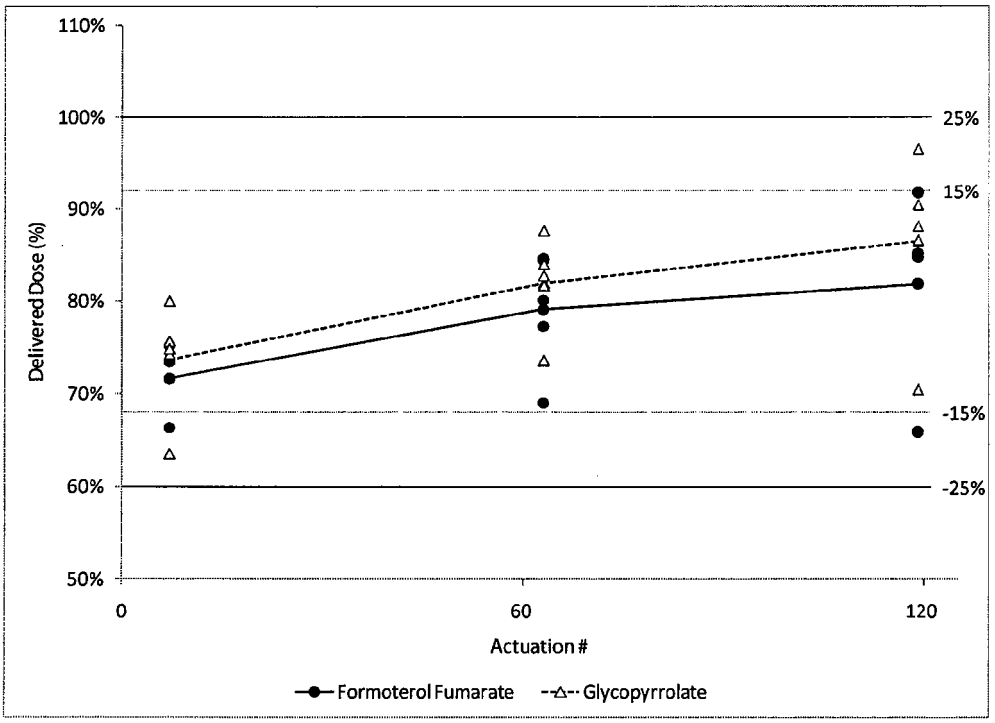

110%
100%
90%
80%
70%
60%
50%
Delivered Dose (%)
25%
15%
-15%
-25%
0
60
120
Actuation #
Formoterol Fumarate
Glycopyrrolate

FIG. 1

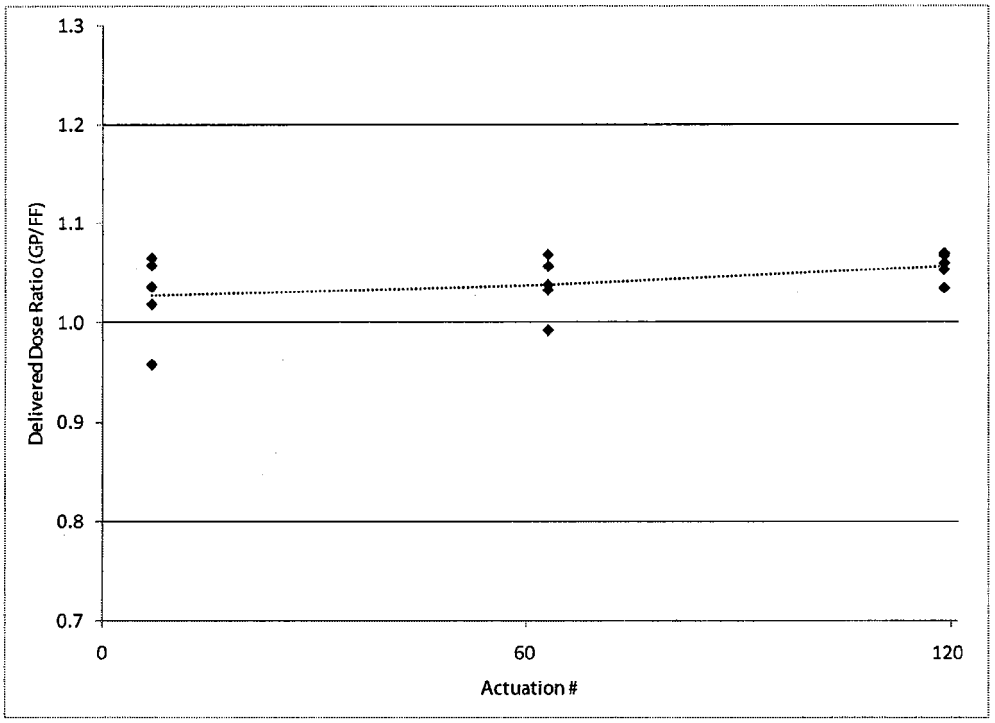

1.3
1.2
1.1
1.0
0.9
0.8
0.7
Delivered Dose Ratio (GP/FF)
0
60
120
Actuation #

FIG. 2

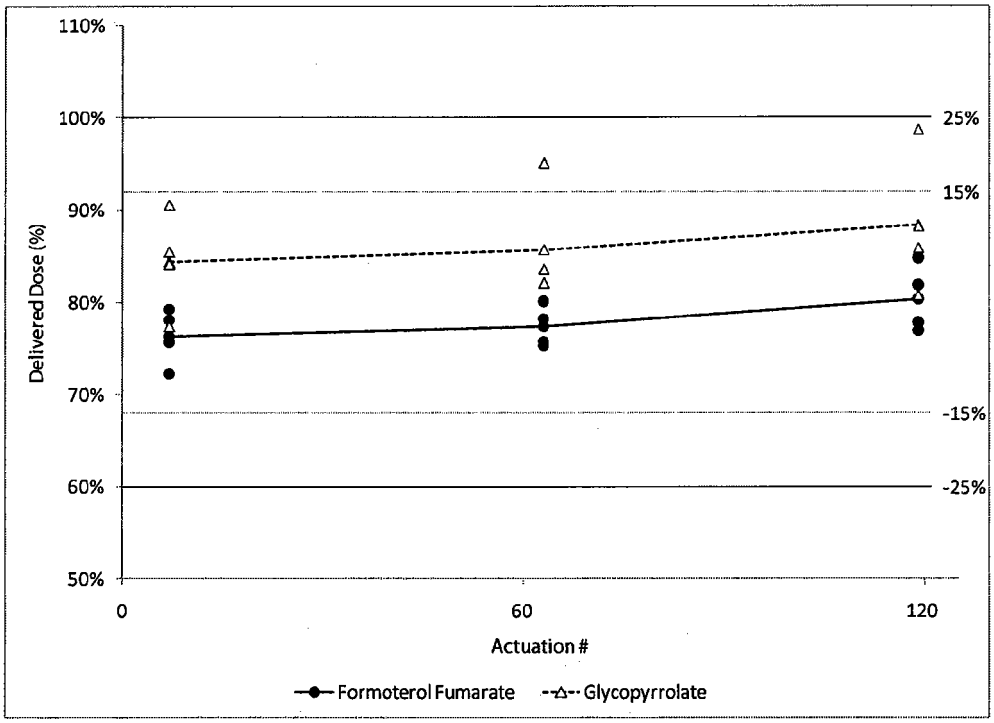

110%
100%
90%
80%
70%
60%
50%
Delivered Dose (%)
25%
15%
-15%
-25%
0
60
120
Actuation #
Formoterol Fumarate
Glycopyrrolate

FIG. 3

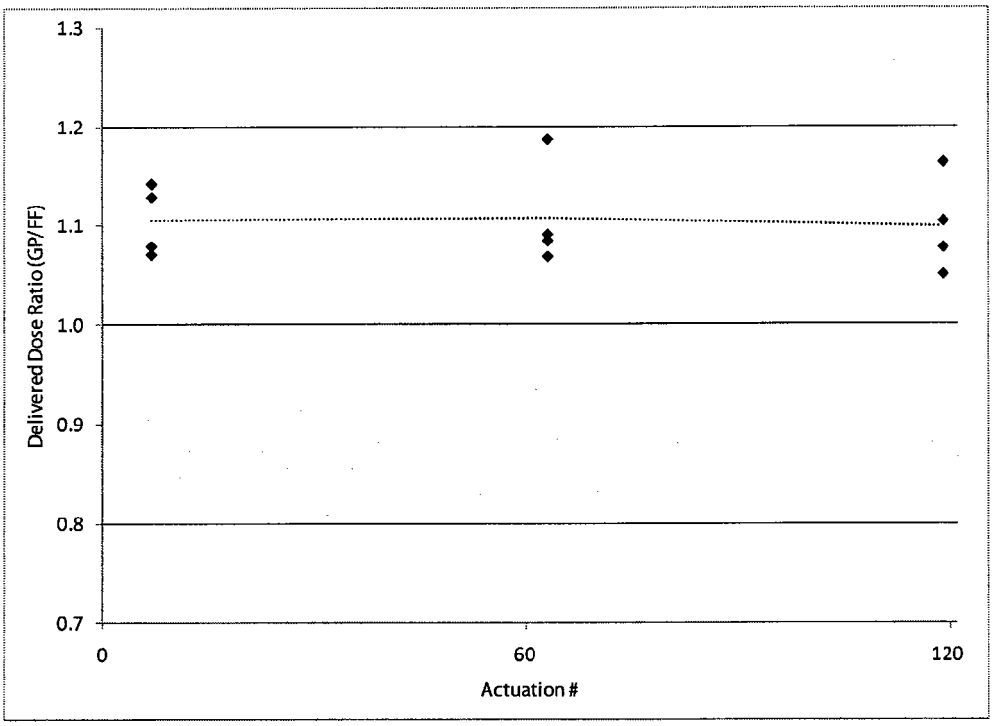

1.3
1.2
1.1
1.0
0.9
0.8
0.7
Delivered Dose Ratio (GP/FF)
0
60
120
Actuation #

FIG. 4

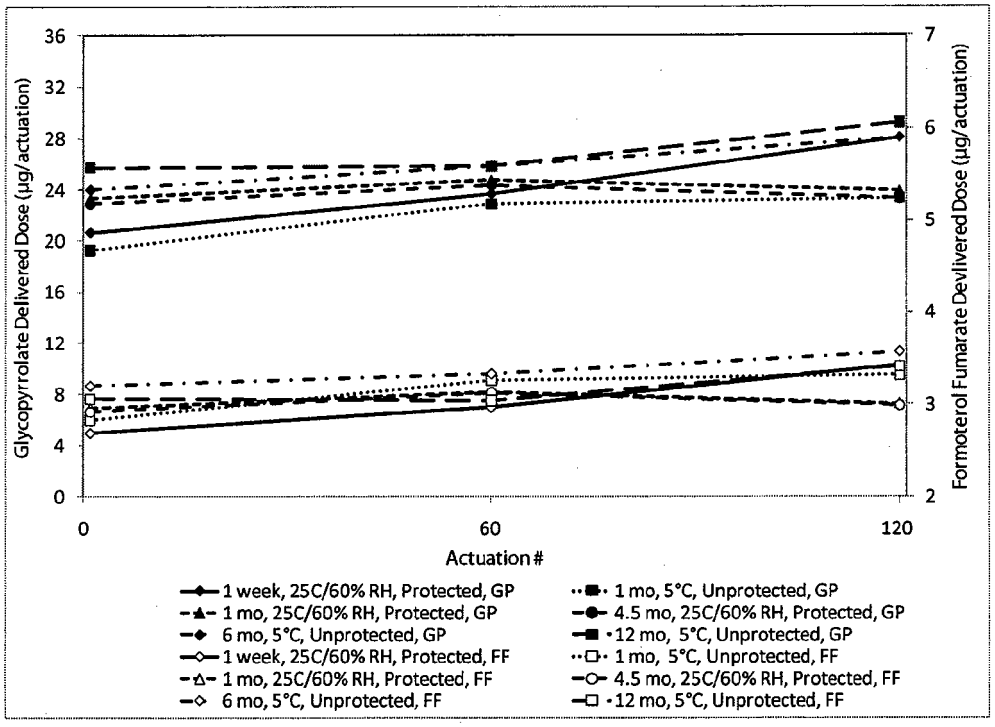

Glycopyrrolate Delivered Dose (µg/actuation)
Formoterol Fumarate Devlivered Dose (µg/actuation)
Actuation #
0
60
120
36
32
28
24
20
16
12
8
4
0
7
6
5
4
3
2
1 week, 25C/60% RH, Protected, GP
1 mo, 25C/60% RH, Protected, GP
6 mo, 5°C, Unprotected, GP
1 week, 25C/60% RH, Protected, FF
1 mo, 25C/60% RH, Protected, FF
6 mo, 5°C, Unprotected, FF
1 mo, 5°C, Unprotected, GP
4.5 mo, 25C/60% RH, Protected, GP
12 mo, 5°C, Unprotected, GP
1 mo, 5°C, Unprotected, FF
4.5 mo, 25C/60% RH, Protected, FF
12 mo, 5°C, Unprotected, FF

FIG. 5

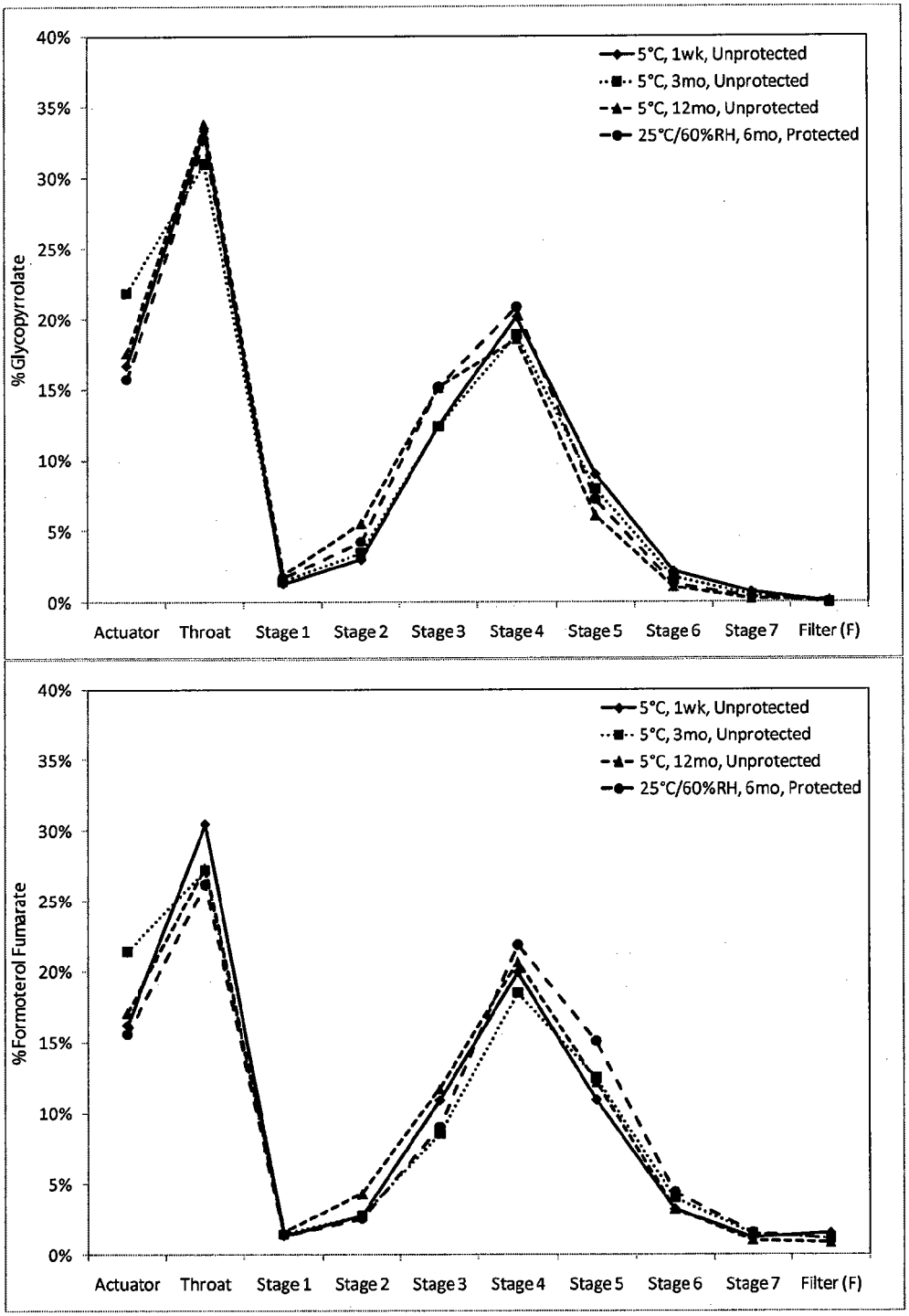

40%
35%
30%
25%
20%
15%
10%
5%
0%
% Glycopyrrolate
5°C, 1wk, Unprotected
5°C, 3mo, Unprotected
5°C, 12mo, Unprotected
25°C/60%RH, 6mo, Protected
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter (F)
% Formoterol Fumarate

FIG. 6

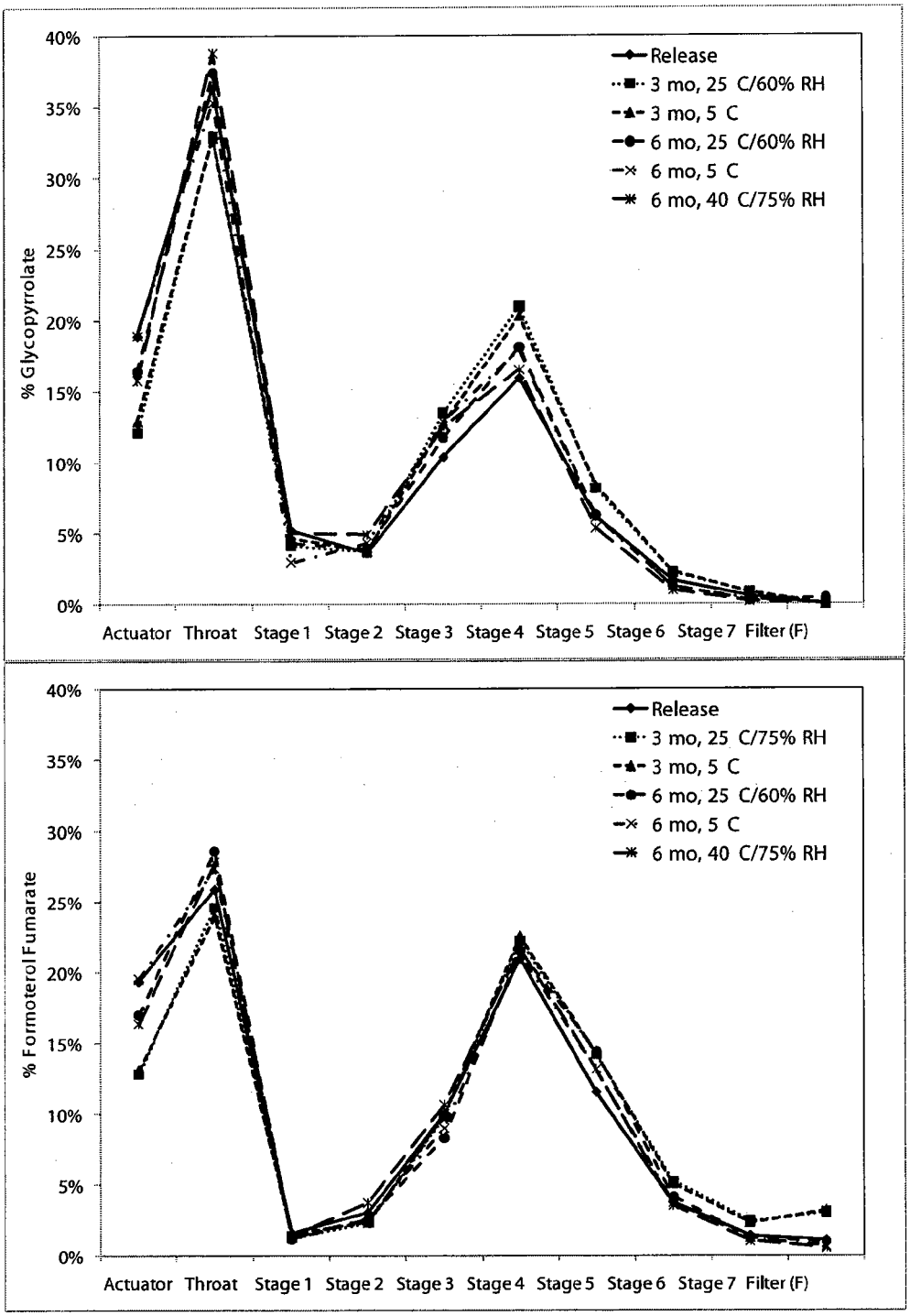

40%
35%
30%
25%
20%
15%
10%
5%
0%
% Glycopyrrolate
Release
3 mo, 25 C/60% RH
3 mo, 5 C
6 mo, 25 C/60% RH
6 mo, 5 C
6 mo, 40 C/75% RH
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter (F)
% Formoterol Fumarate
Release
3 mo, 25 C/75% RH
3 mo, 5 C
6 mo, 25 C/60% RH
6 mo, 5 C
6 mo, 40 C/75% RH

FIG. 7

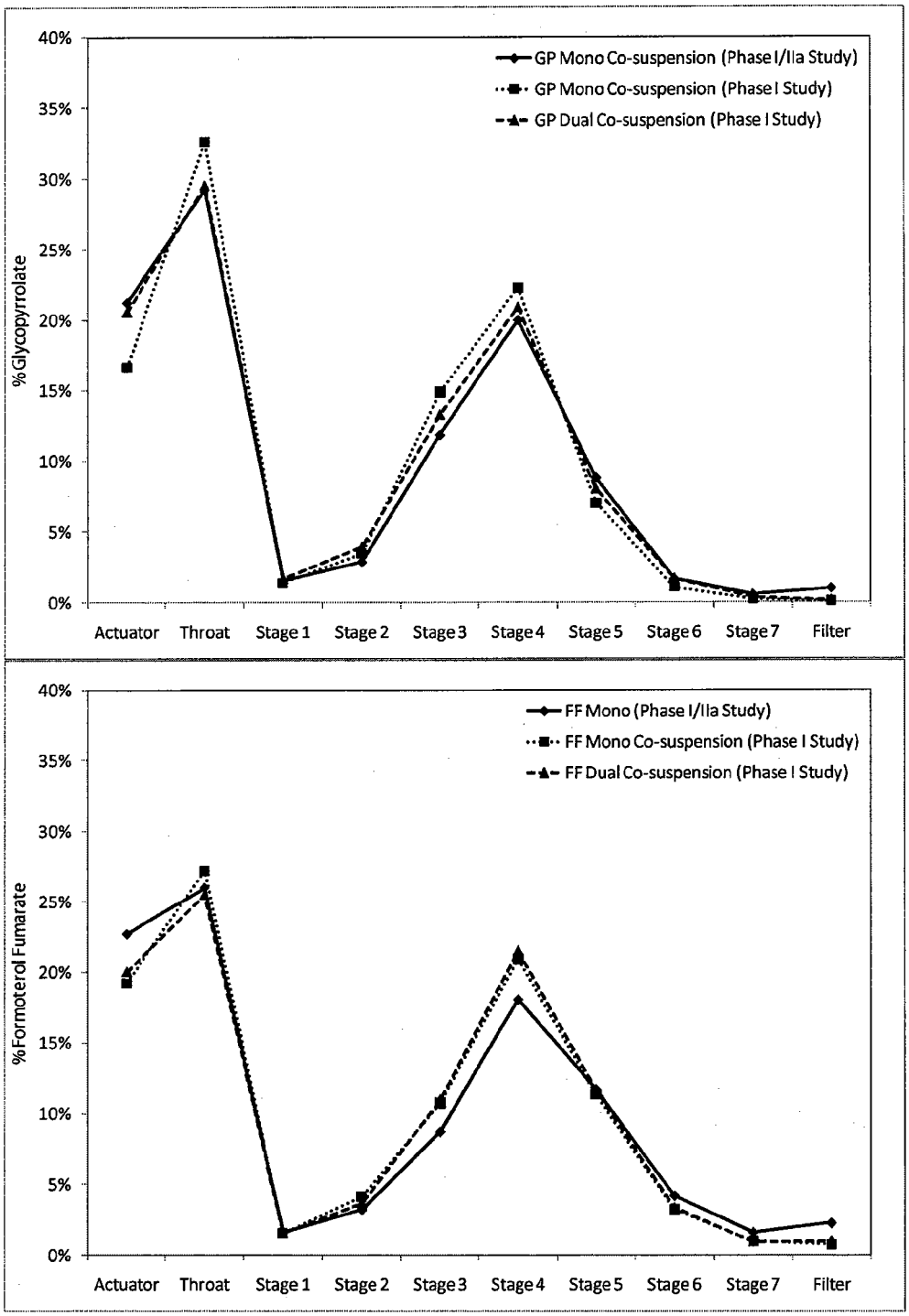

40%
35%
30%
25%
20%
15%
10%
5%
0%
% Glycopyrrolate
GP Mono Co-suspension (Phase I/IIa Study)
GP Mono Co-suspension (Phase I Study)
GP Dual Co-suspension (Phase I Study)
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter
% Formoterol Fumarate
FF Mono (Phase I/IIa Study)
FF Mono Co-suspension (Phase I Study)
FF Dual Co-suspension (Phase I Study)

FIG. 8

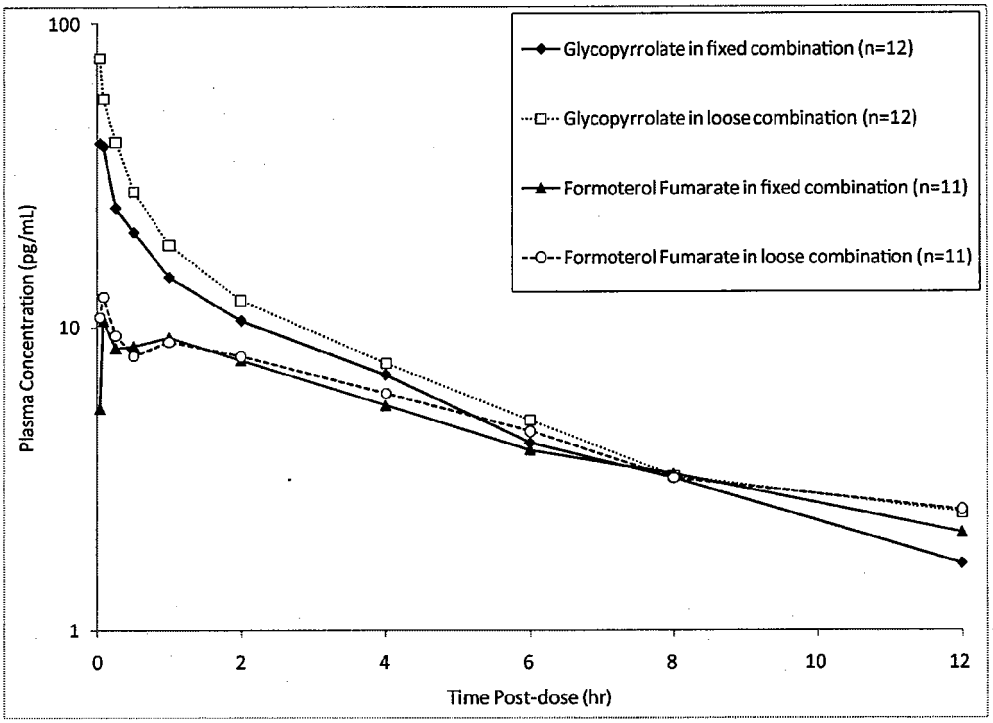

100
10
1
Plasma Concentration (pg/mL)
0
2
4
6
8
10
12
Time Post-dose (hr)
Glycopyrrolate in fixed combination (n=12)
Glycopyrrolate in loose combination (n=12)
Formoterol Fumarate in fixed combination (n=11)
Formoterol Fumarate in loose combination (n=11)

FIG. 9

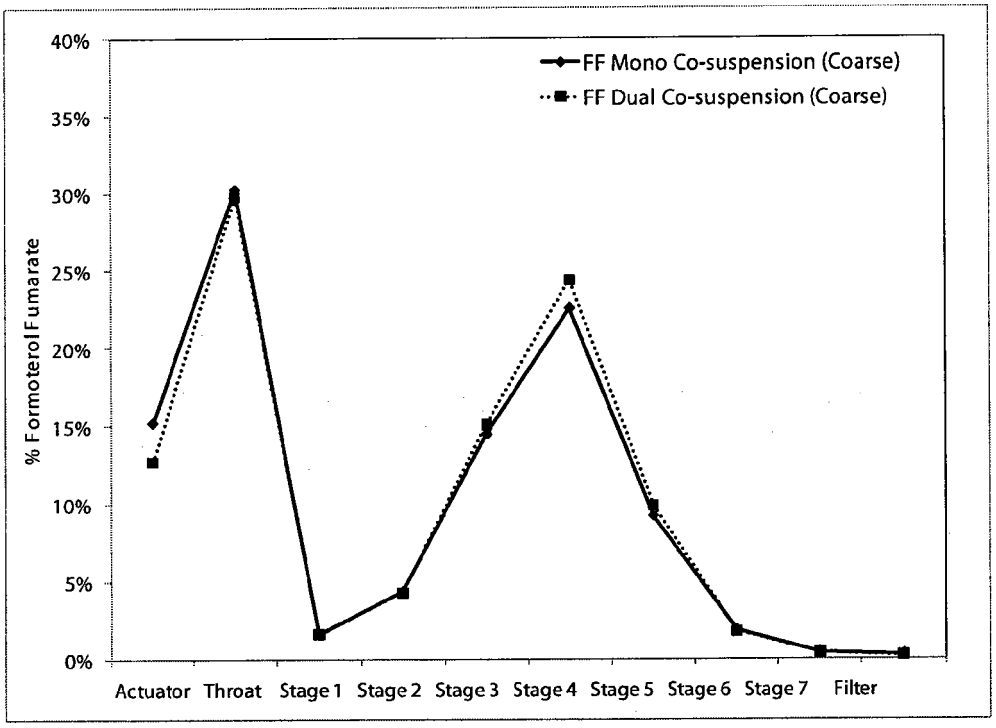

40%
35%
30%
25%
20%
15%
10%
5%
0%
% Formoterol Fumarate
FF Mono Co-suspension (Coarse)
FF Dual Co-suspension (Coarse)
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter

FIG. 10

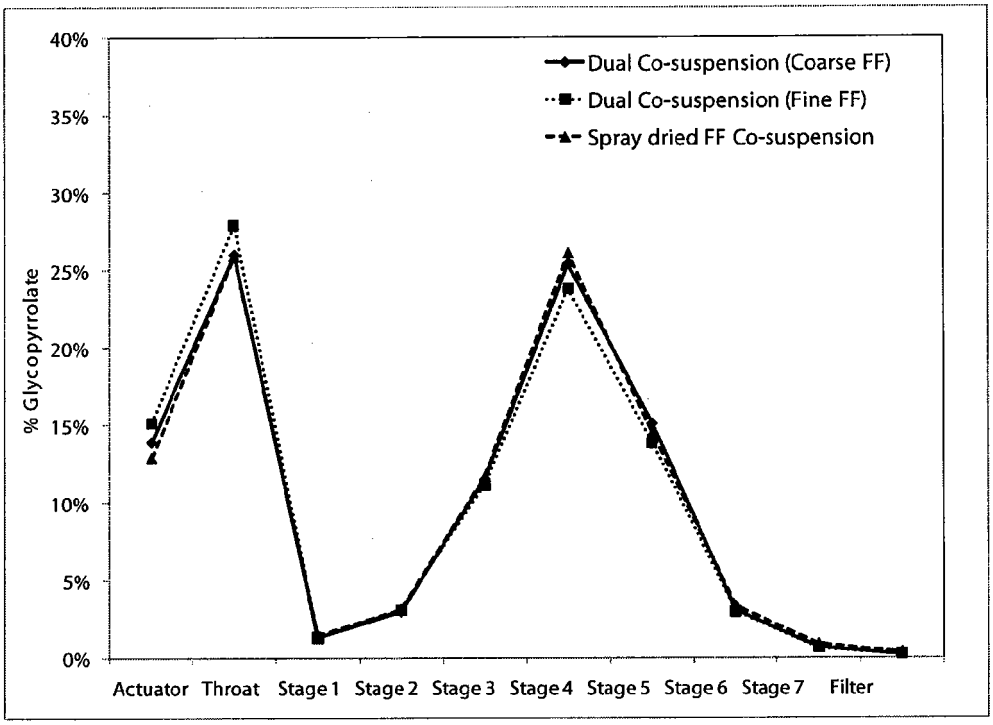

40%
35%
30%
25%
20%
15%
10%
5%
0%
% Glycopyrrolate
Dual Co-suspension (Coarse FF)
Dual Co-suspension (Fine FF)
Spray dried FF Co-suspension
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter

FIG. 11

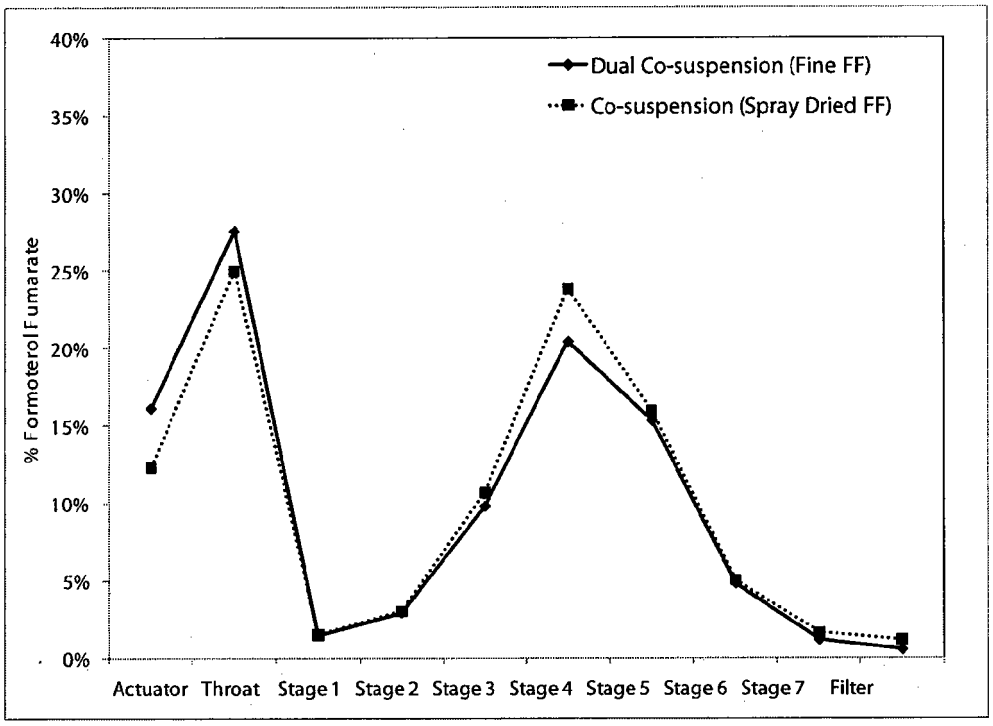

40%
35%
30%
25%
20%
15%
10%
5%
0%
% Formoterol Fumarate
Dual Co-suspension (Fine FF)
Co-suspension (Spray Dried FF)
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter

FIG. 12

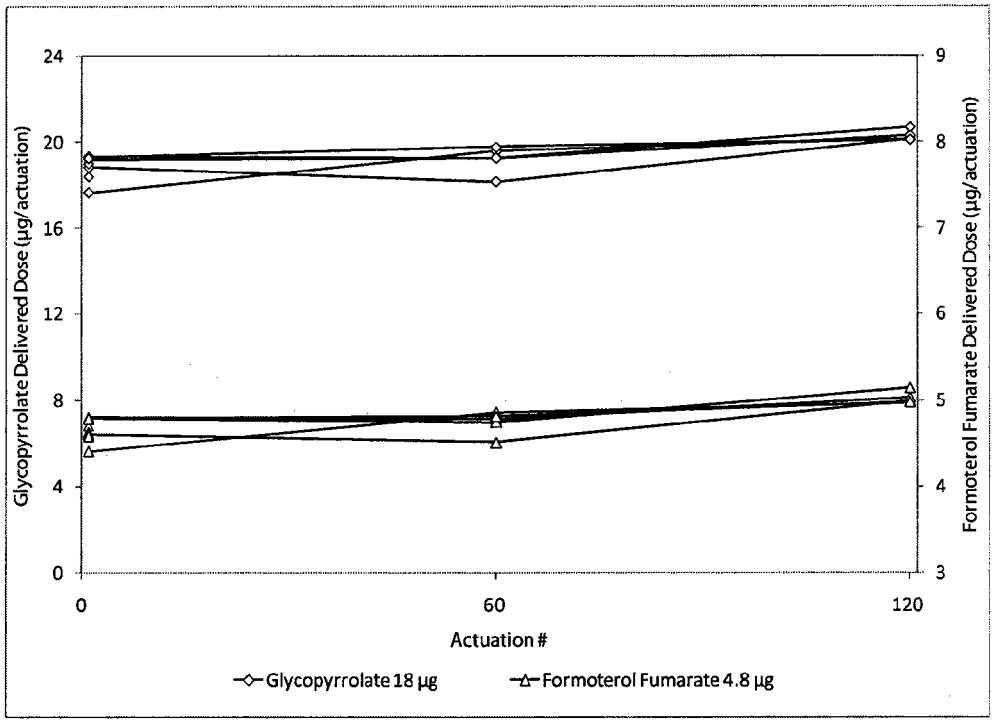

24
20
16
12
8
4
0
9
8
7
6
5
4
3
0
60
120
Actuation #
Glycopyrrolate Delivered Dose (µg/actuation)
Formoterol Fumarate Delivered Dose (µg/actuation)
Glycopyrrolate 18 µg
Formoterol Fumarate 4.8 µg

FIG. 13

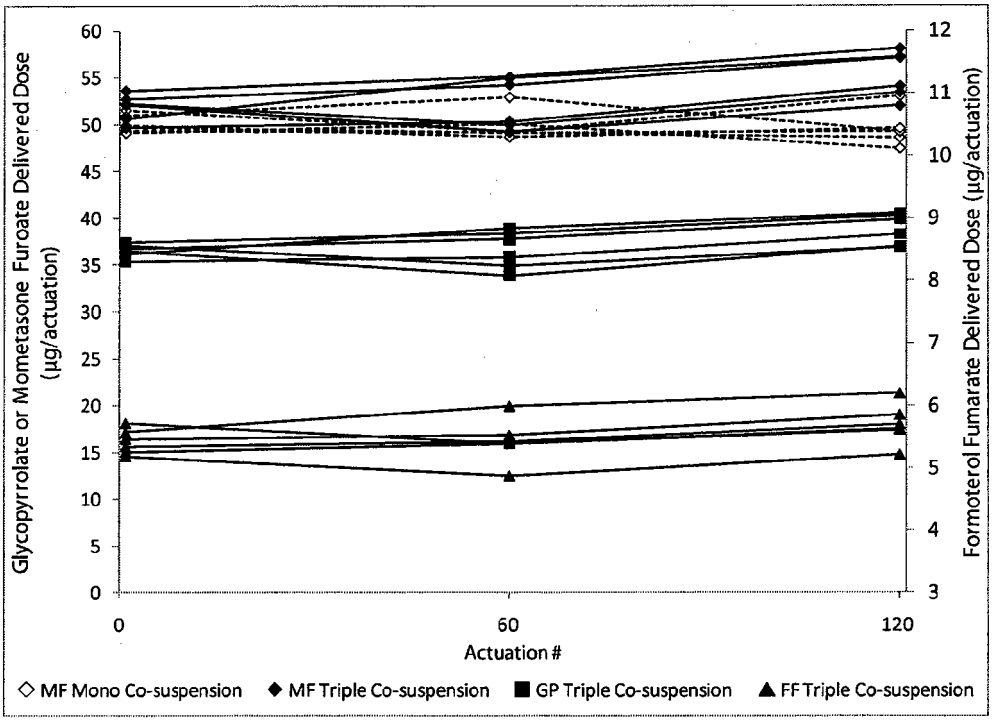

Glycopyrrolate or Mometasone Furoate Delivered Dose (µg/actuation)
Formoterol Fumarate Delivered Dose (µg/actuation)
Actuation #
0
60
120
◇ MF Mono Co-suspension
◆ MF Triple Co-suspension
■ GP Triple Co-suspension
▲ FF Triple Co-suspension

FIG. 14

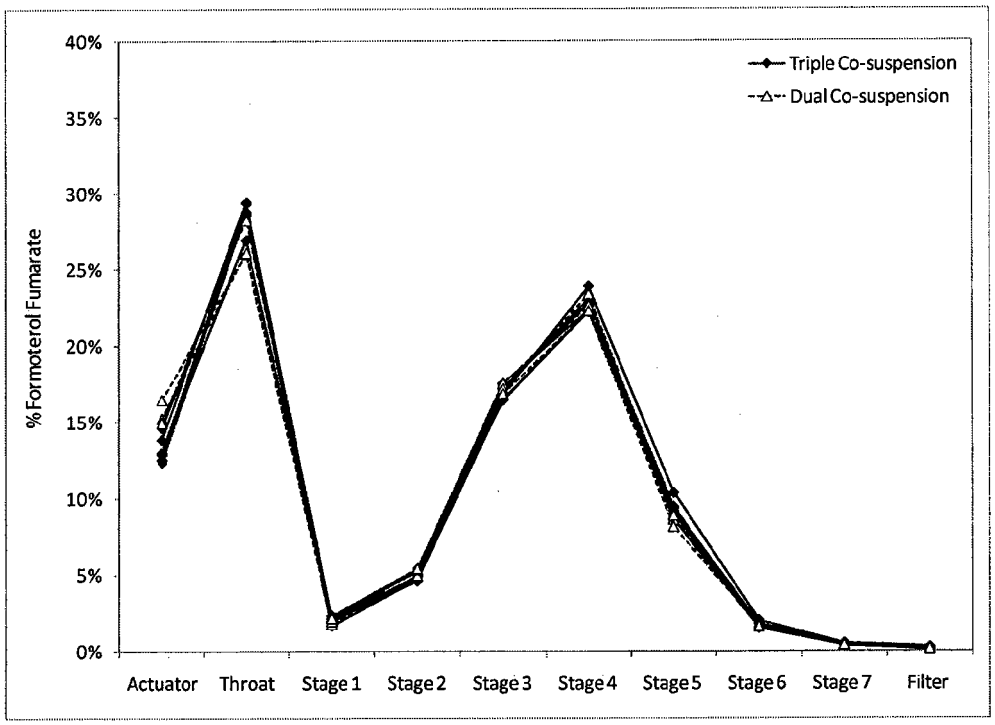

40%
35%
30%
25%
20%
15%
10%
5%
0%
% Formoterol Fumarate
Triple Co-suspension
Dual Co-suspension
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter

FIG. 15

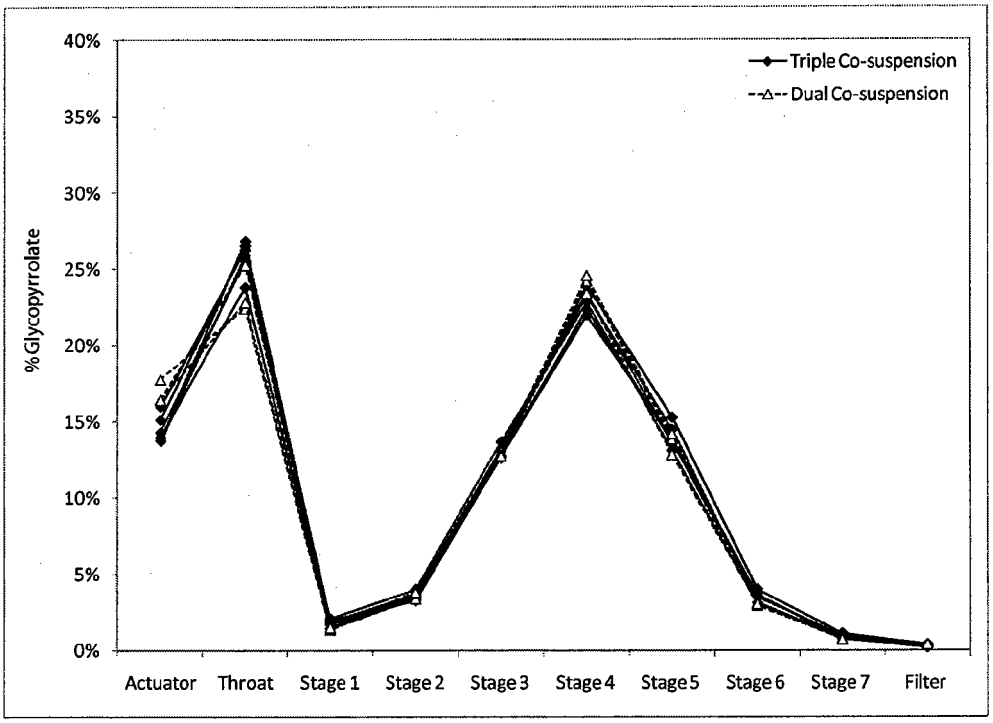

40%
35%
30%
25%
20%
15%
10%
5%
0%
% Glycopyrrolate
Triple Co-suspension
Dual Co-suspension
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter

FIG. 16

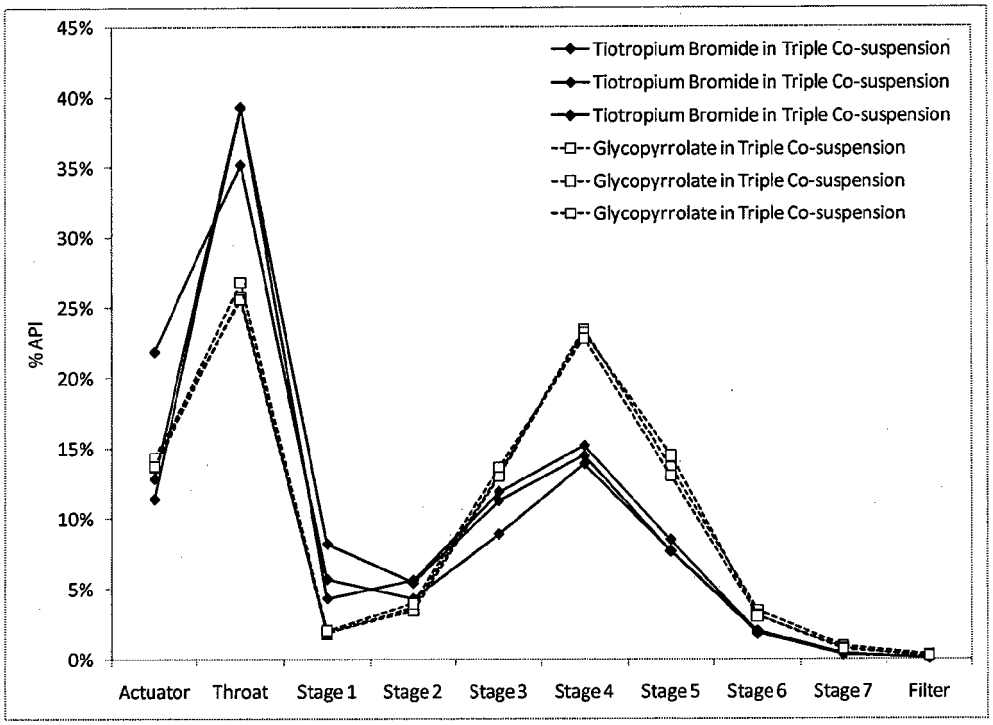

45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
% API
Tiotropium Bromide in Triple Co-suspension
Tiotropium Bromide in Triple Co-suspension
Tiotropium Bromide in Triple Co-suspension
Glycopyrrolate in Triple Co-suspension
Glycopyrrolate in Triple Co-suspension
Glycopyrrolate in Triple Co-suspension
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter

FIG. 17

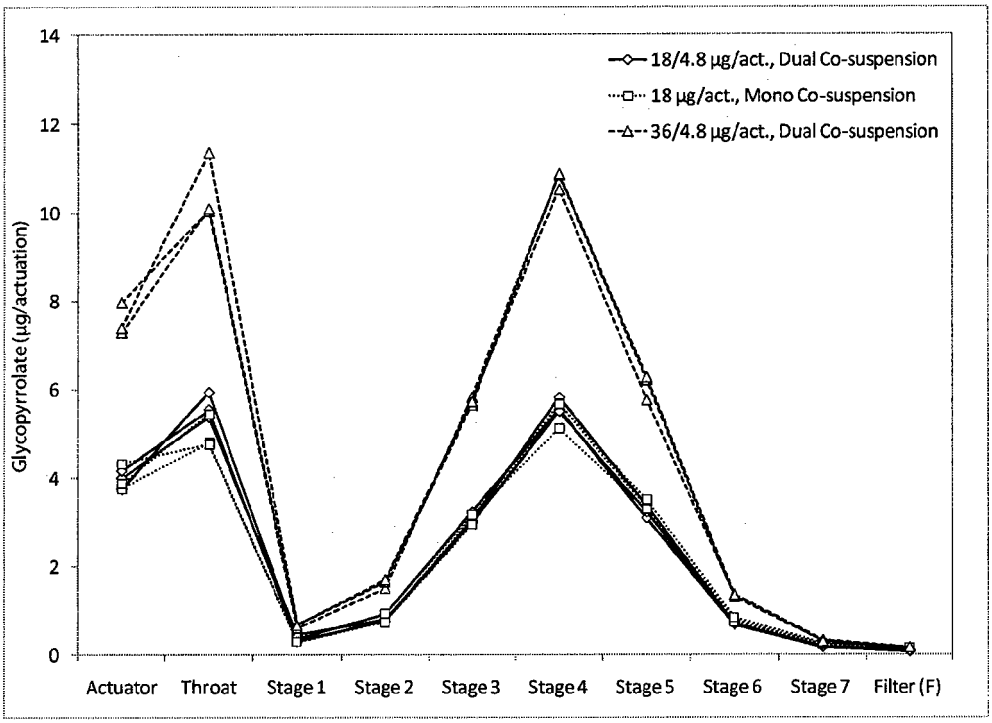

14
12
10
8
6
4
2
0
Glycopyrrolate (µg/actuation)
18/4.8 µg/act., Dual Co-suspension
18 µg/act., Mono Co-suspension
36/4.8 µg/act., Dual Co-suspension
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter (F)

FIG. 18

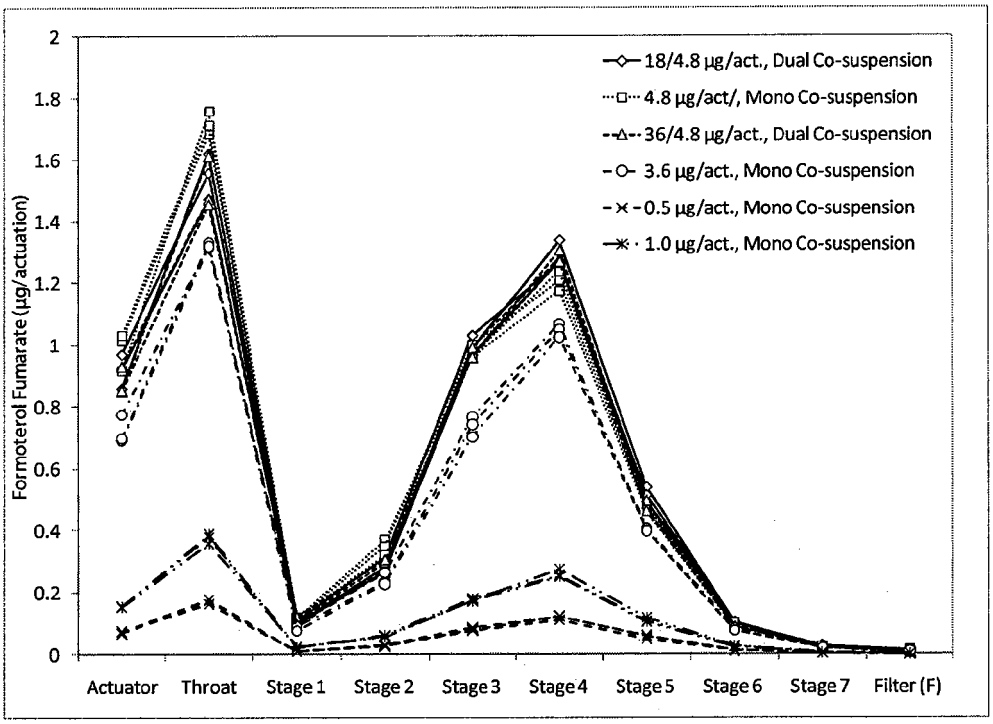

Formoterol Fumarate (µg/actuation)
2
1.8
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
Actuator
Throat
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Filter (F)
18/4.8 µg/act., Dual Co-suspension
4.8 µg/act/, Mono Co-suspension
36/4.8 µg/act., Dual Co-suspension
3.6 µg/act., Mono Co-suspension
0.5 µg/act., Mono Co-suspension
1.0 µg/act., Mono Co-suspension

FIG. 19

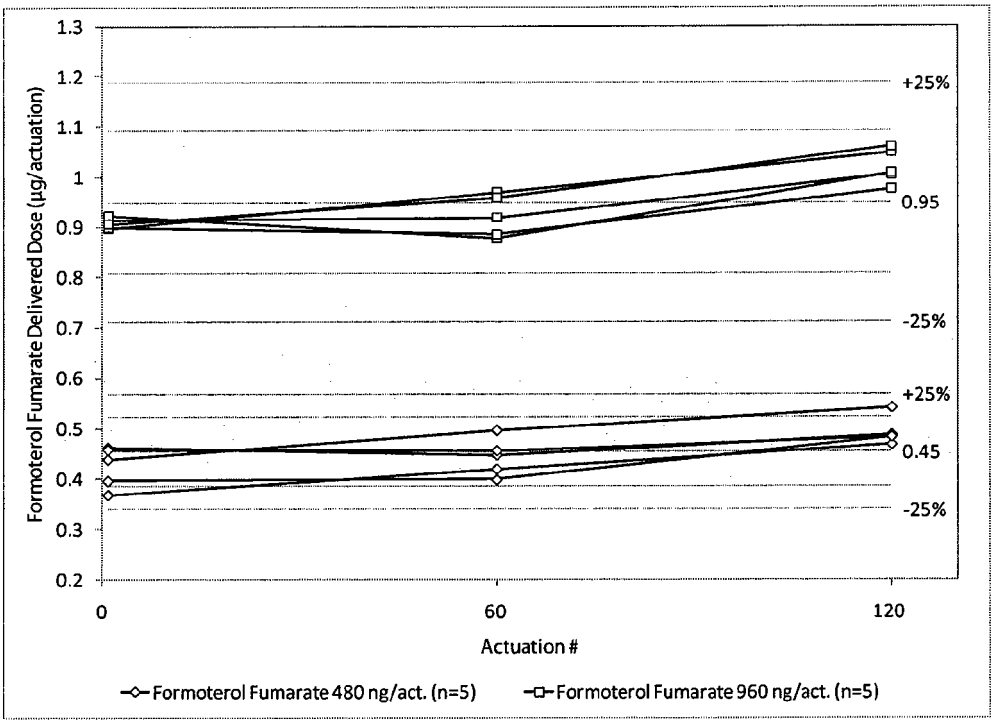

1.3
1.2
1.1
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
Formoterol Fumarate Delivered Dose (µg/actuation)
+25%
0.95
-25%
+25%
0.45
-25%
0
60
120
Actuation #
Formoterol Fumarate 480 ng/act. (n=5)
Formoterol Fumarate 960 ng/act. (n=5)

FIG 20

FIG. 21

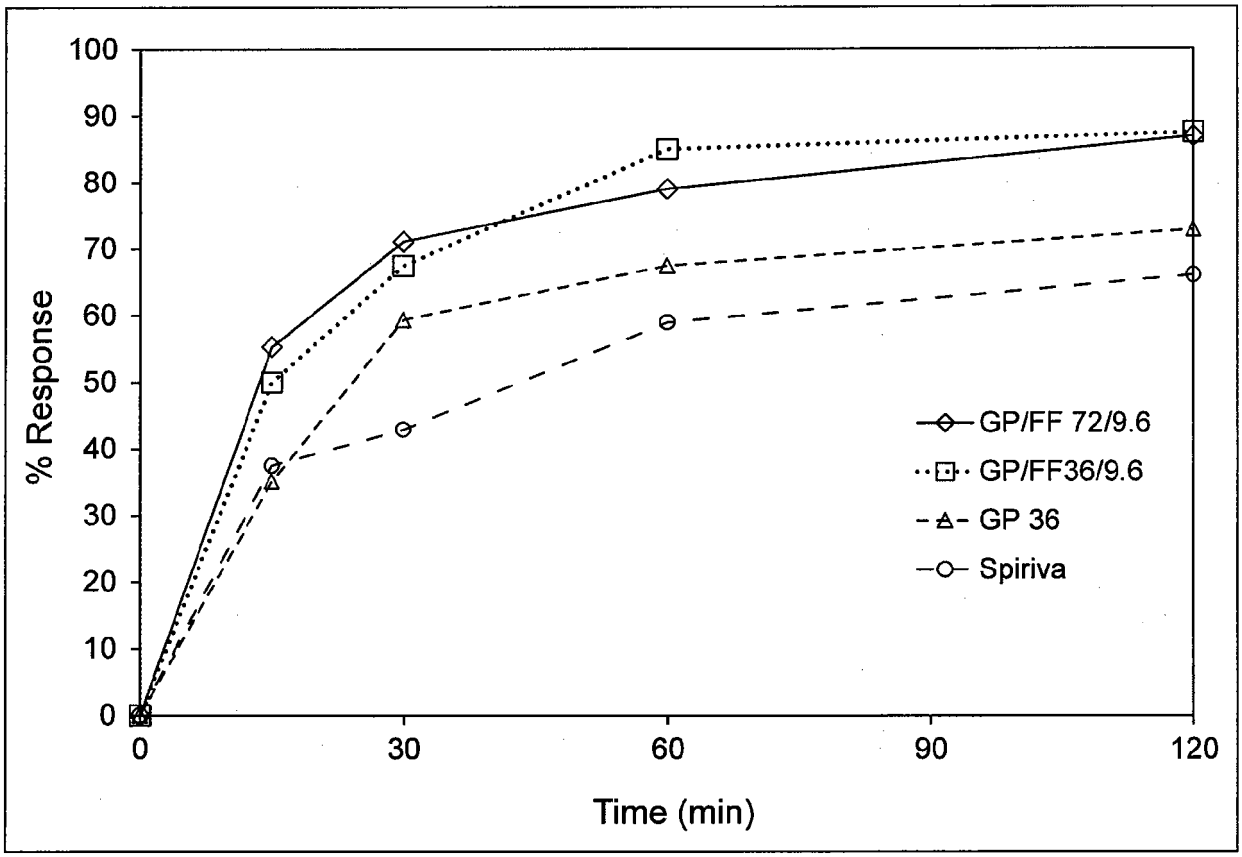

100
90
80
70
60
50
40
30
20
10
0
% Response
0
30
60
90
120
Time (min)
GP/FF 72/9.6
GP/FF36/9.6
GP 36
Spiriva

FIG. 22

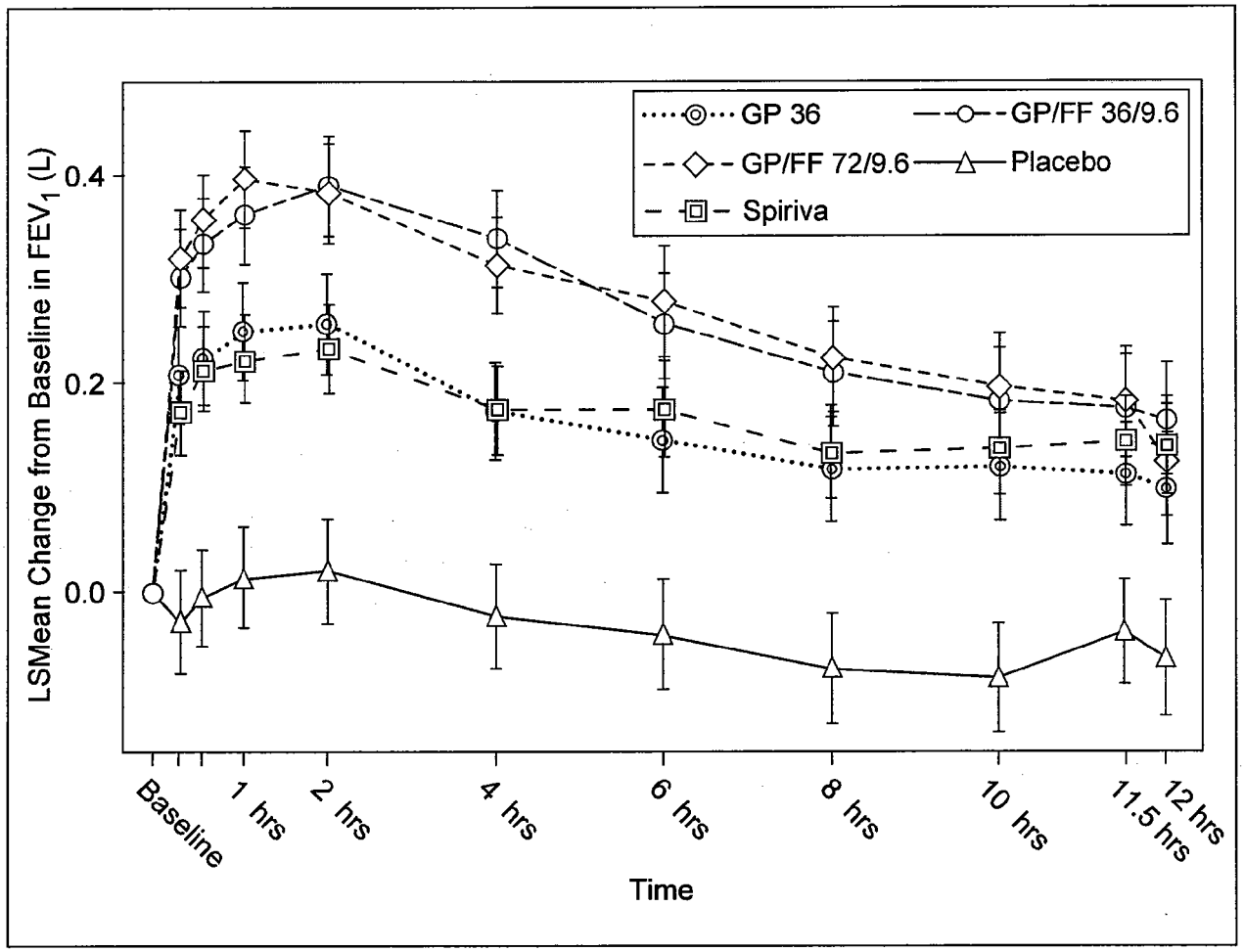

GP 36
GP/FF 36/9.6
GP/FF 72/9.6
Placebo
Spiriva
LSMean Change from Baseline in FEV1 (L)
0.4
0.2
0.0
Baseline
1 hrs
2 hrs
4 hrs
6 hrs
8 hrs
10 hrs
11.5 hrs
12 hrs
Time

FIG. 23

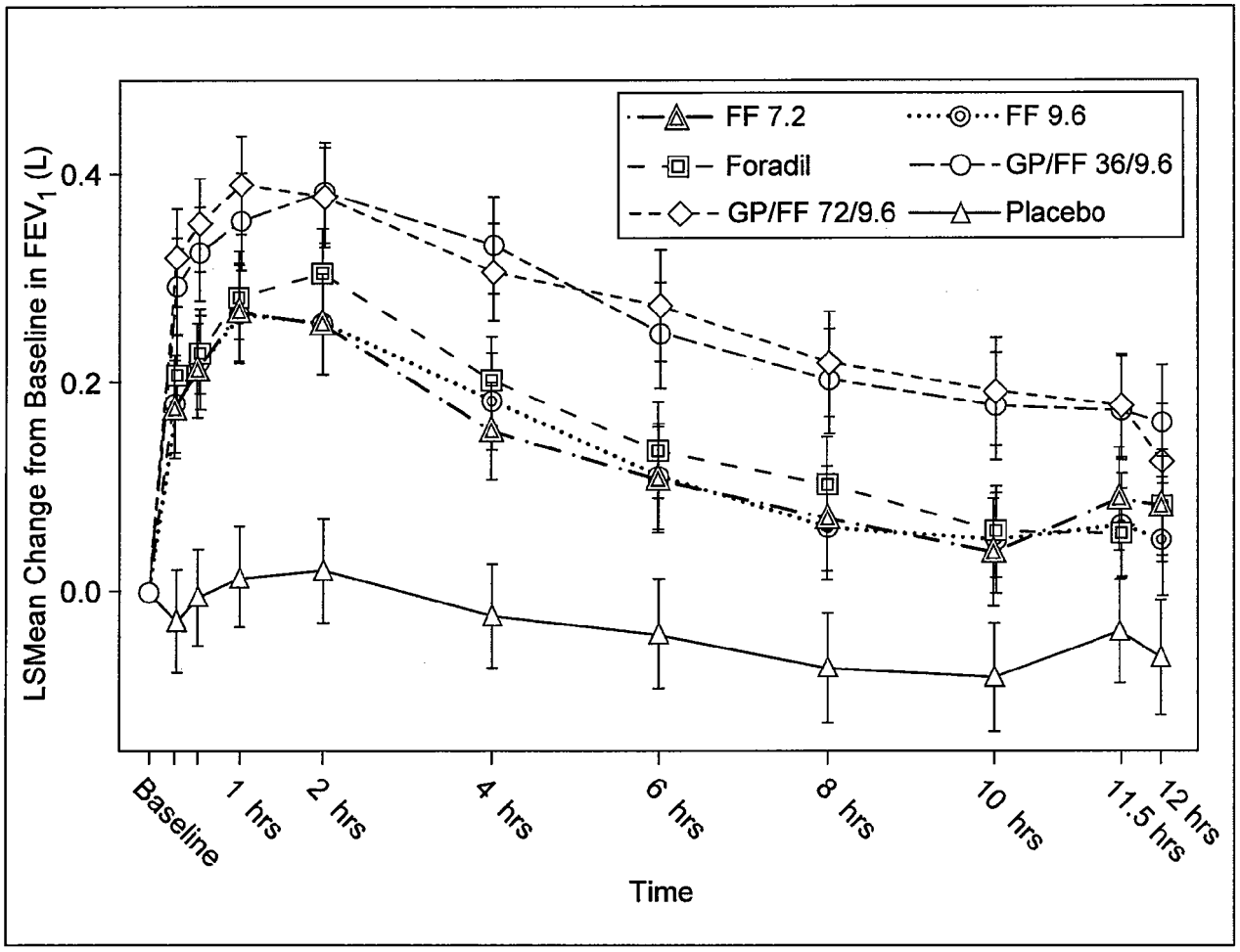

FF 7.2
FF 9.6
Foradil
GP/FF 36/9.6
GP/FF 72/9.6
Placebo
LSMean Change from Baseline in FEV1 (L)
0.4
0.2
0.0
Baseline
1 hrs
2 hrs
4 hrs
6 hrs
8 hrs
10 hrs
11.5 hrs
12 hrs
Time

FIG. 24

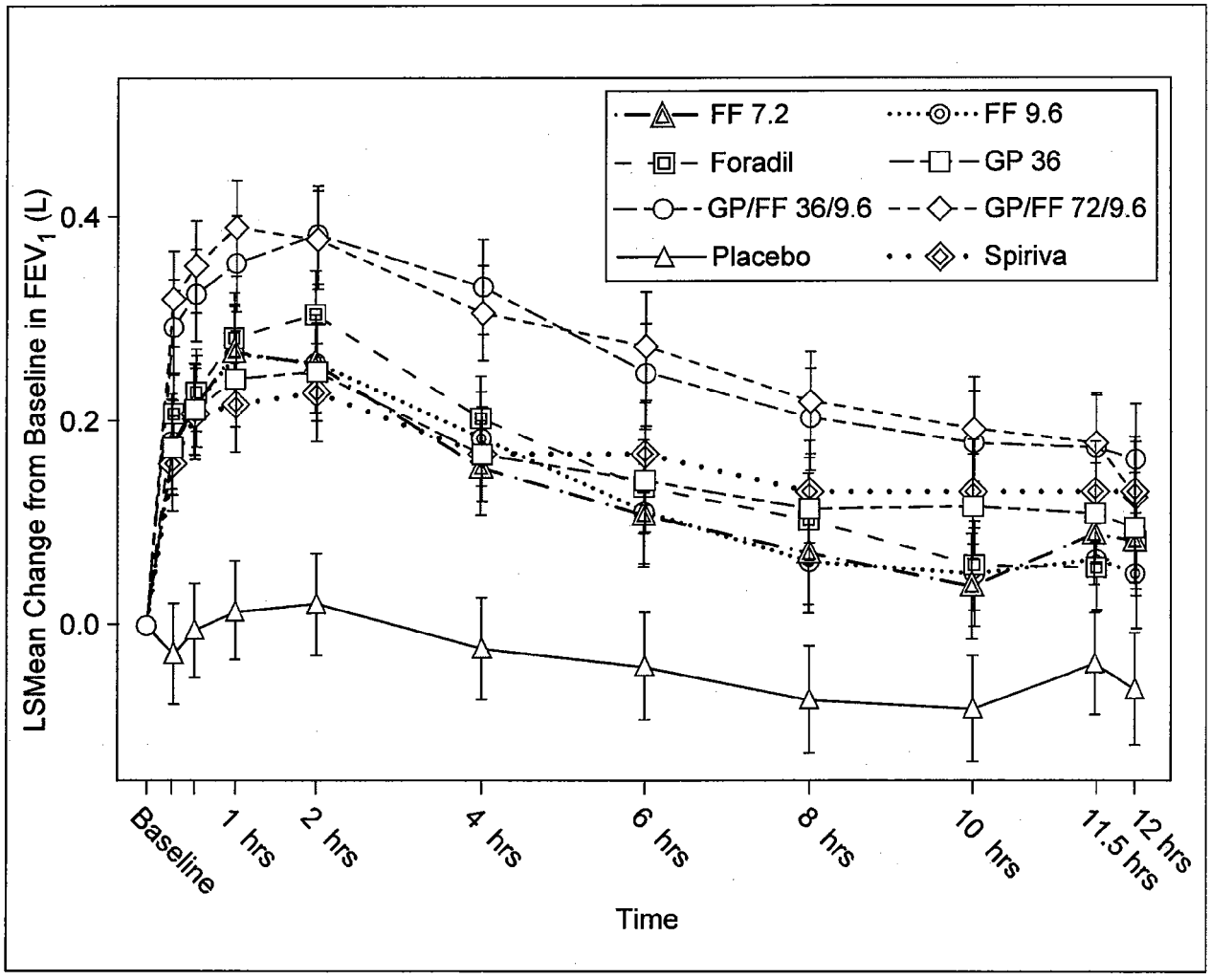

FF 7.2
FF 9.6
Foradil
GP 36
GP/FF 36/9.6
GP/FF 72/9.6
Placebo
Spiriva
LSMean Change from Baseline in FEV1 (L)
0.4
0.2
0.0
Baseline
1 hrs
2 hrs
4 hrs
6 hrs
8 hrs
10 hrs
11.5 hrs
12 hrs
Time

FIG. 25

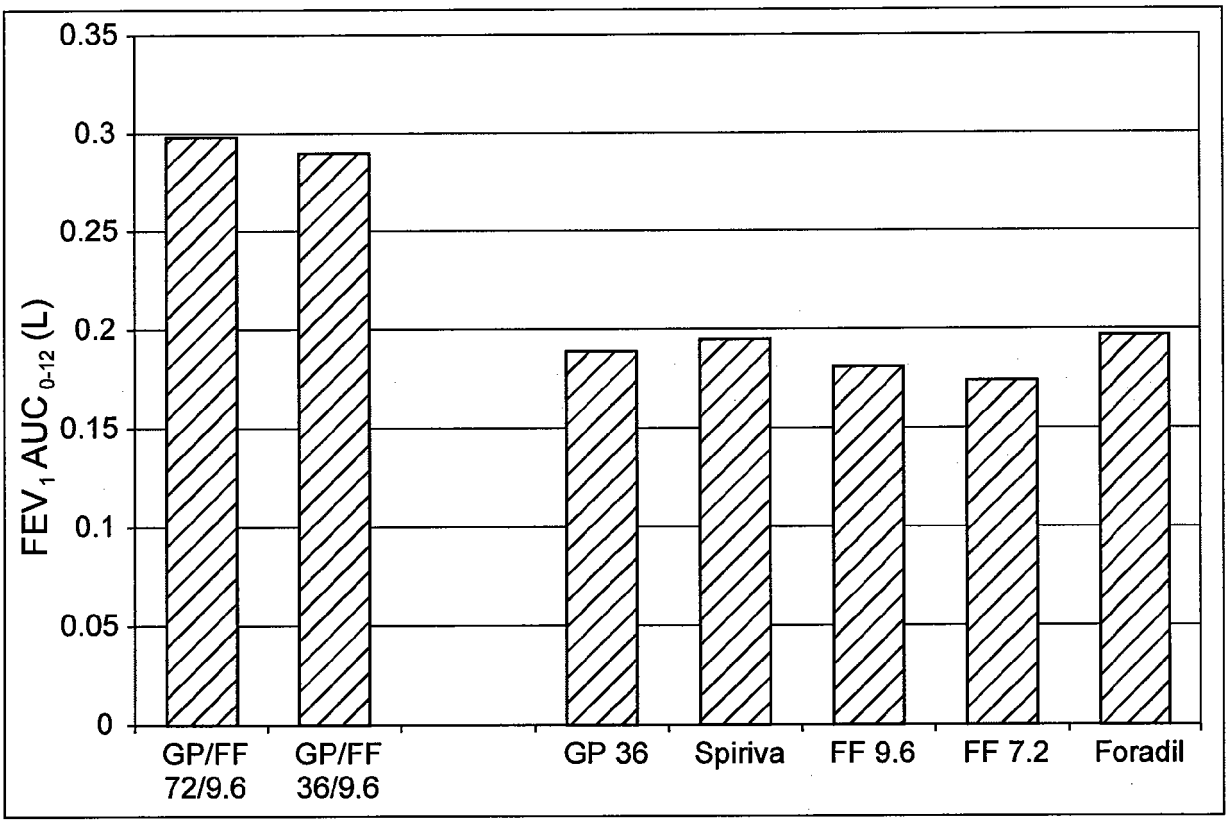

0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
FEV1 AUC0-12 (L)
GP/FF 72/9.6
GP/FF 36/9.6
GP 36
Spiriva
FF 9.6
FF 7.2
Foradil

FIG. 26

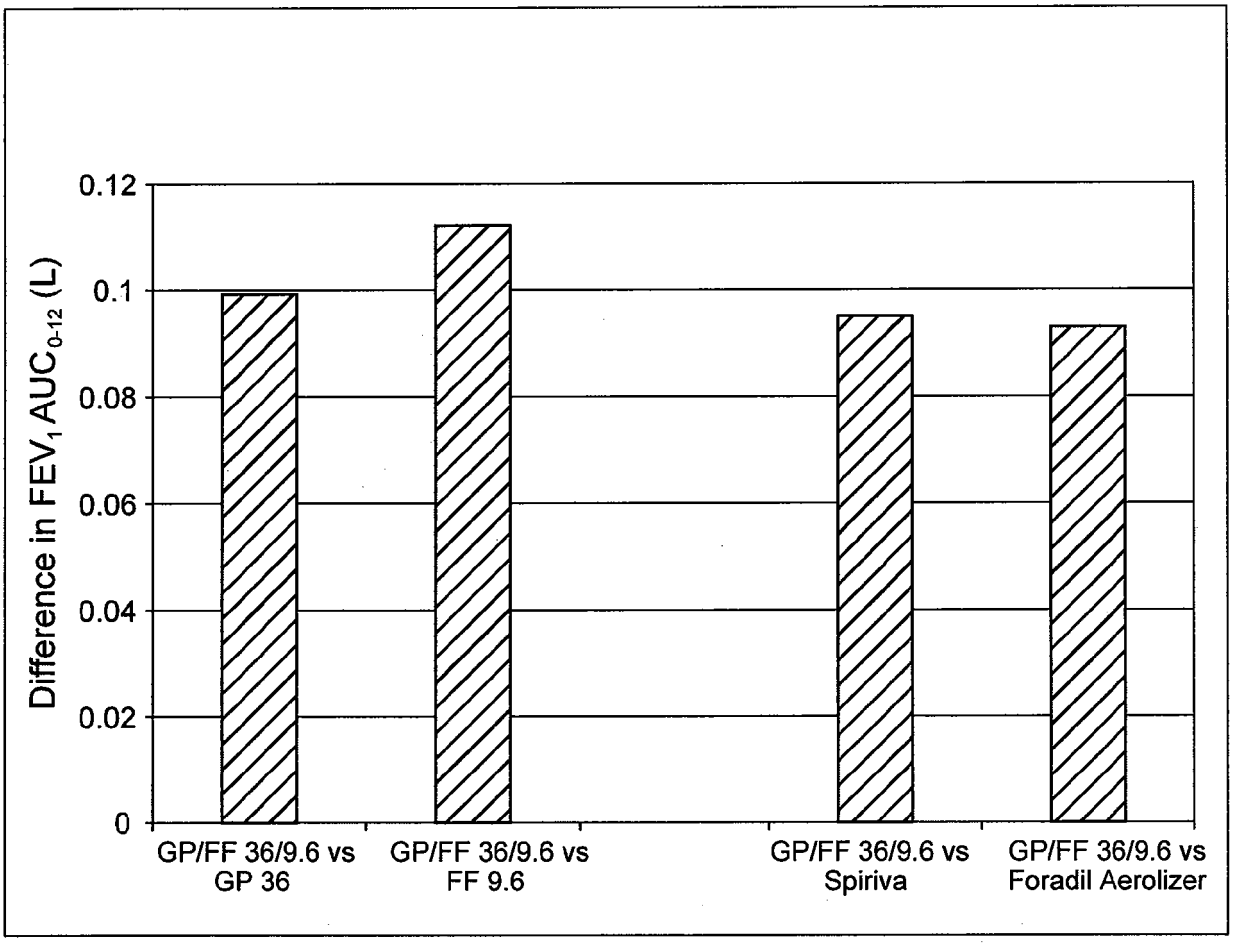

0.12
0.1
0.08
0.06
0.04
0.02
0
Difference in FEV1 AUC0-12 (L)
GP/FF 36/9.6 vs GP 36
GP/FF 36/9.6 vs FF 9.6
GP/FF 36/9.6 vs Spiriva
GP/FF 36/9.6 vs Foradil Aerolizer

FIG. 27

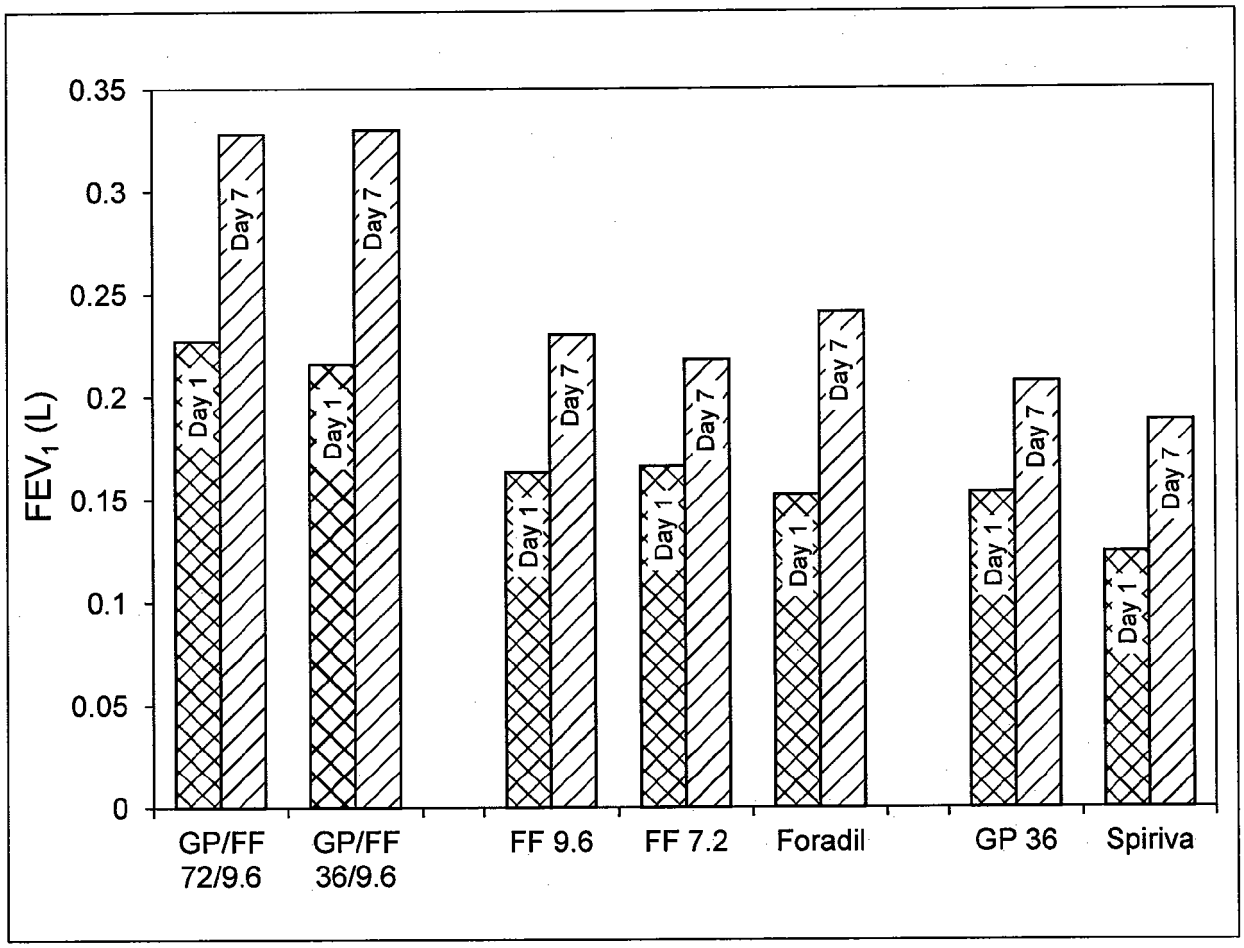

0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
FEV1 (L)
Day 1
Day 7
GP/FF 72/9.6
GP/FF 36/9.6
FF 9.6
FF 7.2
Foradil
GP 36
Spiriva

FIG. 28

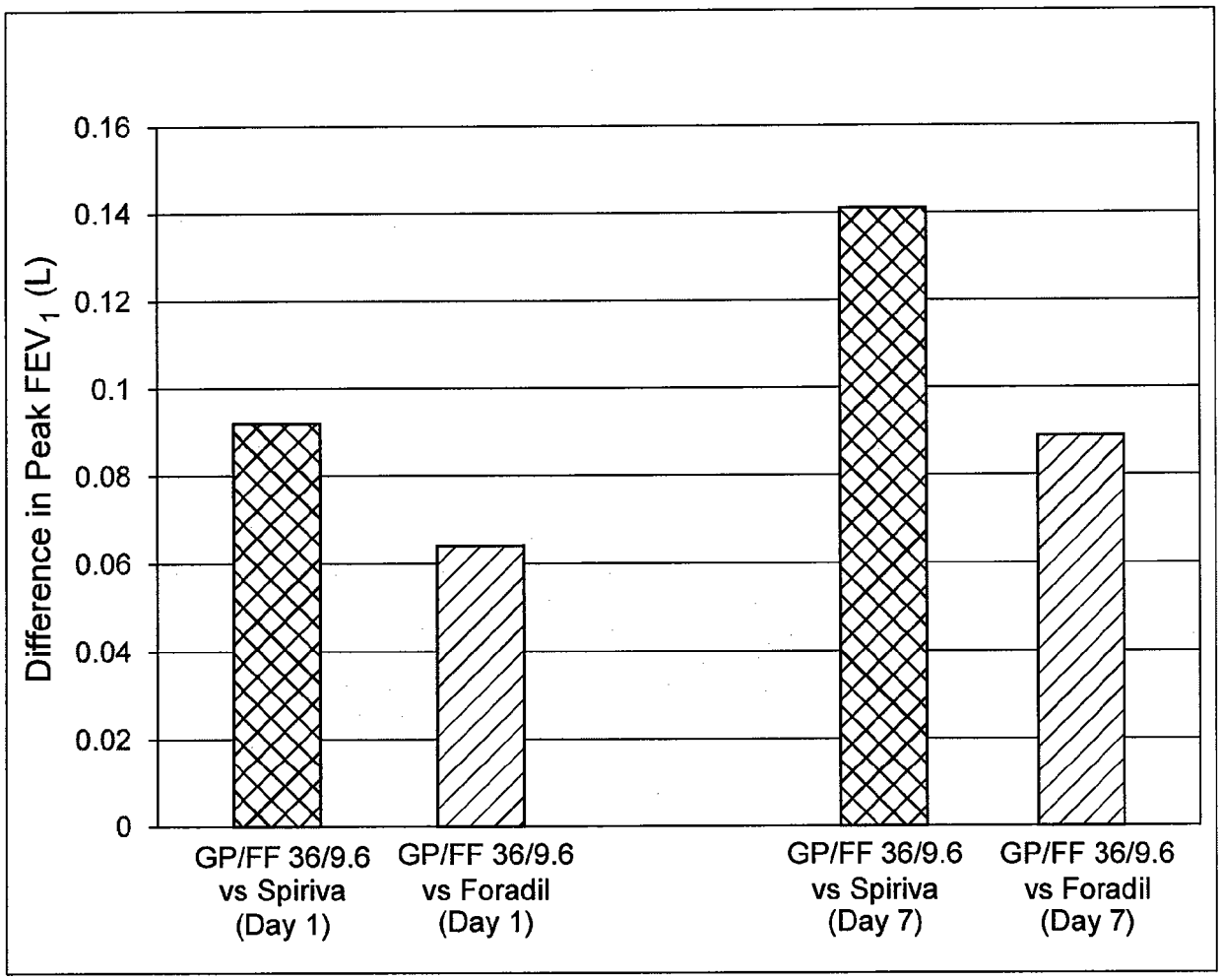

0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
Difference in Peak FEV1 (L)
GP/FF 36/9.6 vs Spiriva (Day 1)
GP/FF 36/9.6 vs Foradil (Day 1)
GP/FF 36/9.6 vs Spiriva (Day 7)
GP/FF 36/9.6 vs Foradil (Day 7)

FIG. 29

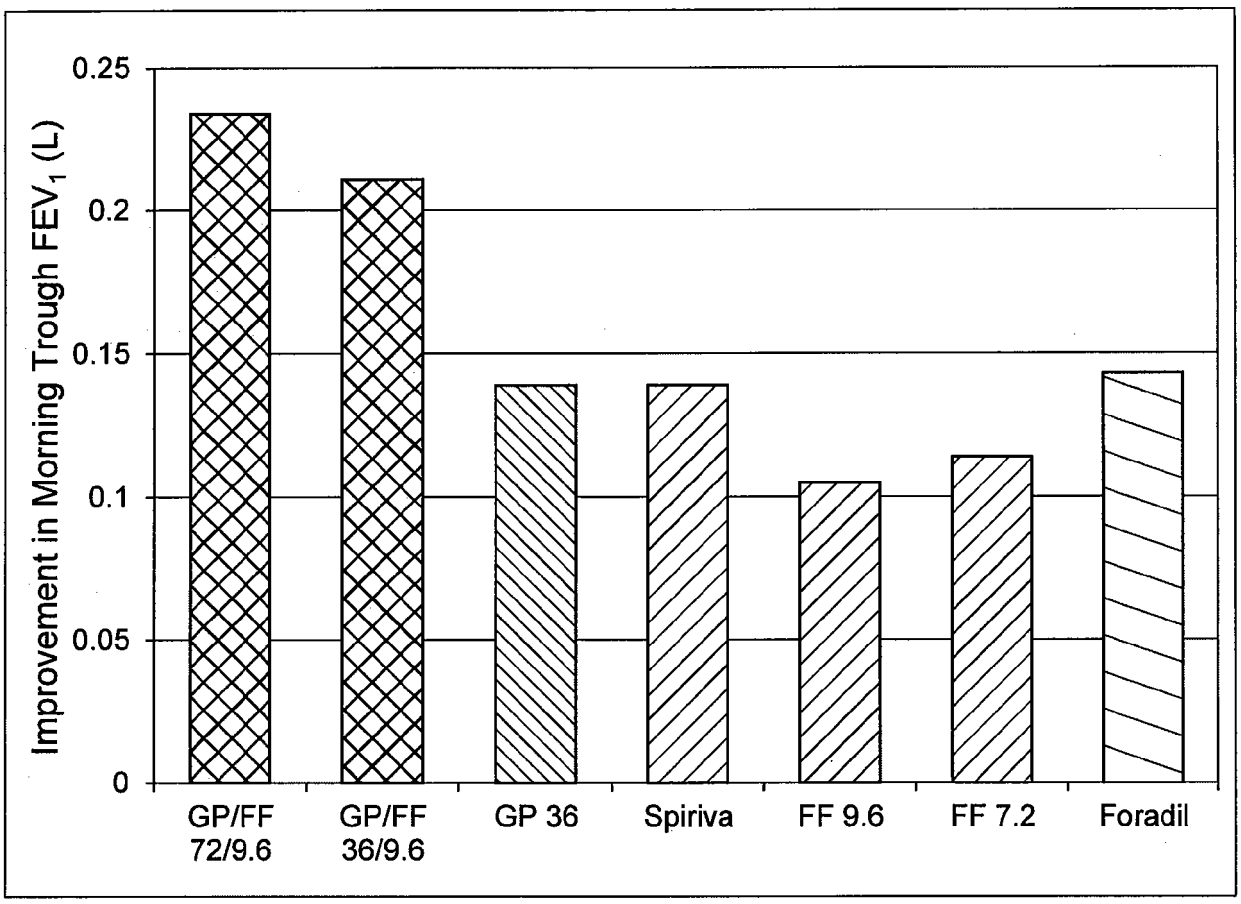

0.25
0.2
0.15
0.1
0.05
0
Improvement in Morning Trough FEV1 (L)
GP/FF 72/9.6
GP/FF 36/9.6
GP 36
Spiriva
FF 9.6
FF 7.2
Foradil

FIG. 30

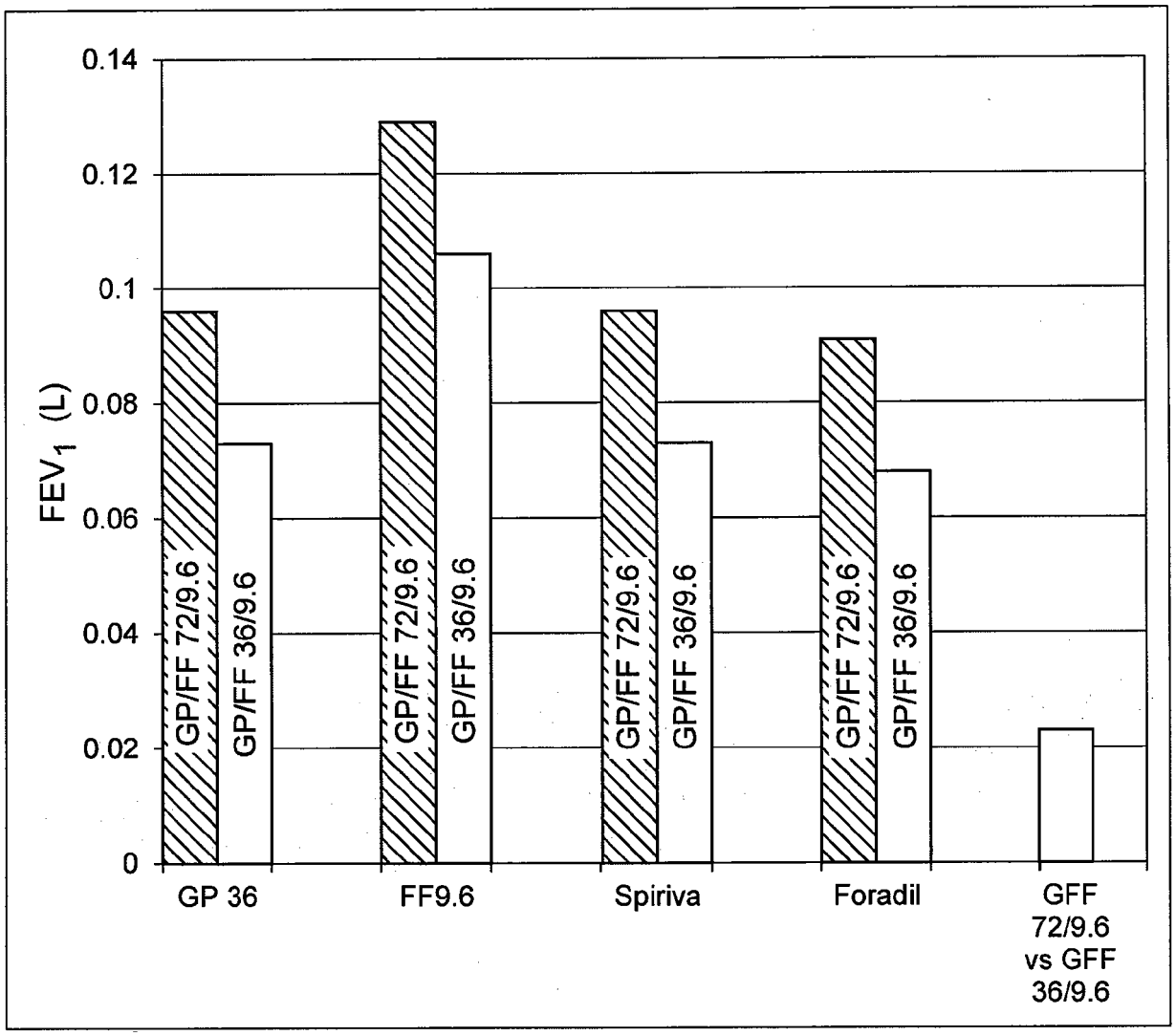

0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
FEV1 (L)
GP/FF 72/9.6
GP/FF 36/9.6
GP/FF 72/9.6
GP/FF 36/9.6
GP/FF 72/9.6
GP/FF 36/9.6
GP/FF 72/9.6
GP/FF 36/9.6
GP 36
FF9.6
Spiriva
Foradil
GFF 72/9.6 vs GFF 36/9.6

FIG. 31

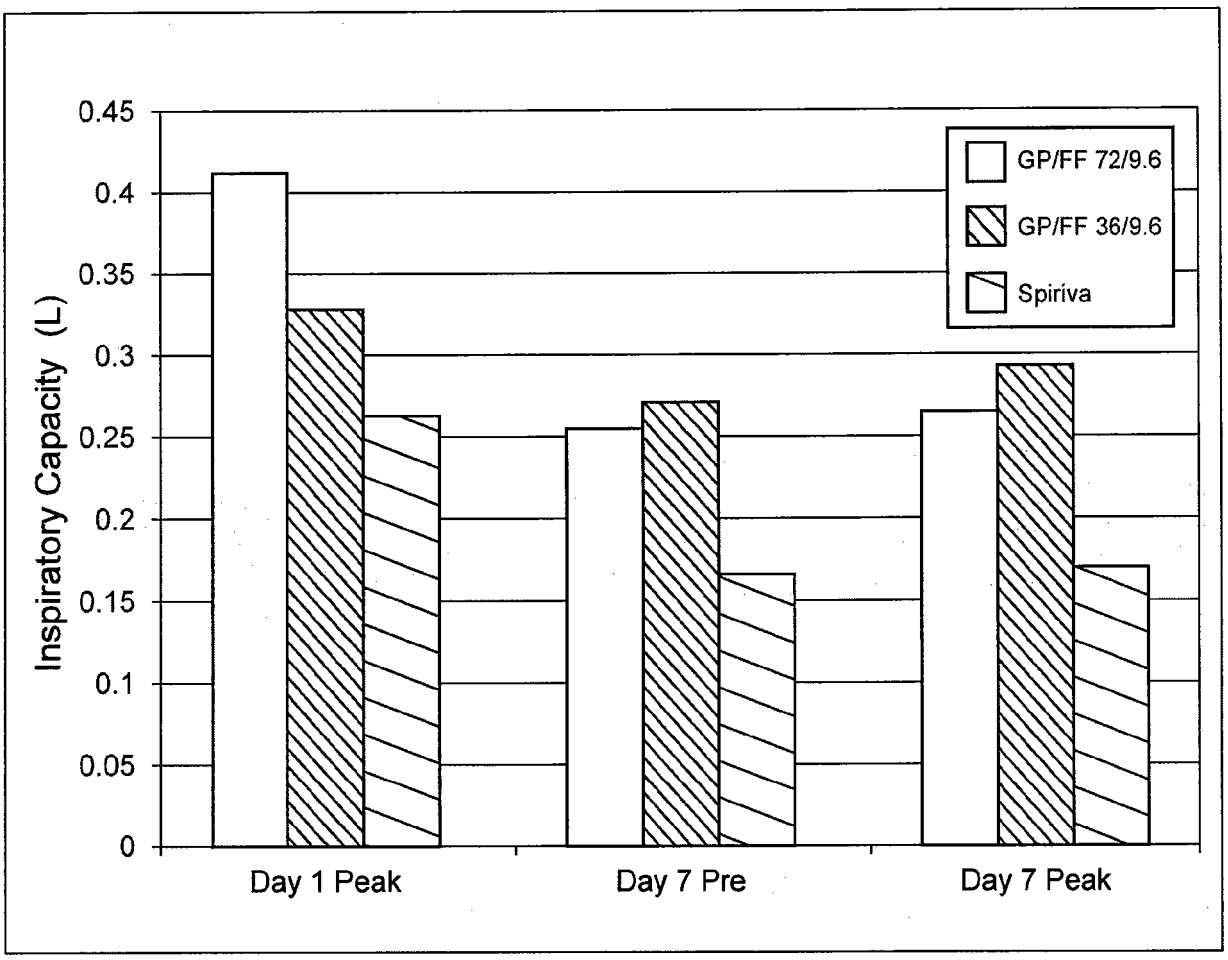
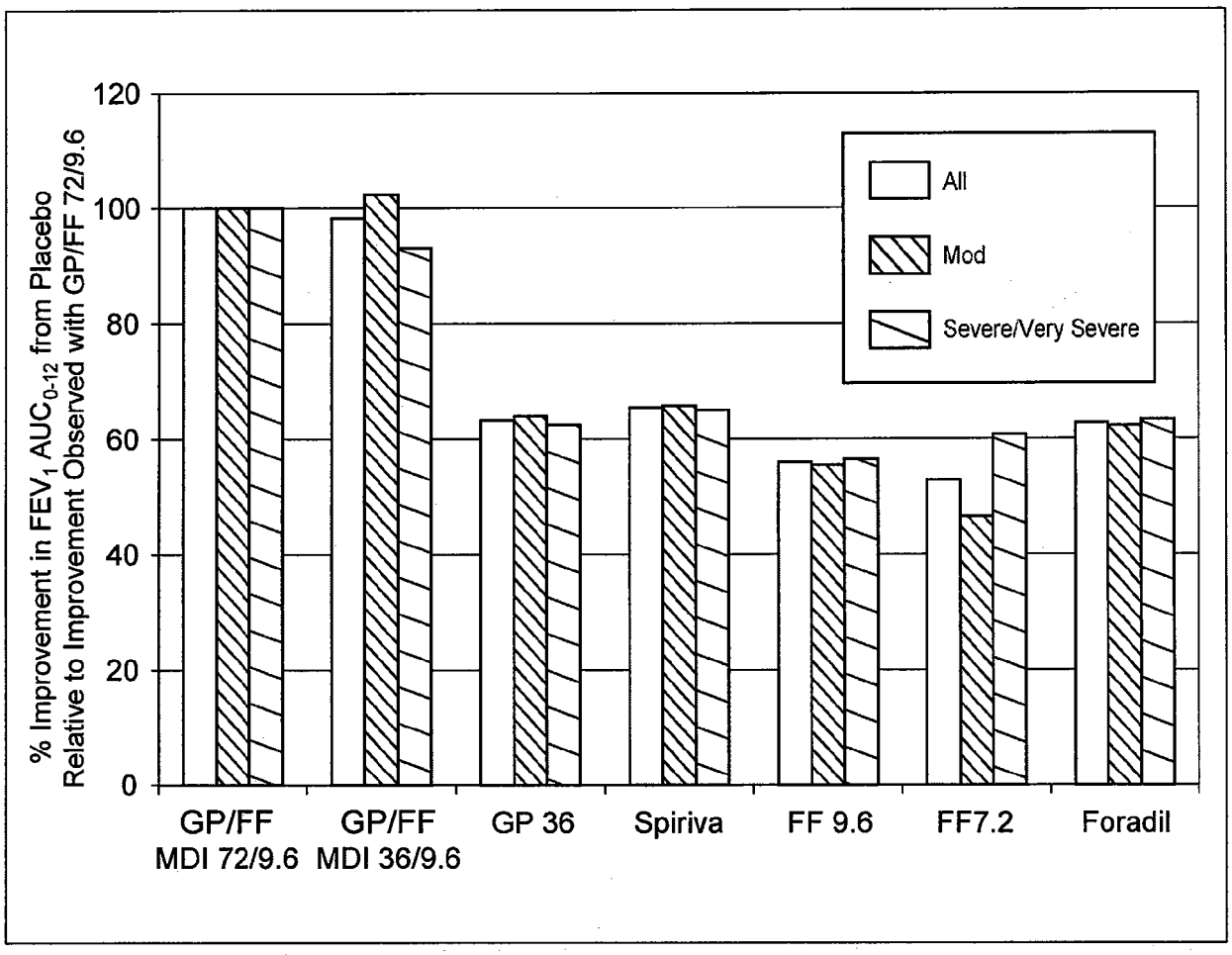

0.45
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
Inspiratory Capacity (L)
GP/FF 72/9.6
GP/FF 36/9.6
Spiriva
Day 1 Peak
Day 7 Pre
Day 7 Peak

FIG. 32


% Improvement in FEV1 AUC0-12 from Placebo
Relative to Improvement Observed with GP/FF 72/9.6
120
100
80
60
40
20
0
All
Mod
Severe/Very Severe
GP/FF MDI 72/9.6
GP/FF MDI 36/9.6
GP 36
Spiriva
FF 9.6
FF7.2
Foradil