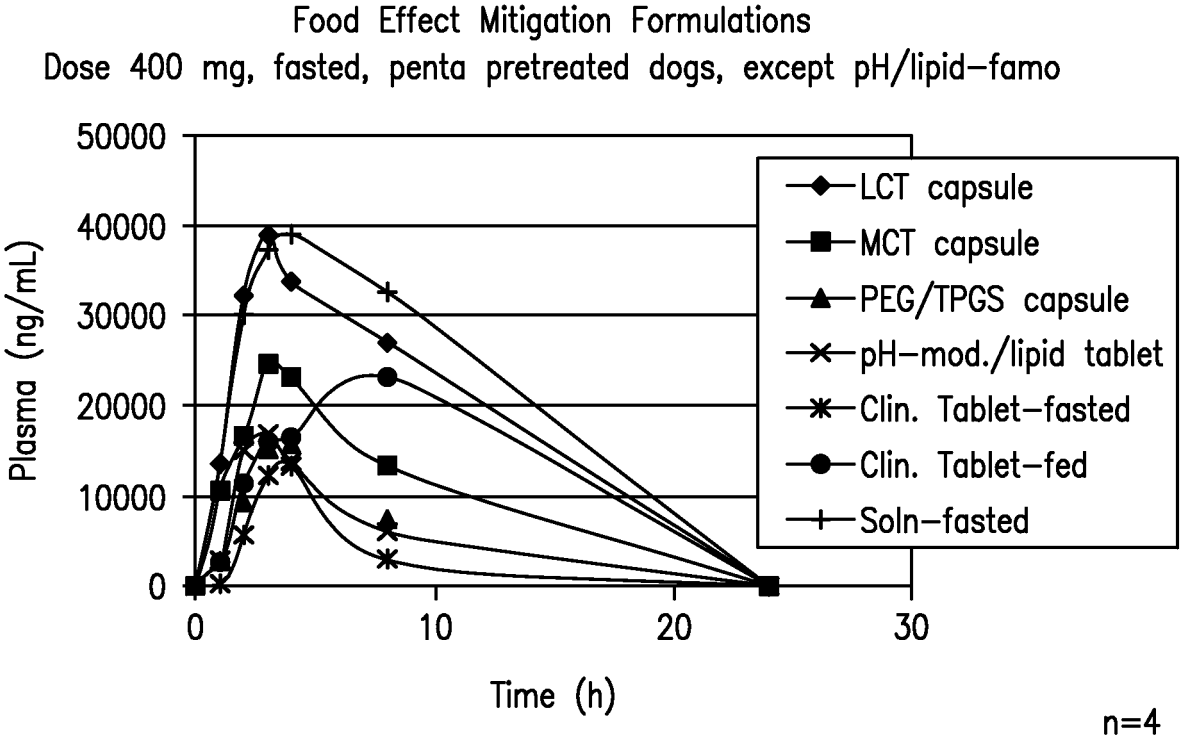

Food Effect Mitigation Formulations
Dose 400 mg, fasted, penta pretreated dogs, except pH/lipid–famo
Plasma (ng/mL)
50000
40000
30000
20000
10000
0
0
10
20
30
Time (h)
LCT capsule
MCT capsule
PEG/TPGS capsule
pH–mod./lipid tablet
Clin. Tablet–fasted
Clin. Tablet–fed
Soln–fasted
n=4

FIG. 1

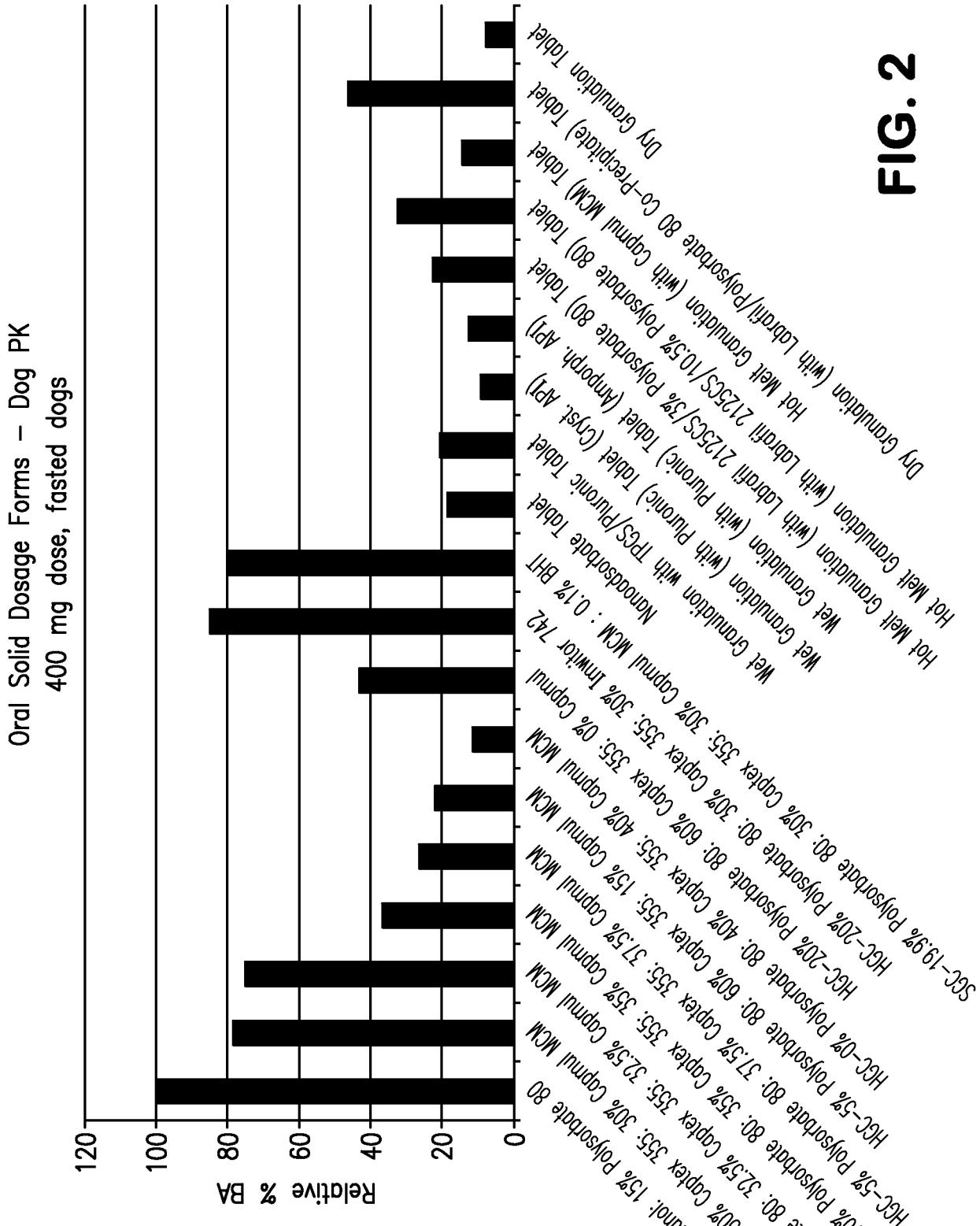

Oral Solid Dosage Forms – Dog PK
400 mg dose, fasted dogs
Relative % BA
0
20
40
60
80
100
120
Solution–50% PEG 400: 35% Ethanol: 15% Polysorbate 80
HGC–20% Polysorbate 80: 30% Capmul MCM
HGC–15% Polysorbate 80: 32.5% Capmul MCM
HGC–10% Polysorbate 80: 35% Capmul MCM
HGC–5% Polysorbate 80: 37.5% Capmul MCM
HGC–0% Polysorbate 80: 40% Capmul MCM
HGC–20% Polysorbate 80: 60% Capmul MCM
SGC–19.9% Polysorbate 80: 30% Capmul MCM : 0.1% BHT
Wet Granulation with TPGS/Pluronic Tablet (Cryst. API)
Wet Granulation (with Pluronic) Tablet (Amporph. API)
Hot Melt Granulation (with Labrafil 2125CS/3% Polysorbate 80) Tablet
Hot Melt Granulation (with Labrafil 2125CS/10.5% Polysorbate 80) Tablet
Dry Granulation (with Labrafil/Polysorbate 80 Co-Precipitate) Tablet
Dry Granulation Tablet

FIG. 2

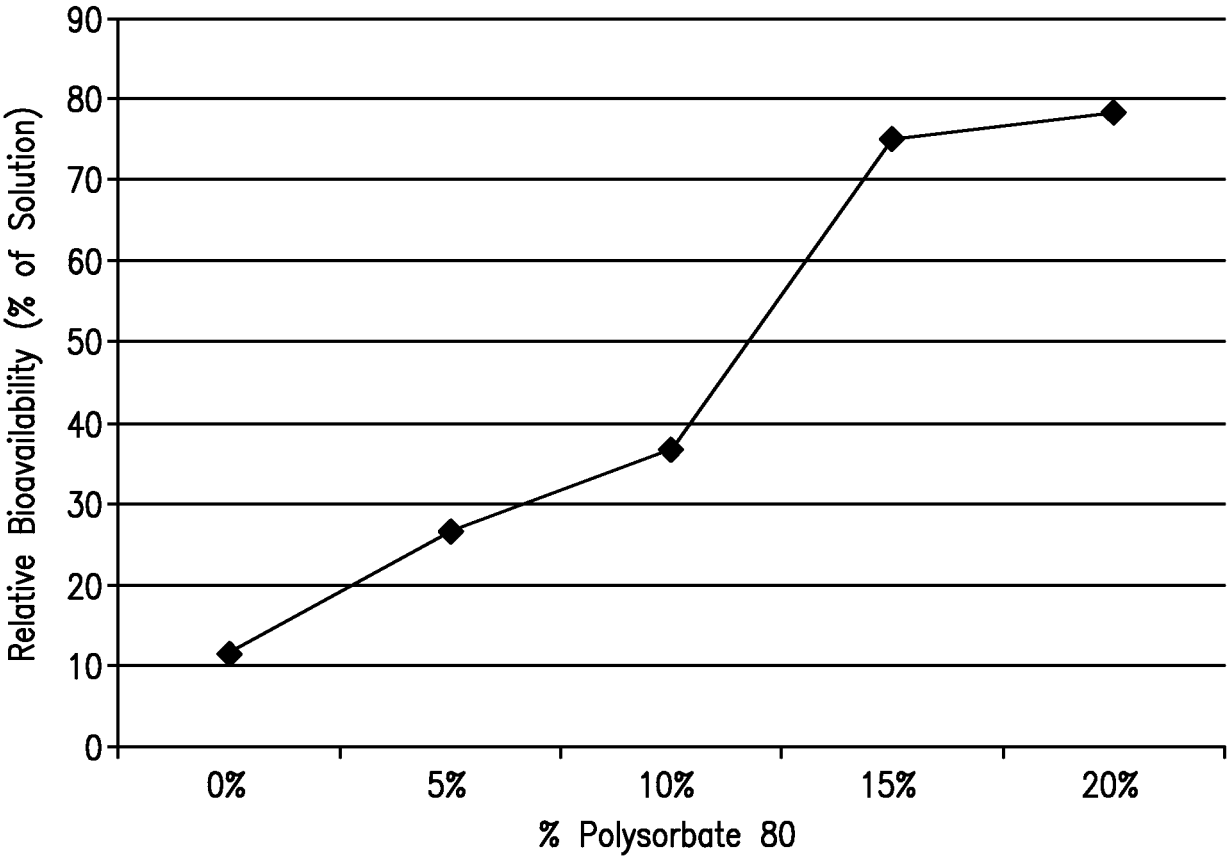

Relative Bioavailability (% of Solution)
90
80
70
60
50
40
30
20
10
0
0%
5%
10%
15%
20%
% Polysorbate 80

FIG. 3

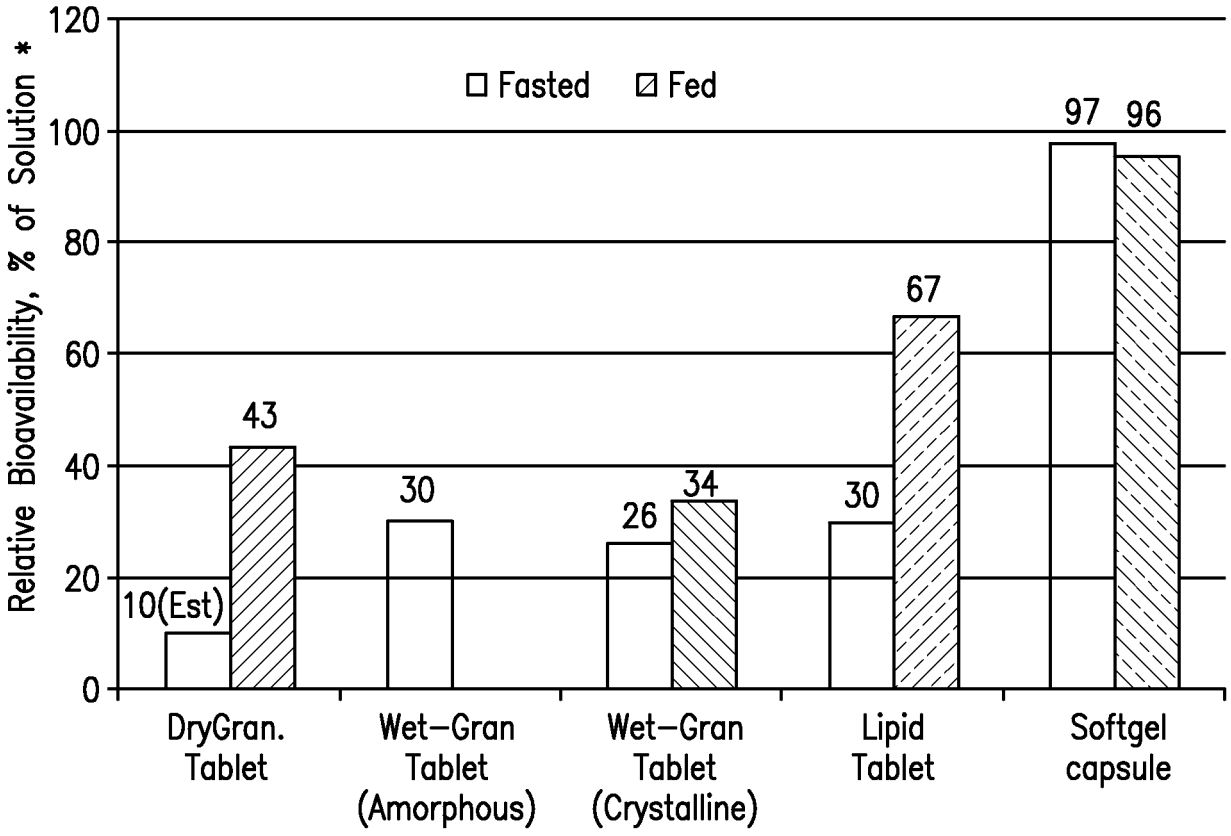

Relative Bioavailability, % of Solution *
120
100
80
60
40
20
0
Fasted
Fed
10(Est)
43
30
26
34
30
67
97
96
DryGran. Tablet
Wet–Gran Tablet (Amorphous)
Wet–Gran Tablet (Crystalline)
Lipid Tablet
Softgel capsule

FIG. 4