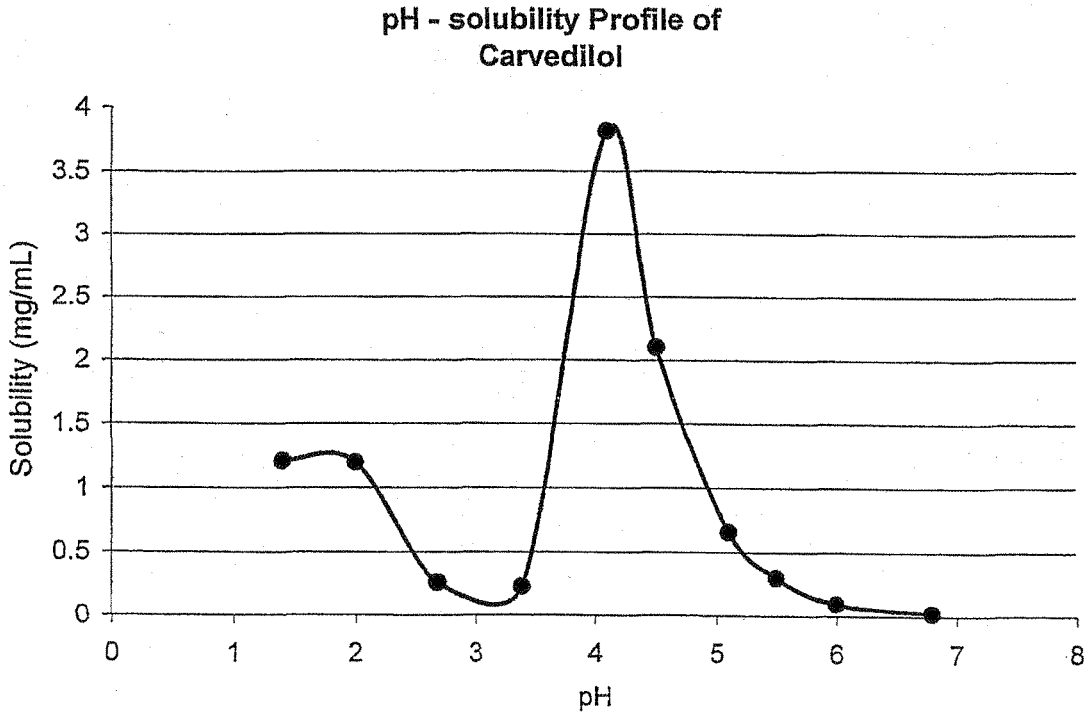

pH - solubility Profile of Carvedilol
Solubility (mg/mL)
4
3.5
3
2.5
2
1.5
1
0.5
0
0
1
2
3
4
5
6
7
8
pH

FIG. 1B

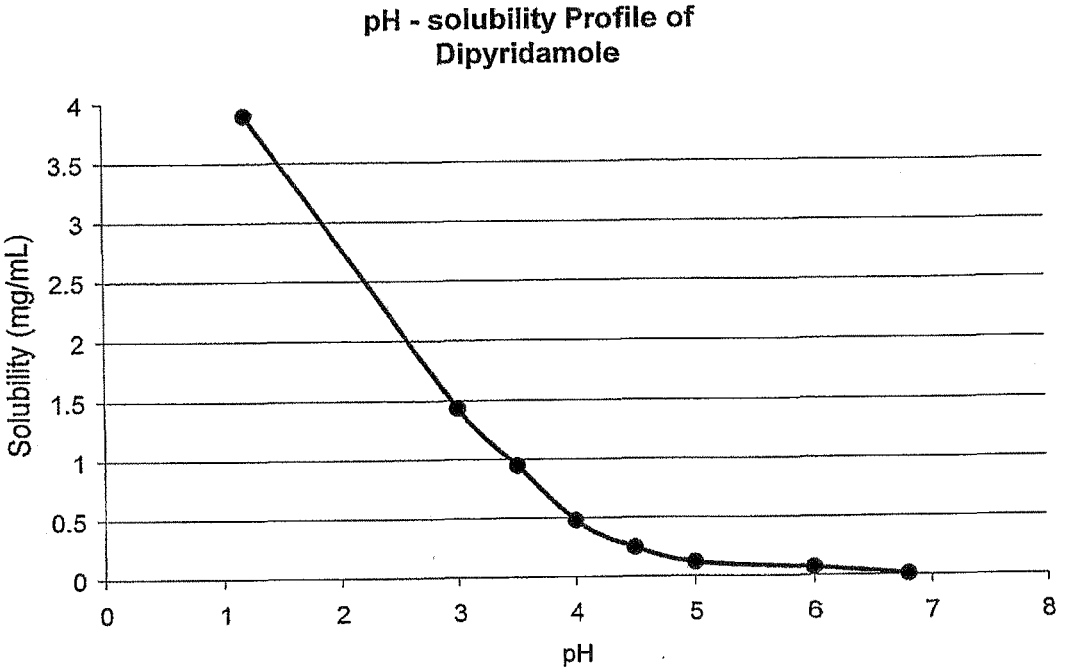

pH - solubility Profile of
Dipyridamole
Solubility (mg/mL)
4
3.5
3
2.5
2
1.5
1
0.5
0
0
1
2
3
4
5
6
7
8
pH

FIG. 1C

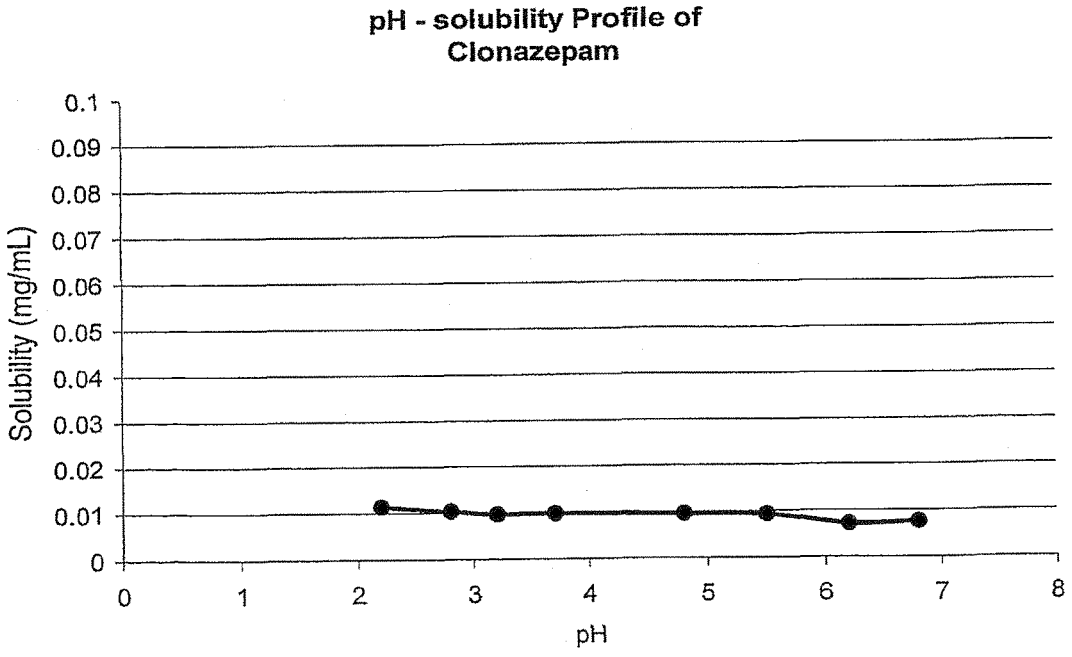

pH - solubility Profile of
Clonazepam
Solubility (mg/mL)
0.1
0.09
0.08
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
0
1
2
3
4
5
6
7
8
pH

FIG. 1D

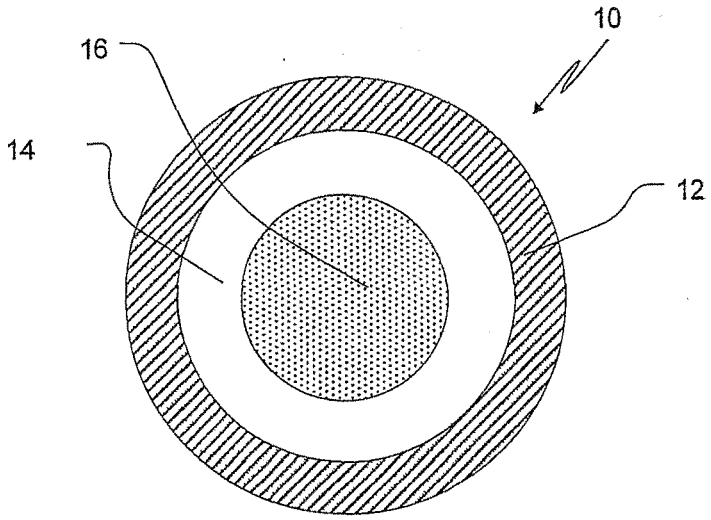


FIG. 2

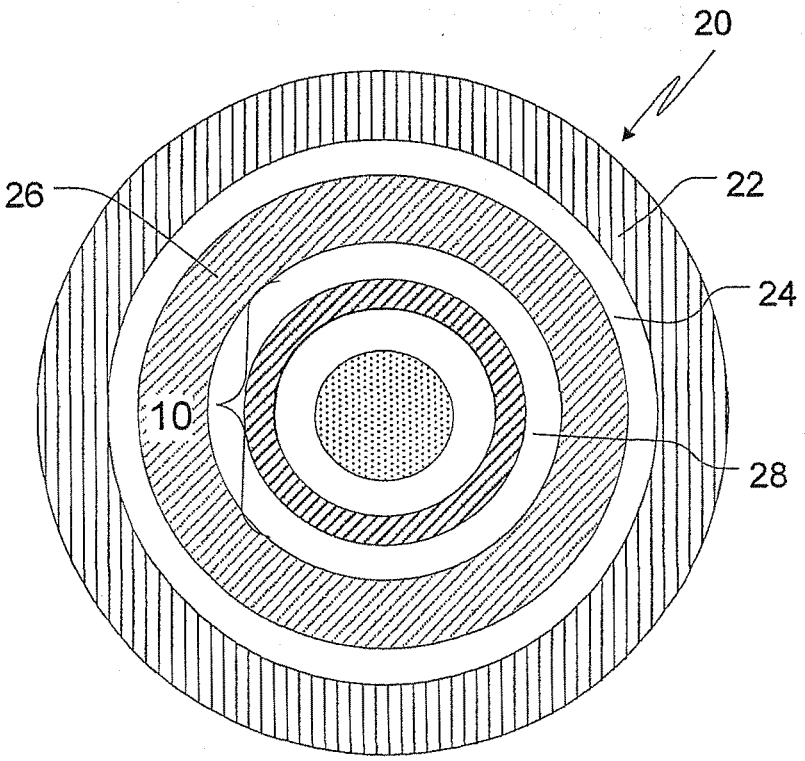


FIG. 3

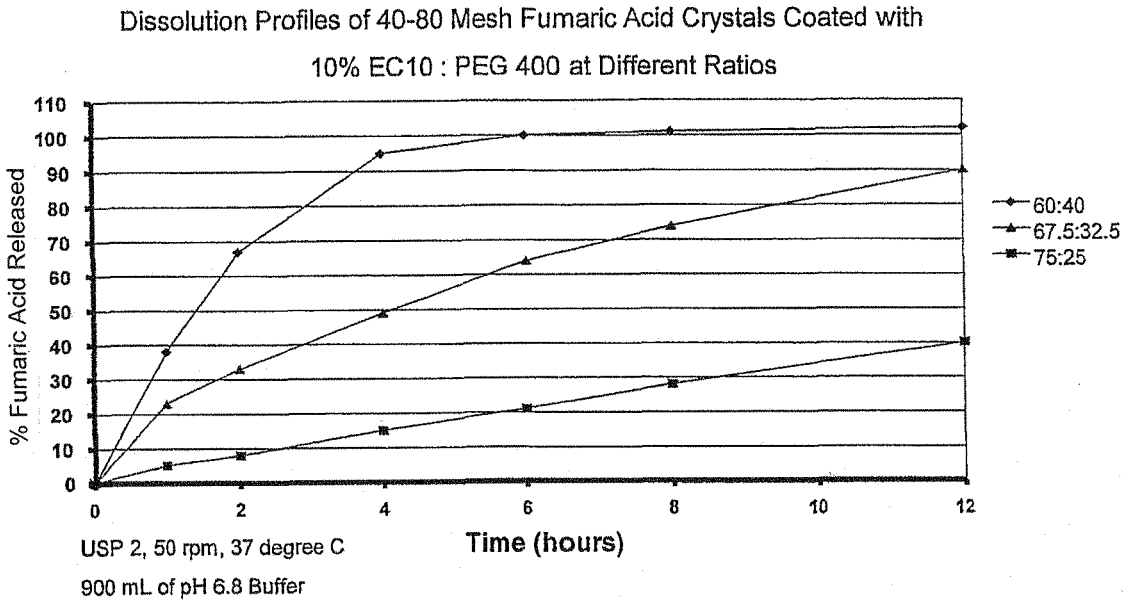

Dissolution Profiles of 40-80 Mesh Fumaric Acid Crystals Coated with
10% EC10 : PEG 400 at Different Ratios
% Fumaric Acid Released
110
100
90
80
70
60
50
40
30
20
10
0
0
2
4
6
8
10
12
Time (hours)
60:40
67.5:32.5
75:25
USP 2, 50 rpm, 37 degree C
900 mL of pH 6.8 Buffer

FIG. 4

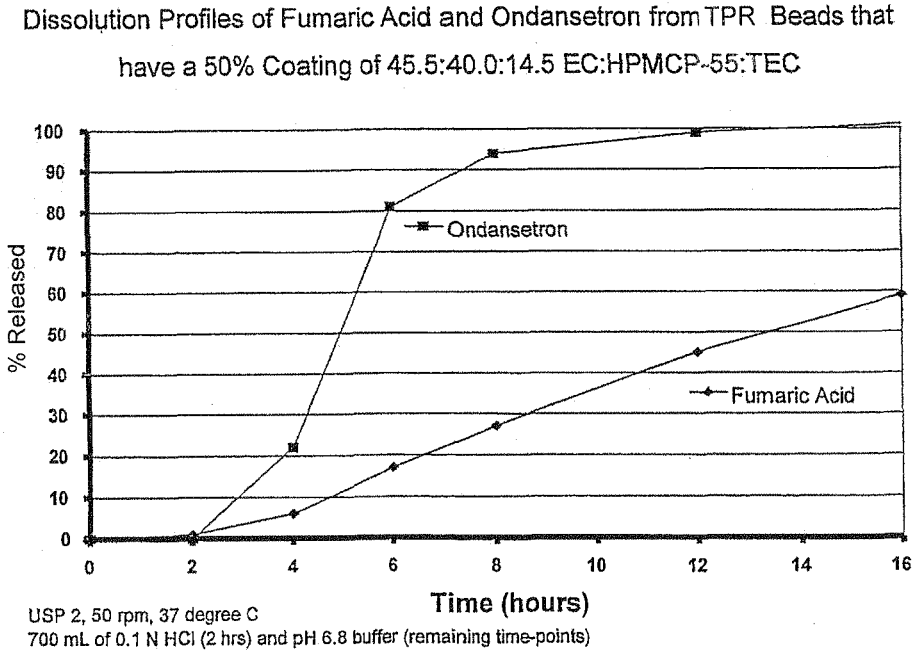

Dissolution Profiles of Fumaric Acid and Ondansetron from TPR Beads that
have a 50% Coating of 45.5:40.0:14.5 EC:HPMCP-55:TEC
% Released
100
90
80
70
60
50
40
30
20
10
0
0
2
4
6
8
10
12
14
16
Time (hours)
Ondansetron
Fumaric Acid
USP 2, 50 rpm, 37 degree C
700 mL of 0.1 N HCl (2 hrs) and pH 6.8 buffer (remaining time-points)

FIG. 5

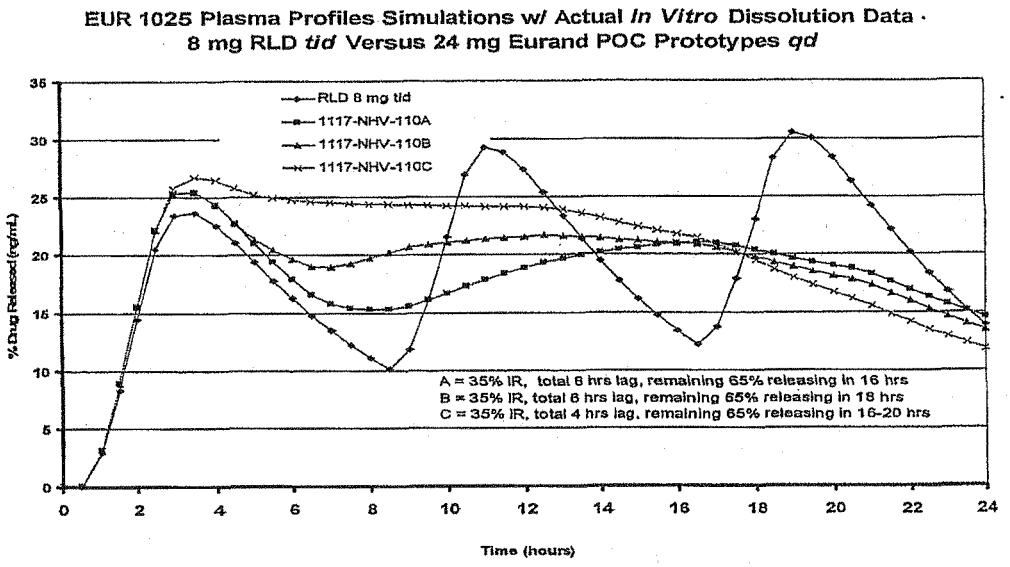

EUR 1025 Plasma Profiles Simulations w/ Actual In Vitro Dissolution Data -
8 mg RLD tid Versus 24 mg Eurand POC Prototypes qd
RLD 8 mg tid
1117-NHV-110A
1117-NHV-110B
1117-NHV-110C
% Drug Released (ng/mL)
A = 35% IR, total 6 hrs lag, remaining 65% releasing in 16 hrs
B = 35% IR, total 6 hrs lag, remaining 65% releasing in 18 hrs
C = 35% IR, total 4 hrs lag, remaining 65% releasing in 16-20 hrs
Time (hours)

FIG. 6

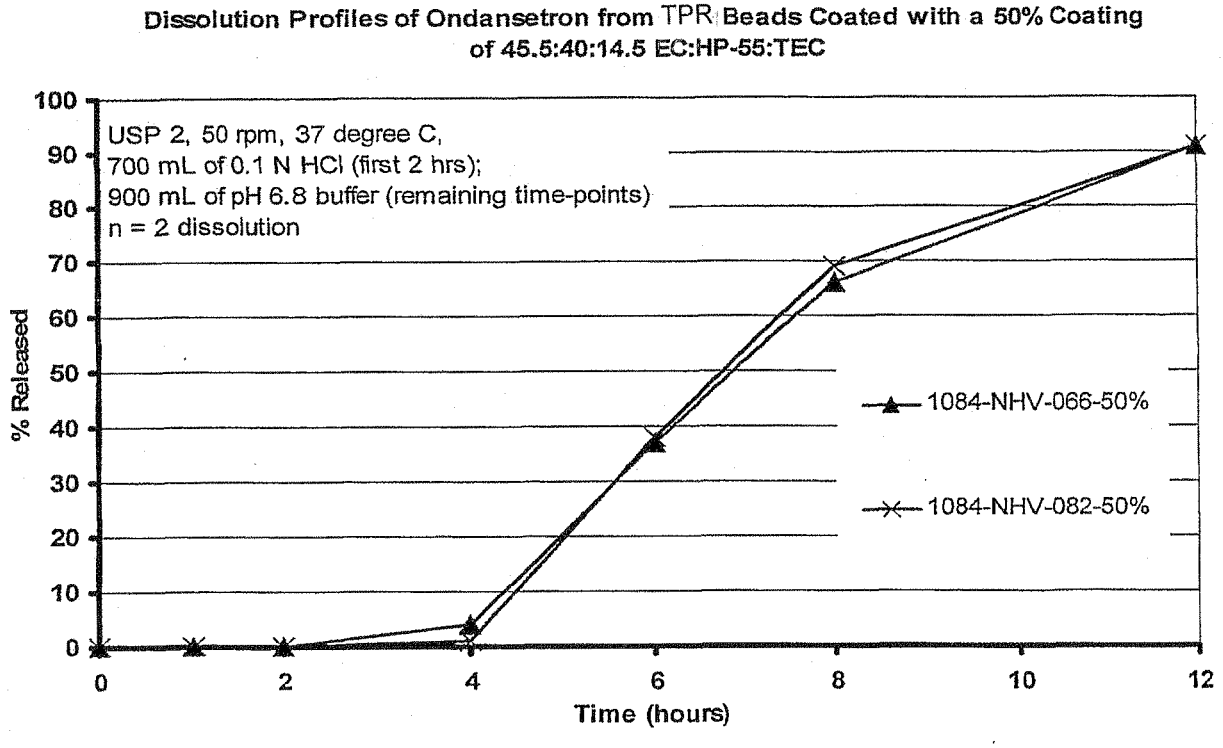

Dissolution Profiles of Ondansetron from TPR Beads Coated with a 50% Coating
of 45.5:40:14.5 EC:HP-55:TEC
USP 2, 50 rpm, 37 degree C,
700 mL of 0.1 N HCl (first 2 hrs);
900 mL of pH 6.8 buffer (remaining time-points)
n = 2 dissolution
1084-NHV-066-50%
1084-NHV-082-50%
% Released
Time (hours)

FIG. 7

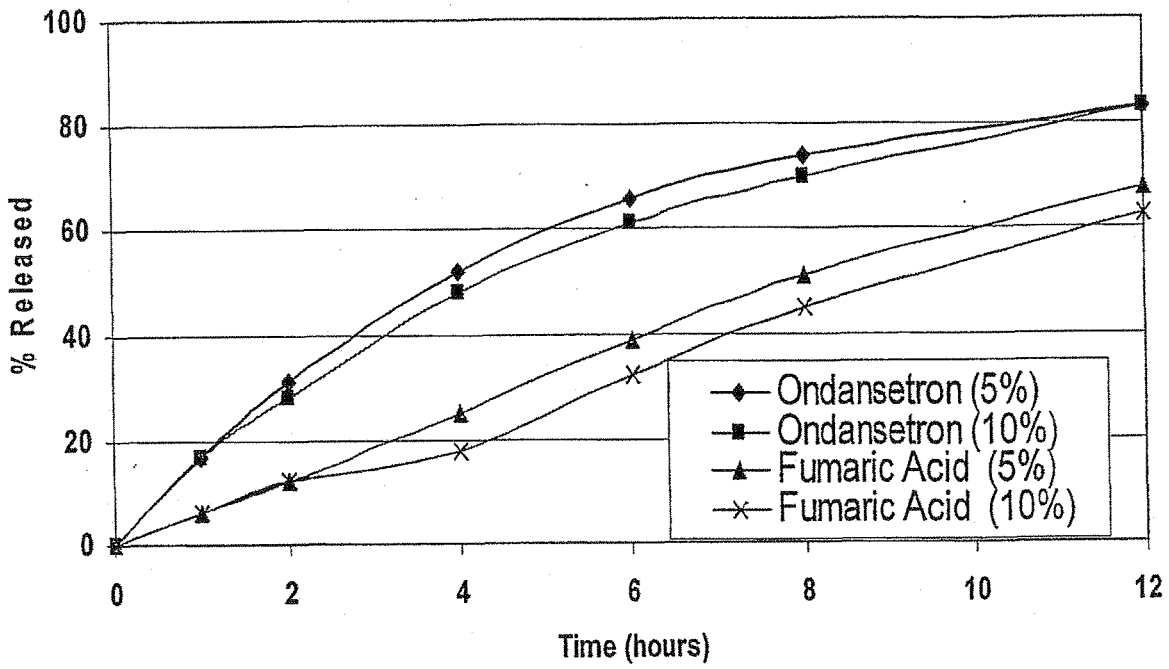

100
80
60
40
20
0
% Released
0
2
4
6
8
10
12
Time (hours)
Ondansetron (5%)
Ondansetron (10%)
Fumaric Acid (5%)
Fumaric Acid (10%)

FIG. 8

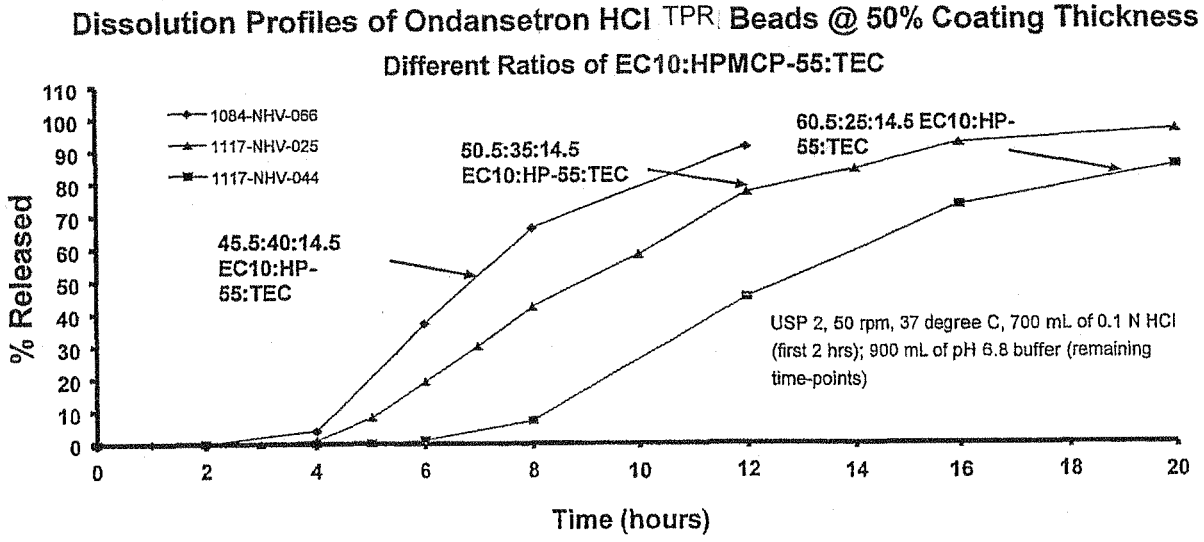

Dissolution Profiles of Ondansetron HCl TPR Beads @ 50% Coating Thickness
Different Ratios of EC10:HPMCP-55:TEC
110
100
90
80
70
60
50
40
30
20
10
0
% Released
1084-NHV-066
1117-NHV-025
1117-NHV-044
45.5:40:14.5 EC10:HP-55:TEC
50.5:35:14.5 EC10:HP-55:TEC
60.5:25:14.5 EC10:HP-55:TEC
USP 2, 50 rpm, 37 degree C, 700 mL of 0.1 N HCl (first 2 hrs); 900 mL of pH 6.8 buffer (remaining time-points)
0
2
4
6
8
10
12
14
16
18
20
Time (hours)

FIG. 9

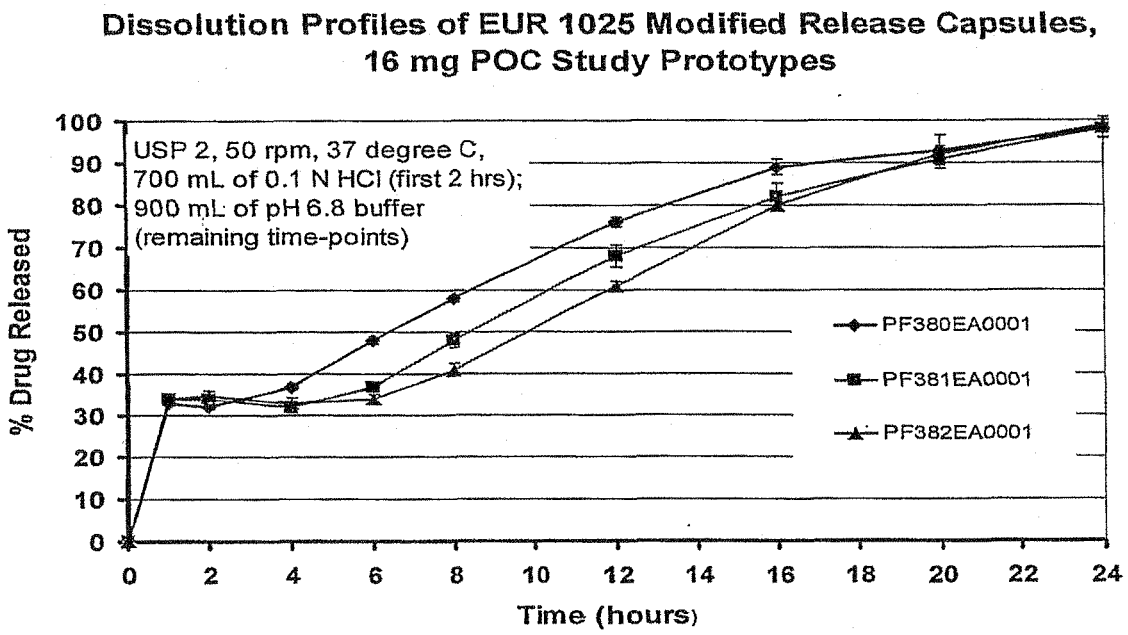

Dissolution Profiles of EUR 1025 Modified Release Capsules, 16 mg POC Study Prototypes
USP 2, 50 rpm, 37 degree C,
700 mL of 0.1 N HCl (first 2 hrs);
900 mL of pH 6.8 buffer
(remaining time-points)
% Drug Released
Time (hours)
PF380EA0001
PF381EA0001
PF382EA0001
0
10
20
30
40
50
60
70
80
90
100
0
2
4
6
8
10
12
14
16
18
20
22
24

FIG. 10