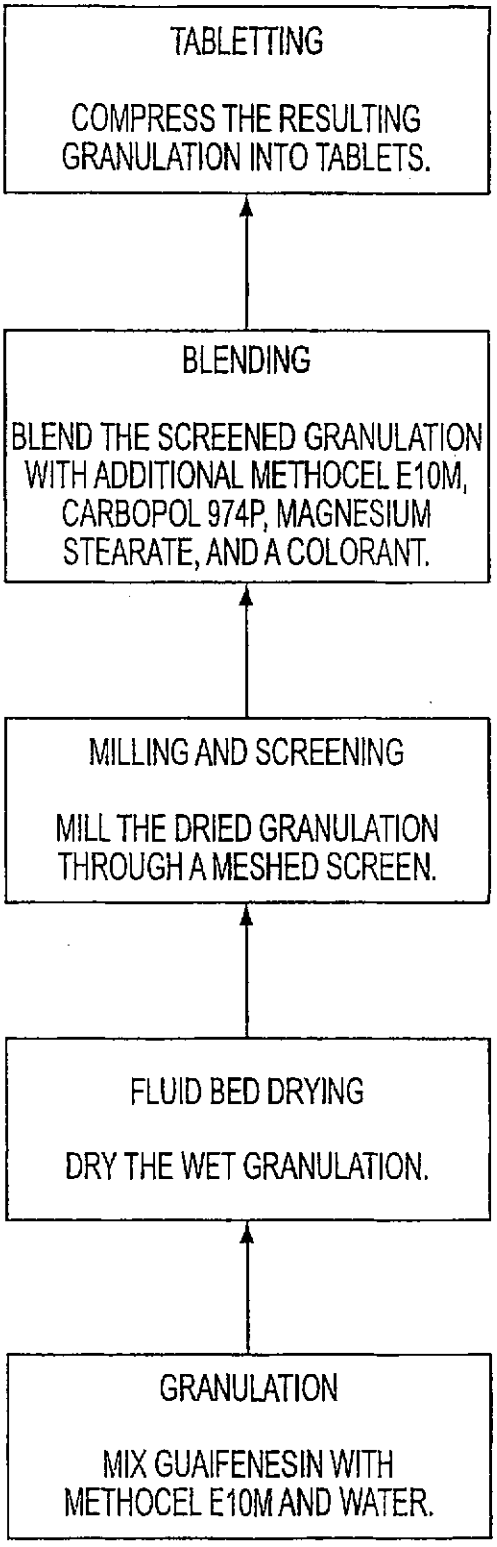

TABLETTING
COMPRESS THE RESULTING GRANULATION INTO TABLETS.
BLENDING
BLEND THE SCREENED GRANULATION WITH ADDITIONAL METHOCEL E10M, CARBOPOL 974P, MAGNESIUM STEARATE, AND A COLORANT.
MILLING AND SCREENING
MILL THE DRIED GRANULATION THROUGH A MESHED SCREEN.
FLUID BED DRYING
DRY THE WET GRANULATION.
GRANULATION
MIX GUAIFENESIN WITH METHOCEL E10M AND WATER.

FIG. 1

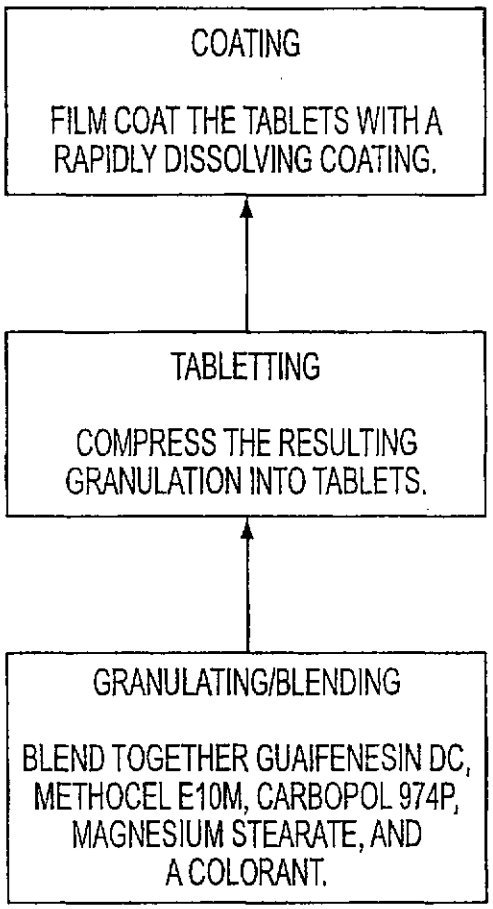

COATING
FILM COAT THE TABLETS WITH A RAPIDLY DISSOLVING COATING.
TABLETTING
COMPRESS THE RESULTING GRANULATION INTO TABLETS.
GRANULATING/BLENDING
BLEND TOGETHER GUAIFENESIN DC, METHOCEL E10M, CARBOPOL 974P, MAGNESIUM STEARATE, AND A COLORANT.

FIG. 2

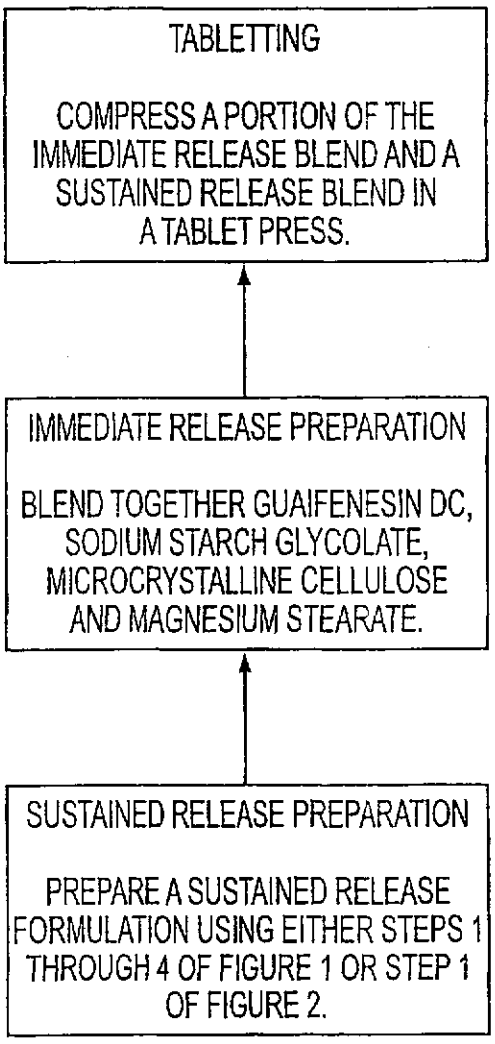

TABLETTING
COMPRESS A PORTION OF THE IMMEDIATE RELEASE BLEND AND A SUSTAINED RELEASE BLEND IN A TABLET PRESS.
IMMEDIATE RELEASE PREPARATION
BLEND TOGETHER GUAIFENESIN DC, SODIUM STARCH GLYCOLATE, MICROCRYSTALLINE CELLULOSE AND MAGNESIUM STEARATE.
SUSTAINED RELEASE PREPARATION
PREPARE A SUSTAINED RELEASE FORMULATION USING EITHER STEPS 1 THROUGH 4 OF FIGURE 1 OR STEP 1 OF FIGURE 2.

FIG. 3

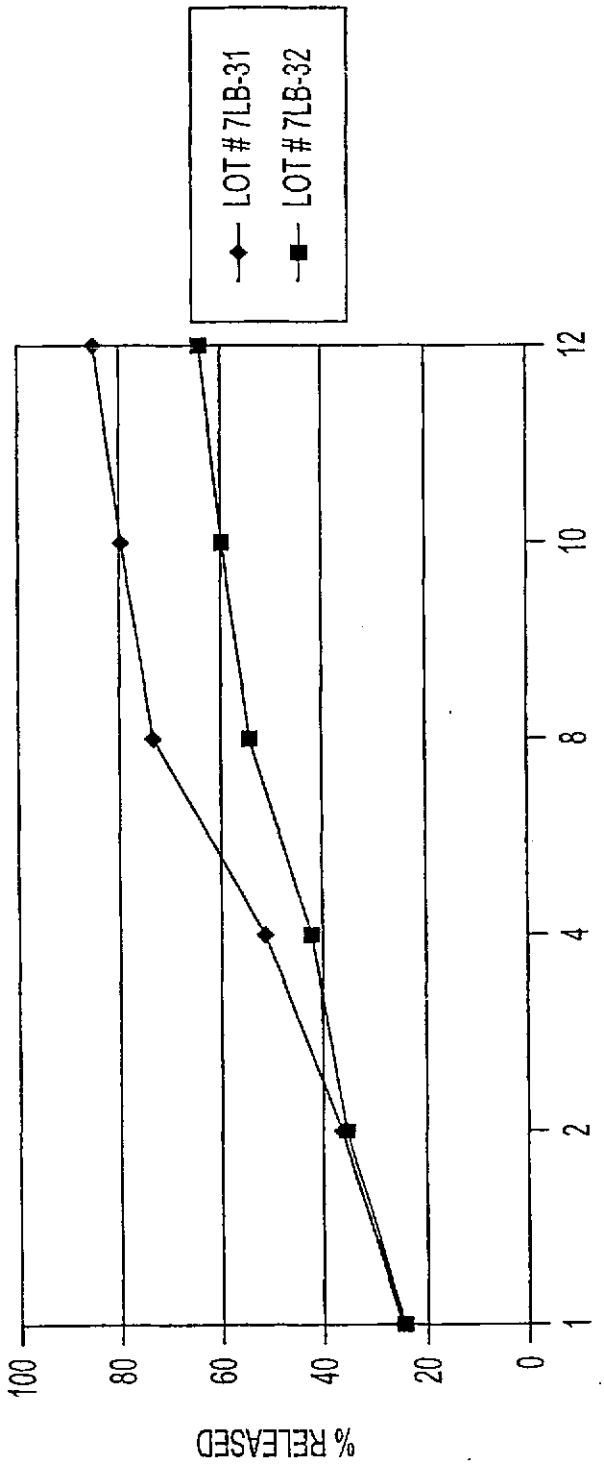

LOT # 7LB-31
LOT # 7LB-32
% RELEASED
0
20
40
60
80
100
TIME (HR)
1
2
4
8
10
12

FIG. 4

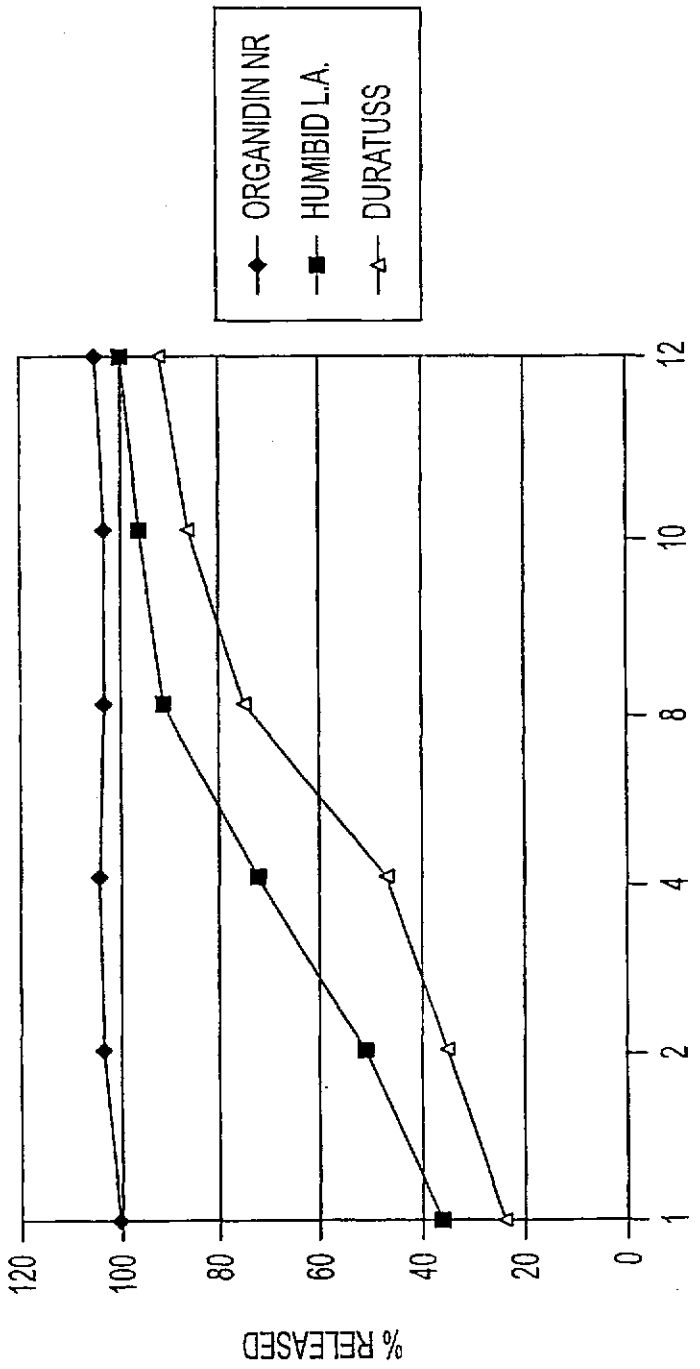

ORGANIDIN NR
HUMIBID L.A.
DURATUSS
% RELEASED
120
100
80
60
40
20
0
TIME (HR)
1
2
4
8
10
12

FIG. 5

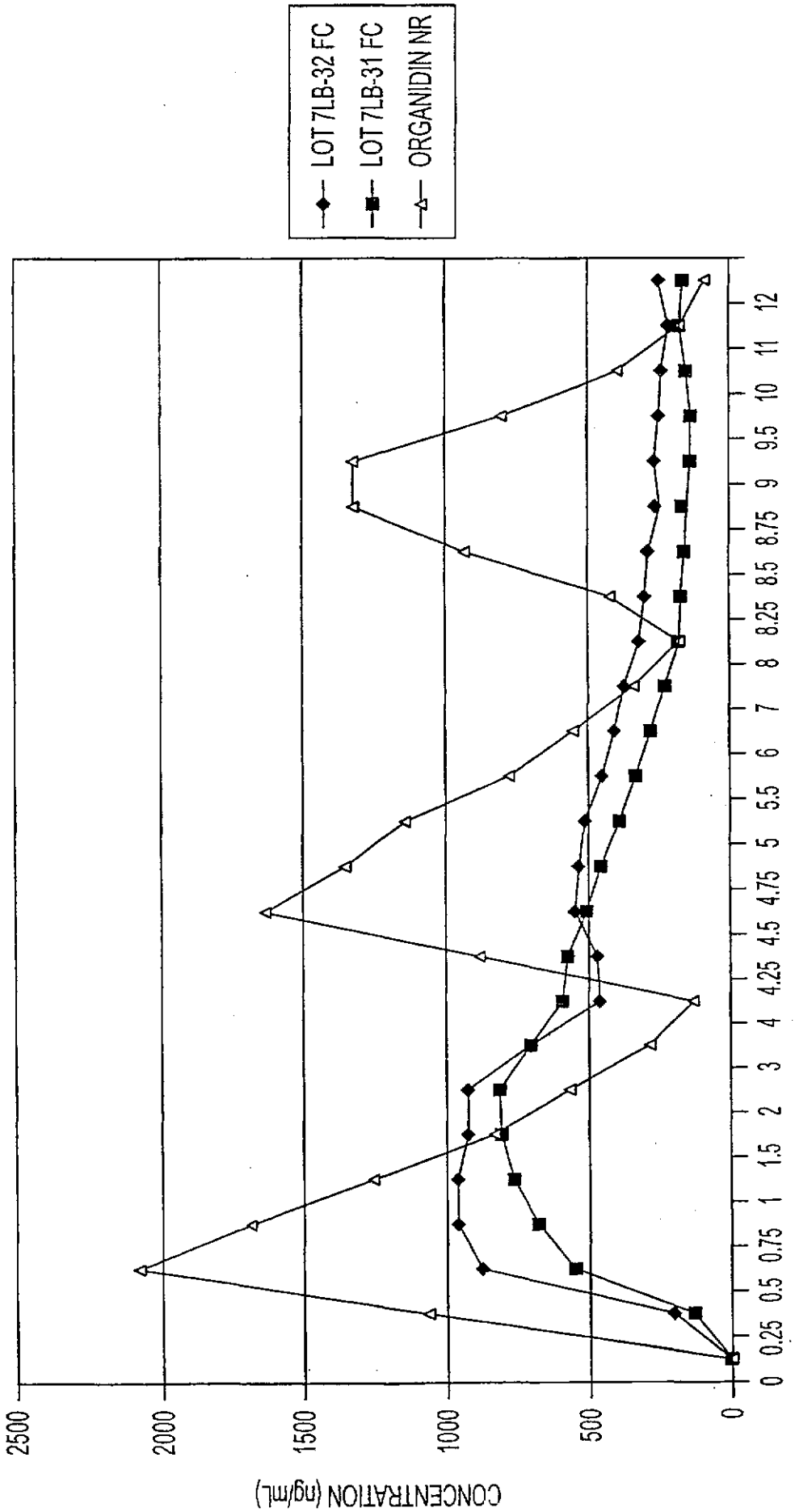

LOT 7LB-32 FC
LOT 7LB-31 FC
ORGANIDIN NR
CONCENTRATION (ng/mL)
2500
2000
1500
1000
500
0
TIME AFTER DOSING (HR)
0 0.25 0.5 0.75 1 1.5 2 3 4 4.25 4.5 4.75 5 5.5 6 7 8 8.25 8.5 8.75 9 9.5 10 11 12

FIG. 6

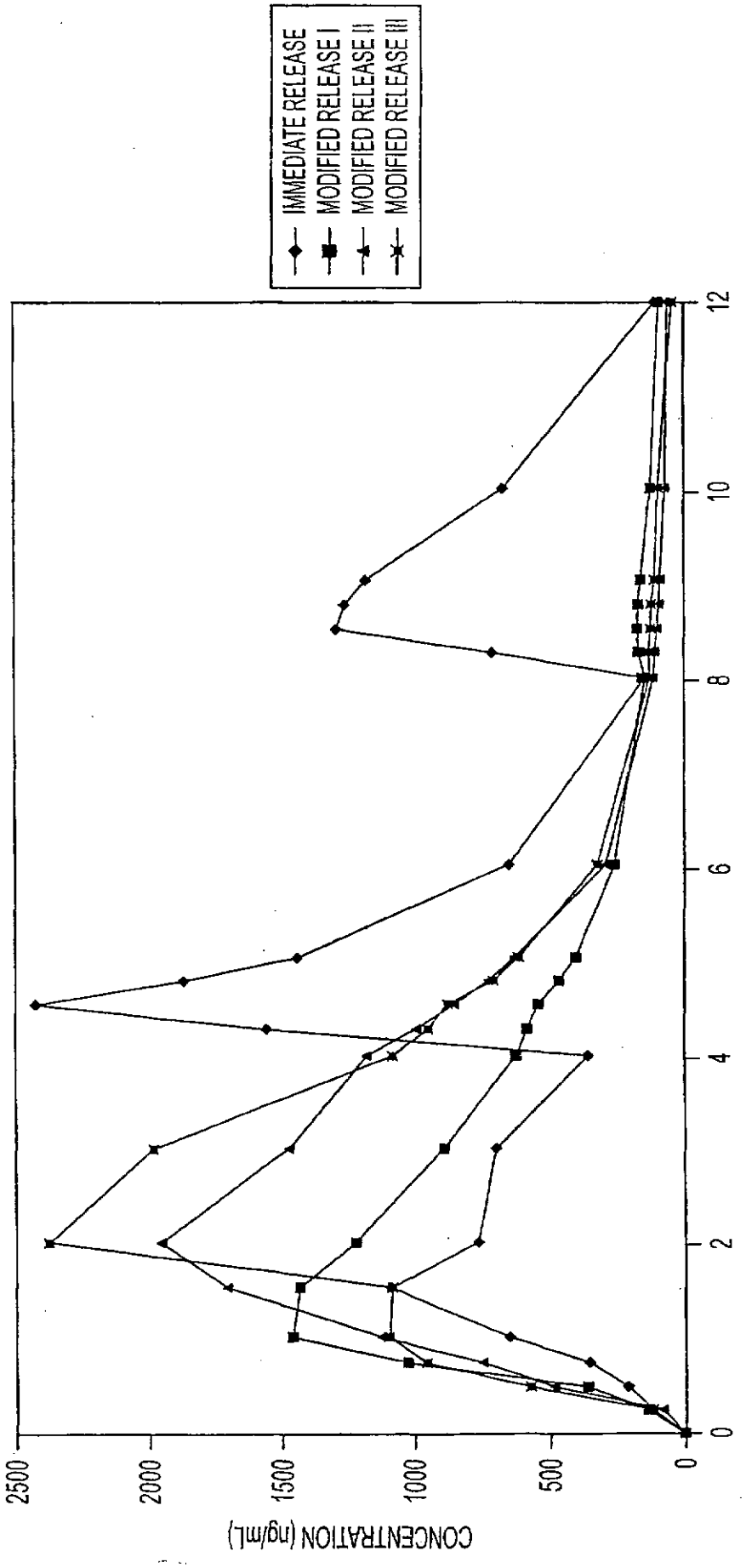

IMMEDIATE RELEASE
MODIFIED RELEASE I
MODIFIED RELEASE II
MODIFIED RELEASE III
CONCENTRATION (ng/mL)
2500
2000
1500
1000
500
0
0
2
4
6
8
10
12
TIME AFTER DOSE (HR)

FIG. 7

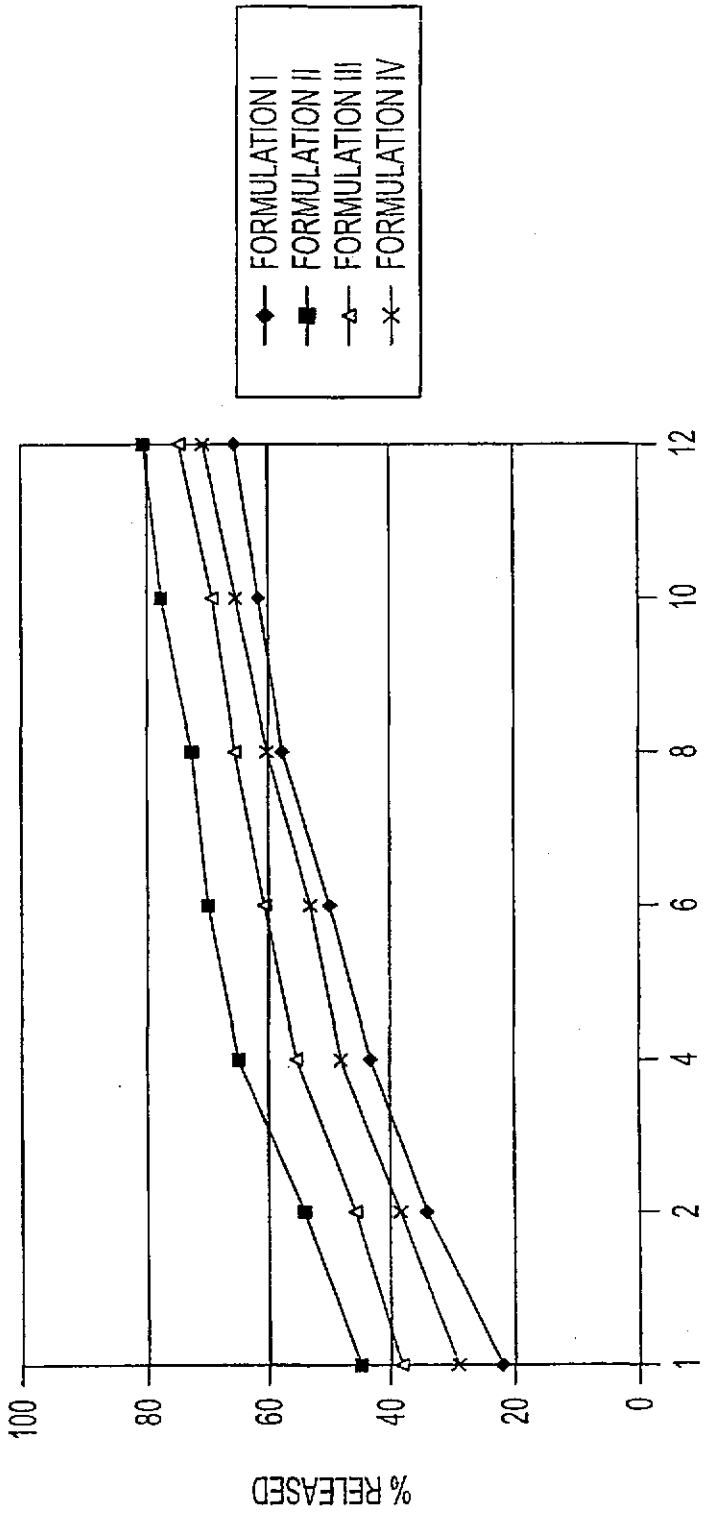

FORMULATION I
FORMULATION II
FORMULATION III
FORMULATION IV
% RELEASED
100
80
60
40
20
0
1
2
4
6
8
10
12
TIME (HR)

FIG. 8

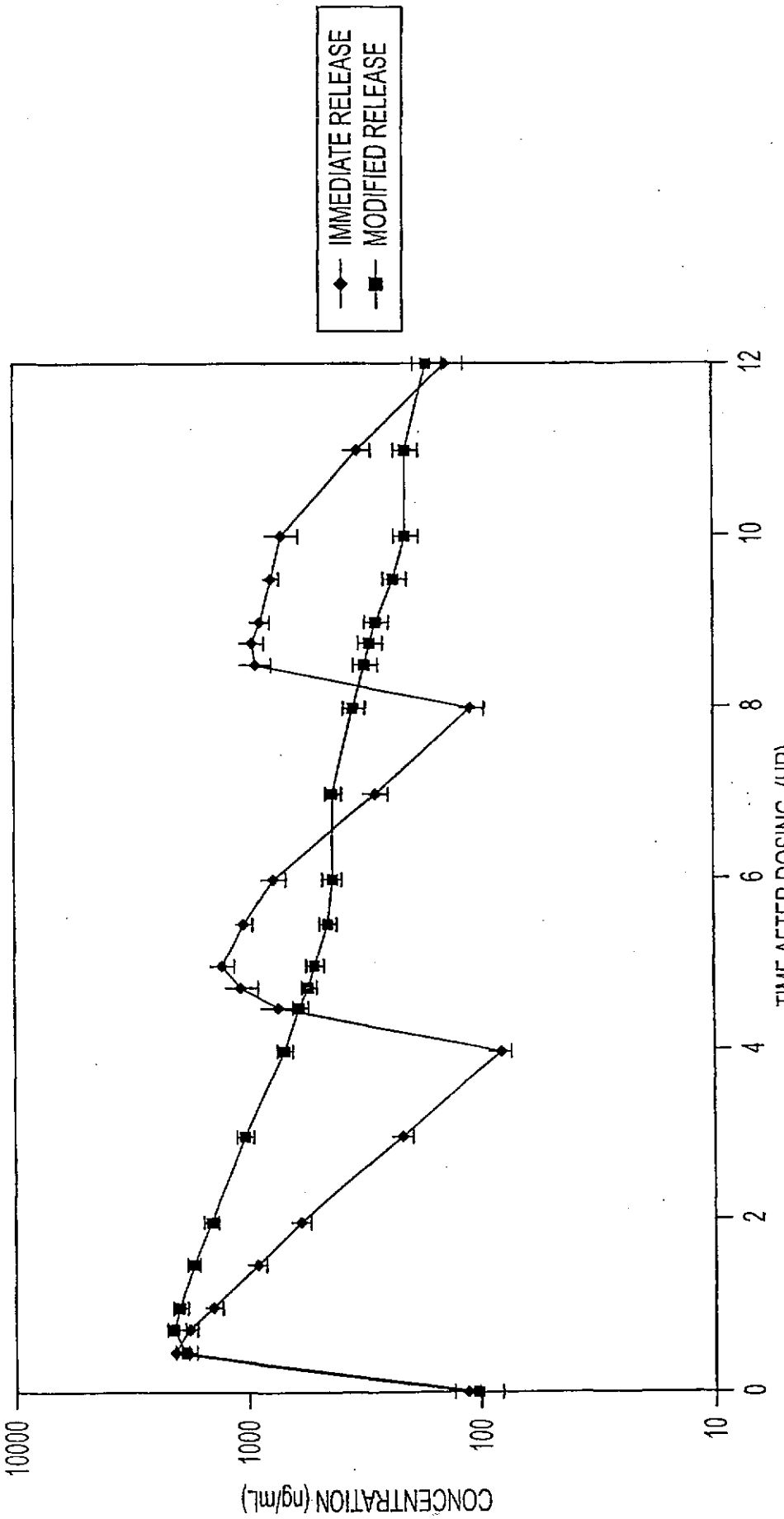

IMMEDIATE RELEASE
MODIFIED RELEASE
CONCENTRATION (ng/mL)
10000
1000
100
10
0
2
4
6
8
10
12
TIME AFTER DOSING (HR)

FIG. 9

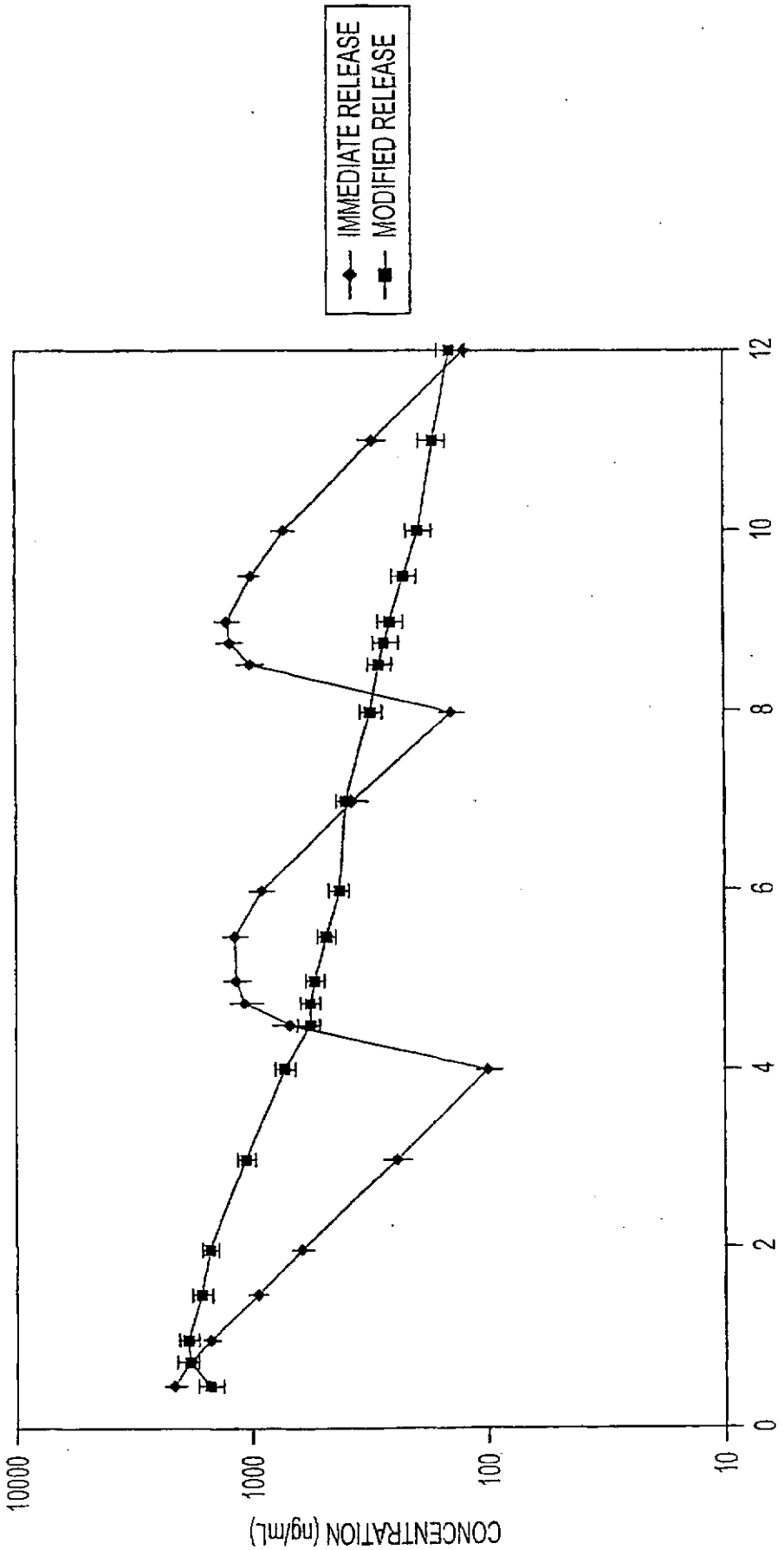

IMMEDIATE RELEASE
MODIFIED RELEASE
CONCENTRATION (ng/mL)
10000
1000
100
10
0
2
4
6
8
10
12
TIME AFTER DOSING (HR)

FIG. 10

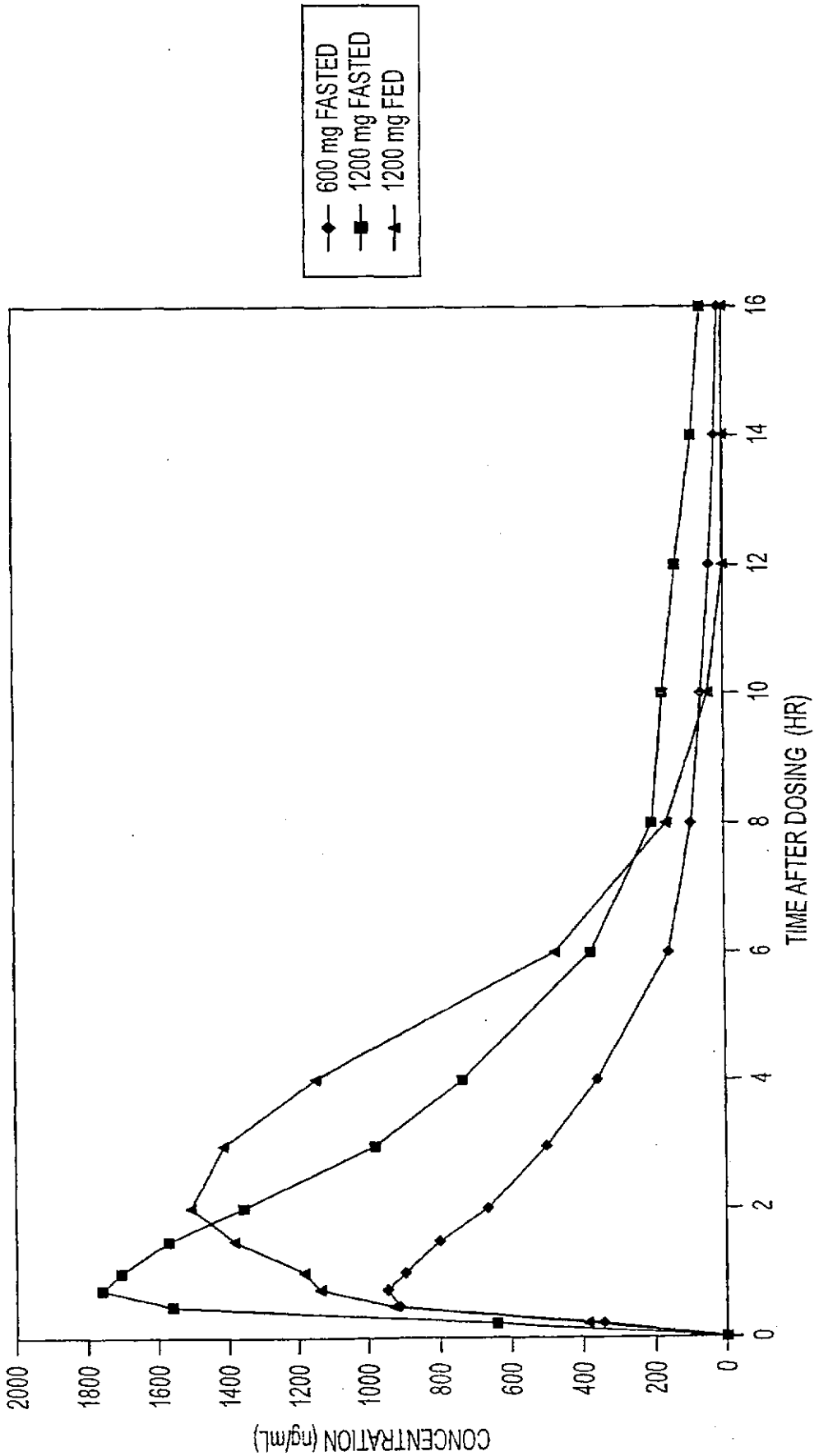

600 mg FASTED
1200 mg FASTED
1200 mg FED
CONCENTRATION (ng/mL)
2000
1800
1600
1400
1200
1000
800
600
400
200
0
0
2
4
6
8
10
12
14
16
TIME AFTER DOSING (HR)

FIG. 11