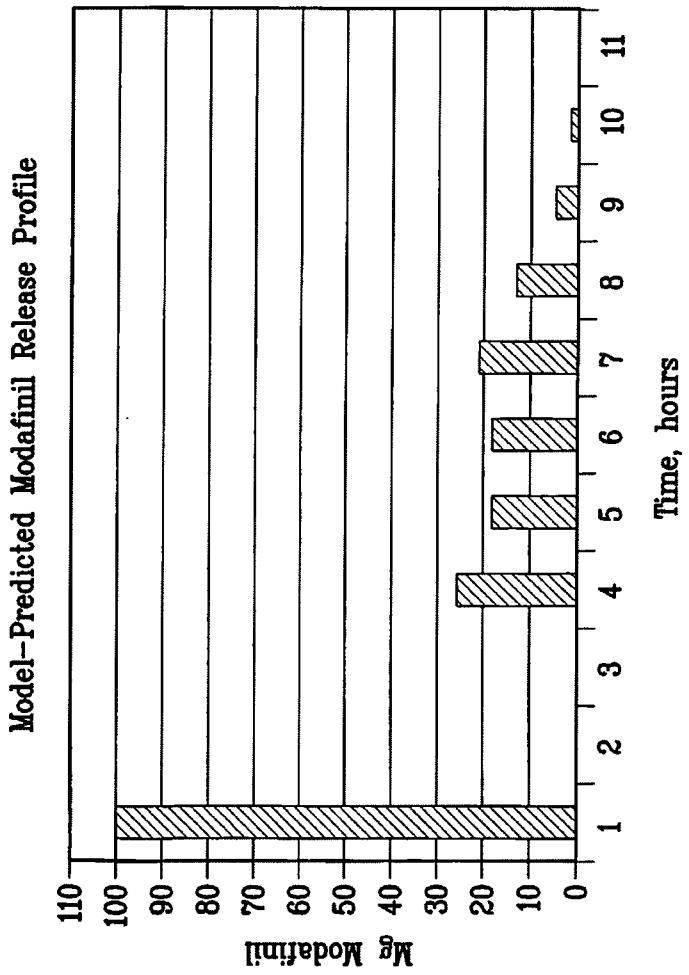

Model-Predicted Modafinil Release Profile
Mg Modafinil
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
6
7
8
9
10
11
Time, hours

FIG. 1

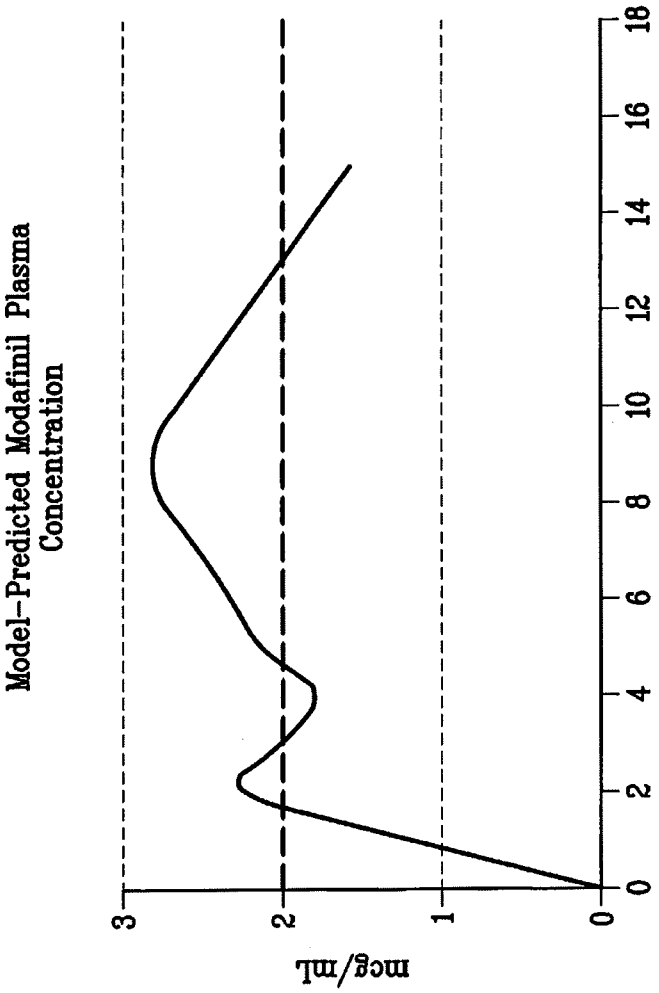

Model-Predicted Modafinil Plasma Concentration
mcg/mL
0
1
2
3
0
2
4
6
8
10
12
14
16
18
Time, hours

FIG. 2

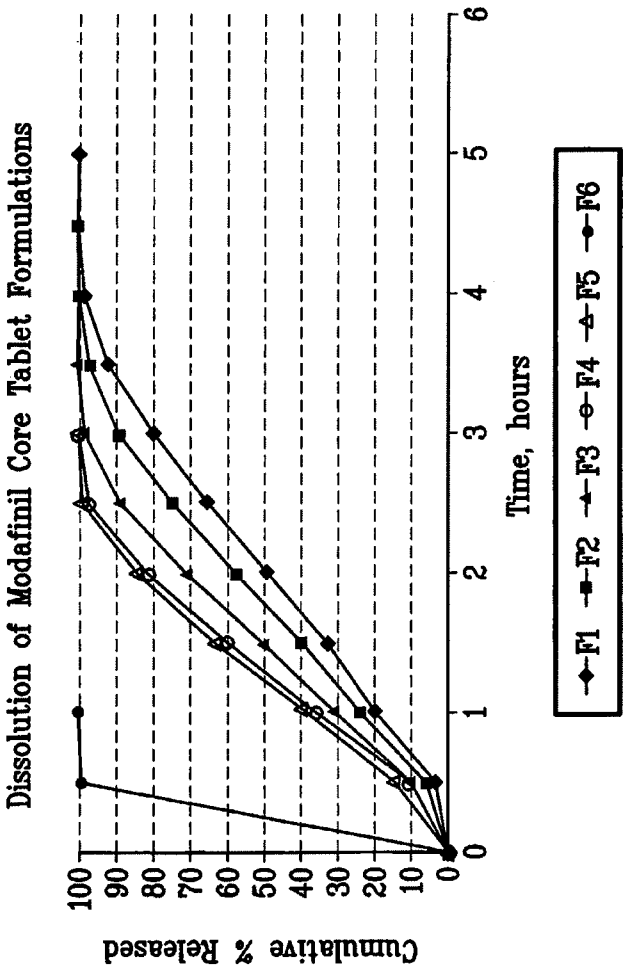

Dissolution of Modafinil Core Tablet Formulations
Cumulative % Released
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
Time, hours
F1
F2
F3
F4
F5
F6

FIG. 3

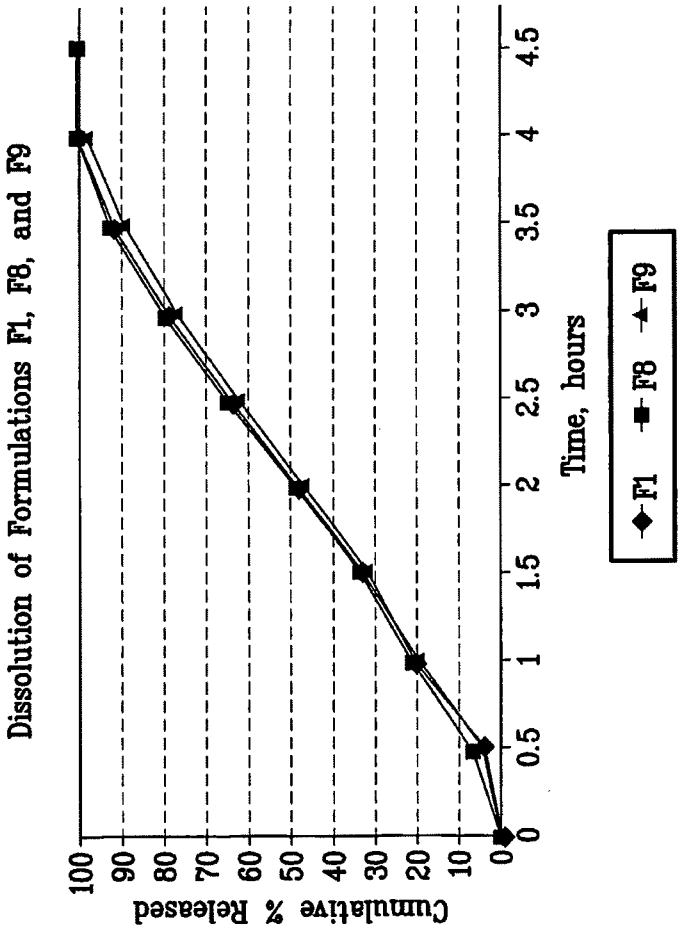

Dissolution of Formulations F1, F8, and F9
Cumulative % Released
100
90
80
70
60
50
40
30
20
10
0
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
Time, hours
F1
F8
F9

FIG. 4

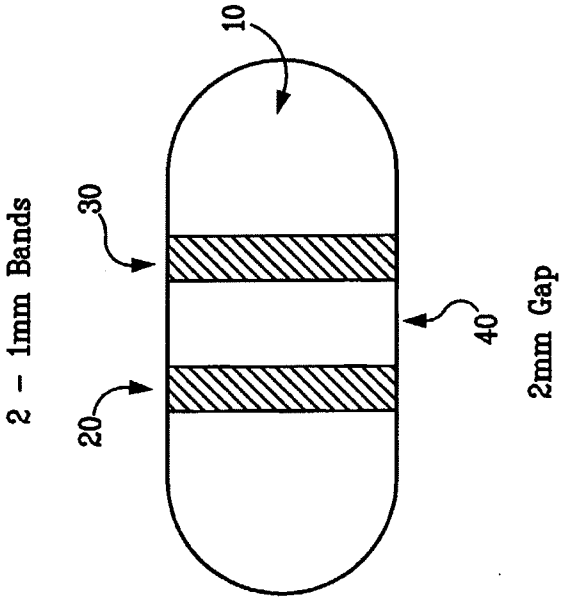


FIG. 5

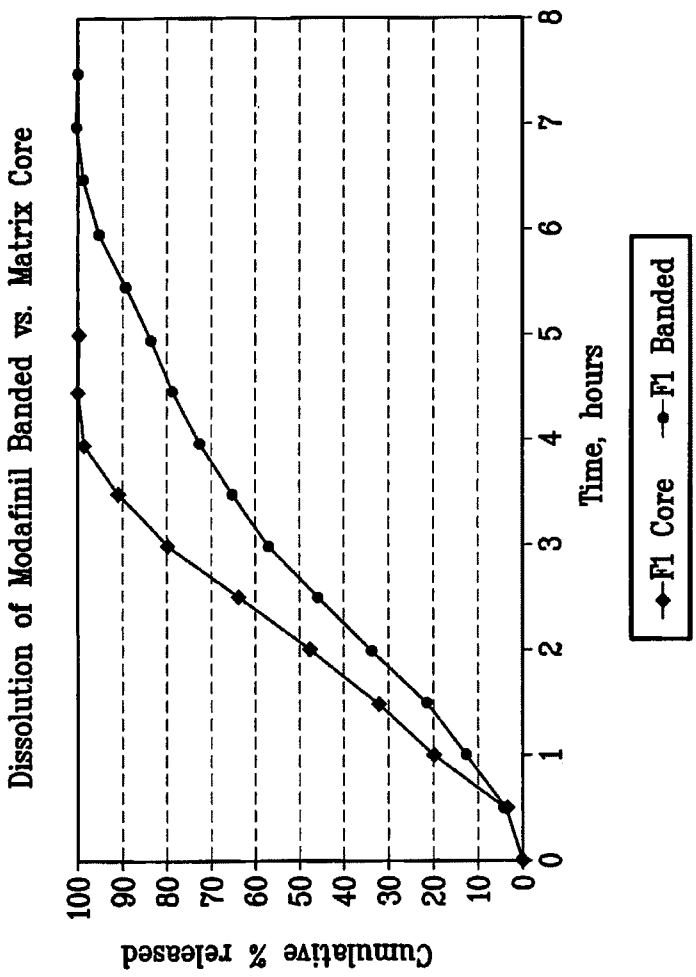

Dissolution of Modafinil Banded vs. Matrix Core
Cumulative % released
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
Time, hours
F1 Core
F1 Banded

FIG. 6

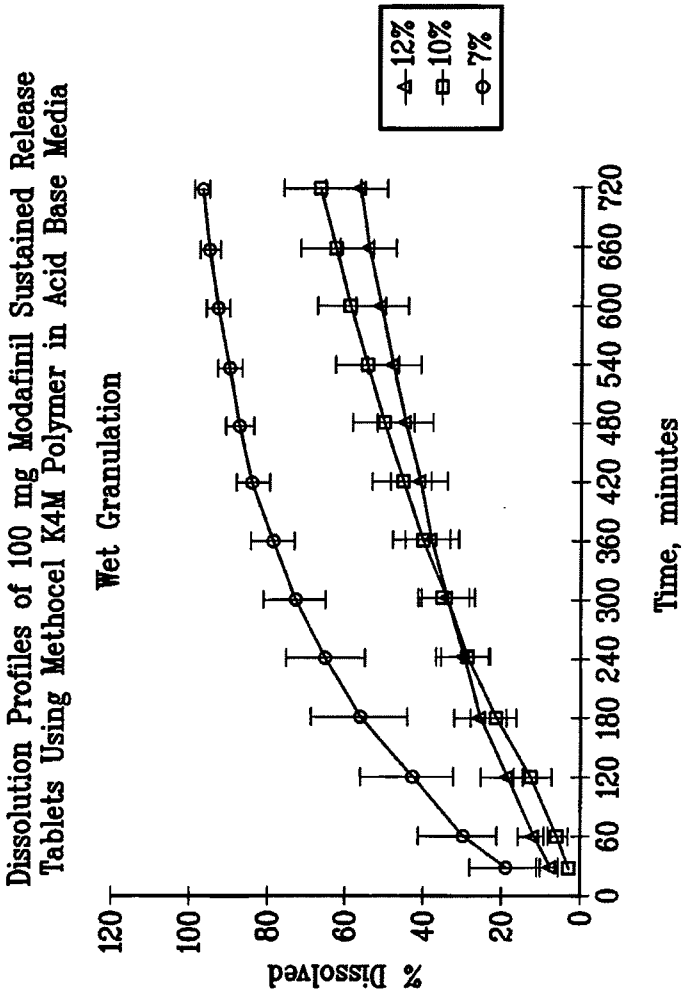

Dissolution Profiles of 100 mg Modafinil Sustained Release Tablets Using Methocel K4M Polymer in Acid Base Media
Wet Granulation
% Dissolved
Time, minutes
12%
10%
7%
0
20
40
60
80
100
120
0
60
120
180
240
300
360
420
480
540
600
660
720

FIG. 7

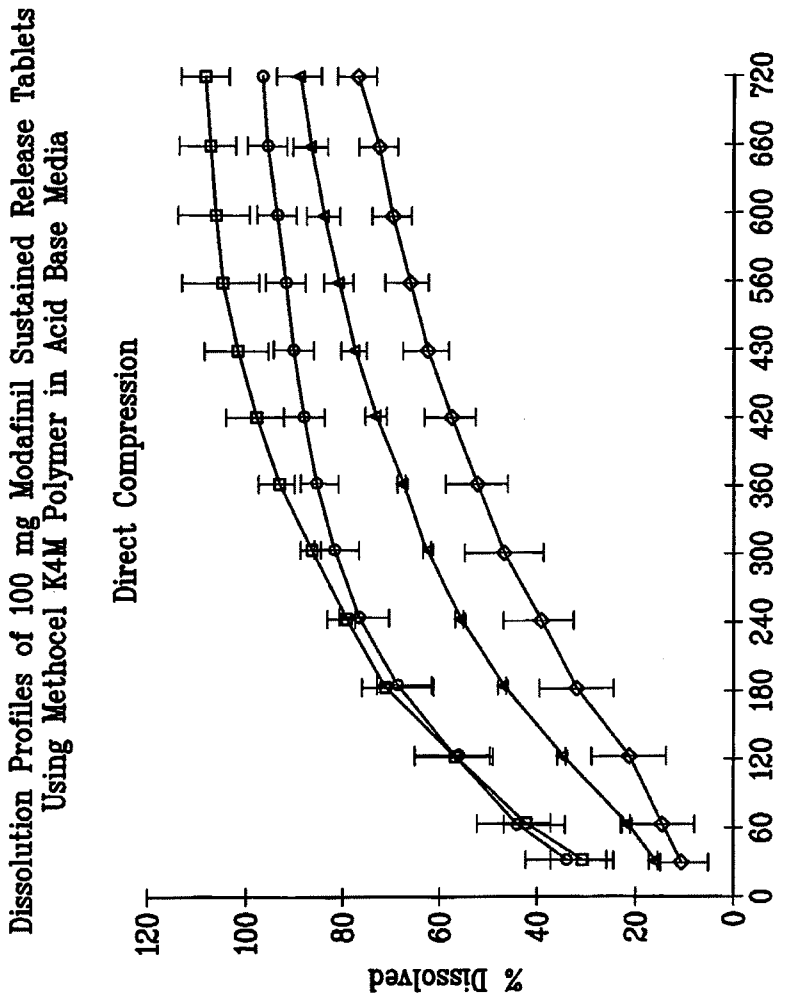

Dissolution Profiles of 100 mg Modafinil Sustained Release Tablets
Using Methocel K4M Polymer in Acid Base Media
Direct Compression
% Dissolved
Time, minutes
0
20
40
60
80
100
120
0
60
120
180
240
300
360
420
430
560
600
660
720

FIG. 8

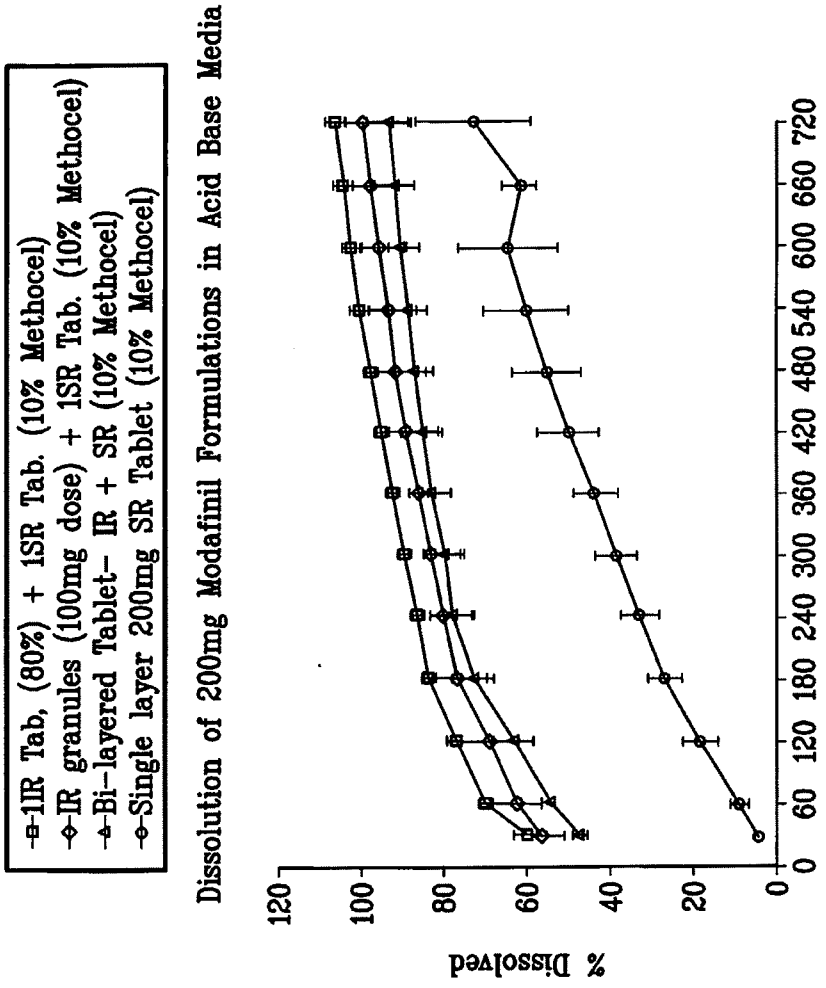

-■-1IR Tab, (80%) + 1SR Tab. (10% Methocel)
-◇-IR granules (100mg dose) + 1SR Tab. (10% Methocel)
-▲-Bi-layered Tablet- IR + SR (10% Methocel)
-○-Single layer 200mg SR Tablet (10% Methocel)
Dissolution of 200mg Modafinil Formulations in Acid Base Media
% Dissolved
120
100
80
60
40
20
0
0 60 120 180 240 300 360 420 480 540 600 660 720
Time, minutes

FIG. 9