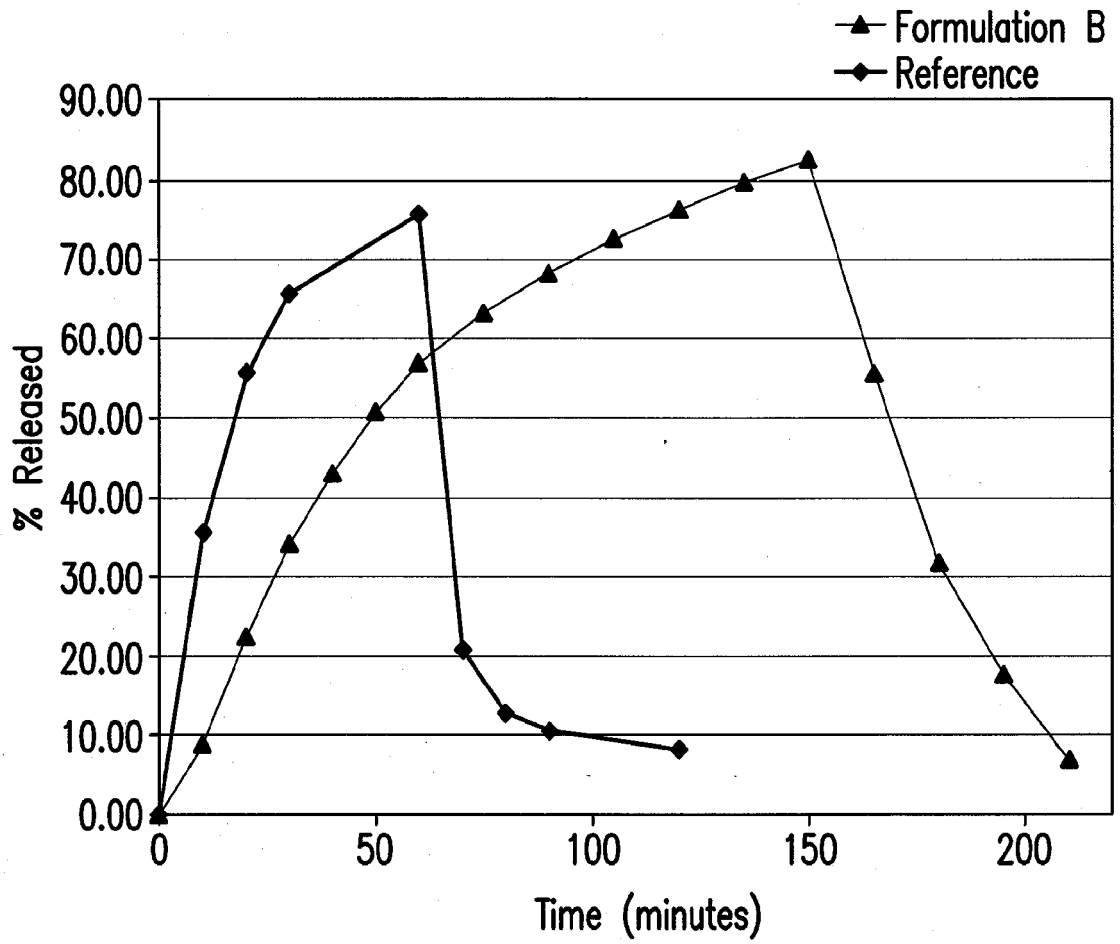

Formulation B
Reference
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
% Released
0
50
100
150
200
Time (minutes)

FIG.1

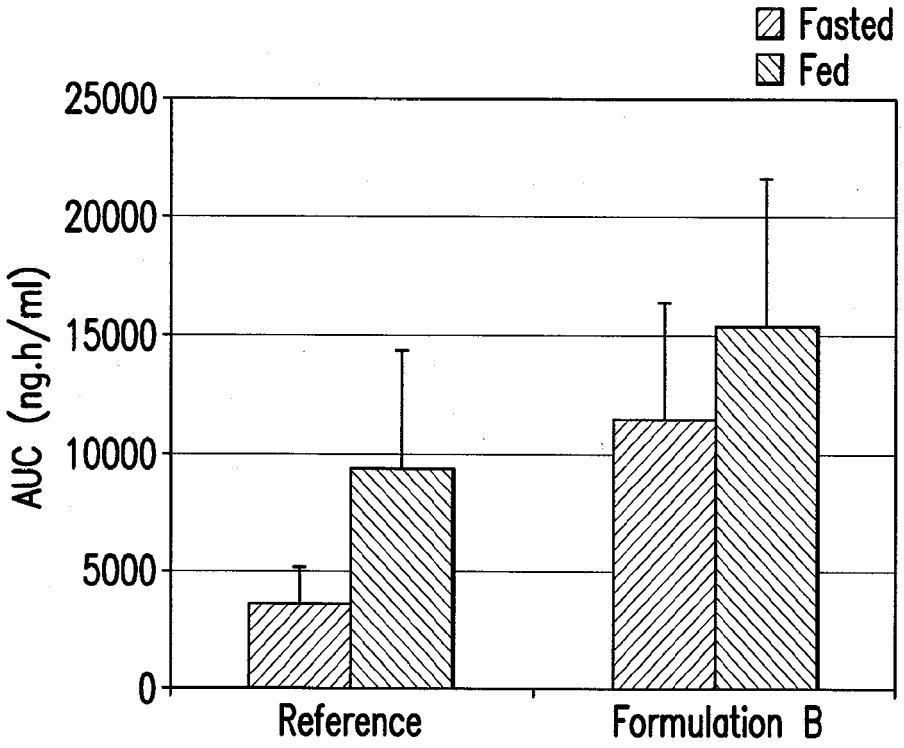

Fasted
Fed
25000
20000
15000
10000
5000
0
AUC (ng.h/ml)
Reference
Formulation B

FIG.2

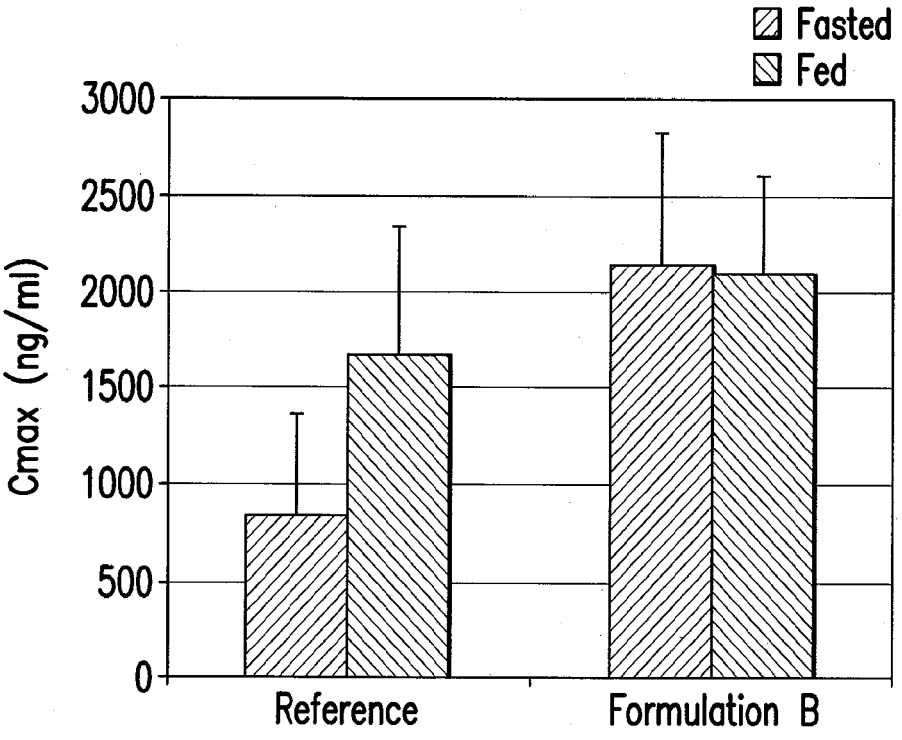

Fasted
Fed
3000
2500
2000
1500
1000
500
0
Cmax (ng/ml)
Reference
Formulation B

FIG.3

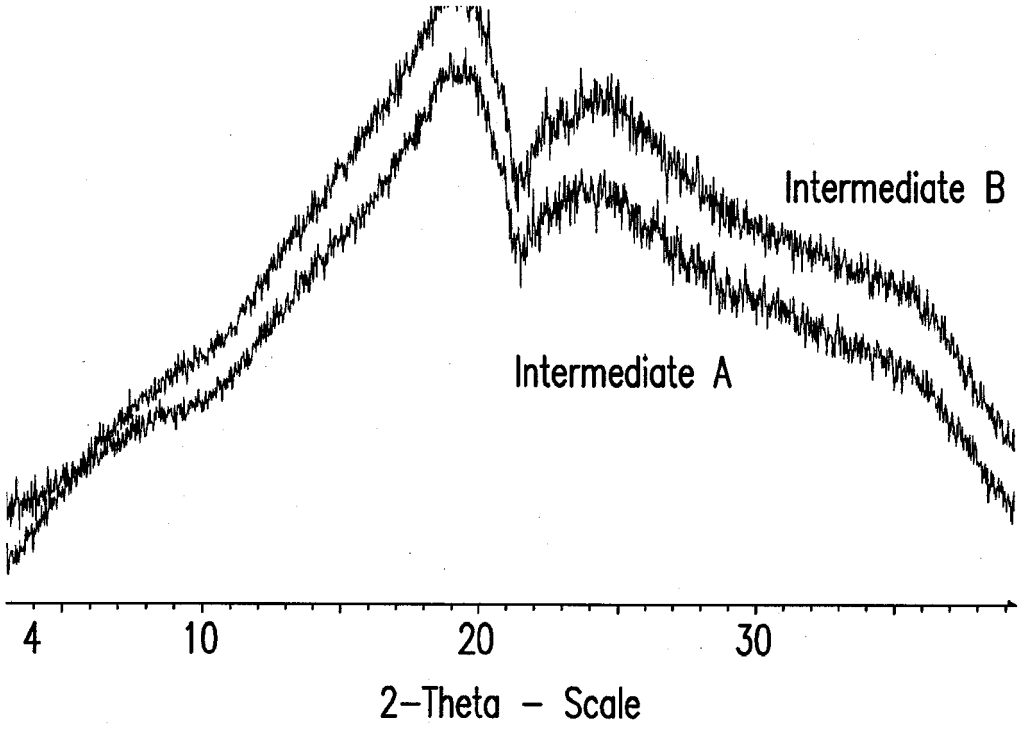


FIG.4

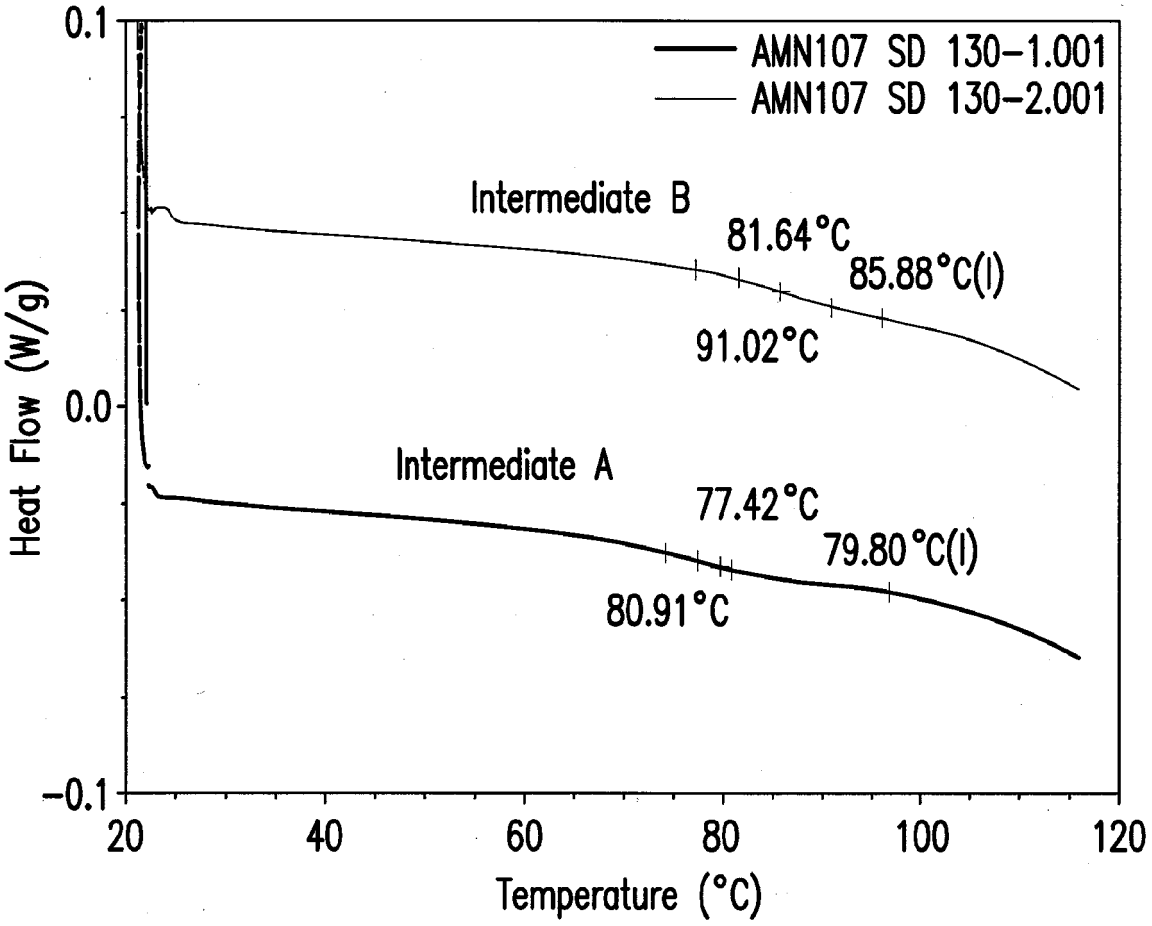

AMN107 SD 130-1.001
AMN107 SD 130-2.001
Intermediate B
81.64°C
85.88°C(I)
91.02°C
Intermediate A
77.42°C
79.80°C(I)
80.91°C
Heat Flow (W/g)
0.1
0.0
-0.1
20
40
60
80
100
120
Temperature (°C)

FIG.5

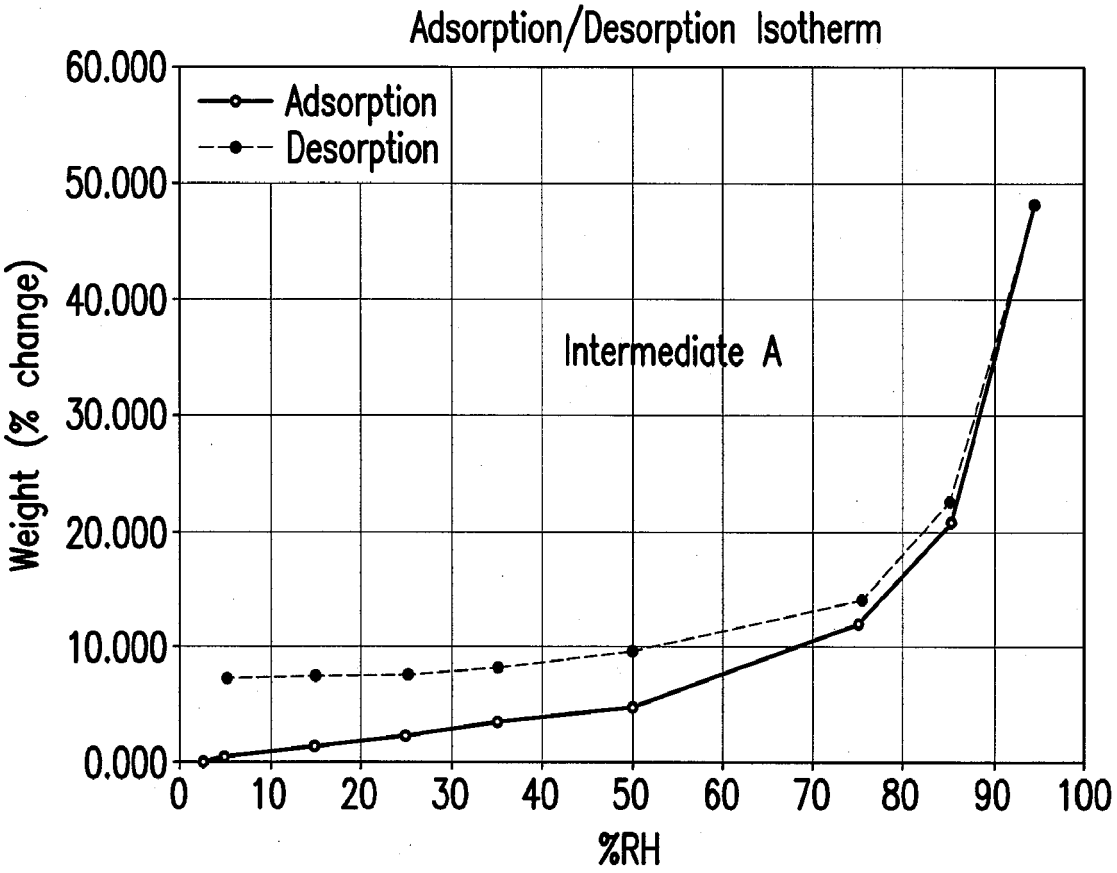

Adsorption/Desorption Isotherm
Adsorption
Desorption
Intermediate A
Weight (% change)
60.000
50.000
40.000
30.000
20.000
10.000
0.000
0
10
20
30
40
50
60
70
80
90
100
%RH

FIG.6

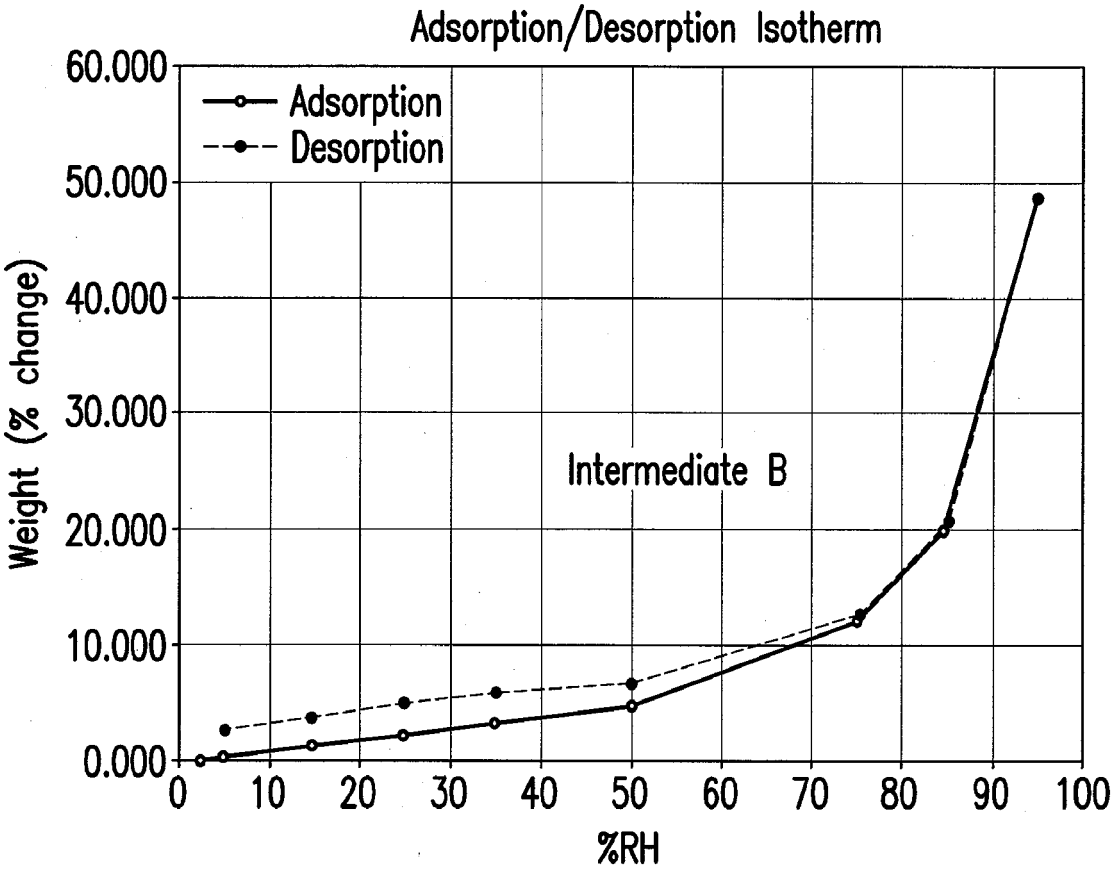

Adsorption/Desorption Isotherm
Adsorption
Desorption
Intermediate B
Weight (% change)
60.000
50.000
40.000
30.000
20.000
10.000
0.000
0
10
20
30
40
50
60
70
80
90
100
%RH

FIG.7

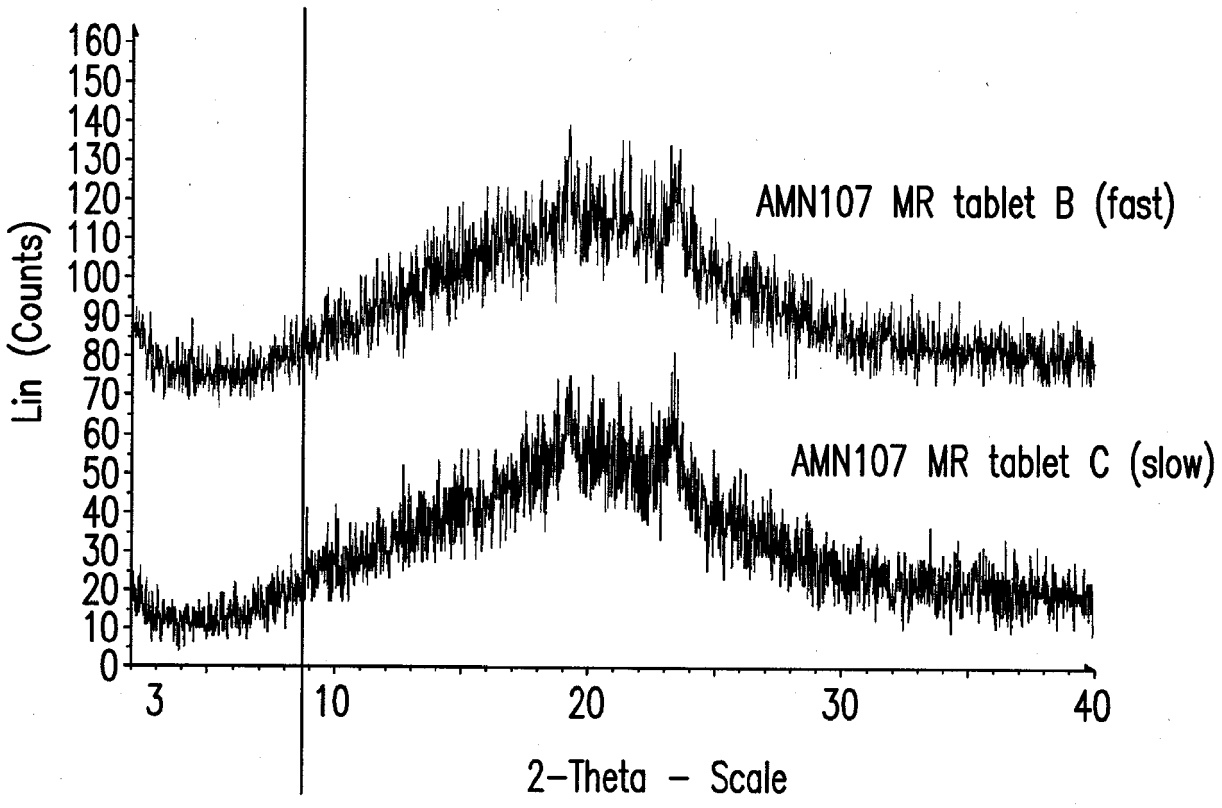

Lin (Counts)
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
3
10
20
30
40
2-Theta - Scale
AMN107 MR tablet B (fast)
AMN107 MR tablet C (slow)

FIG.8

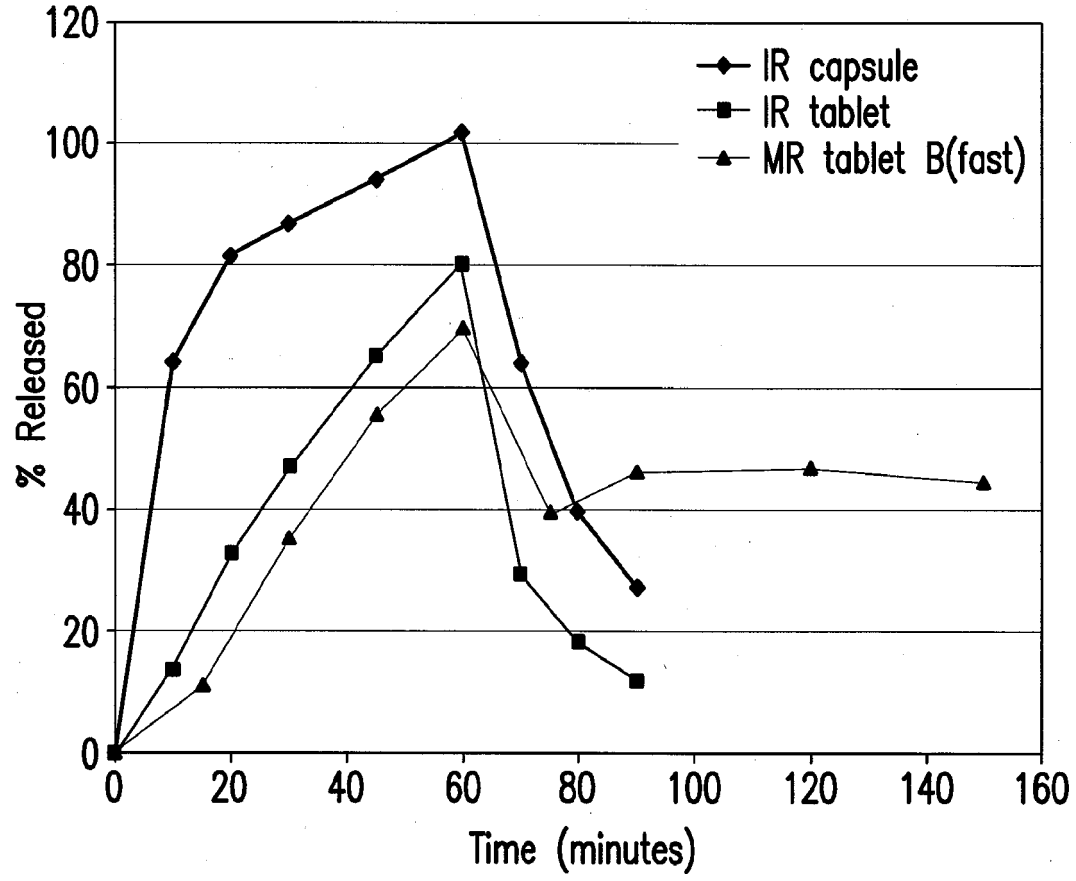

IR capsule
IR tablet
MR tablet B(fast)
% Released
Time (minutes)
0
20
40
60
80
100
120
140
160

FIG.9

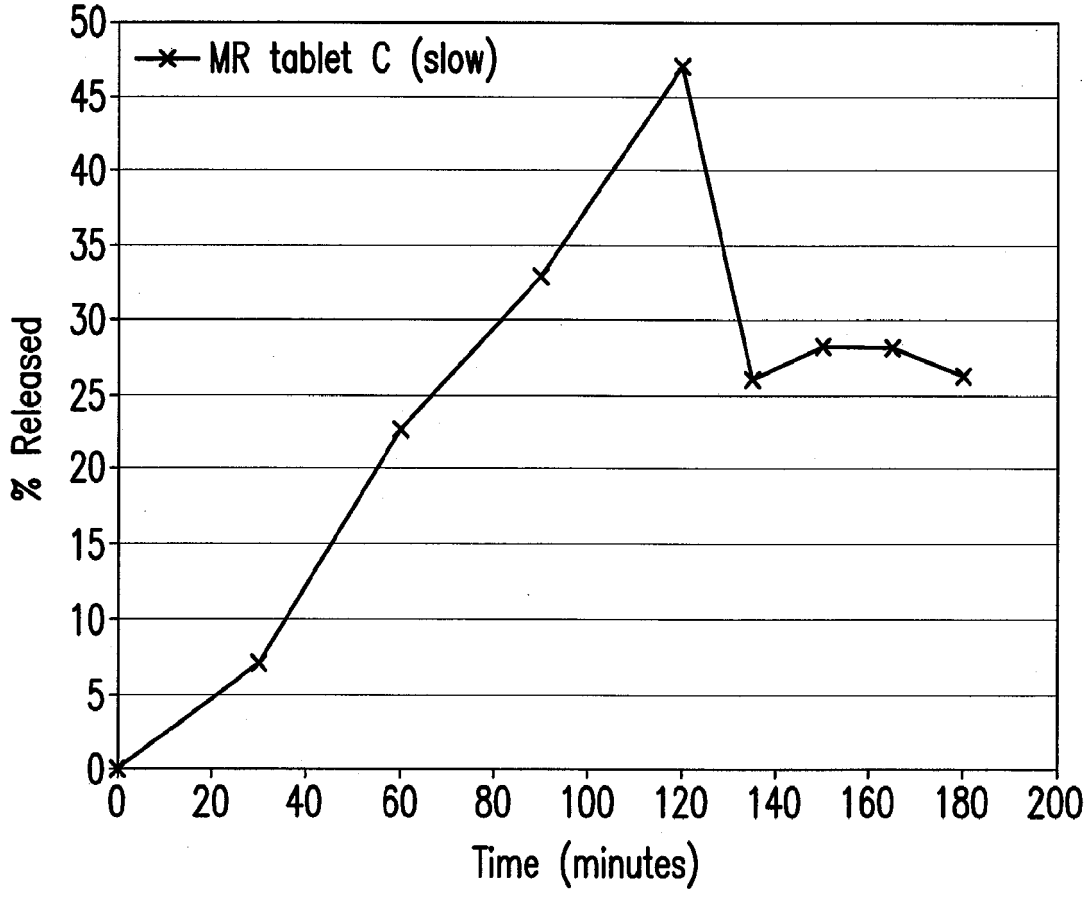

MR tablet C (slow)
% Released
Time (minutes)
0
5
10
15
20
25
30
35
40
45
50
0
20
40
60
80
100
120
140
160
180
200

FIG.10

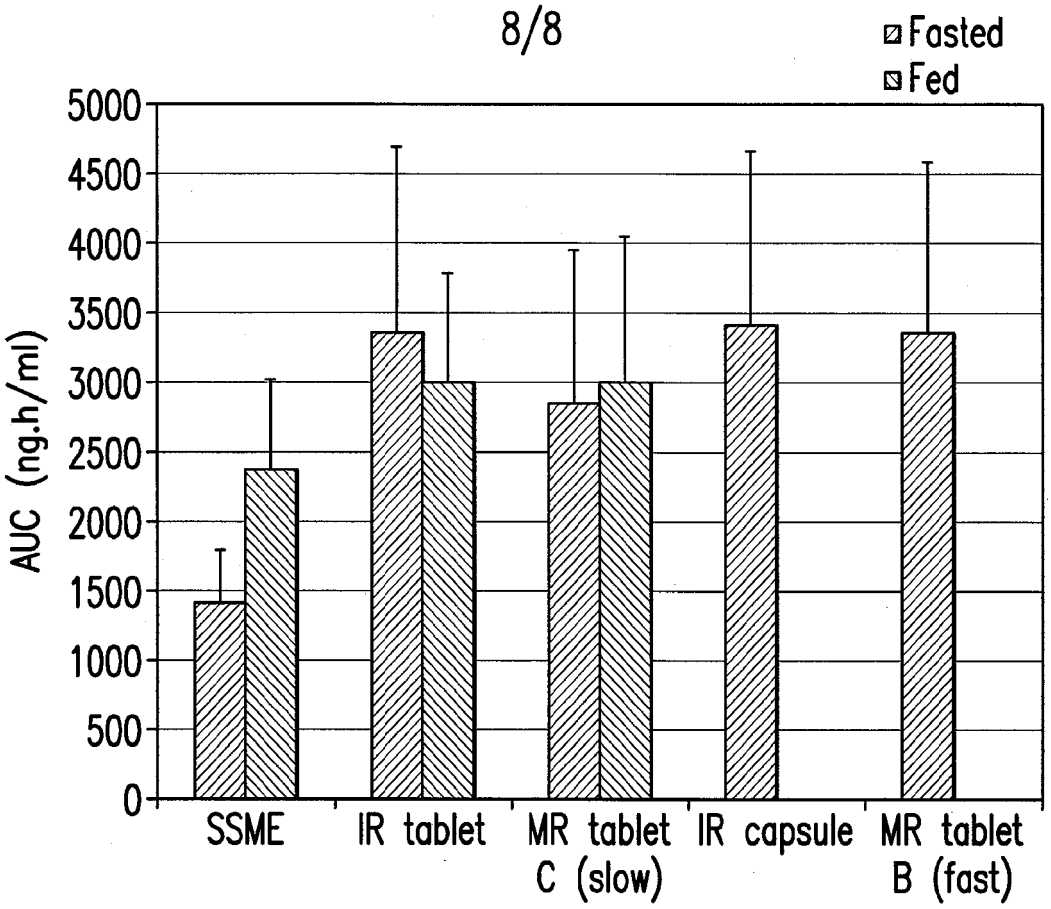

Fasted
Fed
AUC (ng.h/ml)
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
SSME
IR tablet
MR tablet C (slow)
IR capsule
MR tablet B (fast)

FIG.11

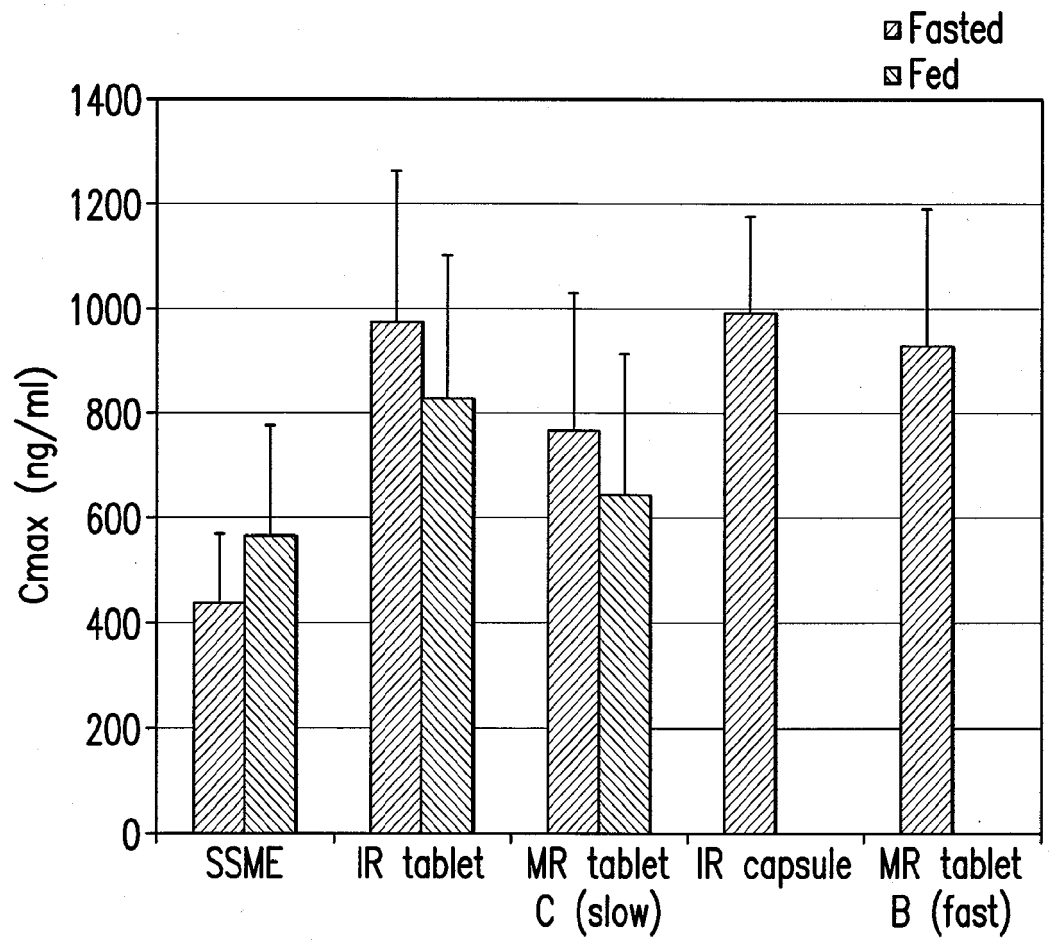

Fasted
Fed
Cmax (ng/ml)
1400
1200
1000
800
600
400
200
0
SSME
IR tablet
MR tablet C (slow)
IR capsule
MR tablet B (fast)

FIG.12