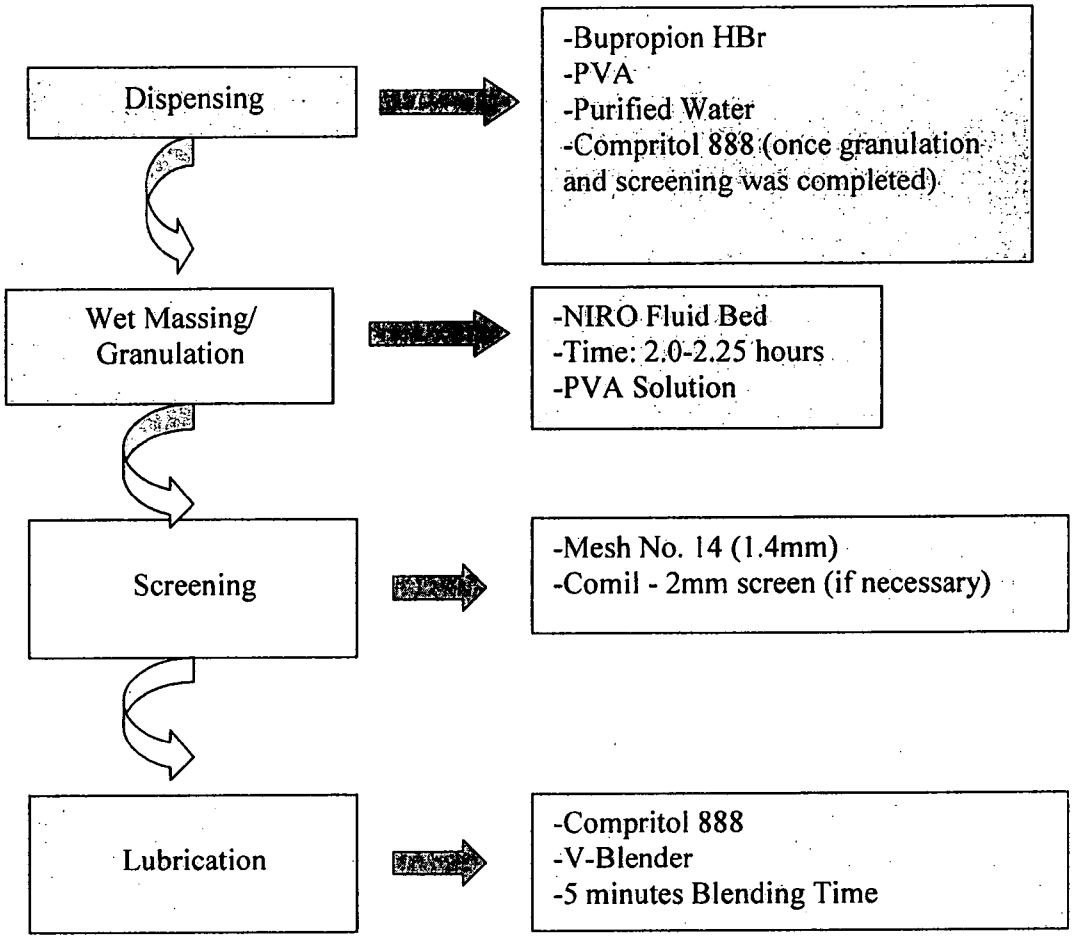

Dispensing
-Bupropion HBr
-PVA
-Purified Water
-Compritol 888 (once granulation and screening was completed)
Wet Massing/ Granulation
-NIRO Fluid Bed
-Time: 2.0-2.25 hours
-PVA Solution
Screening
-Mesh No. 14 (1.4mm)
-Comil - 2mm screen (if necessary)
Lubrication
-Compritol 888
-V-Blender
-5 minutes Blending Time

Figure 2

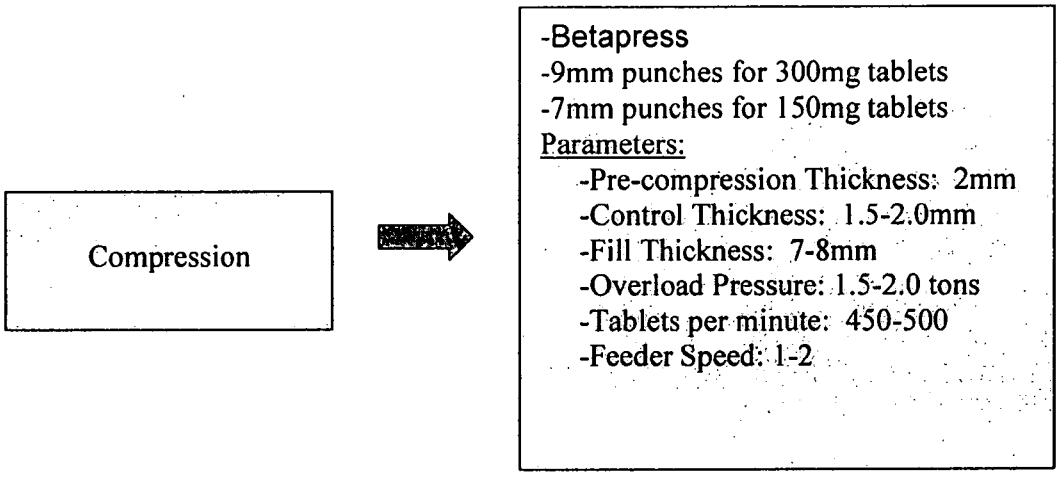


Figure 3

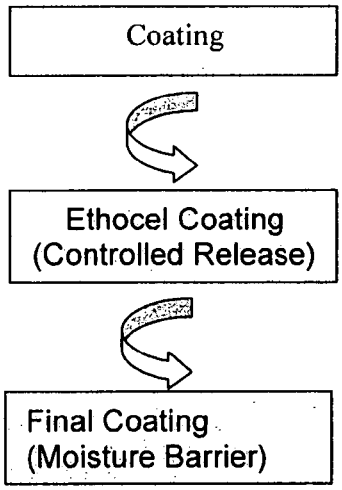


Figure 4

Figure 5

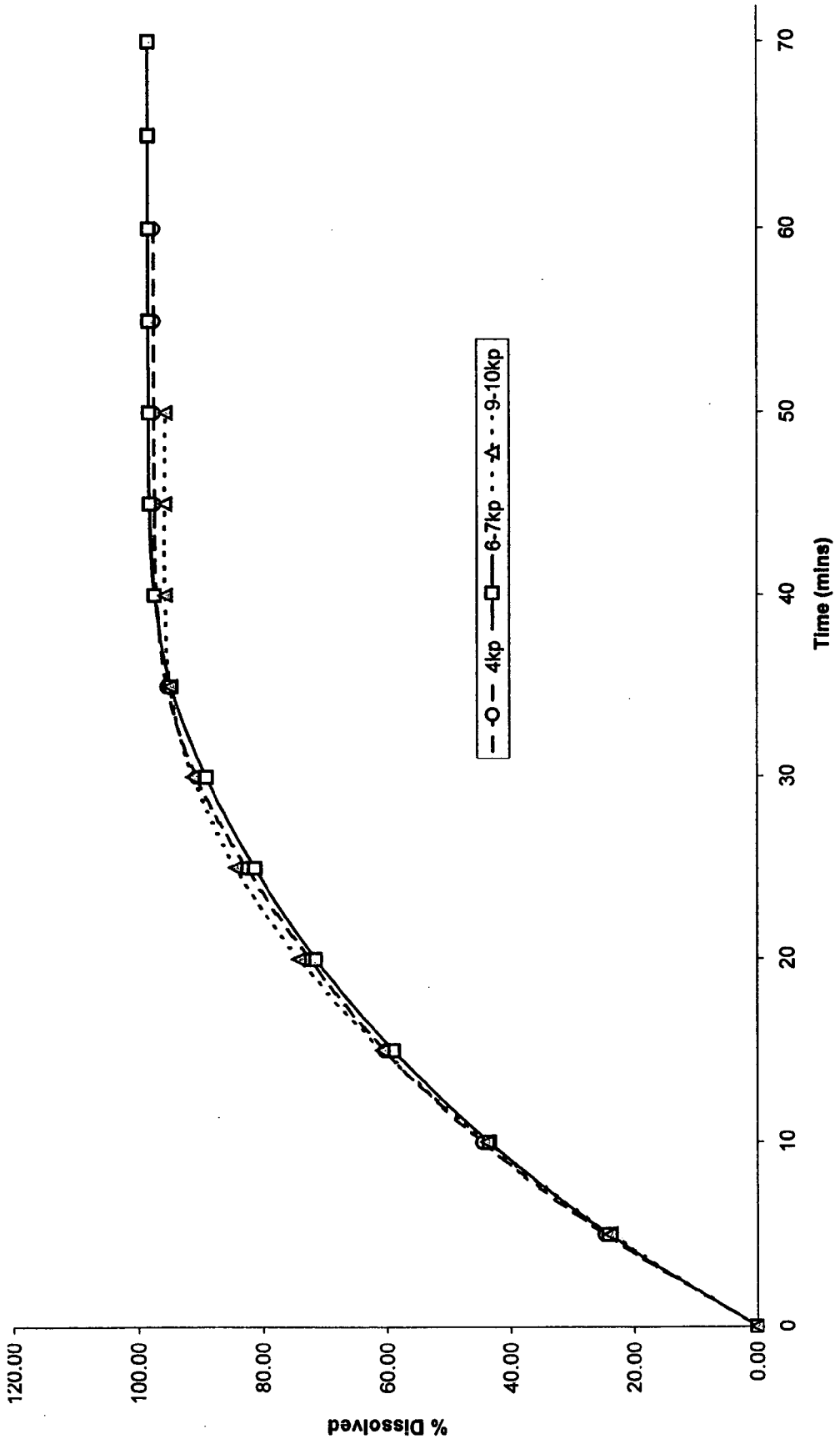

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
10
20
30
40
50
60
70
Time (mins)
4kp
6-7kp
9-10kp

Figure 6

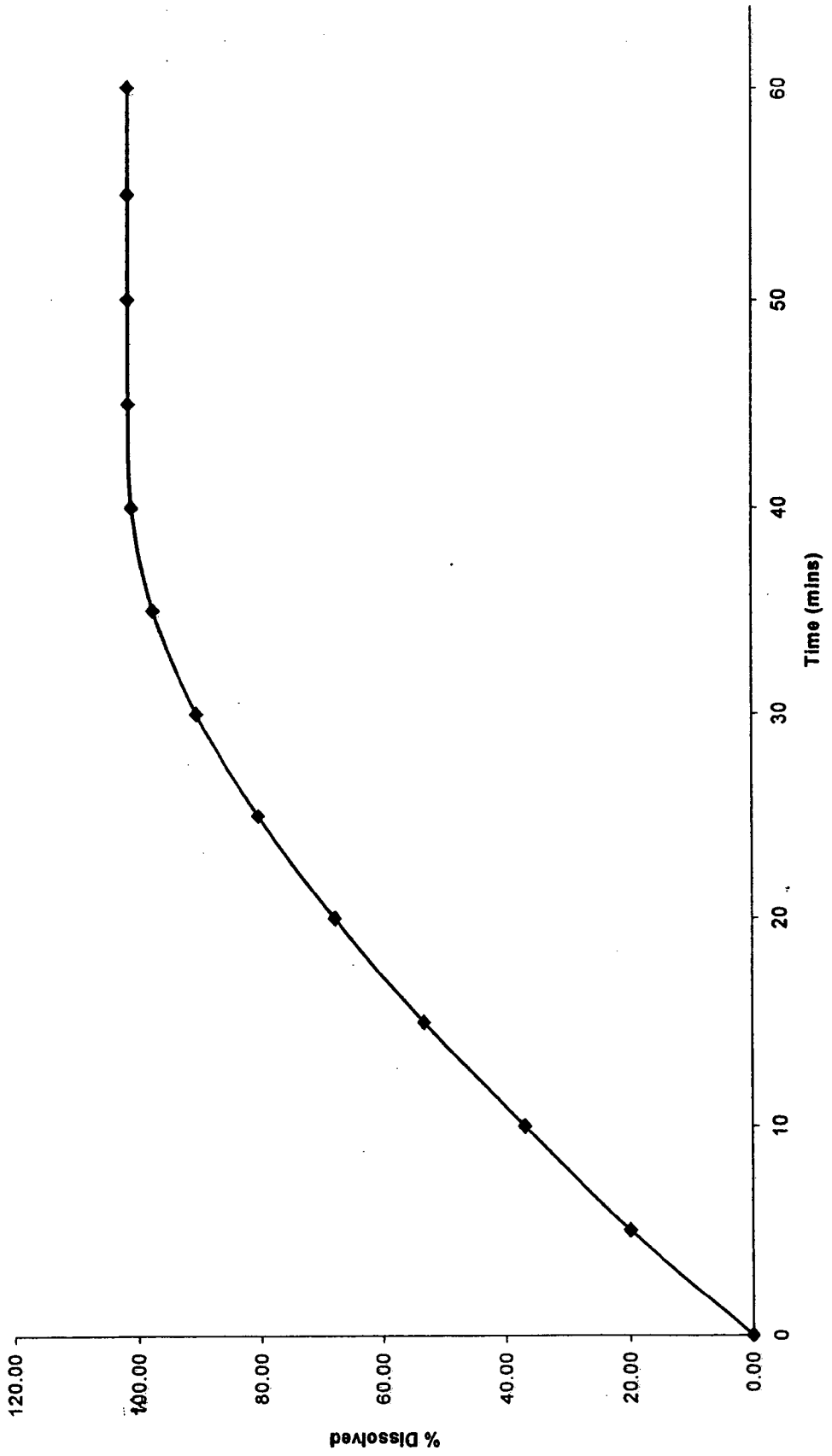

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
10
20
30
40
50
60
Time (mins)

Figure 7

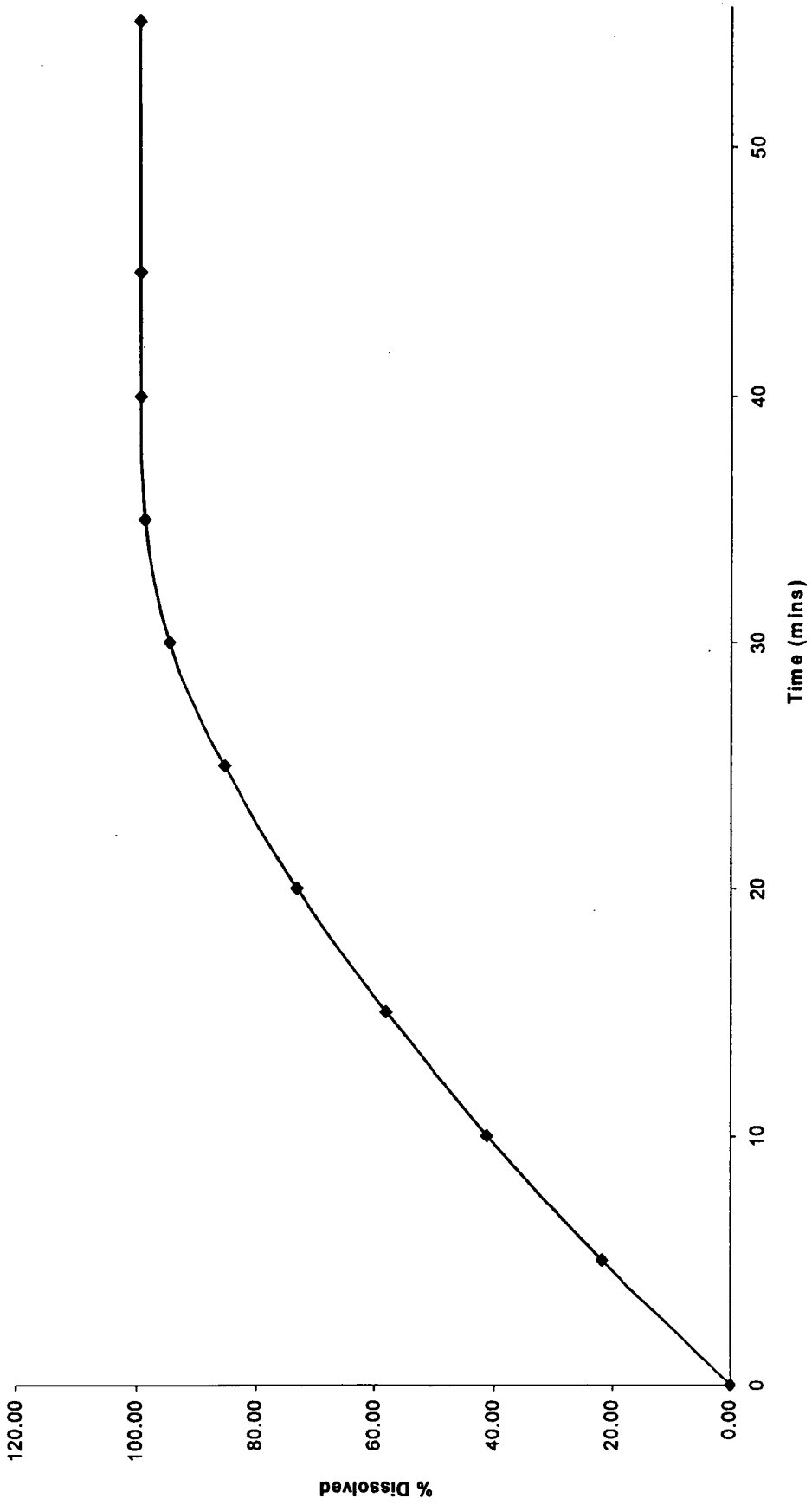

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
10
20
30
40
50
Time (mins)

Figure 8

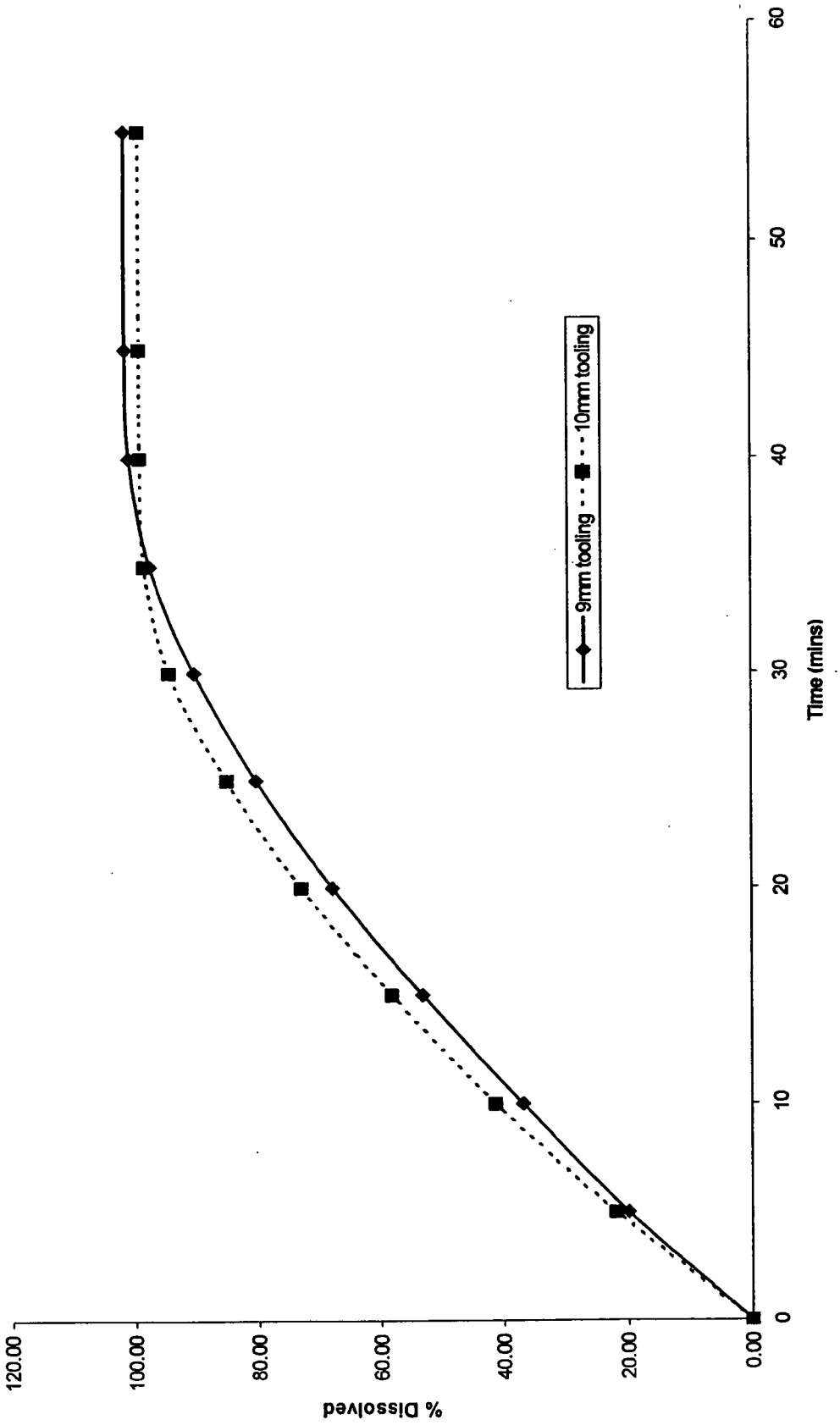

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
10
20
30
40
50
60
Time (mins)
9mm tooling
10mm tooling

Figure 9

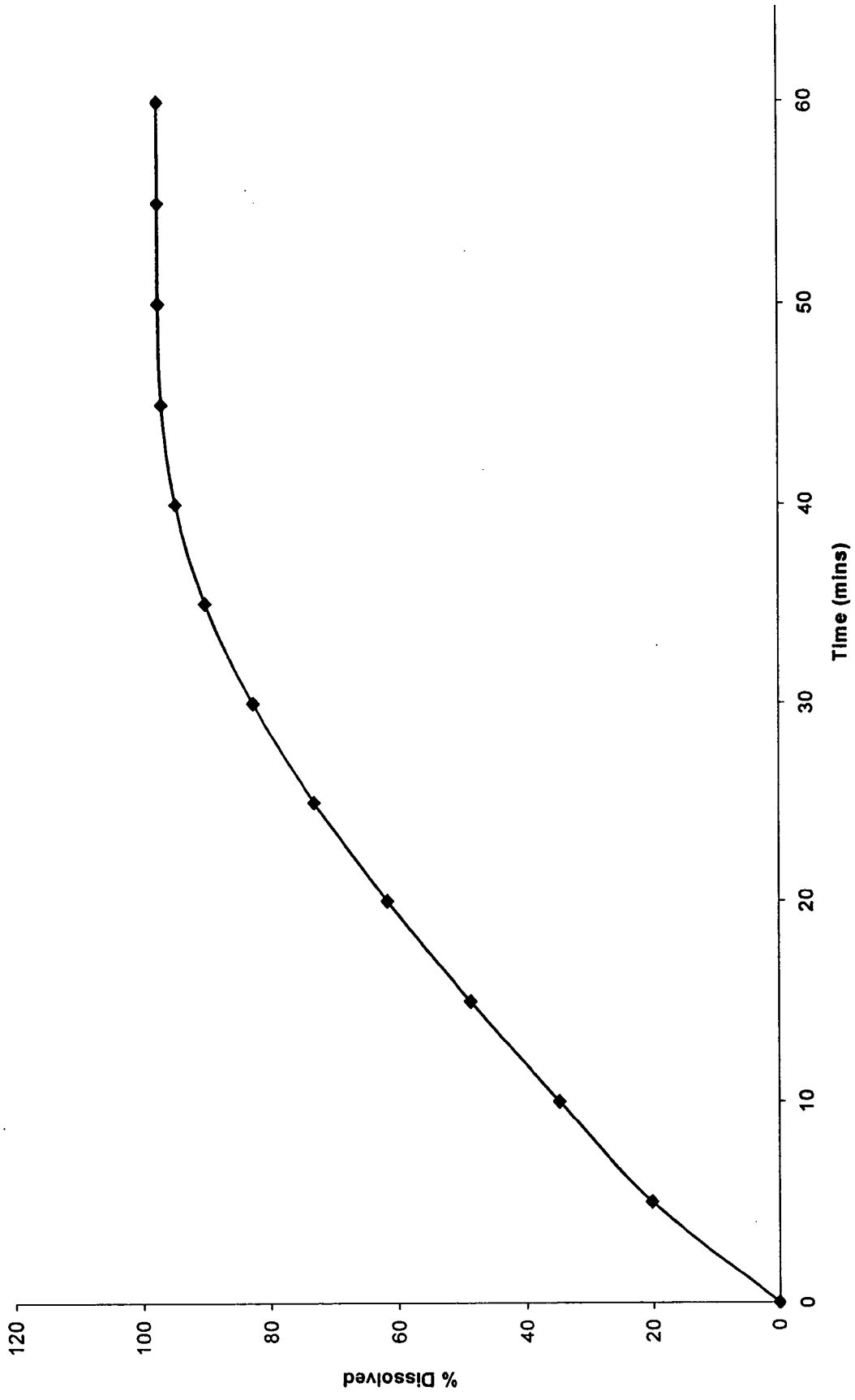


Figure 10

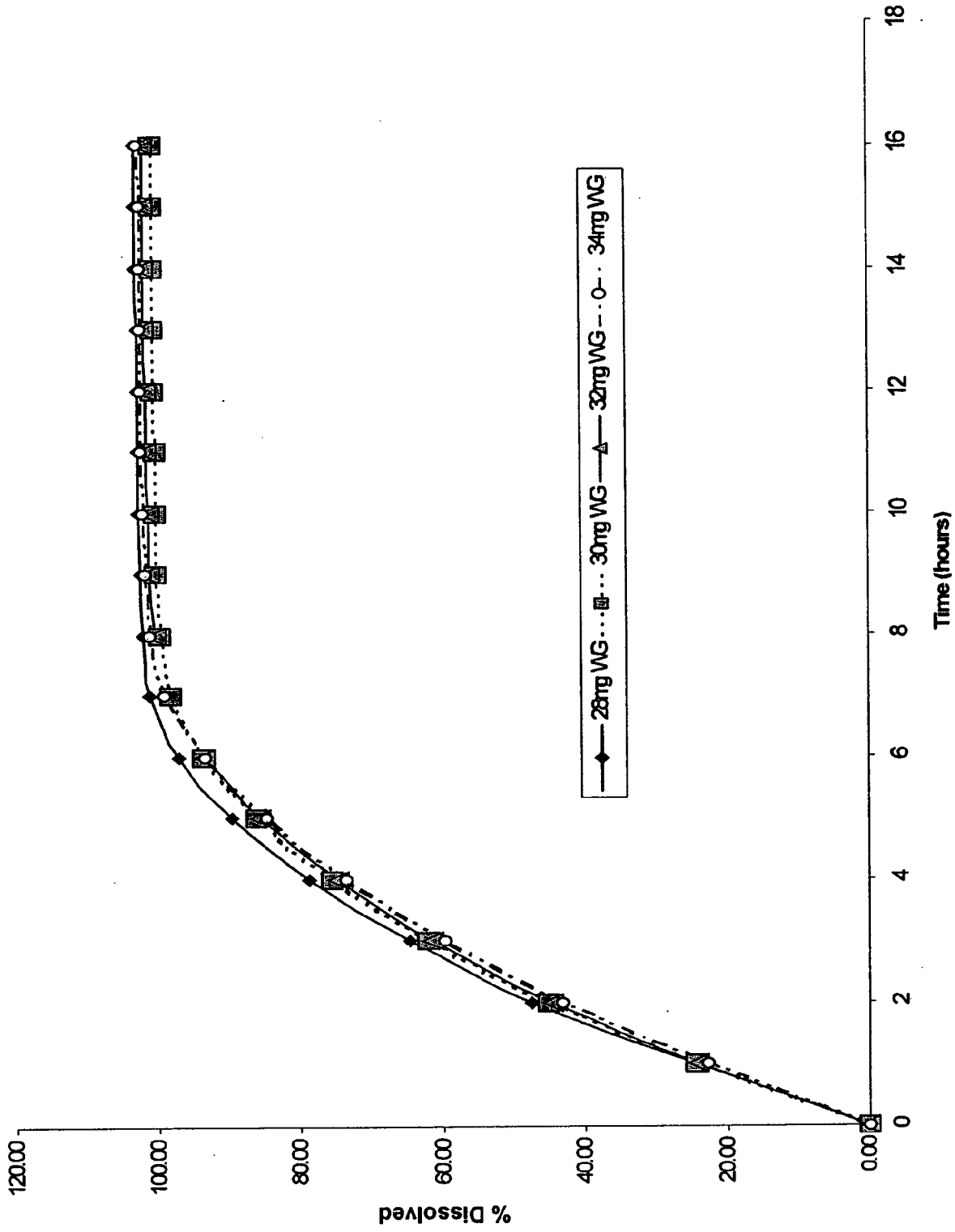

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
28mg WG
30mg WG
32mg WG
34mg WG

Figure 11

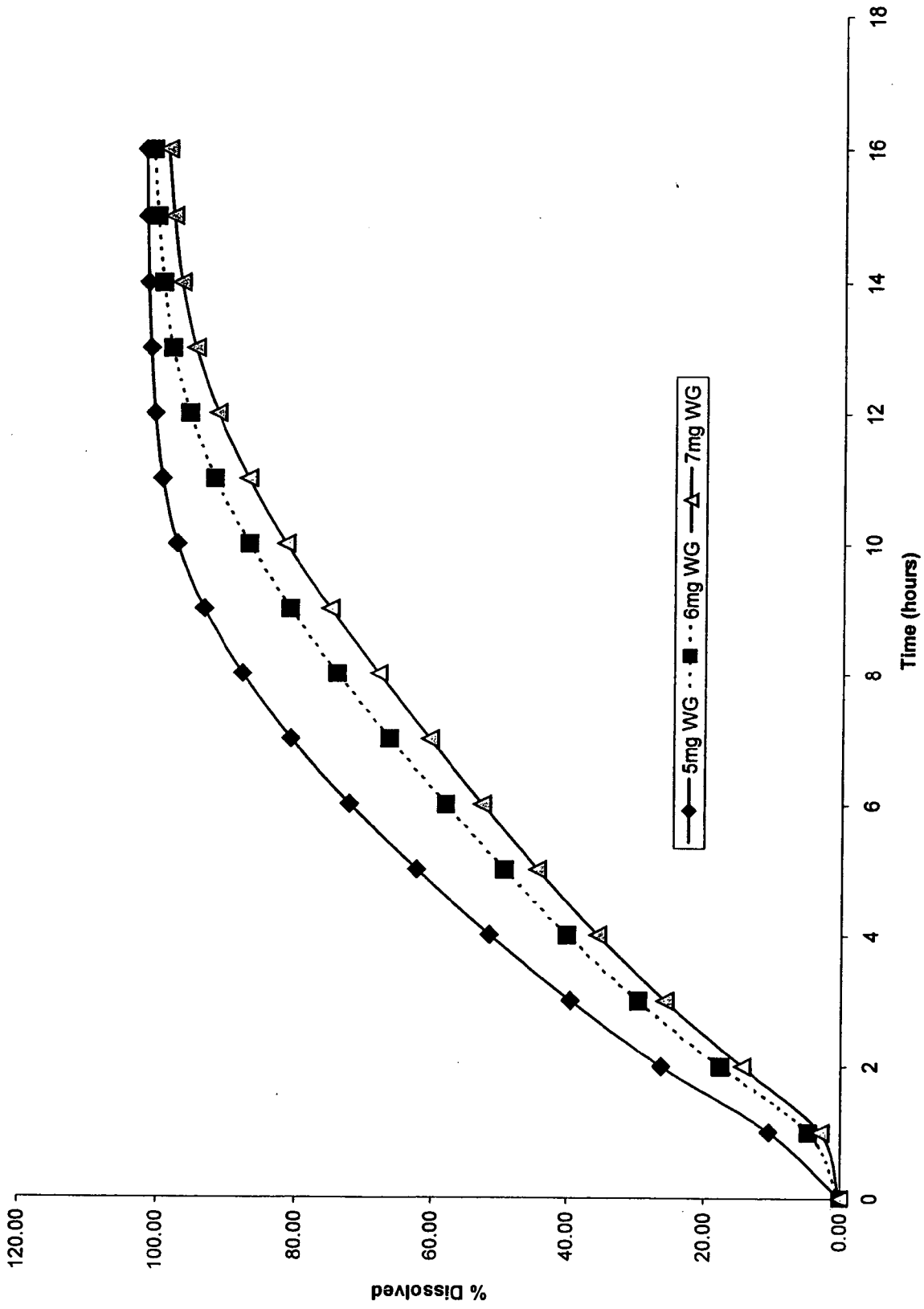

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
5mg WG
6mg WG
7mg WG

Figure 12

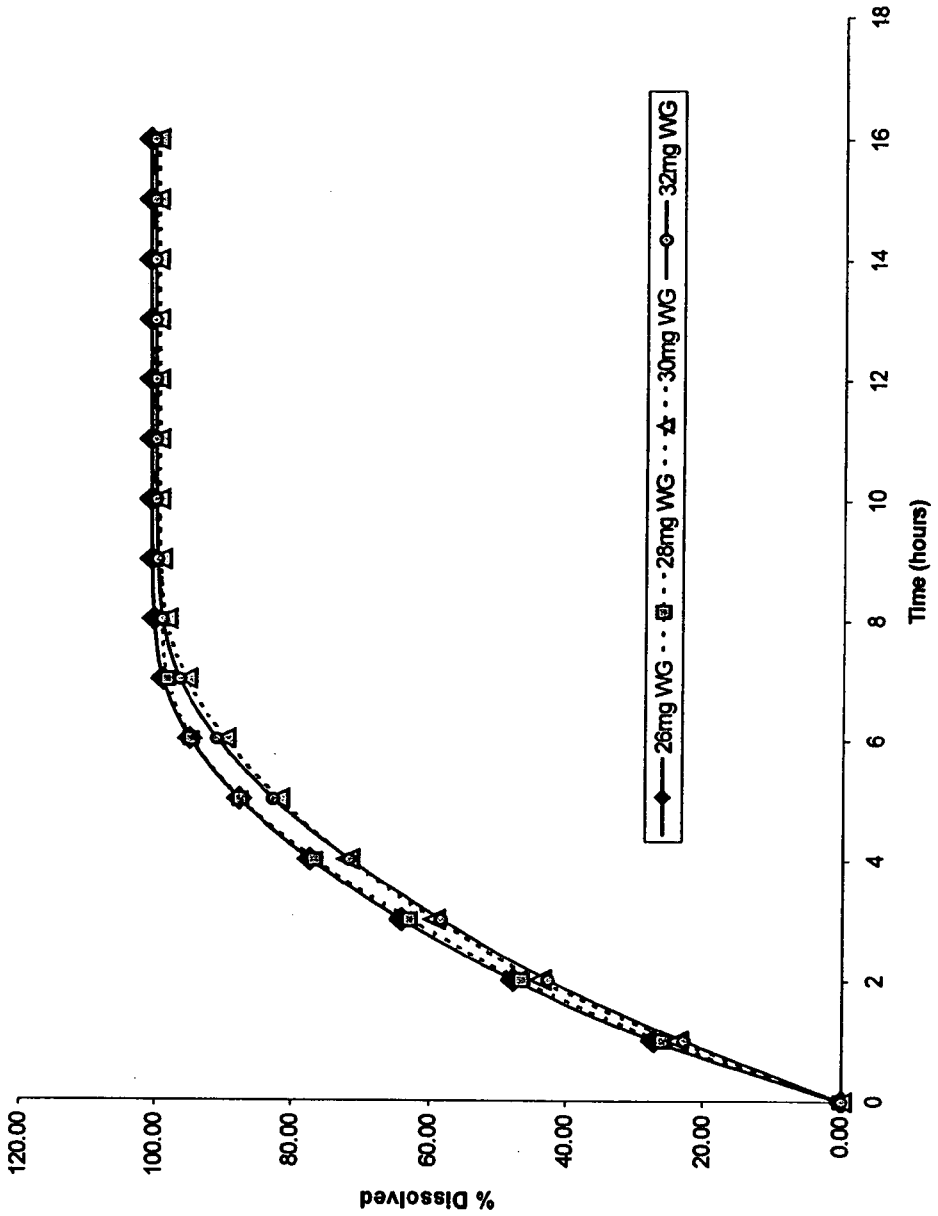

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
26mg WG
28mg WG
30mg WG
32mg WG

Figure 13

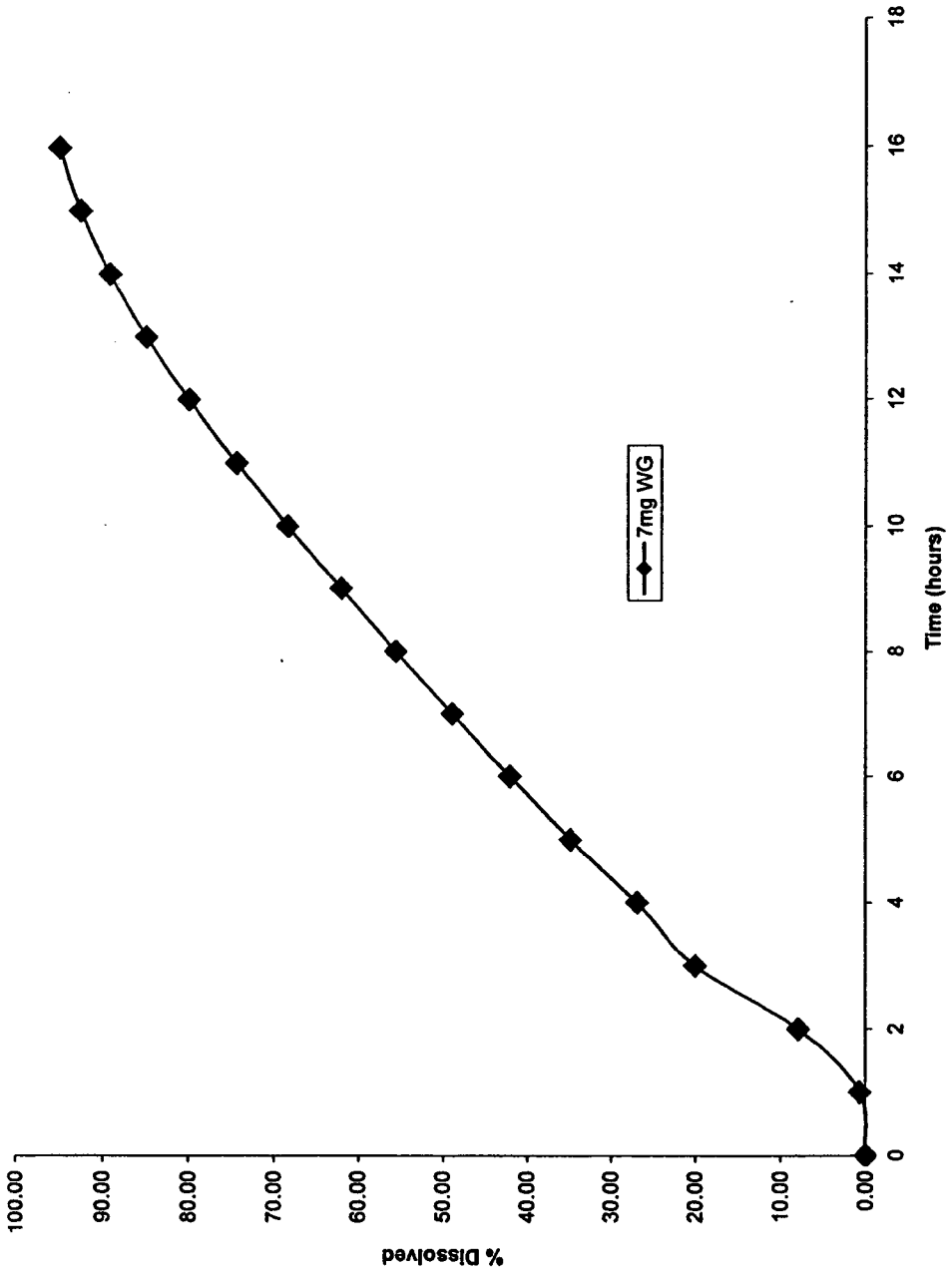

% Dissolved
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
7mg WG

Figure 14

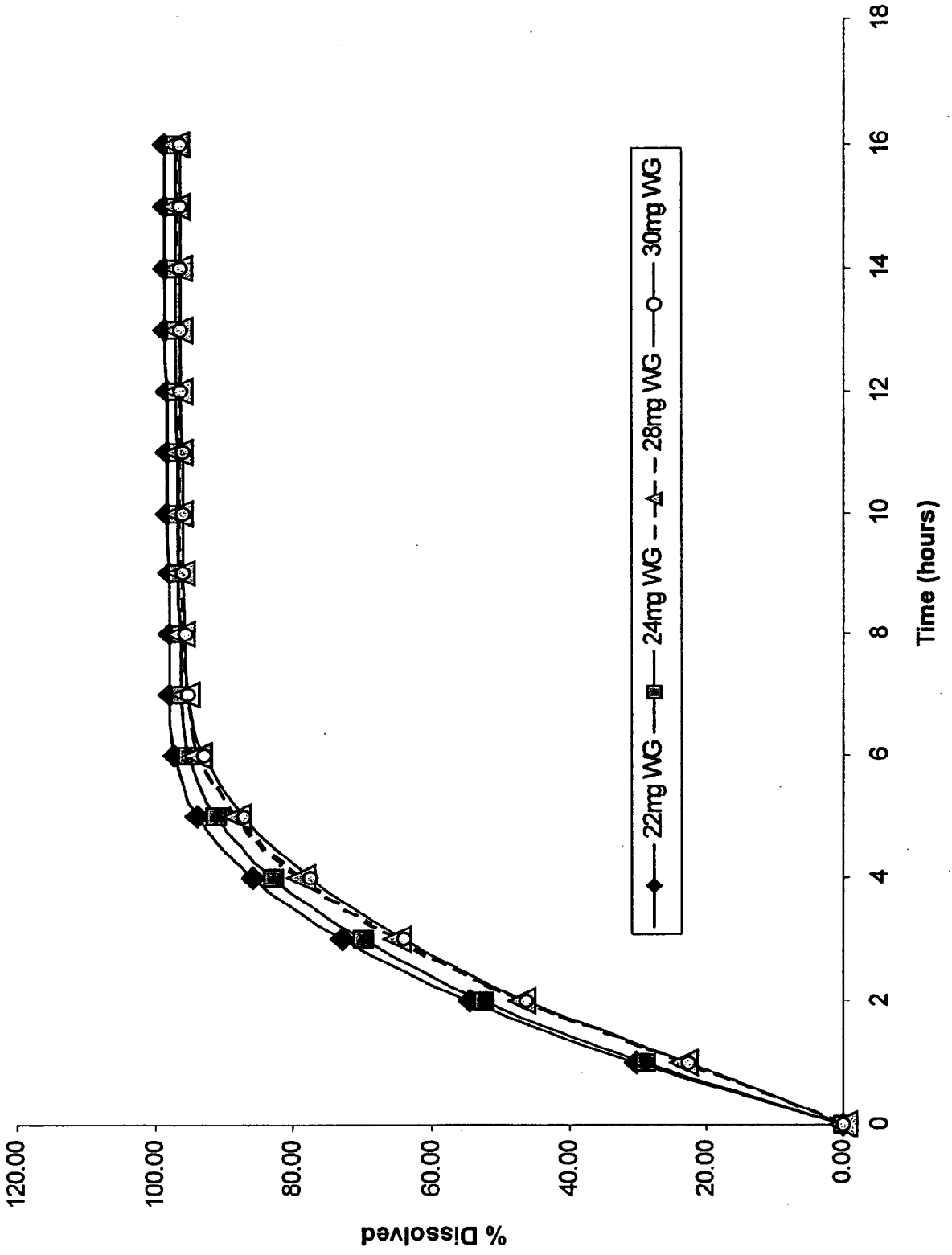

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
22mg WG
24mg WG
28mg WG
30mg WG

Figure 15

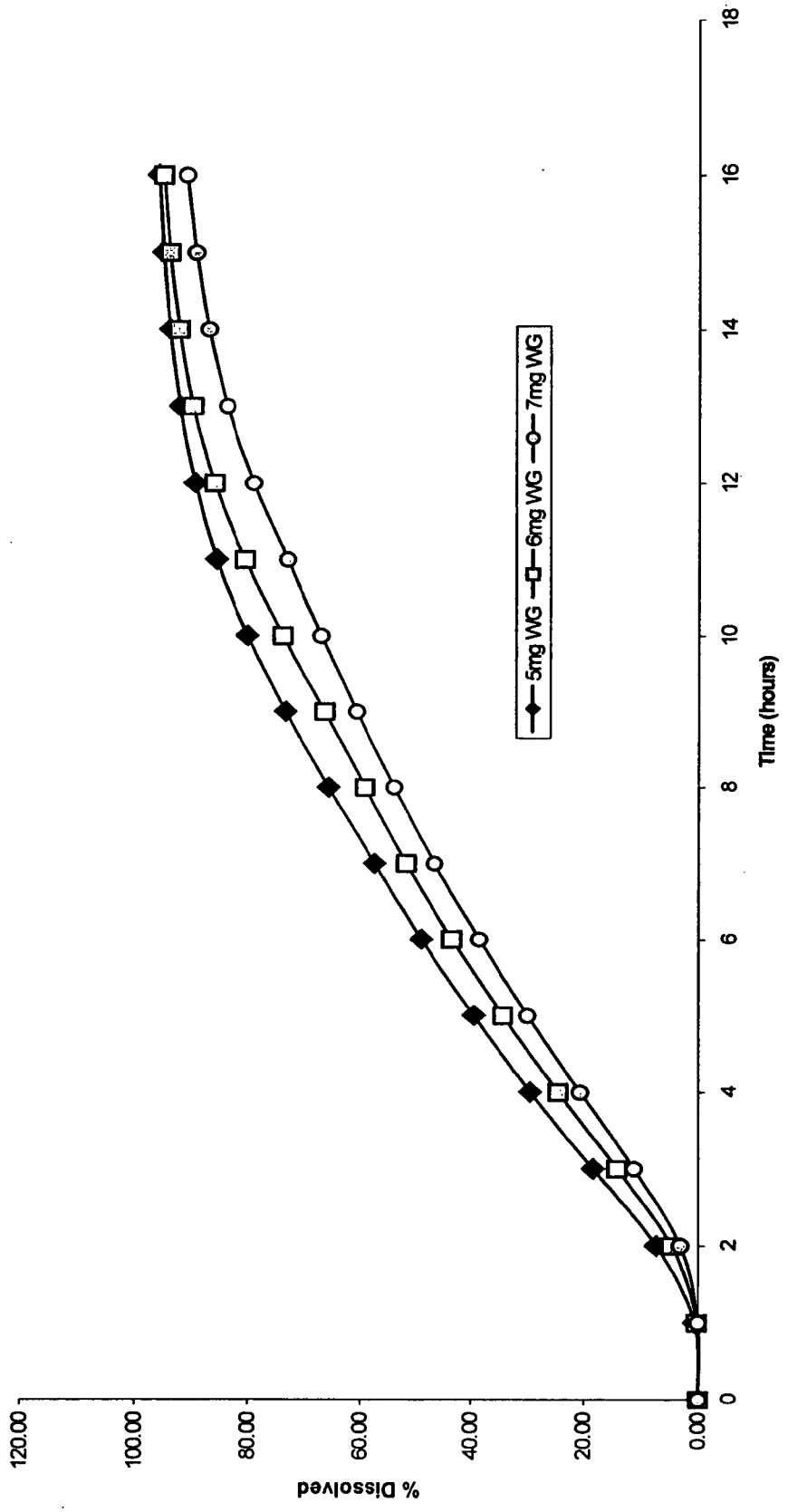

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
5mg WG
6mg WG
7mg WG

Figure 16

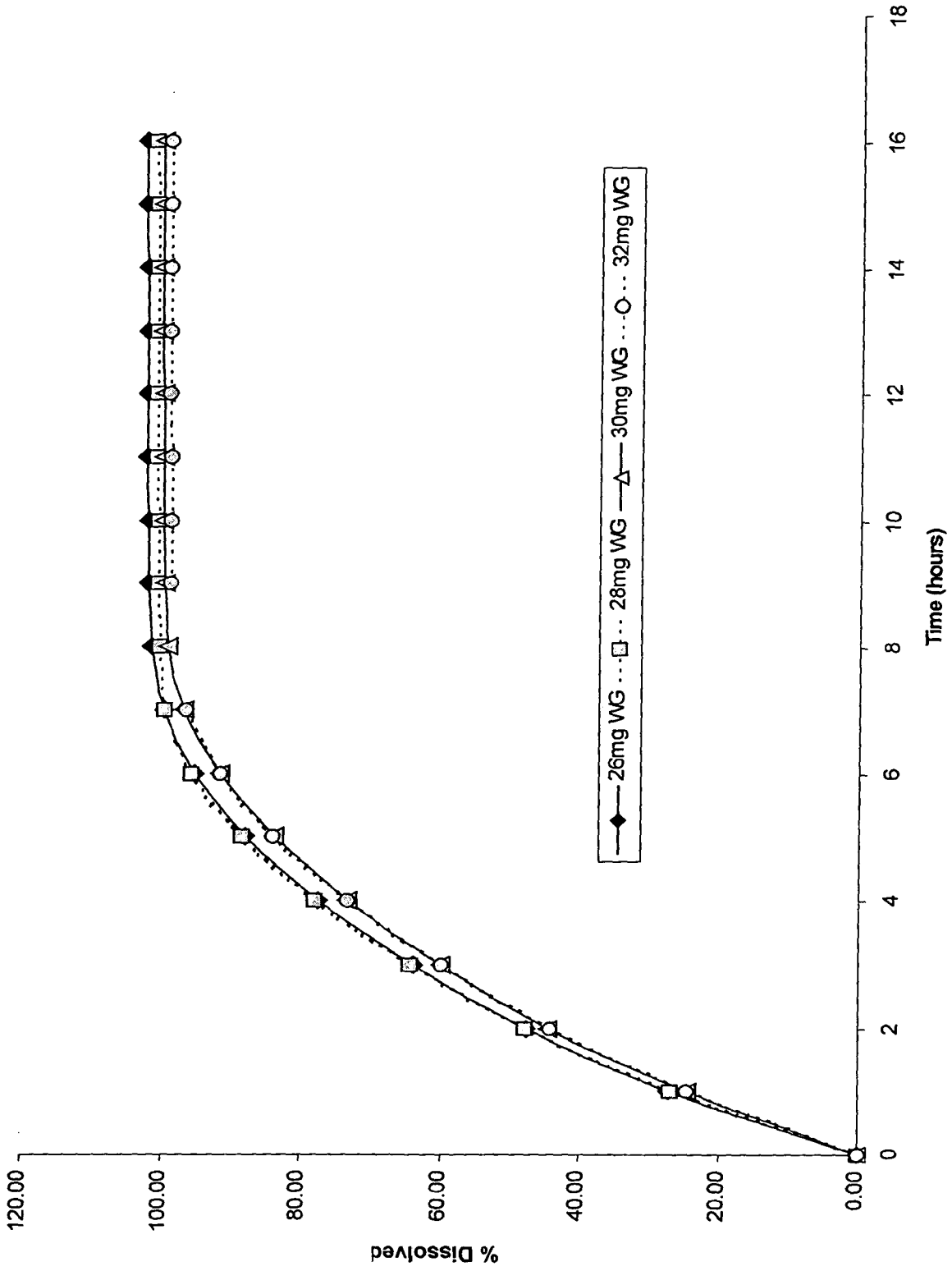

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
26mg WG
28mg WG
30mg WG
32mg WG

Figure 17

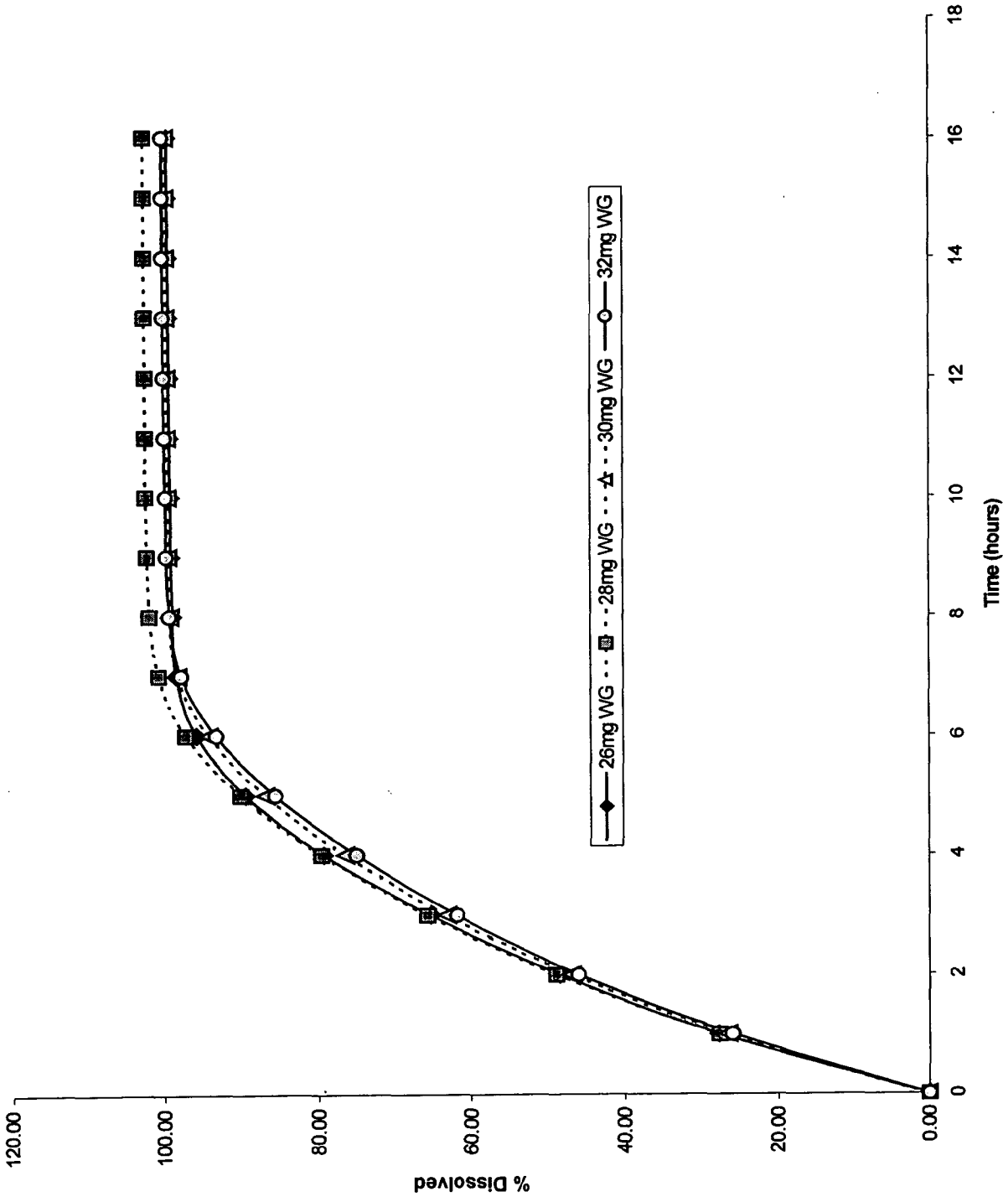

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
26mg WG
28mg WG
30mg WG
32mg WG

Figure 18

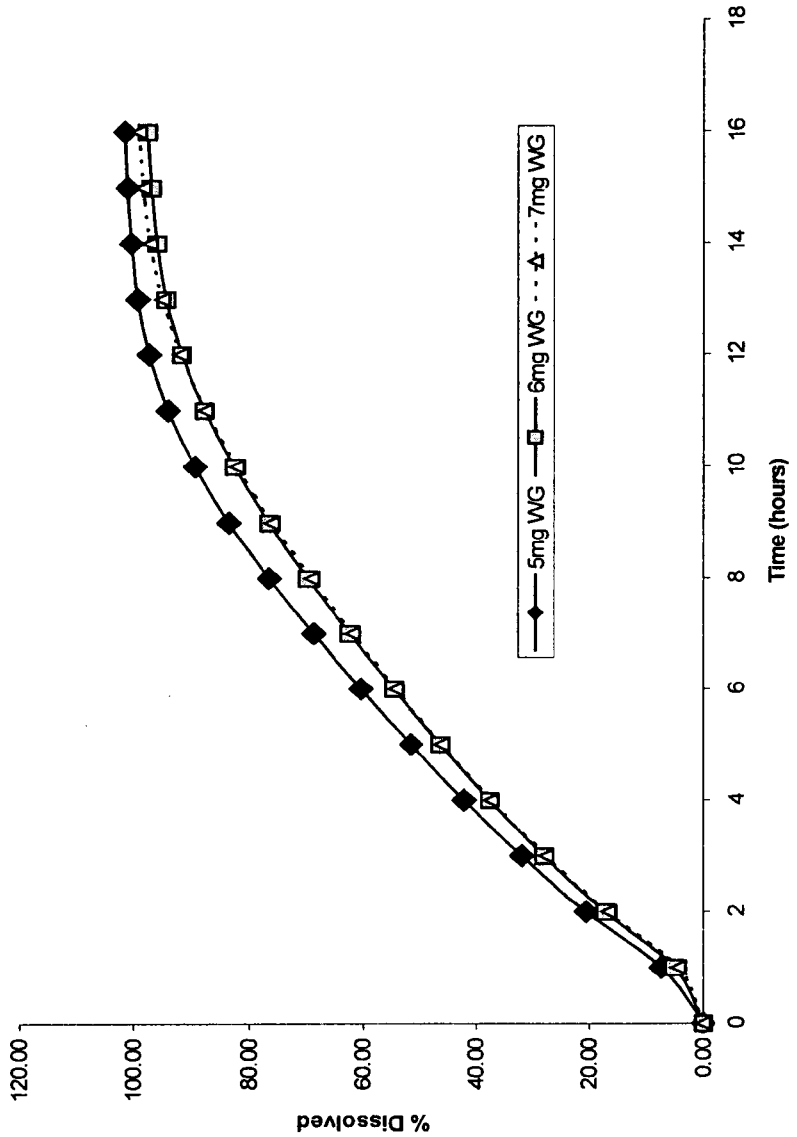

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
5mg WG
6mg WG
7mg WG

Figure 19

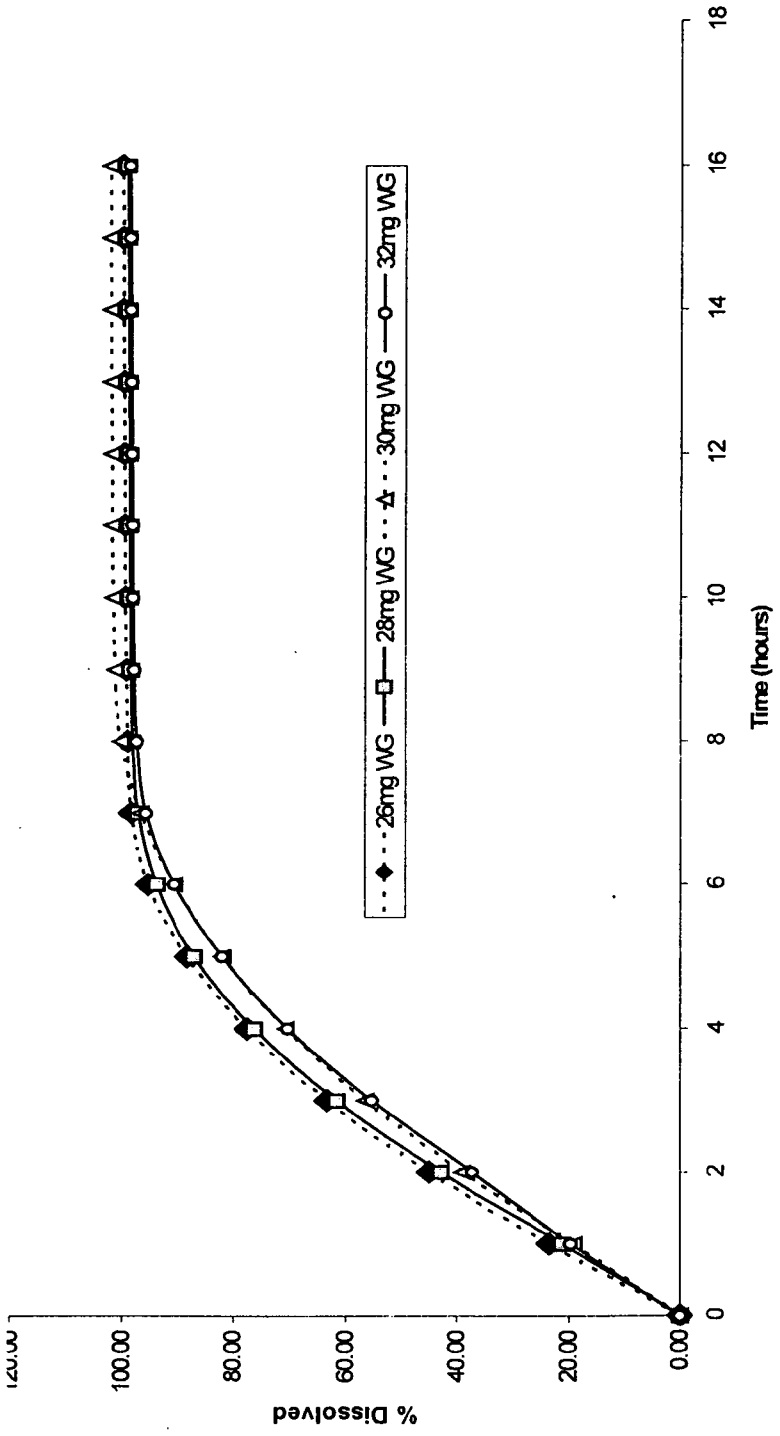

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
26mg WG
28mg WG
30mg WG
32mg WG

Figure 20

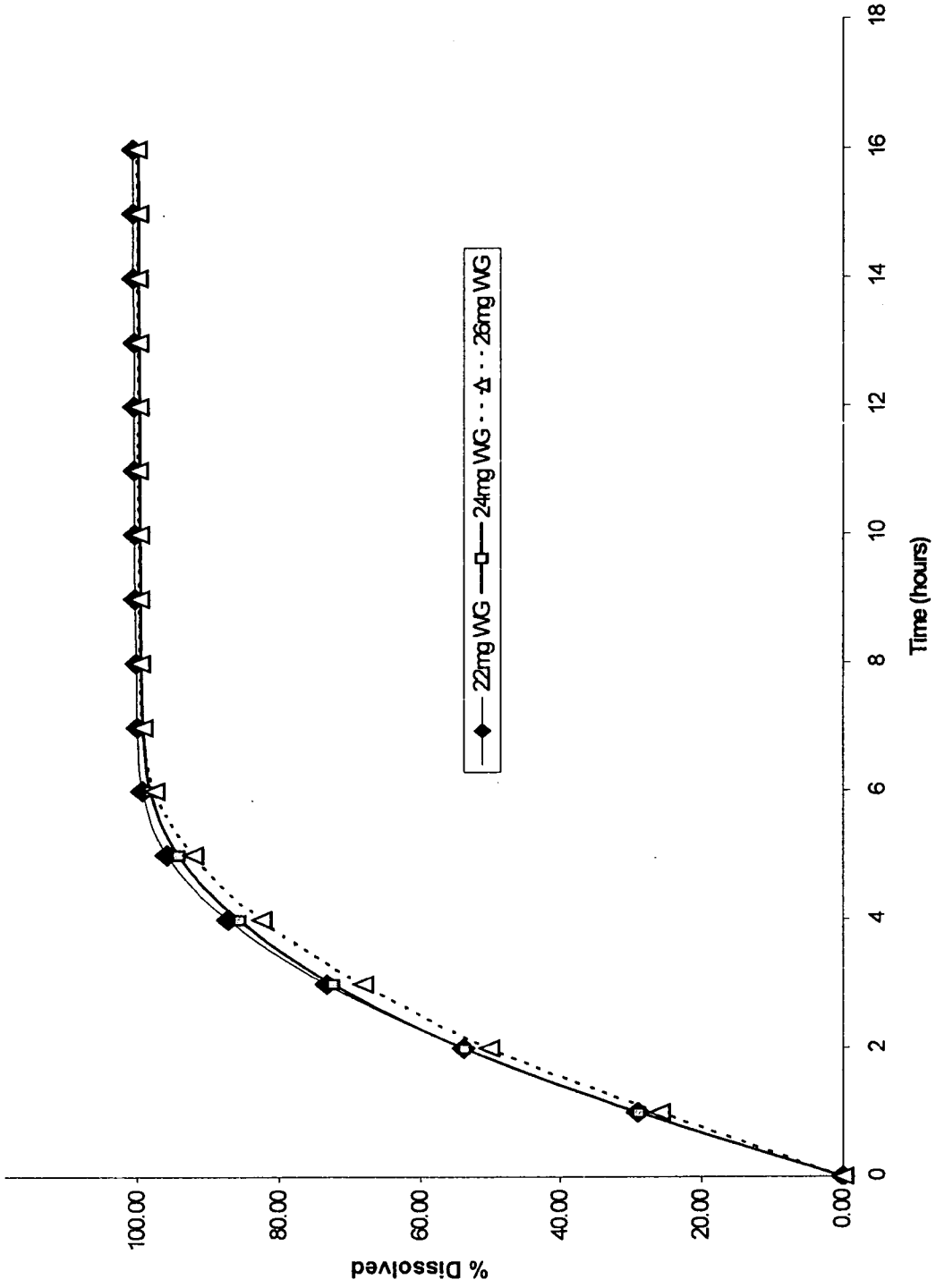

22mg WG
24mg WG
26mg WG
% Dissolved
100.00
80.00
60.00
40.00
20.00
0.00
Time (hours)
0
2
4
6
8
10
12
14
16
18

Figure 21

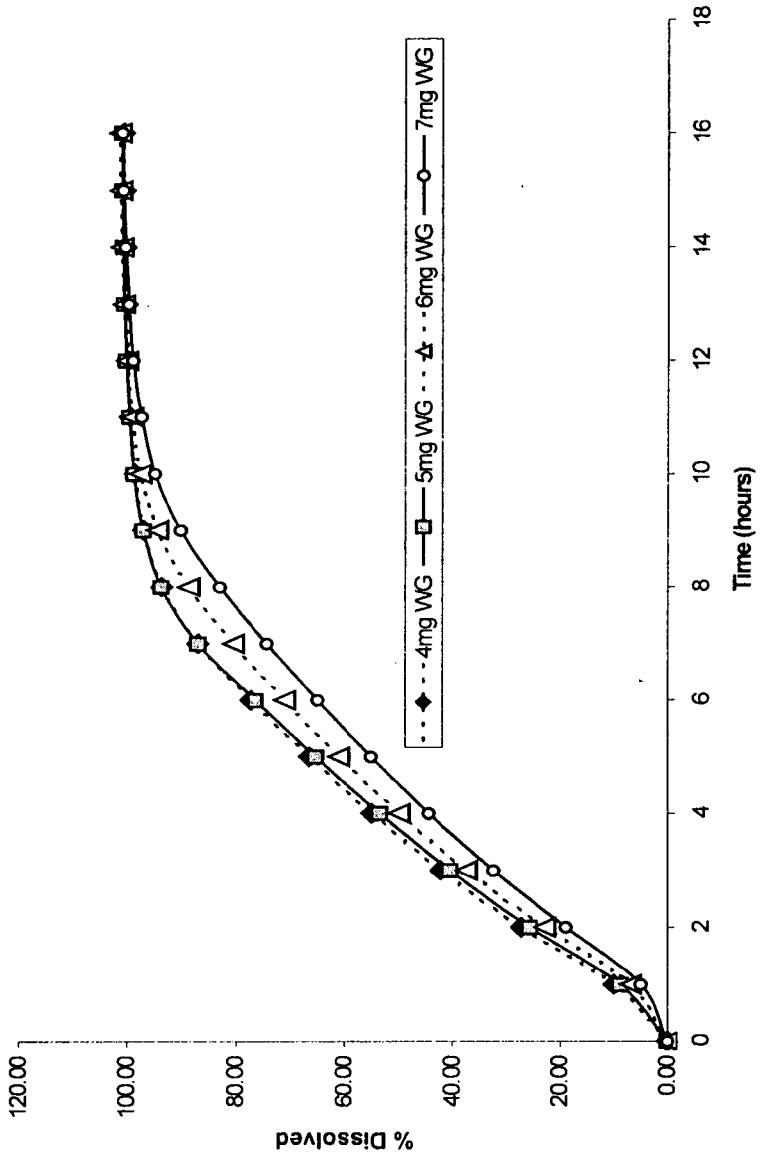

% Dissolved
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
2
4
6
8
10
12
14
16
18
Time (hours)
4mg WG
5mg WG
6mg WG
7mg WG

Figure 22

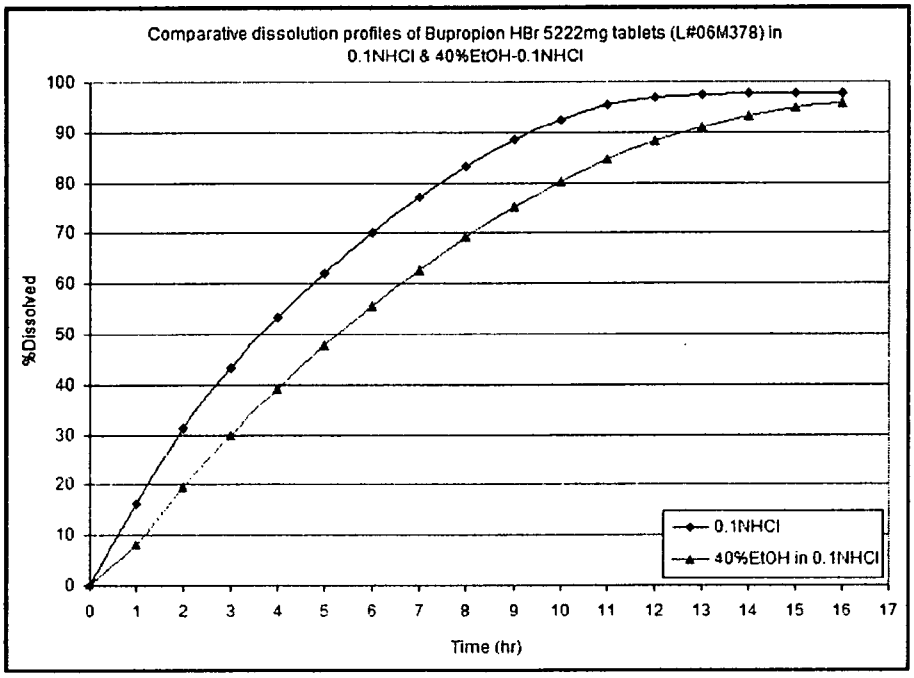

Comparative dissolution profiles of Bupropion HBr 5222mg tablets (L#06M378) in 0.1NHCl & 40%EtOH-0.1NHCl
%Dissolved
Time (hr)
0.1NHCl
40%EtOH in 0.1NHCl

Figure 23

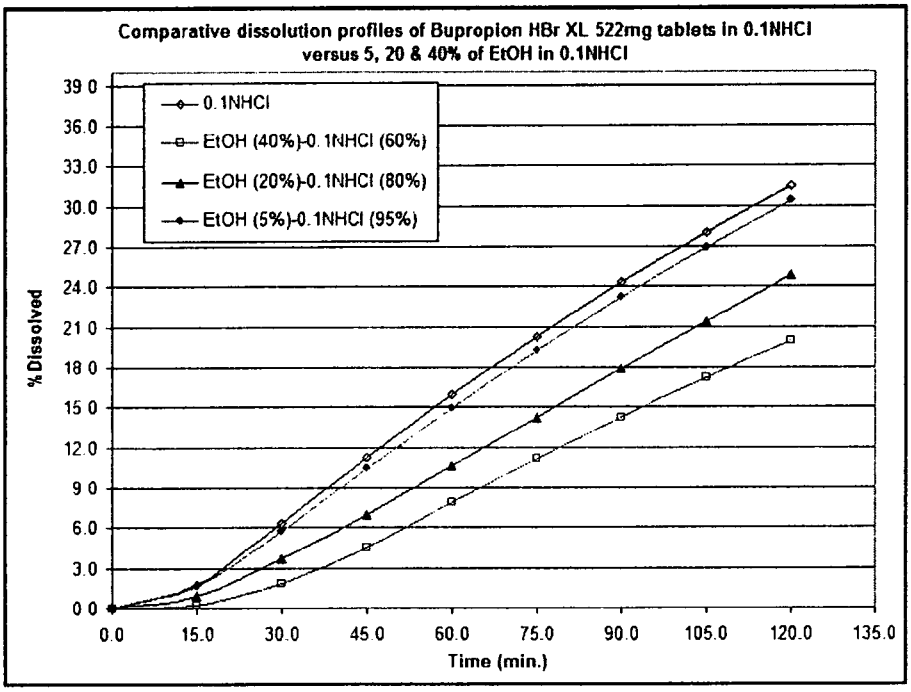

Comparative dissolution profiles of Bupropion HBr XL 522mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
EtOH (40%)-0.1NHCl (60%)
EtOH (20%)-0.1NHCl (80%)
EtOH (5%)-0.1NHCl (95%)
% Dissolved
39.0
36.0
33.0
30.0
27.0
24.0
21.0
18.0
15.0
12.0
9.0
6.0
3.0
0.0
0.0
15.0
30.0
45.0
60.0
75.0
90.0
105.0
120.0
135.0
Time (min.)

Figure 24

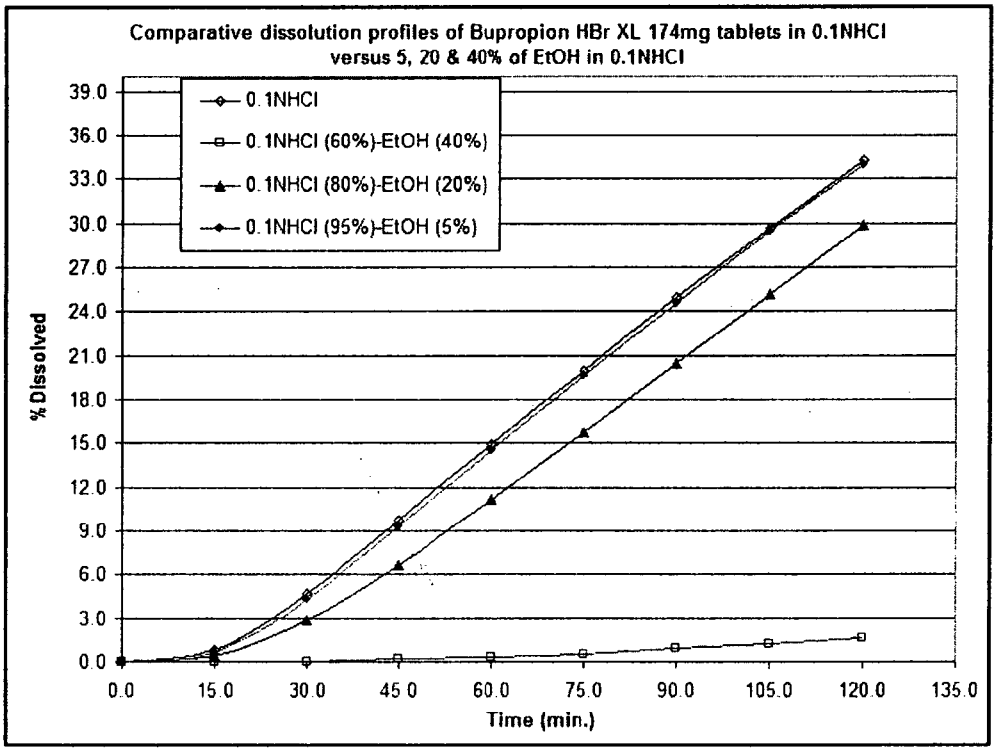

Comparative dissolution profiles of Bupropion HBr XL 174mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
0.1NHCl (60%)-EtOH (40%)
0.1NHCl (80%)-EtOH (20%)
0.1NHCl (95%)-EtOH (5%)
% Dissolved
39.0
36.0
33.0
30.0
27.0
24.0
21.0
18.0
15.0
12.0
9.0
6.0
3.0
0.0
0.0
15.0
30.0
45.0
60.0
75.0
90.0
105.0
120.0
135.0
Time (min.)

Figure 25

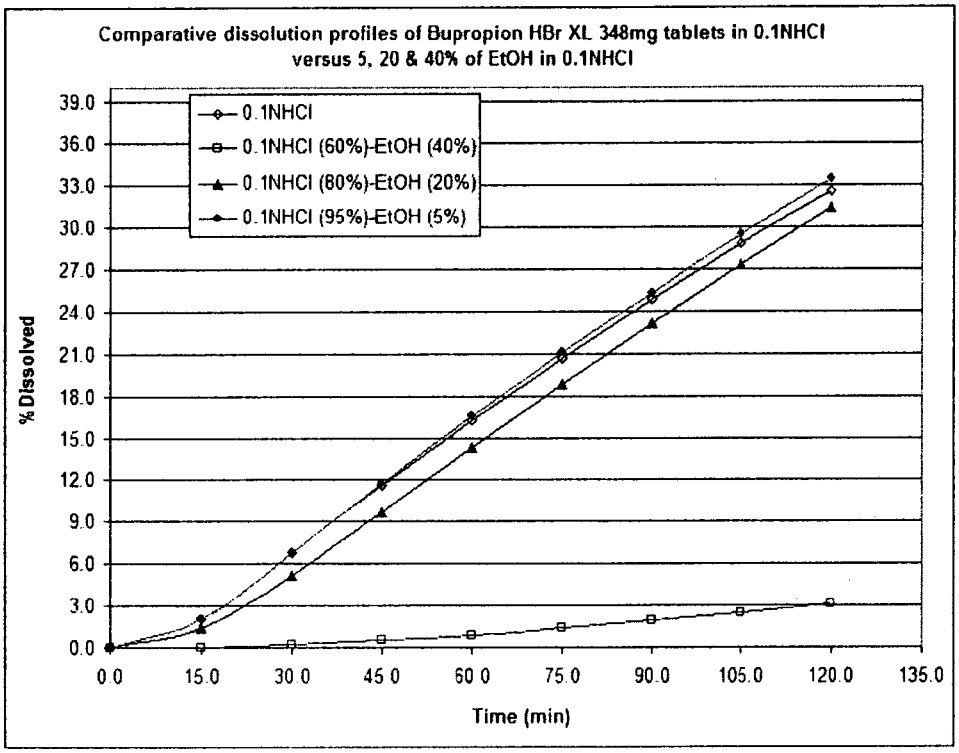

Comparative dissolution profiles of Bupropion HBr XL 348mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
0.1NHCl (60%)-EtOH (40%)
0.1NHCl (80%)-EtOH (20%)
0.1NHCl (95%)-EtOH (5%)
% Dissolved
39.0
36.0
33.0
30.0
27.0
24.0
21.0
18.0
15.0
12.0
9.0
6.0
3.0
0.0
0.0
15.0
30.0
45.0
60.0
75.0
90.0
105.0
120.0
135.0
Time (min)

Figure 26

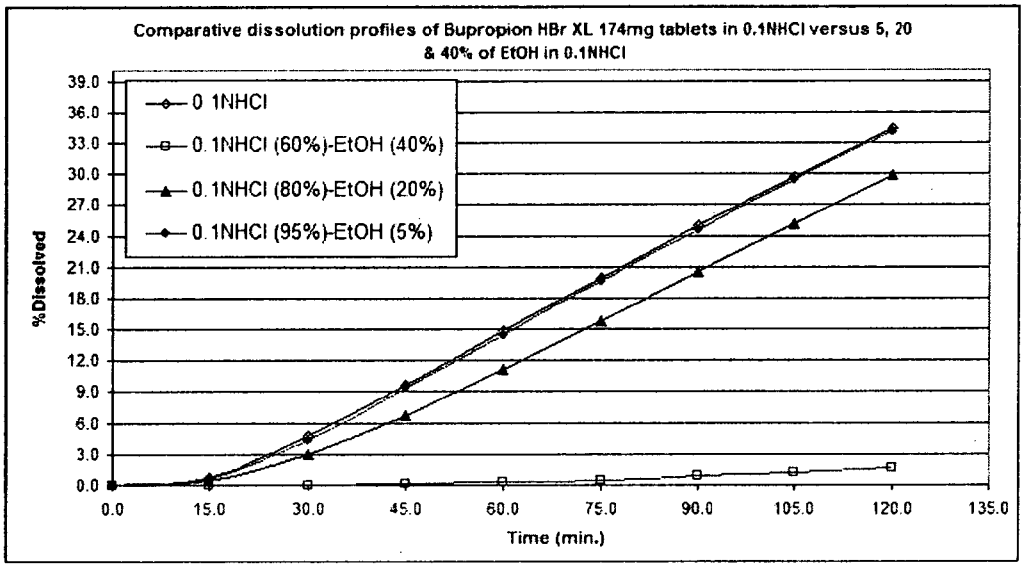

Comparative dissolution profiles of Bupropion HBr XL 174mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
0.1NHCl (60%)-EtOH (40%)
0.1NHCl (80%)-EtOH (20%)
0.1NHCl (95%)-EtOH (5%)
%Dissolved
Time (min.)
0.0
3.0
6.0
9.0
12.0
15.0
18.0
21.0
24.0
27.0
30.0
33.0
36.0
39.0
0.0
15.0
30.0
45.0
60.0
75.0
90.0
105.0
120.0
135.0

Figure 27

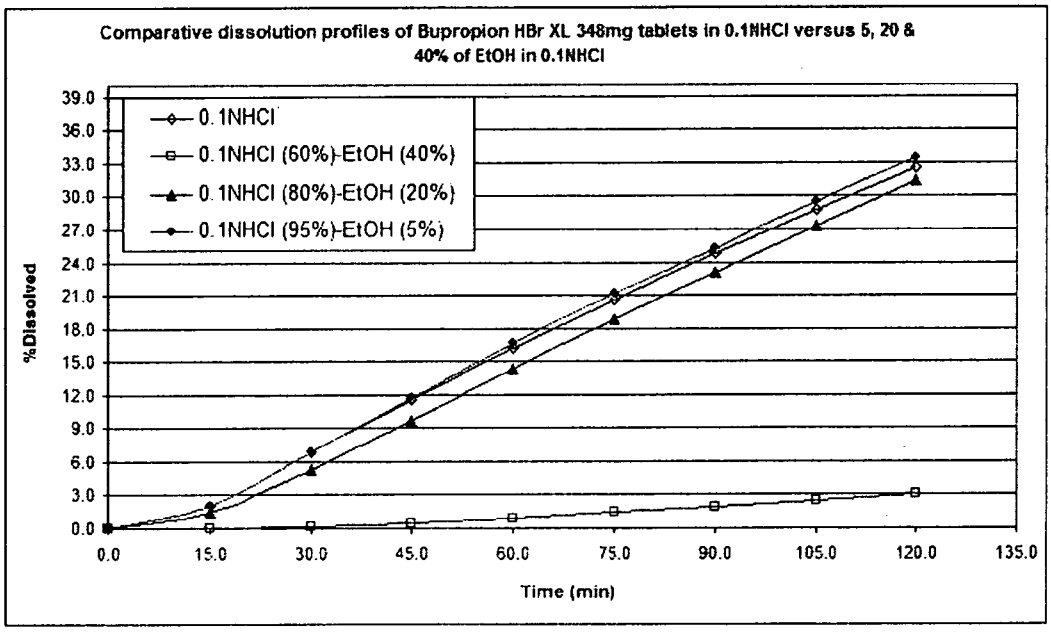

Comparative dissolution profiles of Bupropion HBr XL 348mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
0.1NHCl (60%)-EtOH (40%)
0.1NHCl (80%)-EtOH (20%)
0.1NHCl (95%)-EtOH (5%)
%Dissolved
39.0
36.0
33.0
30.0
27.0
24.0
21.0
18.0
15.0
12.0
9.0
6.0
3.0
0.0
0.0
15.0
30.0
45.0
60.0
75.0
90.0
105.0
120.0
135.0
Time (min)

Figure 28

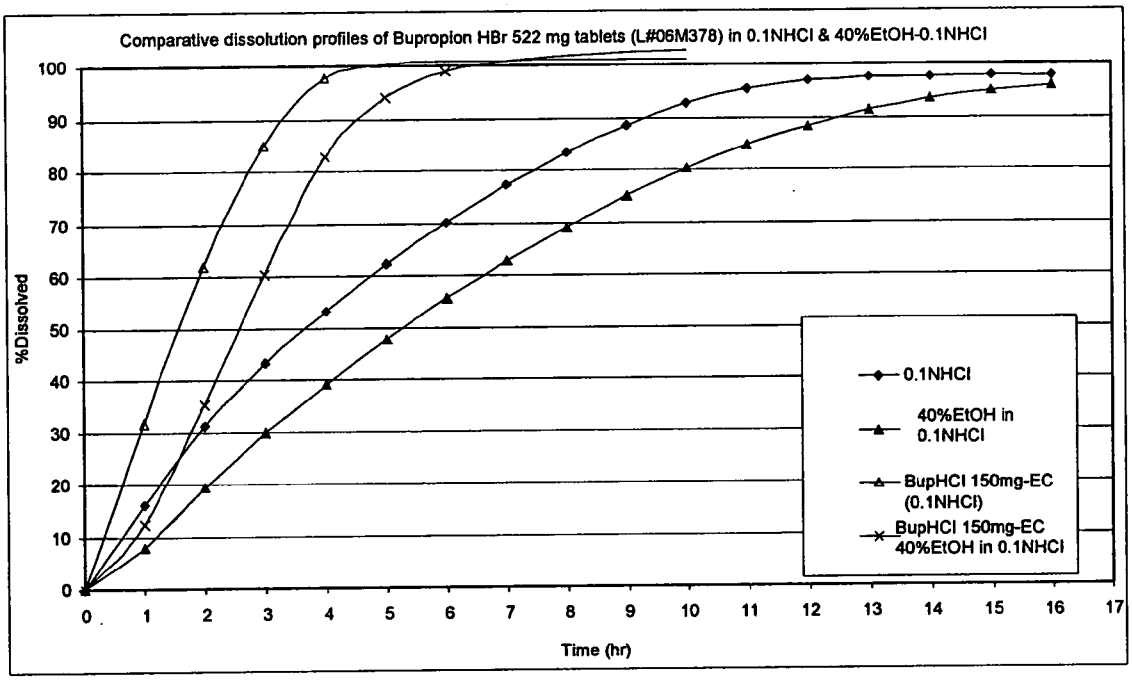

Comparative dissolution profiles of Bupropion HBr 522 mg tablets (L#06M378) in 0.1NHCl & 40%EtOH-0.1NHCl
%Dissolved
Time (hr)
0.1NHCl
40%EtOH in 0.1NHCl
BupHCl 150mg-EC (0.1NHCl)
BupHCl 150mg-EC 40%EtOH in 0.1NHCl

Figure 29

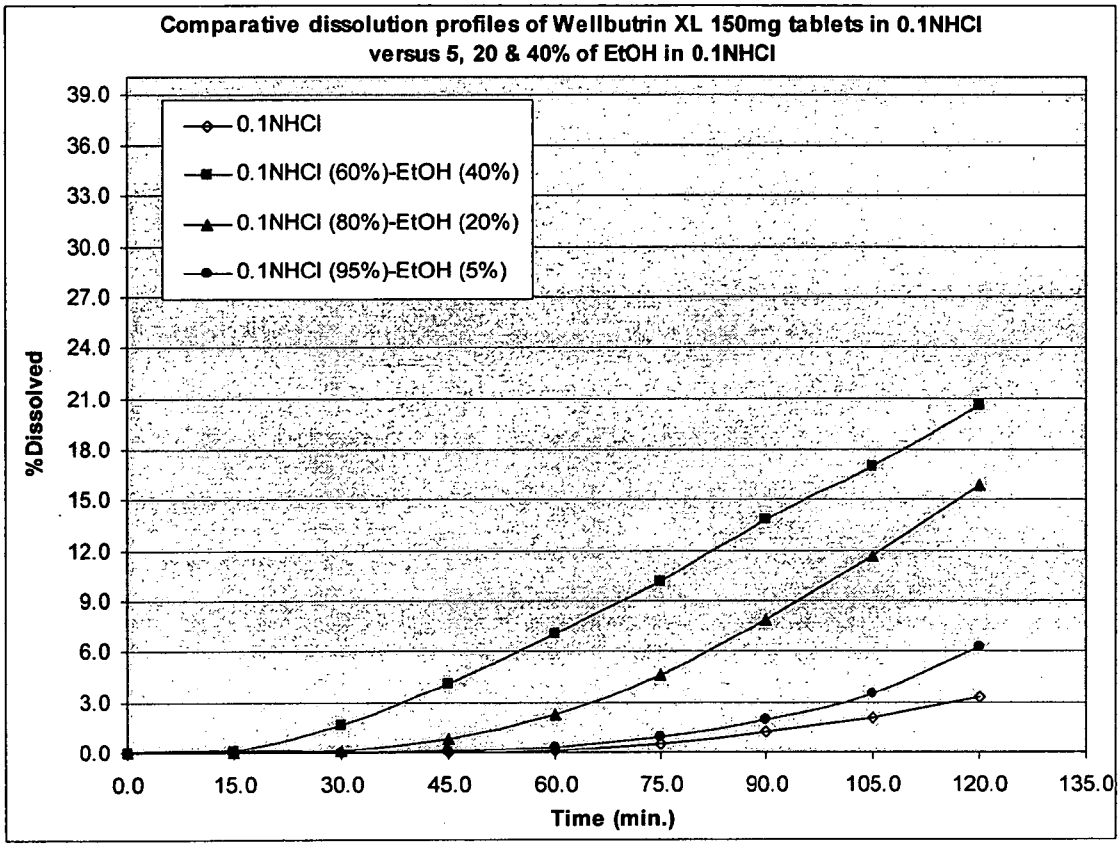

Comparative dissolution profiles of Wellbutrin XL 150mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
0.1NHCl (60%)-EtOH (40%)
0.1NHCl (80%)-EtOH (20%)
0.1NHCl (95%)-EtOH (5%)
%Dissolved
39.0
36.0
33.0
30.0
27.0
24.0
21.0
18.0
15.0
12.0
9.0
6.0
3.0
0.0
0.0
15.0
30.0
45.0
60.0
75.0
90.0
105.0
120.0
135.0
Time (min.)

Figure 30

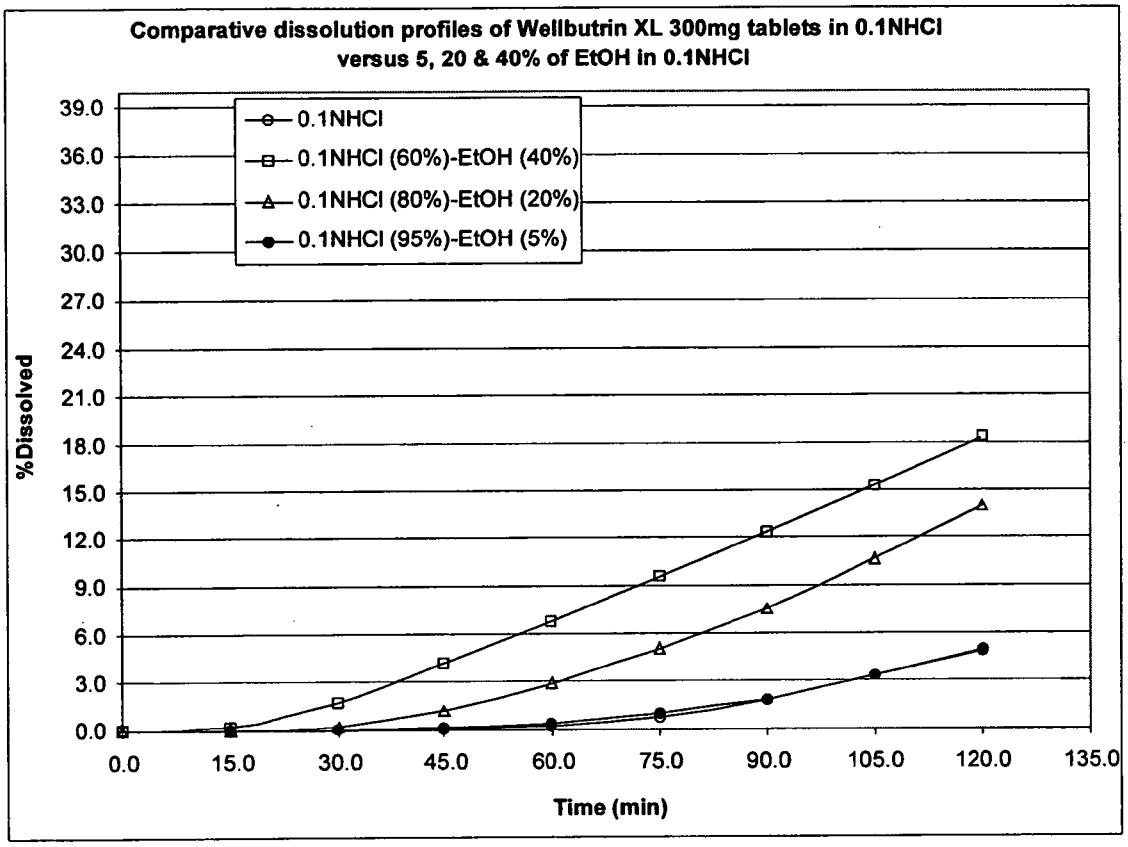

Comparative dissolution profiles of Wellbutrin XL 300mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
0.1NHCl (60%)-EtOH (40%)
0.1NHCl (80%)-EtOH (20%)
0.1NHCl (95%)-EtOH (5%)
%Dissolved
39.0
36.0
33.0
30.0
27.0
24.0
21.0
18.0
15.0
12.0
9.0
6.0
3.0
0.0
0.0
15.0
30.0
45.0
60.0
75.0
90.0
105.0
120.0
135.0
Time (min)

Figure 31

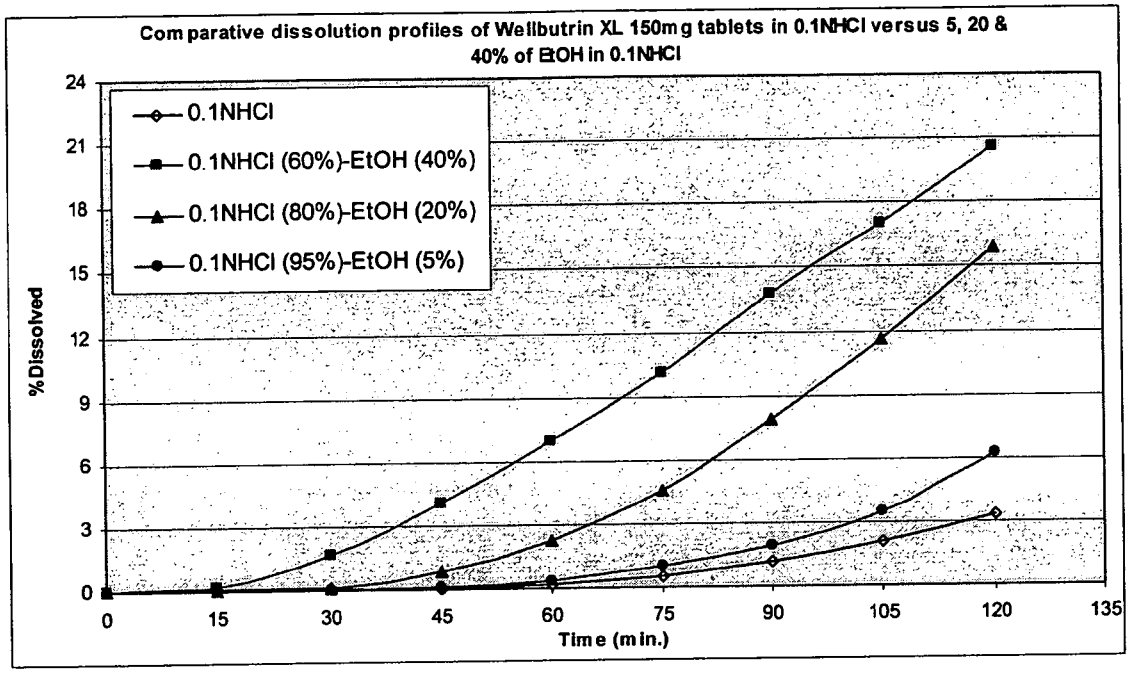

Comparative dissolution profiles of Wellbutrin XL 150mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
0.1NHCl (60%)-EtOH (40%)
0.1NHCl (80%)-EtOH (20%)
0.1NHCl (95%)-EtOH (5%)
% Dissolved
Time (min.)
0
3
6
9
12
15
18
21
24
0
15
30
45
60
75
90
105
120
135

Figure 32

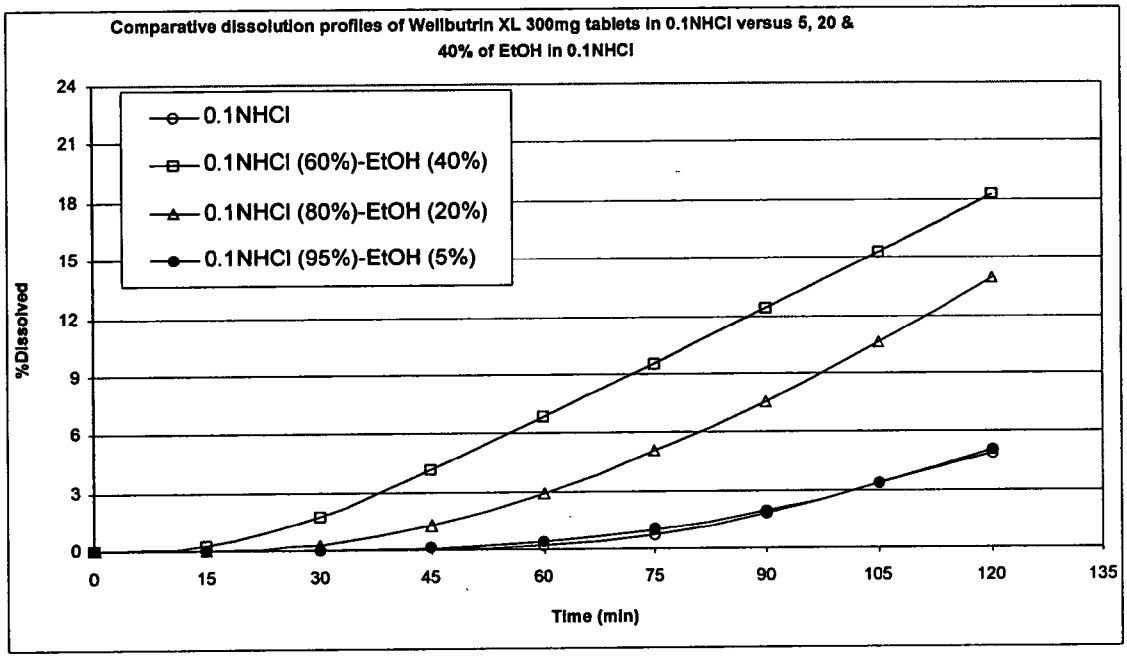

Comparative dissolution profiles of Wellbutrin XL 300mg tablets in 0.1NHCl versus 5, 20 & 40% of EtOH in 0.1NHCl
0.1NHCl
0.1NHCl (60%)-EtOH (40%)
0.1NHCl (80%)-EtOH (20%)
0.1NHCl (95%)-EtOH (5%)
%Dissolved
Time (min)
0
3
6
9
12
15
18
21
24
0
15
30
45
60
75
90
105
120
135

Figure 33

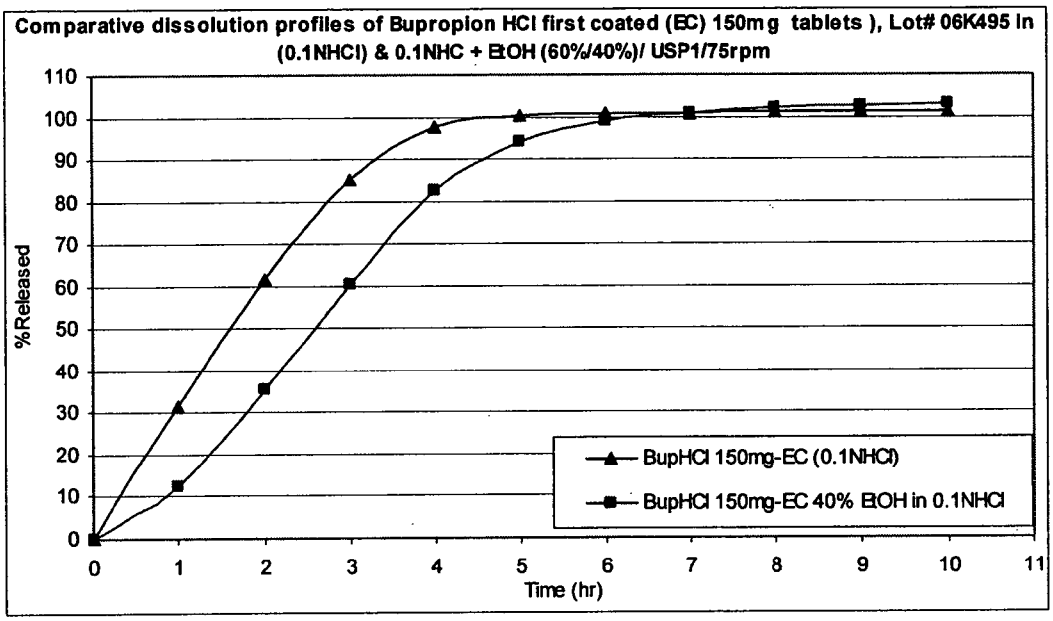

Comparative dissolution profiles of Bupropion HCl first coated (EC) 150mg tablets), Lot# 06K495 in (0.1NHCl) & 0.1NHC + EtOH (60%/40%)/ USP1/75rpm
%Released
Time (hr)
BupHCl 150mg-EC (0.1NHCl)
BupHCl 150mg-EC 40% EtOH in 0.1NHCl

Figure 34

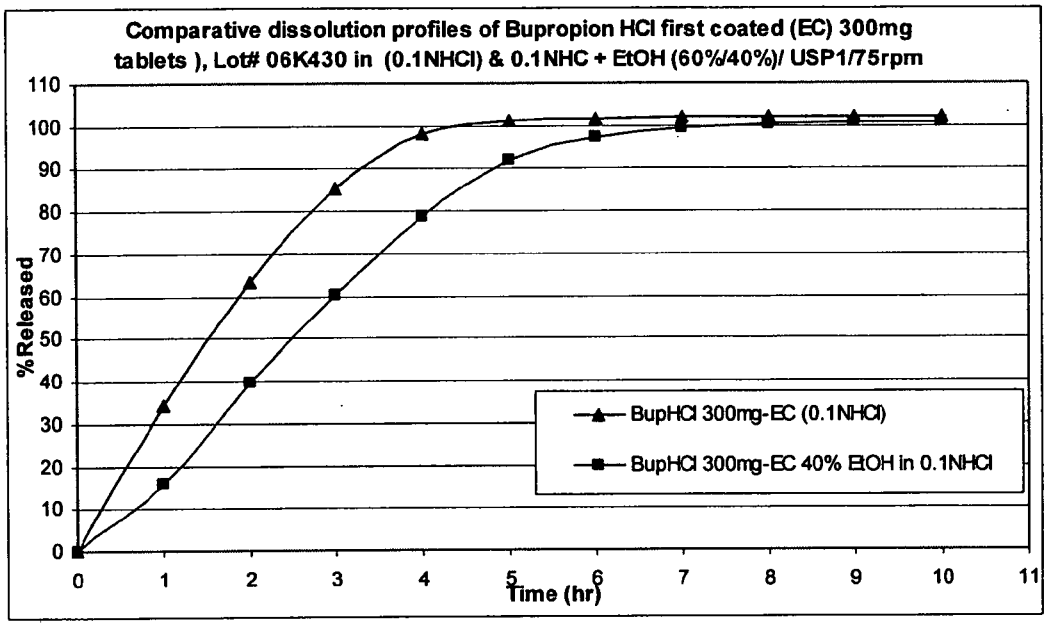
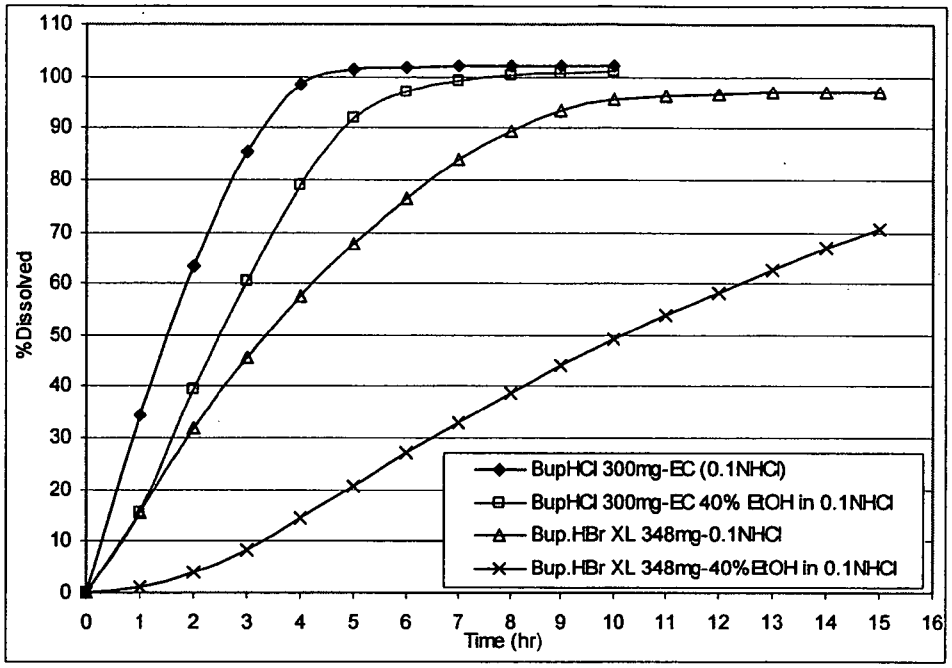

Comparative dissolution profiles of Bupropion HCl first coated (EC) 300mg tablets), Lot# 06K430 in (0.1NHCl) & 0.1NHC + EtOH (60%/40%)/ USP1/75rpm
% Released
Time (hr)
BupHCl 300mg-EC (0.1NHCl)
BupHCl 300mg-EC 40% EtOH in 0.1NHCl

Figure 35



Bup.HCl (EC & Final) 300mg tablets-vs BupHBr348mg-HCl-Ethanol

Figure 36

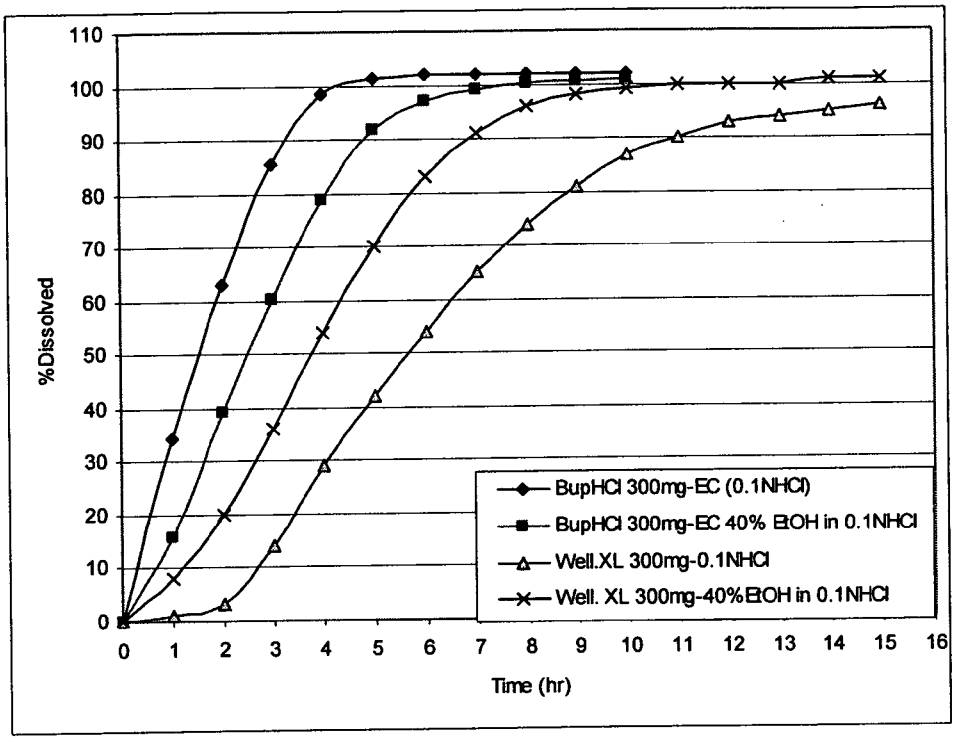

%Dissolved
Time (hr)
BupHCl 300mg-EC (0.1NHCl)
BupHCl 300mg-EC 40% EtOH in 0.1NHCl
Well.XL 300mg-0.1NHCl
Well. XL 300mg-40%EtOH in 0.1NHCl

Figure 37

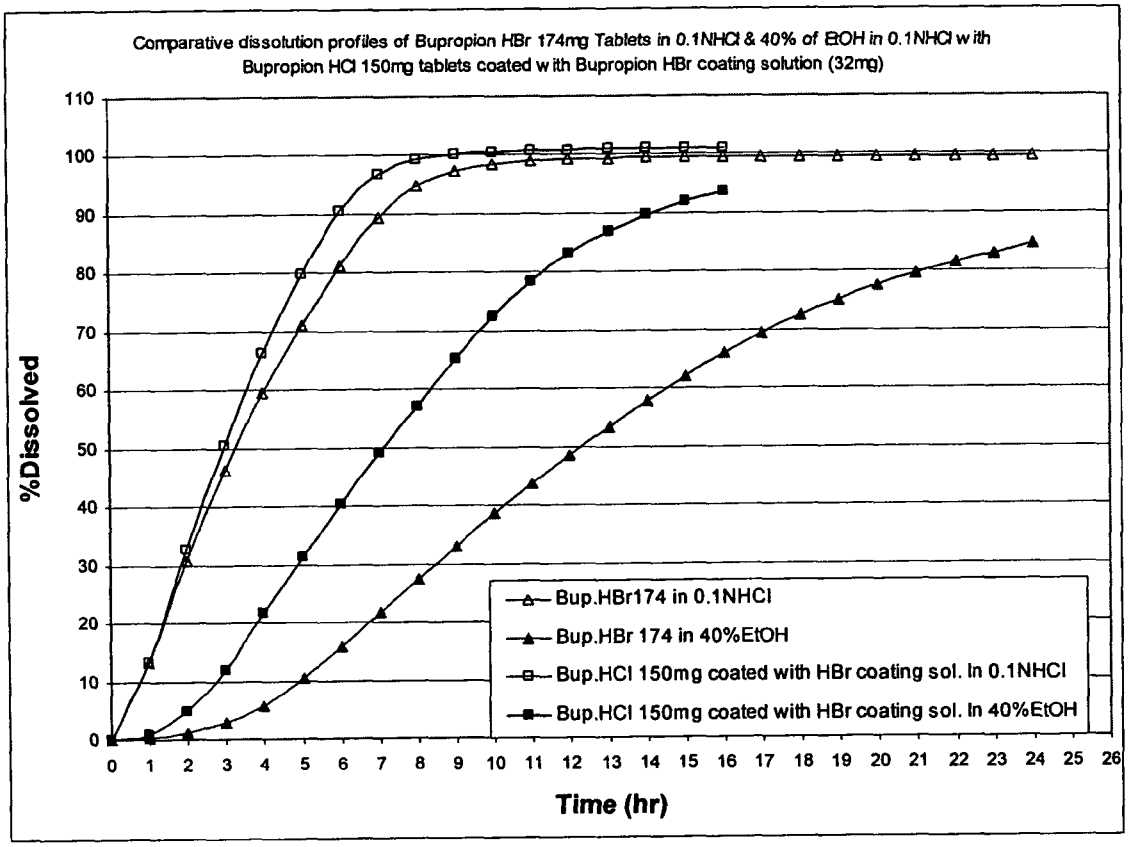

Comparative dissolution profiles of Bupropion HBr 174mg Tablets in 0.1NHCl & 40% of EtOH in 0.1NHCl with Bupropion HCl 150mg tablets coated with Bupropion HBr coating solution (32mg)
%Dissolved
Time (hr)
Bup.HBr174 in 0.1NHCl
Bup.HBr 174 in 40%EtOH
Bup.HCl 150mg coated with HBr coating sol. In 0.1NHCl
Bup.HCl 150mg coated with HBr coating sol. In 40%EtOH

Figure 38

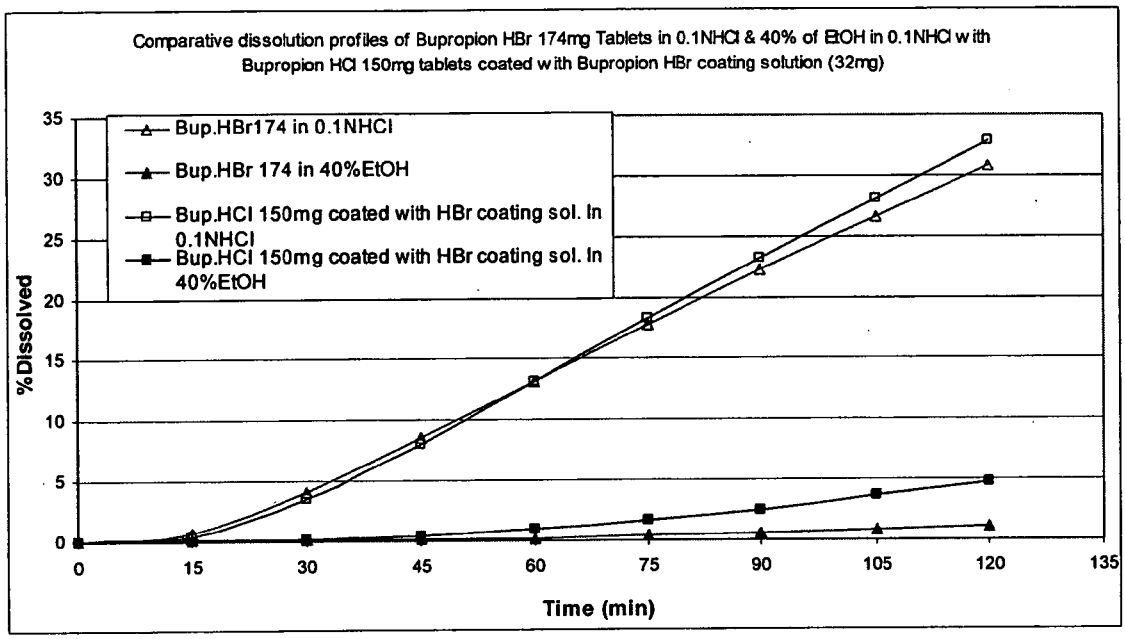

Comparative dissolution profiles of Bupropion HBr 174mg Tablets in 0.1NHCl & 40% of EtOH in 0.1NHCl with Bupropion HCl 150mg tablets coated with Bupropion HBr coating solution (32mg)
Bup.HBr174 in 0.1NHCl
Bup.HBr 174 in 40%EtOH
Bup.HCl 150mg coated with HBr coating sol. In 0.1NHCl
Bup.HCl 150mg coated with HBr coating sol. In 40%EtOH
%Dissolved
Time (min)
0
5
10
15
20
25
30
35
0
15
30
45
60
75
90
105
120
135

Figure 39

Sample ID	0.1NHCl	0.1NHCl+0.1%SLS	0.1NHCl+0.1%Cetr.	40%EtOH in0.1NHCl	95% EtOH	Water
Bupropion.HCl	235	237	233	340	80	270
Bupropion.HBr	123	131	110	355	92	143

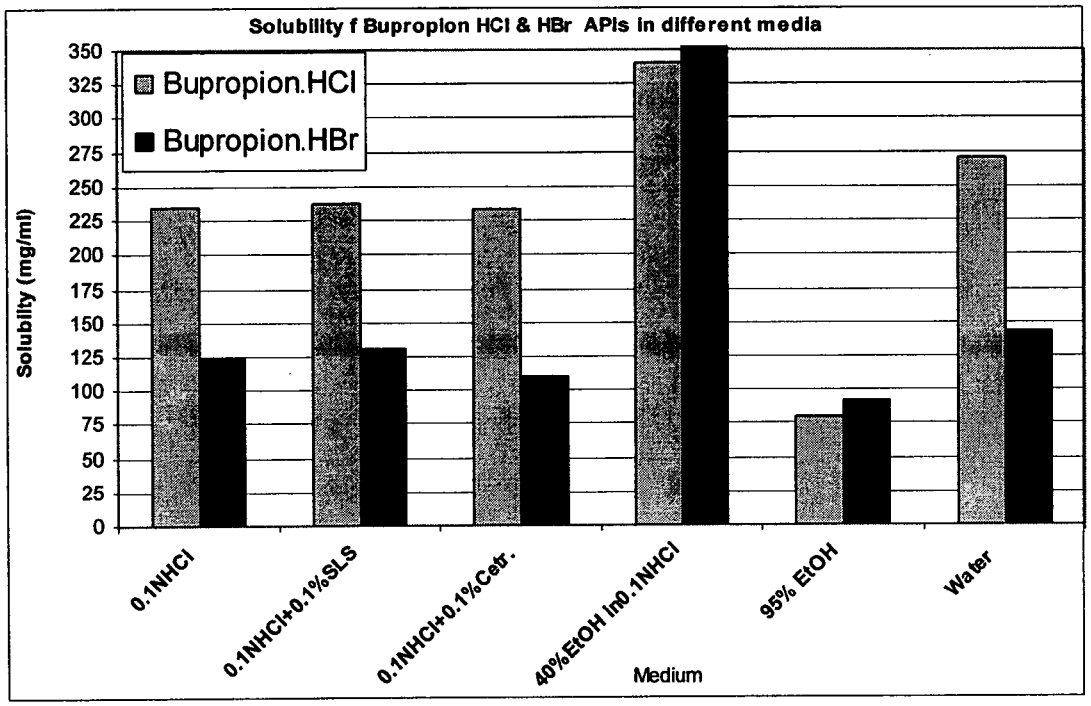


Figure 40

Sample ID	0.1NHCl	10%EtOH in0.1NHCl	40%EtOH in0.1NHCl	70%EtOH in0.1NHCl	90%EtOH in0.1NHCl	95%EtOH in water	100% Pure EtOH
Bupropion.HCl	235	292	340	363	245	80	100
Bupropion.HBr	123	188	355	433	303	92	98

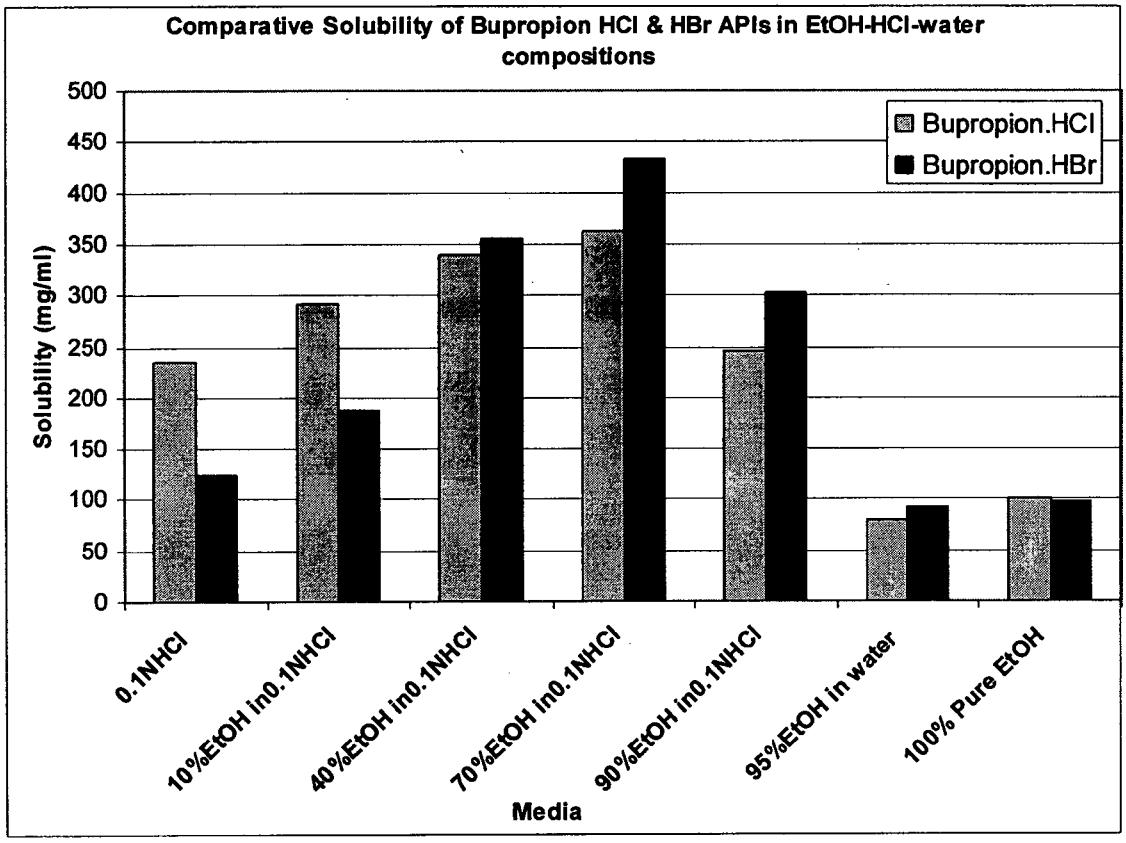


Figure 41

Name	0.1NHCl	10%EtOH in0.1NHCl	40%EtOH in0.1NHCl	70%EtOH in0.1NHCl	90%EtOH in0.1NHCl	95%EtOH in water	100% Pure EtOH
Bupropion.HCl	235	292	340	363	245	80	100
Bupropion.HBr	123	188	355	433	303	92	98

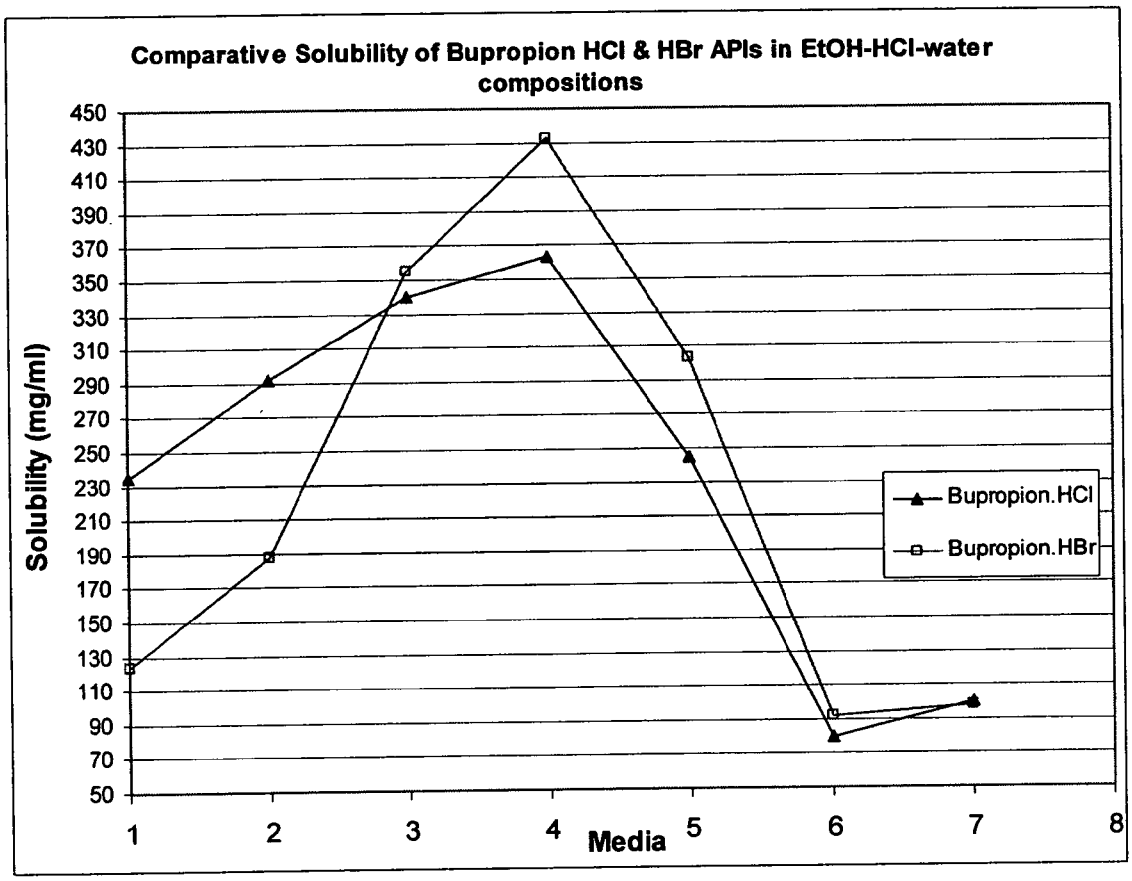


Figure 42

Bupropion HBr 174mg Tablets **USP1/75rpm/900ml/ 252nm-1 mm cell**

Bupropion HBr 174mg Tablets, Lot# 07B077P **0.1NHCl**

	%Dissolved										
Time (min)	T1	T2	T3	T4	T5	T6	Min	Max	Avg.	SD	%RSD
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.6	0.6	0.6	0.9	0.6	0.8	0.6	0.9	0.7	0.2	22.2
30	3.7	3.9	3.9	4.7	3.7	4.7	3.7	4.7	4.1	0.5	11.5
45	8.1	8.2	8.2	9.4	8.1	9.3	8.1	9.4	8.6	0.6	7.3
60	12.5	12.8	12.7	14.3	12.5	14.3	12.5	14.3	13.2	0.9	6.5
75	17.1	17.3	17.1	19.0	16.9	19.2	16.9	19.2	17.8	1.0	5.8
90	21.5	21.7	21.5	23.6	21.2	23.9	21.2	23.9	22.2	1.2	5.4
105	25.8	26.1	25.6	28.0	25.4	28.3	25.4	28.3	26.5	1.3	4.8
120	30.0	30.3	29.8	32.3	29.5	32.7	29.5	32.7	30.8	1.4	4.4

Figure 43

Bupropion HBr 174mg Tablets, Lot# 07B077P

5%EtOH in 0.1NHCl

	%Dissolved										
Time (min)	T1	T2	T3	T4	T5	T6	Min	Max	Avg.	SD	%RSD
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.6	0.7	0.5	0.4	0.6	0.7	0.4	0.7	0.6	0.1	17.4
30	3.7	4.2	3.4	3.2	4.1	4.2	3.2	4.2	3.8	0.4	11.3
45	8.2	9.1	7.8	7.5	8.9	9.1	7.5	9.1	8.4	0.7	8.3
60	13.1	13.9	12.6	12.1	13.8	14.0	12.1	14.0	13.2	0.8	6.1
75	17.9	18.8	17.1	16.4	18.8	18.7	16.4	18.8	18.0	1.0	5.6
90	22.5	23.4	21.8	20.9	23.5	23.6	20.9	23.6	22.6	1.1	4.7
105	27.1	28.0	26.4	25.2	28.1	28.1	25.2	28.1	27.1	1.2	4.4
120	31.6	32.5	30.6	29.4	32.6	32.5	29.4	32.6	31.5	1.3	4.1

Figure 44

Bupropion HBr 174mg Tablets, Lot# 07B077P

20%EtOH in 0.1NHCl

	%Dissolved										
Time (min)	T1	T2	T3	T4	T5	T6	Min	Max	Avg.	SD	%RSD
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.4	0.3	0.3	0.4	0.3	0.2	0.2	0.4	0.3	0.1	16.4
30	2.8	2.7	2.4	2.4	2.7	2.2	2.2	2.8	2.5	0.2	8.7
45	6.6	6.2	5.6	5.8	6.3	5.4	5.4	6.6	6.0	0.4	7.3
60	10.8	10.3	9.5	9.7	10.6	9.2	9.2	10.8	10.0	0.7	6.6
75	15.4	14.9	13.7	14.0	15.2	13.5	13.5	15.4	14.4	0.8	5.6
90	20.1	19.5	18.0	18.4	19.9	17.8	17.8	20.1	18.9	1.0	5.4
105	24.8	24.0	22.3	22.8	24.4	22.2	22.2	24.8	23.4	1.1	4.8
120	29.3	28.3	26.5	27.1	28.9	26.5	26.5	29.3	27.8	1.2	4.5

Figure 45

Bupropion HBr 174mg Tablets, Lot# 07B077P

40%EtOH in 0.1NHCl

	%Dissolved										
Time (min)	T1	T2	T3	T4	T5	T6	Min	Max	Avg.	SD	%RSD
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.1	0.2	0.0	0.1	0.1	0.1	0.0	0.2	0.1	0.0	54.4
30	0.1	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.1	0.0	49.5
45	0.2	0.1	0.1	0.2	0.2	0.1	0.1	0.2	0.2	0.0	19.7
60	0.3	0.2	0.2	0.3	0.3	0.2	0.2	0.3	0.2	0.1	22.0
75	0.5	0.4	0.4	0.4	0.5	0.3	0.3	0.5	0.4	0.1	14.8
90	0.7	0.5	0.6	0.6	0.6	0.5	0.5	0.7	0.6	0.1	15.2
105	1.0	0.7	0.9	0.9	1.0	0.7	0.7	1.0	0.8	0.1	15.1
120	1.4	0.9	1.2	1.2	1.3	0.9	0.9	1.4	1.1	0.2	16.5

Figure 46

Time (min)	0.1NHCl	EtOH (40%)-0.1NHCl (60%)	EtOH (20%)-0.1NHCl (80%)	EtOH (5%)-0.1NHCl (95%)
0.0	0.0	0.0	0.0	0.0
15.0	0.7	0.1	0.3	0.6
30.0	4.1	0.1	2.5	3.8
45.0	8.6	0.2	6.0	8.4
60	13.2	0.2	10.0	13.3
75	17.8	0.4	14.4	18.0
90	22.2	0.6	18.9	22.6
105	26.5	0.8	23.4	27.2
120	30.8	1.1	27.8	31.5

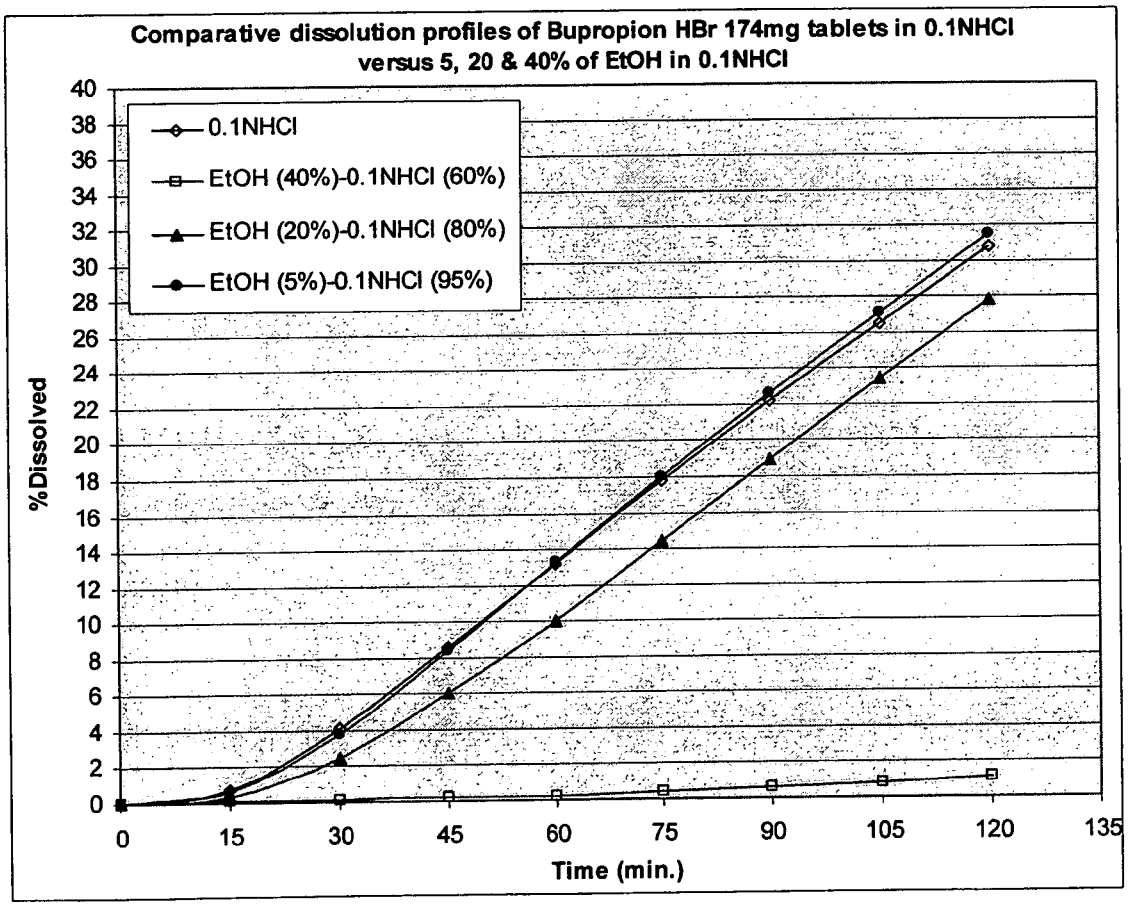


Figure 47

Time (hr)	0.1NHCl	40%EtOH
0	0.0	0.0
1	13.2	0.3
2	30.8	1.2
3	46.2	2.7
4	59.5	5.6
5	71.0	10.4
6	81.3	15.8
7	89.5	21.6
8	94.7	27.4
9	97.4	33.1
10	98.5	38.5
11	99.0	43.7
12	99.3	48.6
13	99.3	53.3
14	99.4	57.9
15	99.5	62.1
16	99.5	66.0
17	99.5	69.5
18	99.6	72.5
19	99.6	75.2
20	99.6	77.5
21	99.6	79.6
22	99.6	81.4
23	99.6	83.0
24	99.6	84.5

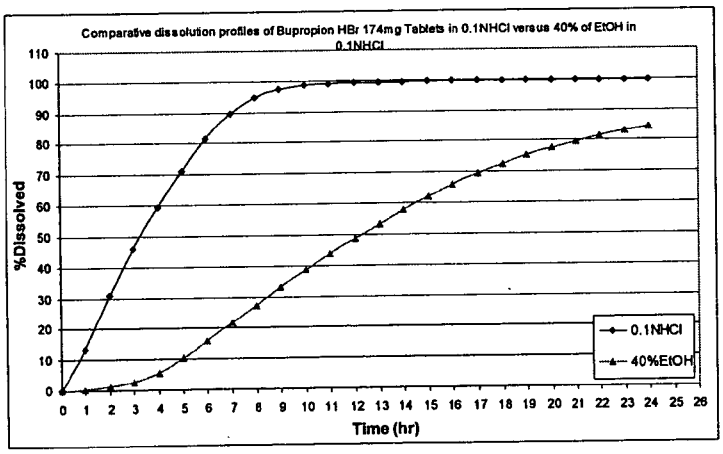


Figure 48

Bupropion HBr XL 522mg Tablets

Lot #06M378

0.1NHCl (100%)
USP1/75rpm/0.1NHCl-900ml/252nm-1mm cell

Time (min)	% Released											
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.8	1.6	1.9	2.2	1.8	1.1	1.8	1.7	1.9	1.7	1.7	1.9
30	5.2	5.8	6.5	7.2	6.4	5.5	6.5	6.3	6.5	6.4	6.3	6.8
45	10.1	10.6	11.4	12.7	11.2	10.5	11.3	11.5	11.4	11.3	11.1	12.1
60	14.8	15.3	16.0	17.7	15.7	15.3	16.2	16.1	15.5	16.1	15.7	17.2
75	19.1	19.7	20.4	22.4	19.8	19.7	20.7	20.6	19.6	20.3	19.9	21.7
90	23.0	23.6	24.3	26.5	23.6	23.7	24.7	24.6	23.4	24.3	23.7	25.9
105	26.8	27.3	28.0	30.4	27.1	27.4	28.4	28.4	26.8	28.1	27.3	29.8
120	30.3	30.7	31.3	34.0	30.7	30.9	31.9	32.0	30.3	31.6	30.7	33.5

% Released				%RSD
Min	Max	Avg.	SD	
0.0	0.0	0.0	0.0	0.0
0.8	2.2	1.7	0.4	22.5
5.2	7.2	6.3	0.5	8.4
10.1	12.7	11.3	0.7	6.2
14.8	17.7	16.0	0.8	5.1
19.1	22.4	20.3	0.9	4.6
23.0	26.5	24.3	1.0	4.3
26.8	30.4	28.0	1.2	4.1
30.3	34.0	31.5	1.2	3.8

Figure 49

Bupropion HBr XL 522mg Tablets

Lot #06M378

EtOH (40%) and 0.1NHCl (60%)
USP1/75rpm/0.1NHCl-900ml/252nm-1mm cell

Time (min)	% Released											
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.3	0.4	0.2	0.2	0.2	0.4	0.2	0.2	0.2	0.2	0.2	0.2
30	2.2	2.0	1.9	2.0	1.1	2.6	1.4	1.3	1.5	2.3	1.7	1.9
45	5.7	5.2	4.9	4.8	2.5	5.9	4.4	2.8	3.8	5.9	4.4	3.7
60	9.5	9.3	8.1	8.1	4.2	9.6	8.5	6.0	6.7	10.1	8.6	6.0
75	13.1	13.3	11.4	11.8	6.0	12.2	12.4	9.9	10.4	13.5	12.0	8.4
90	16.6	16.7	14.6	15.0	8.1	14.8	15.9	12.9	13.6	15.8	15.4	11.1
105	19.9	19.1	17.5	18.7	10.3	17.5	19.4	16.0	16.7	18.4	18.5	13.9
120	23.0	21.7	20.3	21.8	12.6	20.3	22.6	18.9	19.6	21.2	21.6	16.6

% Released				
Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
0.2	0.4	0.2	0.1	29.7
1.1	2.6	1.8	0.4	23.5
2.5	5.9	4.5	1.1	25.2
4.2	10.1	7.9	1.8	22.8
6.0	13.5	11.2	2.2	19.7
8.1	16.7	14.2	2.5	17.7
10.3	19.9	17.2	2.7	16.0
12.6	23.0	20.0	2.9	14.6

Figure 50

Bupropion HBr XL 522mg Tablets

Lot #06M378

EtOH (20%) and 0.1NHCl (80%)
USP1/75rpm/0.1NHCl-900ml/252nm-1mm cell

Time (min)	% Released											
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	1.0	0.9	1.0	1.3	0.7	1.1	0.8	1.2	0.9	0.7	1.0	0.8
30	3.8	3.7	4.0	4.4	3.0	4.1	3.4	4.3	3.4	3.2	3.8	3.3
45	7.1	7.1	7.7	7.9	5.7	7.6	6.6	7.7	6.7	6.1	7.0	6.6
60	10.8	10.8	11.6	11.8	8.8	11.4	10.3	11.5	10.3	9.4	10.5	10.1
75	14.5	14.5	15.5	15.7	11.7	15.2	13.8	15.3	14.0	12.7	14.1	13.8
90	18.2	18.2	19.5	19.5	14.8	19.0	17.5	18.9	17.7	16.2	17.8	17.6
105	21.8	21.9	23.3	23.2	17.8	22.6	21.0	22.3	21.5	19.4	21.3	21.2
120	25.2	25.3	26.9	26.8	20.8	26.2	24.5	25.7	25.1	22.7	24.8	24.8

% Released				%RSD
Min	Max	Avg.	SD	
0.0	0.0	0.0	0.0	0.0
0.7	1.3	0.9	0.2	19.1
3.0	4.4	3.7	0.4	11.6
5.7	7.9	7.0	0.7	9.6
8.8	11.8	10.6	0.9	8.7
11.7	15.7	14.2	1.2	8.2
14.8	19.5	17.9	1.4	7.6
17.8	23.3	21.4	1.5	7.2
20.8	26.9	24.9	1.7	6.9

Figure 51

Bupropion HBr XL 522mg Tablets

Lot #06M378

EtOH (5%) and 0.1NHCl (95%)
USP1/75rpm/0.1NHCl-900ml/252nm-1mm cell

Time (min)	% Released											
	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	1.8	1.2	1.5	1.4	1.6	1.2	1.5	1.7	1.7	1.9	1.6	1.6
30	6.0	5.0	5.8	5.2	5.6	4.7	5.6	5.9	6.0	6.4	6.0	5.9
45	10.7	9.3	10.6	9.6	10.4	9.0	10.2	10.7	10.9	11.4	11.0	10.6
60	15.2	13.7	15.2	13.8	15.2	13.4	14.7	15.2	15.5	16.1	15.8	15.3
75	19.4	18.1	19.6	17.9	19.5	17.6	18.9	19.4	19.7	20.7	20.1	19.8
90	23.4	22.1	23.6	21.6	23.6	21.5	22.8	23.3	23.6	24.7	24.3	23.9
105	27.2	25.8	27.4	25.0	27.4	25.2	26.5	26.9	27.3	28.6	28.0	27.8
120	30.7	29.4	30.9	28.3	31.0	28.7	29.9	30.2	30.8	32.1	31.6	31.3

% Released				%RSD
Min	Max	Avg.	SD	
0.0	0.0	0.0	0.0	0.0
1.2	1.9	1.6	0.2	13.7
4.7	6.4	5.7	0.5	8.4
9.0	11.4	10.4	0.7	6.9
13.4	16.1	14.9	0.9	5.7
17.6	20.7	19.2	0.9	4.9
21.5	24.7	23.2	1.0	4.4
25.0	28.6	26.9	1.1	4.1
28.3	32.1	30.4	1.2	3.8

Figure 52

Comparitive Dissolution Profiles of Bupropion HBr XL 522 mg tablets

Lot #06M378

USP1/75rpm/252nm – 1mm cell

Time (min)	Average % Released			
	0.1NHCl	EtOH (40%)-0.1NHCl (60%)	EtOH (20%)-0.1NHCl (80%)	EtOH (5%)-0.1NHCl (95%)
0.0	0.0	0.0	0.0	0.0
15.0	1.7	0.2	0.9	1.6
30.0	6.3	1.8	3.7	5.7
45.0	11.3	4.5	7.0	10.4
60	16.0	7.9	10.6	14.9
75	20.3	11.2	14.2	19.2
90	24.3	14.2	17.9	23.2
105	28.0	17.2	21.4	26.9
120	31.5	20.0	24.9	30.4

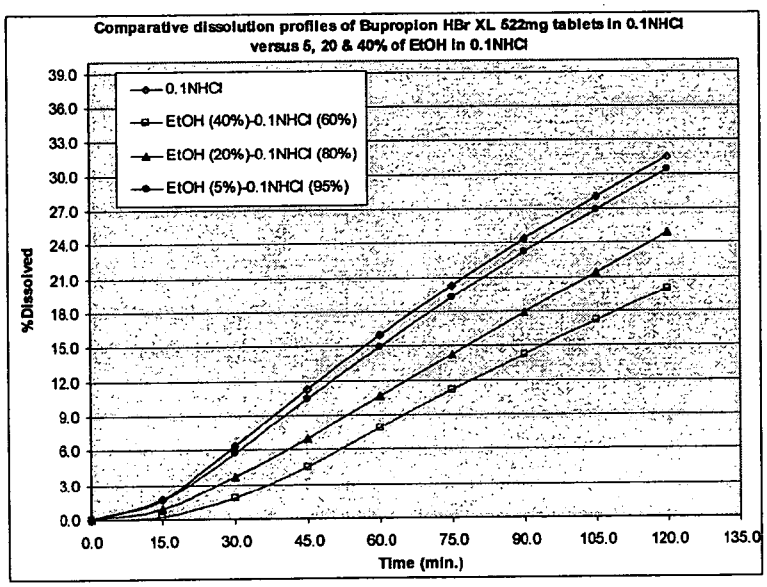


Figure 53(a)

Bupropion HBr XL 174mg Tablets, Lot# 06C611 **0.1NHCl**

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.6	1.0	1.0	0.8	0.9	0.8	0.9	1.1	0.7	0.8	0.9	0.8
30	3.9	4.9	5.2	4.4	4.6	4.4	4.9	5.5	4.4	4.6	5.0	5.0
45	8.7	10.0	10.3	9.3	9.6	9.2	9.9	10.7	9.3	9.2	10.2	10.3
60	13.6	15.4	15.8	14.6	14.7	14.4	15.0	16.2	14.4	14.1	15.3	15.6
75	18.7	20.5	21.0	19.5	20.0	19.5	19.9	21.4	19.4	19.0	20.4	21.0
90	23.6	25.4	26.0	24.3	24.9	24.5	24.8	26.6	24.5	23.7	25.5	26.1
105	28.3	30.3	30.7	29.1	29.7	29.2	29.4	31.3	29.2	28.2	30.3	30.8
120	32.8	34.9	35.4	33.5	34.4	33.8	33.9	36.0	33.7	32.5	34.8	35.4

Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
0.6	1.1	0.8	0.1	17.8
3.9	5.5	4.7	0.4	9.0
8.7	10.7	9.7	0.6	6.2
13.6	16.2	14.9	0.7	5.0
18.7	21.4	20.0	0.9	4.2
23.6	26.6	25.0	0.9	3.8
28.2	31.3	29.7	1.0	3.4
32.5	36.0	34.3	1.1	3.1

Bupropion HBr XL 174mg Tablets, Lot# 06C611 **0.1NHCl (60%)-EtOH (40%)**

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.1	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
30	0.1	0.1	0.1	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0
45	0.2	0.3	0.2	0.1	0.2	0.2	0.1	0.2	0.2	0.1	0.1	0.2
60	0.3	0.5	0.3	0.3	0.4	0.3	0.3	0.4	0.3	0.3	0.4	0.3
75	0.5	0.8	0.5	0.5	0.6	0.6	0.4	0.6	0.5	0.4	0.6	0.6
90	0.9	1.1	0.8	0.8	0.9	0.9	0.7	1.0	0.8	0.7	0.9	0.9
105	1.2	1.5	1.2	1.1	1.3	1.2	1.0	1.3	1.2	1.0	1.2	1.3
120	1.5	1.9	1.5	1.5	1.7	1.8	1.5	1.8	1.6	1.4	1.6	1.7

Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
0.0	0.2	0.0	0.0	146.2
0.0	0.1	0.0	0.0	105.0
0.1	0.3	0.2	0.1	35.7
0.3	0.5	0.3	0.1	14.8
0.4	0.8	0.5	0.1	17.5
0.7	1.1	0.9	0.1	13.9
1.0	1.5	1.2	0.1	11.2
1.4	1.9	1.6	0.2	10.1

Figure 53(b)

Bupropion HBr 174mg Tablets, Lot# 06C611 **0.1NHCl (80%)-EtOH (20%)**

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.3	0.4	0.5	0.3	0.3	0.6	0.4	0.5	0.5	0.4	0.4	0.5
30	2.6	2.8	3.2	2.7	2.6	3.4	2.7	3.2	3.0	2.7	2.8	3.4
45	6.2	6.4	7.1	6.4	6.1	7.4	6.6	7.1	6.7	6.3	6.7	7.6
60	10.4	10.6	11.7	10.6	10.1	12.0	11.0	11.7	11.1	10.4	11.1	12.2
75	15.1	15.2	16.7	15.3	14.8	17.1	15.7	16.5	15.4	14.9	15.7	17.3
90	19.5	19.8	21.6	20.0	19.2	22.0	20.5	21.5	20.0	19.4	20.5	22.3
105	24.2	24.5	26.4	24.8	23.7	26.9	25.2	26.3	24.5	24.0	25.1	27.1
120	28.9	29.0	31.3	29.4	28.3	31.6	30.0	31.1	28.8	28.7	29.8	32.0

Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
0.3	0.6	0.4	0.1	20.1
2.6	3.4	2.9	0.3	10.9
6.1	7.6	6.7	0.5	7.4
10.1	12.2	11.1	0.7	6.4
14.8	17.3	15.8	0.9	5.5
19.2	22.3	20.5	1.1	5.1
23.7	27.1	25.2	1.2	4.6
28.3	32.0	29.9	1.3	4.2

Bupropion HBr XL 174mg Tablets, Lot# 06C611 **0.1NHCl (95%)-EtOH (5%)**

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.8	0.6	0.5	0.7	0.5	0.5	0.6	0.5	0.4	0.7	0.7	0.7
30	5.1	4.0	3.9	4.6	4.2	3.8	4.4	4.3	3.6	4.8	4.7	4.3
45	10.5	9.0	8.7	9.6	9.2	8.4	9.6	9.2	8.4	10.1	9.8	9.5
60	15.9	14.1	13.9	14.6	14.3	13.3	14.8	14.4	13.2	15.2	15.3	14.7
75	21.2	19.1	19.0	19.4	19.5	18.3	19.9	19.5	18.2	20.5	20.6	19.8
90	26.2	24.2	23.8	24.2	24.6	23.1	24.9	24.5	22.9	25.7	25.9	24.9
105	31.2	28.7	28.8	28.9	29.6	27.9	30.0	29.5	27.7	30.4	30.8	29.8
120	35.8	33.6	33.3	33.2	34.1	32.3	34.6	34.1	32.2	35.1	35.5	34.4

Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
0.4	0.8	0.6	0.1	20.8
3.6	5.1	4.3	0.5	10.5
8.4	10.5	9.3	0.7	7.0
13.2	15.9	14.5	0.8	5.4
18.2	21.2	19.6	0.9	4.5
22.9	26.2	24.6	1.0	4.1
27.7	31.2	29.4	1.1	3.7
32.2	35.8	34.0	1.1	3.4

Time (min)	0.1NHCl	0.1NHCl (60%)-EtOH (40%)	0.1NHCl (80%)-EtOH (20%)	0.1NHCl (95%)-EtOH (5%)
0.0	0.0	0.0	0.0	0.0
15.0	0.8	0.0	0.4	0.6
30.0	4.7	0.0	2.9	4.3
45.0	9.7	0.2	6.7	9.3
60	14.9	0.3	11.1	14.5
75	20	0.5	15.8	19.6
90	25	0.9	20.5	24.6
105	29.7	1.2	25.2	29.4
120	34.3	1.6	29.9	34.0

Figure 53(c)

Bupropion HBr XL 348mg Tablets, Lot# 06C468 **0.1NHCl**

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	2.1	2.2	2.3	1.4	1.8	2.0	1.7	1.7	1.6	2.7	2.3	2.4
30	7.0	7.4	7.5	5.5	6.5	6.8	6.3	6.1	6.0	7.9	7.1	7.5
45	11.5	12.4	12.5	9.8	11.2	11.7	11.0	10.7	10.9	13.0	12.0	12.4
60	16.2	17.3	17.5	14.0	15.5	16.5	15.6	15.3	15.4	17.7	16.5	17.4
75	20.5	21.7	22.0	18.0	19.8	20.9	20.0	19.8	19.8	22.4	21.2	21.8
90	24.8	25.9	26.4	21.8	23.8	25.1	24.2	24.0	23.8	26.6	25.4	26.1
105	28.8	29.9	30.5	25.4	27.7	29.3	28.3	27.9	27.7	30.6	29.6	30.2
120	32.7	33.6	34.5	28.9	31.3	33.2	32.3	31.8	31.3	34.4	33.3	34.1

Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
1.4	2.7	2.0	0.4	18.9
5.5	7.9	6.8	0.7	10.4
9.8	13.0	11.6	0.9	7.9
14.0	17.7	16.2	1.1	6.9
18.0	22.4	20.6	1.3	6.1
21.8	26.6	24.8	1.4	5.6
25.4	30.6	28.8	1.5	5.2
28.9	34.5	32.6	1.6	4.9

Bupropion HBr XL 348mg Tablets, Lot# 06C468 **0.1NHCl (60%)-EtOH (40%)**

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.0	0.1
30	0.2	0.3	0.1	0.2	0.2	0.2	0.3	0.2	0.3	0.3	0.2	0.3
45	0.3	0.5	0.2	0.3	0.3	0.3	0.5	0.4	0.5	1.6	0.3	0.5
60	0.5	0.9	0.5	0.6	0.5	0.6	0.7	0.6	0.8	3.6	0.5	0.7
75	0.8	1.3	0.8	0.9	0.9	0.9	1.2	1.0	1.2	5.5	0.9	1.2
90	1.1	1.7	1.1	1.3	1.2	1.2	1.6	1.4	1.7	7.4	1.3	1.6
105	1.5	2.3	1.5	1.7	1.6	1.6	2.1	1.8	2.2	9.5	1.6	2.2
120	2.0	3.1	2.0	2.3	2.1	2.0	2.7	2.3	2.9	11.6	2.1	2.8

Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
0.0	0.1	0.0	0.0	99.4
0.1	0.3	0.2	0.1	27.1
0.2	1.6	0.5	0.4	75.2
0.5	3.6	0.9	0.9	97.6
0.8	5.5	1.4	1.3	95.4
1.1	7.4	1.9	1.8	94.1
1.5	9.5	2.5	2.2	90.7
2.0	11.6	3.1	2.7	85.7

Figure 53(d)

Bupropion HBr XL 348mg Tablets, Lot# 06C468 **0.1NHCl (80%)-EtOH (20%)**

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	1.5	1.7	1.4	1.2	1.2	1.2	1.5	1.5	1.4	1.6	1.5	1.2
30	5.1	5.8	5.3	4.7	4.6	4.6	5.7	5.5	5.3	5.7	5.2	4.8
45	9.6	10.6	9.8	9.0	8.9	8.7	10.3	10.0	9.7	10.5	9.7	9.3
60	14.1	15.4	14.5	13.6	13.2	13.1	15.1	14.8	14.3	15.2	14.2	13.7
75	18.4	20.1	19.1	18.1	17.5	17.5	19.7	19.4	18.9	19.8	18.7	18.3
90	22.7	24.6	23.4	22.4	21.9	21.7	24.0	23.9	23.3	24.2	22.8	22.6
105	26.7	28.8	27.7	26.7	25.9	25.7	28.2	28.3	27.5	28.4	27.0	26.8
120	30.6	33.0	31.8	30.6	29.9	29.7	32.3	32.5	31.7	32.6	31.0	30.9

Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
1.2	1.7	1.4	0.2	12.9
4.6	5.8	5.2	0.4	8.3
8.7	10.6	9.7	0.6	6.4
13.1	15.4	14.3	0.8	5.3
17.5	20.1	18.8	0.9	4.6
21.7	24.6	23.1	0.9	4.0
25.7	28.8	27.3	1.0	3.6
29.7	33.0	31.4	1.1	3.5

Bupropion HBr XL 348mg Tablets, Lot# 06C468 **0.1NHCl (95%)-EtOH (5%)**

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15	1.8	2.2	2.2	2.2	1.9	1.9	1.6	1.8	2.0	2.3	1.5	2.2
30	6.4	7.5	7.2	7.2	6.6	6.7	6.0	6.6	6.9	7.4	5.6	7.0
45	11.5	12.8	12.2	12.3	11.6	11.6	10.9	11.4	11.9	12.4	10.2	12.0
60	16.2	18.0	17.0	17.0	16.6	16.4	15.6	16.3	16.7	17.4	14.7	16.9
75	20.7	22.7	21.5	21.5	21.2	20.9	20.0	20.9	21.4	21.9	19.0	21.5
90	24.8	27.1	25.8	25.8	25.5	25.2	24.2	25.2	25.7	26.1	23.1	25.8
105	29.0	31.4	30.0	29.9	29.8	29.3	28.4	29.3	29.9	30.2	27.2	29.9
120	32.9	35.6	33.9	33.7	33.8	33.2	32.2	33.2	33.9	34.1	31.1	33.8

Min	Max	Avg.	SD	%RSD
0.0	0.0	0.0	0.0	0.0
1.5	2.3	2.0	0.3	14.3
5.6	7.5	6.8	0.6	8.3
10.2	12.8	11.7	0.7	6.1
14.7	18.0	16.6	0.8	5.0
19.0	22.7	21.1	0.9	4.4
23.1	27.1	25.3	1.0	4.0
27.2	31.4	29.5	1.0	3.5
31.1	35.6	33.4	1.1	3.3

Time (min)	0.1NHCl	0.1NHCl (60%)-EtOH (40%)	0.1NHCl (80%)-EtOH (20%)	0.1NHCl (95%)-EtOH (5%)
0.0	0.0	0.0	0.0	0.0
15.0	2.0	0.0	1.4	2.0
30.0	6.8	0.2	5.2	6.8
45.0	11.6	0.5	9.7	11.7
60	16.2	0.9	14.3	16.6
75	20.6	1.4	18.8	21.1
90	24.8	1.9	23.1	25.3
105	28.8	2.5	27.3	29.5
120	32.6	3.1	31.4	33.4

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