Figure 1

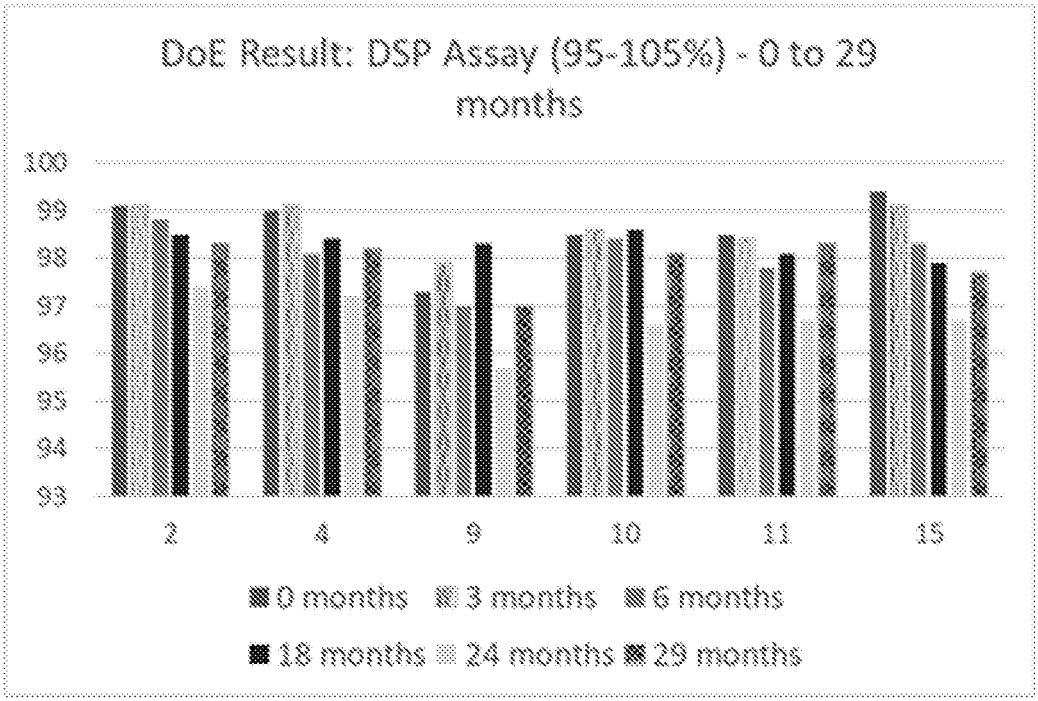


Figure 2

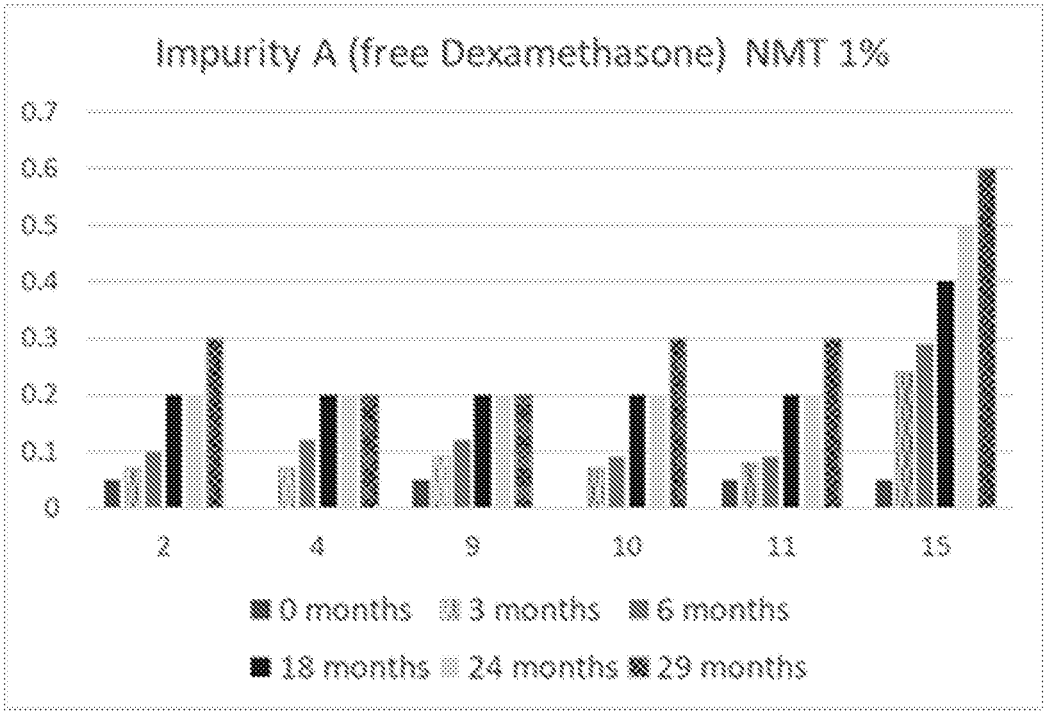


Figure 3

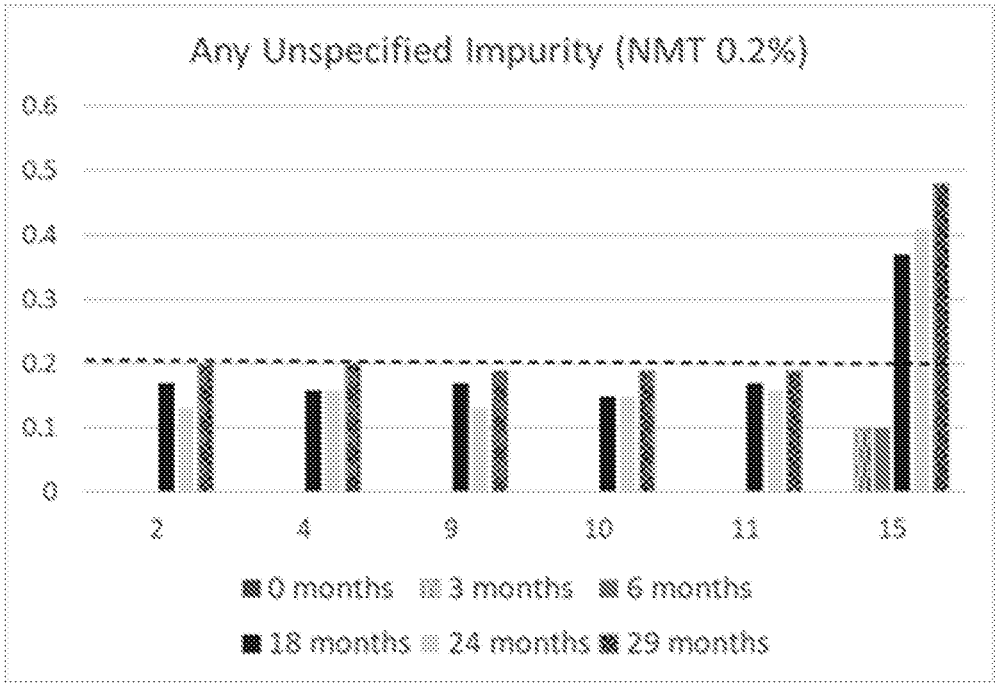


Figure 4

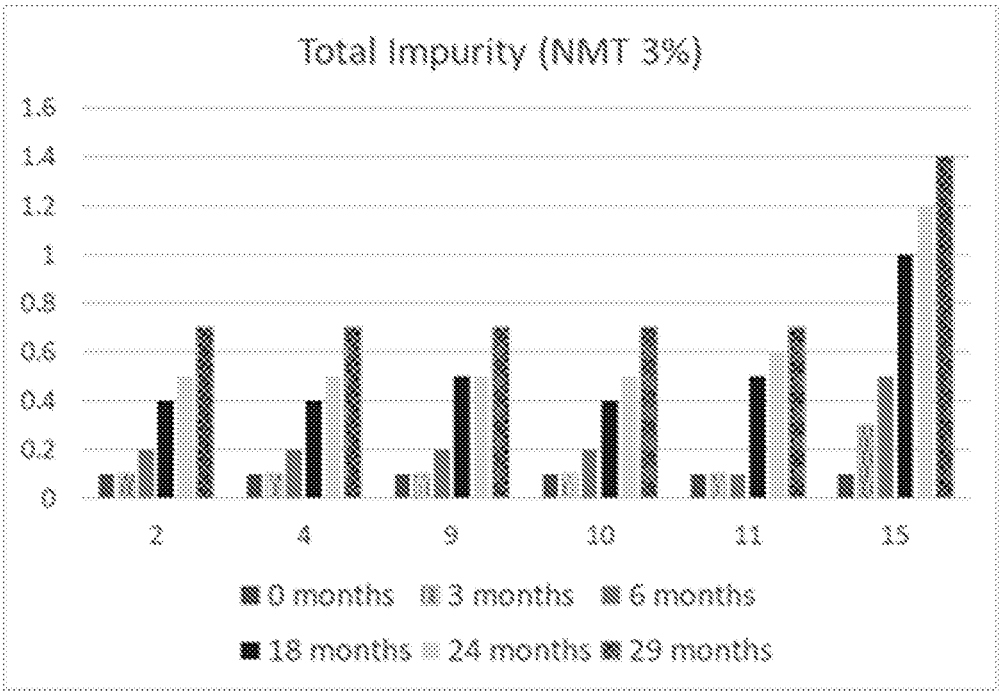
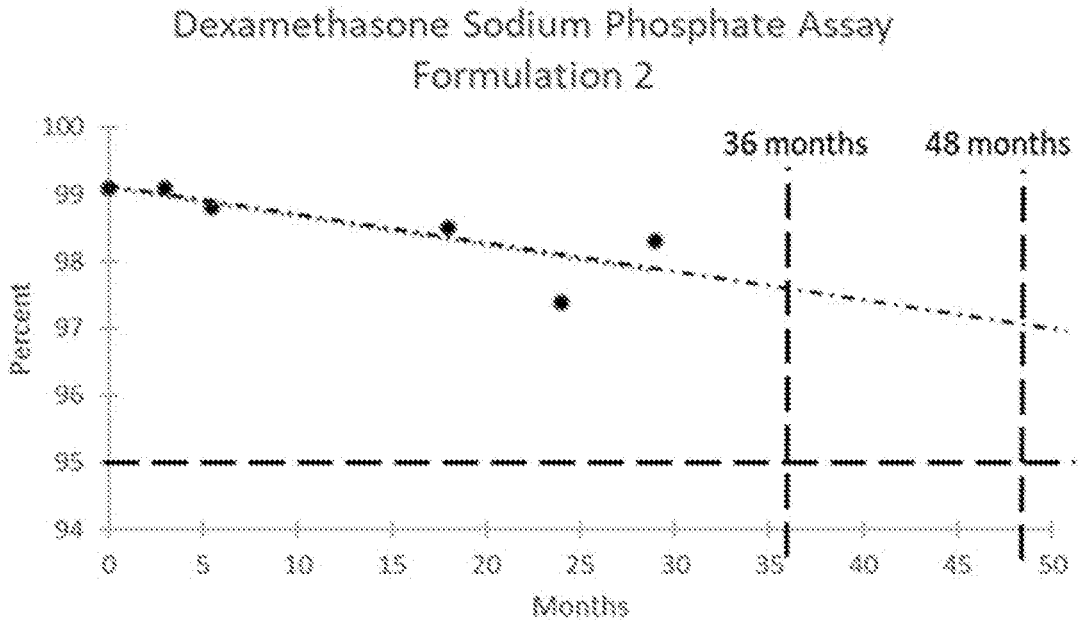


Figure 5


Dexamethasone Sodium Phosphate Assay
Formulation 2
36 months
48 months
Percent
100
99
98
97
96
95
94
0
5
10
15
20
25
30
35
40
45
50
Months

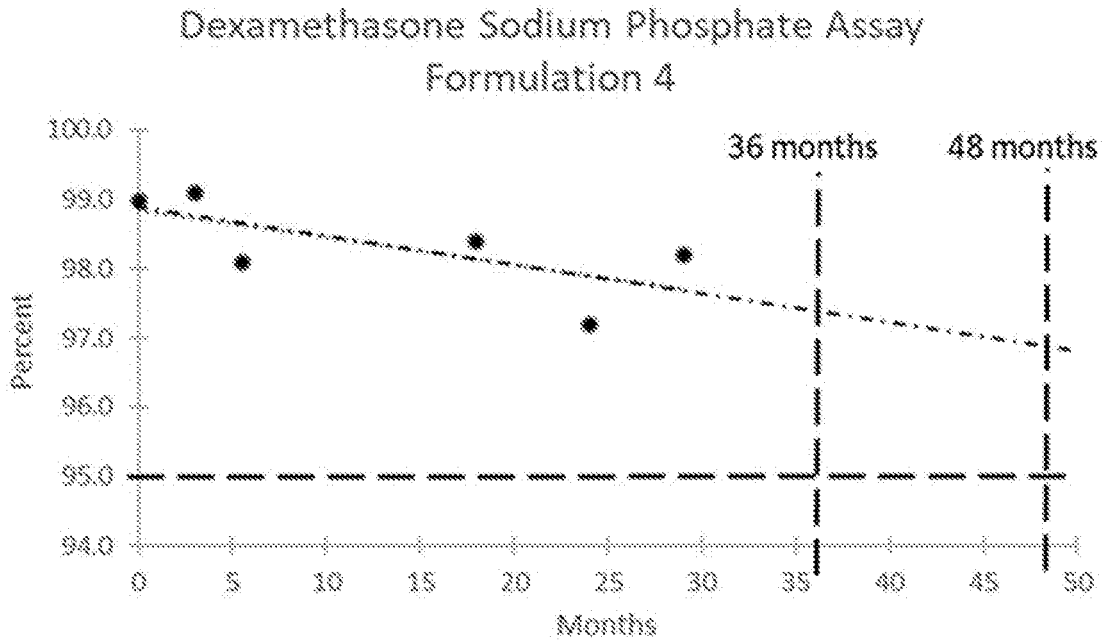

Dexamethasone Sodium Phosphate Assay
Formulation 4
36 months
48 months
Percent
100.0
99.0
98.0
97.0
96.0
95.0
94.0
0
5
10
15
20
25
30
35
40
45
50
Months

Figure 6

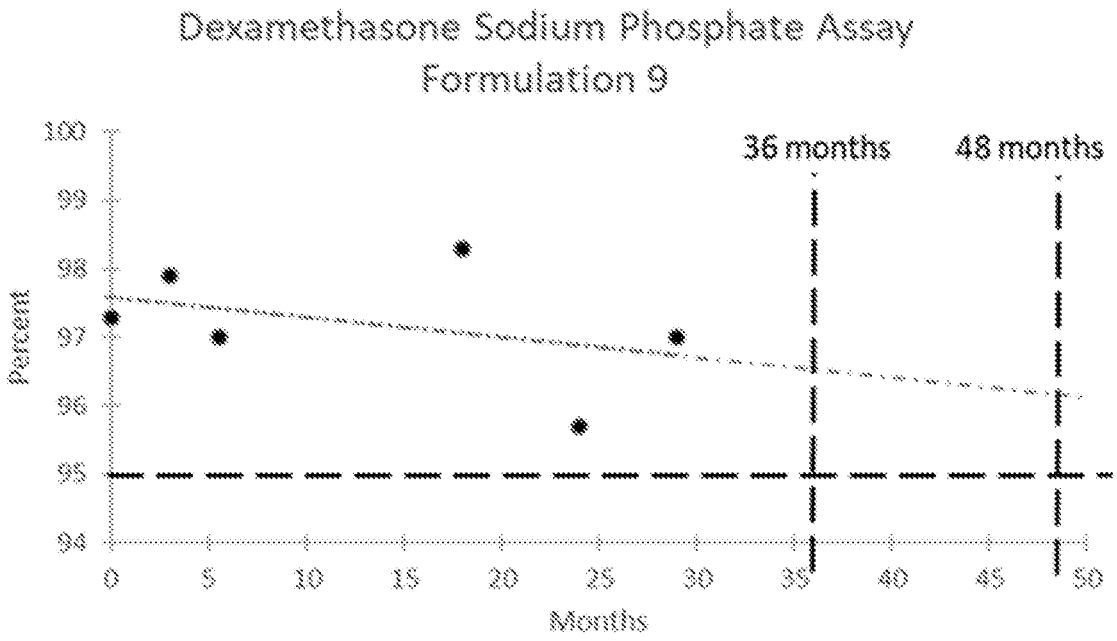


Figure 7

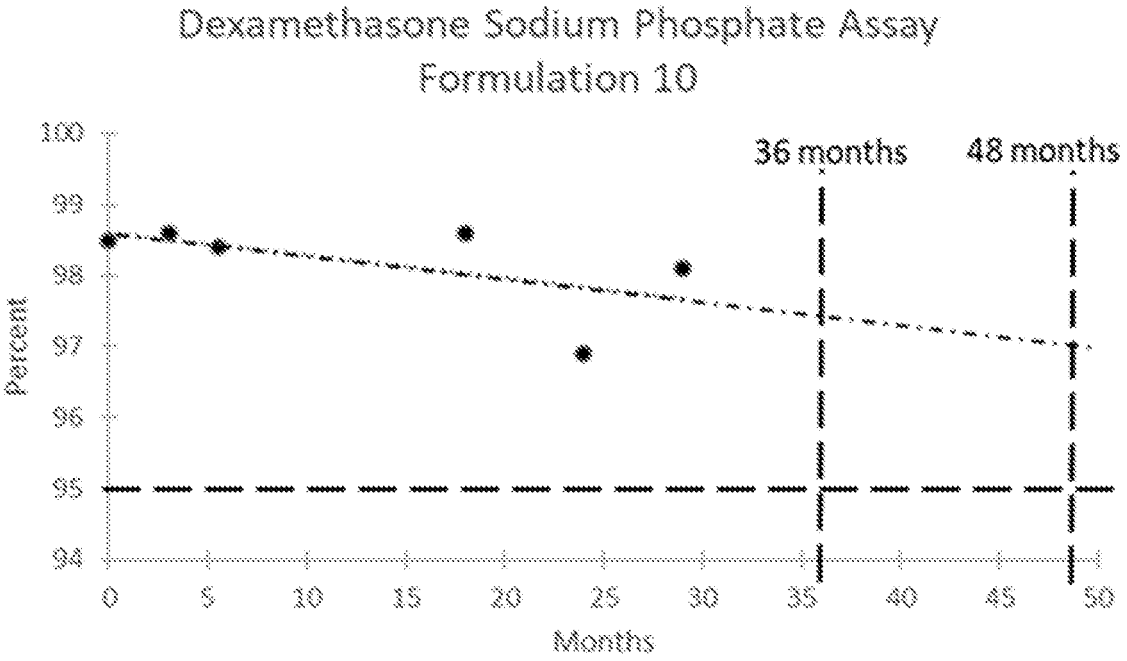


Figure 8

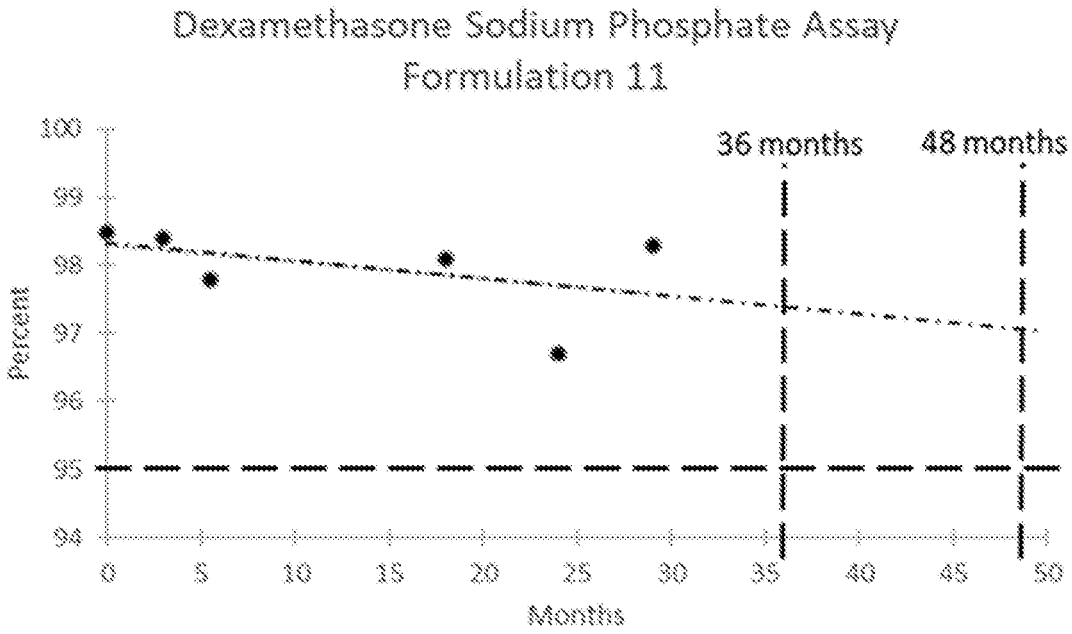


Figure 9

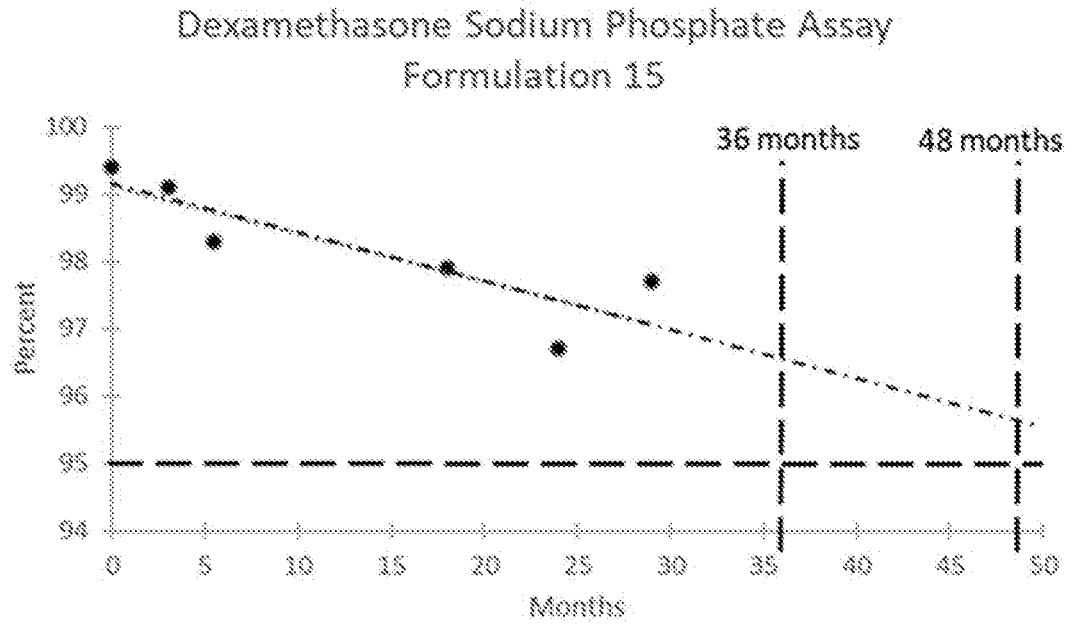


Figure 10

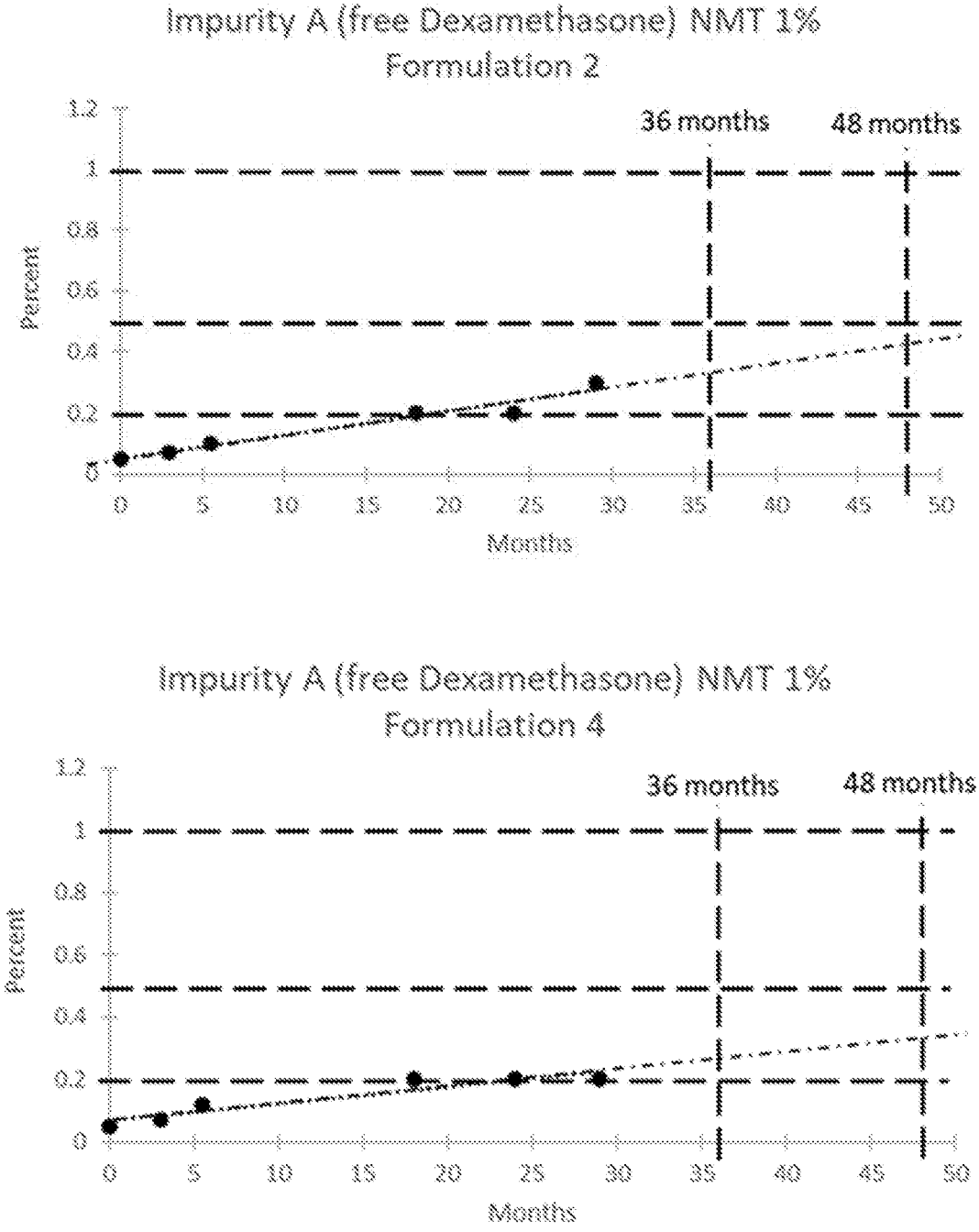

Impurity A (free Dexamethasone) NMT 1%
Formulation 2
36 months
48 months
Percent
1.2
1
0.8
0.6
0.4
0.2
0
0
5
10
15
20
25
30
35
40
45
50
Months
Impurity A (free Dexamethasone) NMT 1%
Formulation 4
36 months
48 months
Percent
1.2
1
0.8
0.6
0.4
0.2
0
0
5
10
15
20
25
30
35
40
45
50
Months

Figure 11

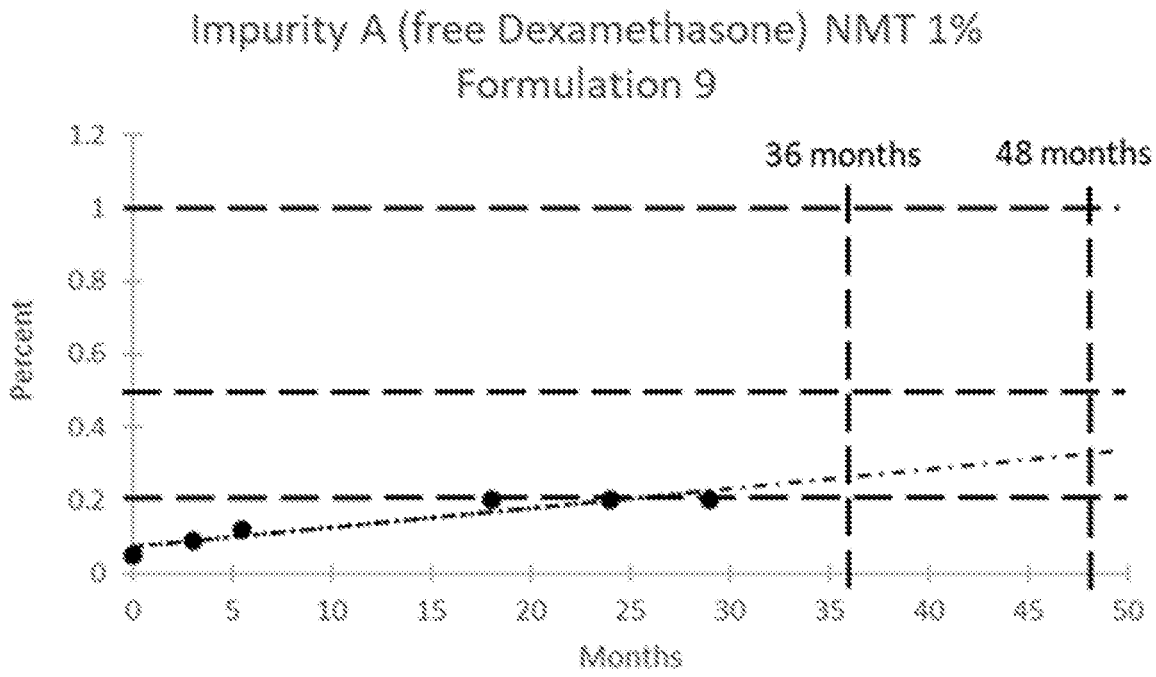


Figure 12

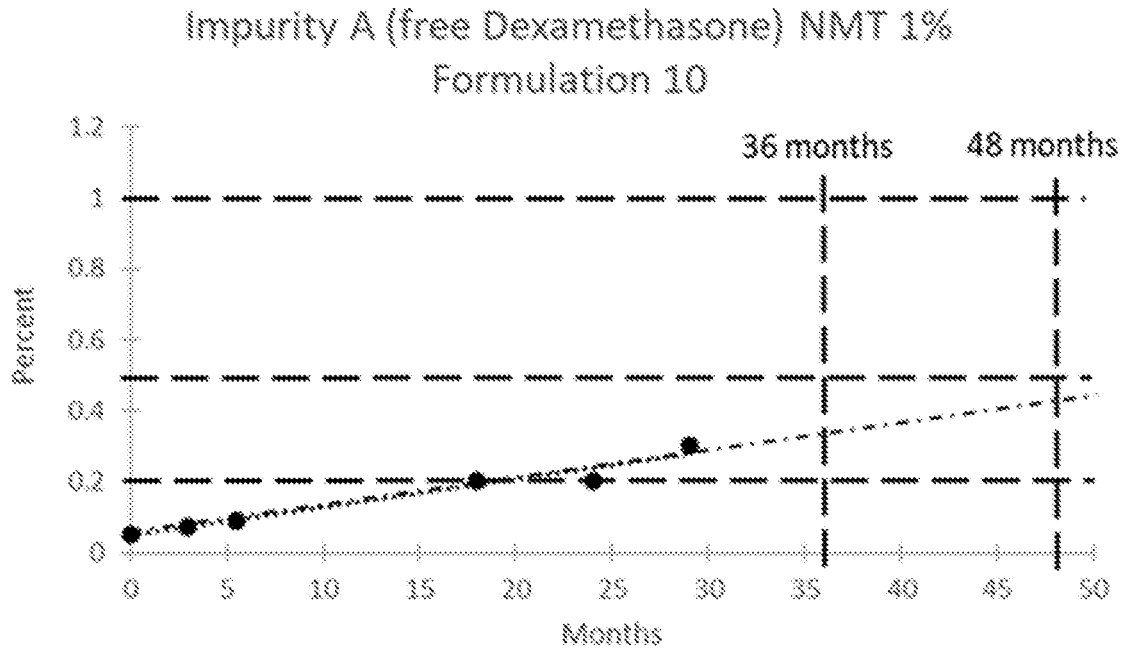


Figure 13

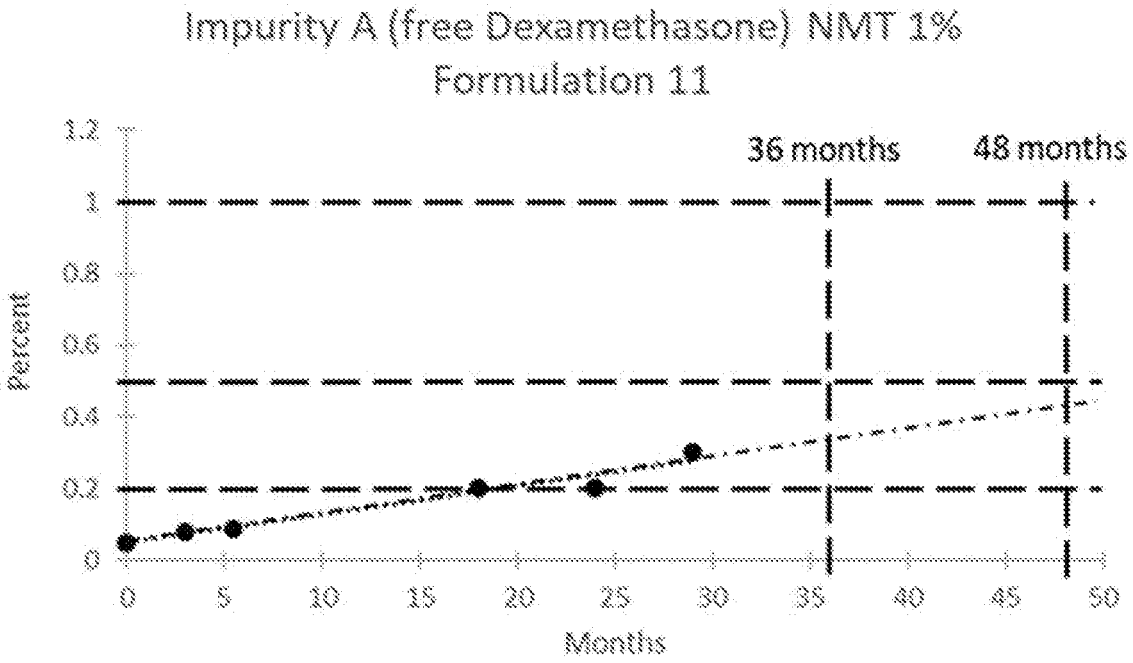


Figure 14

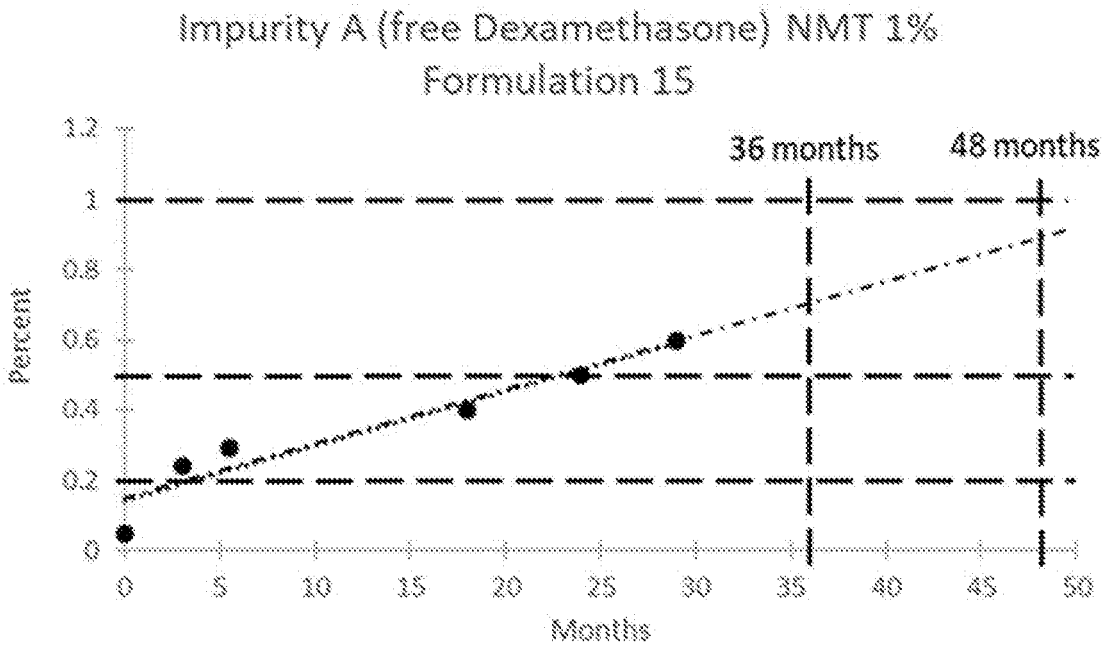


Figure 15

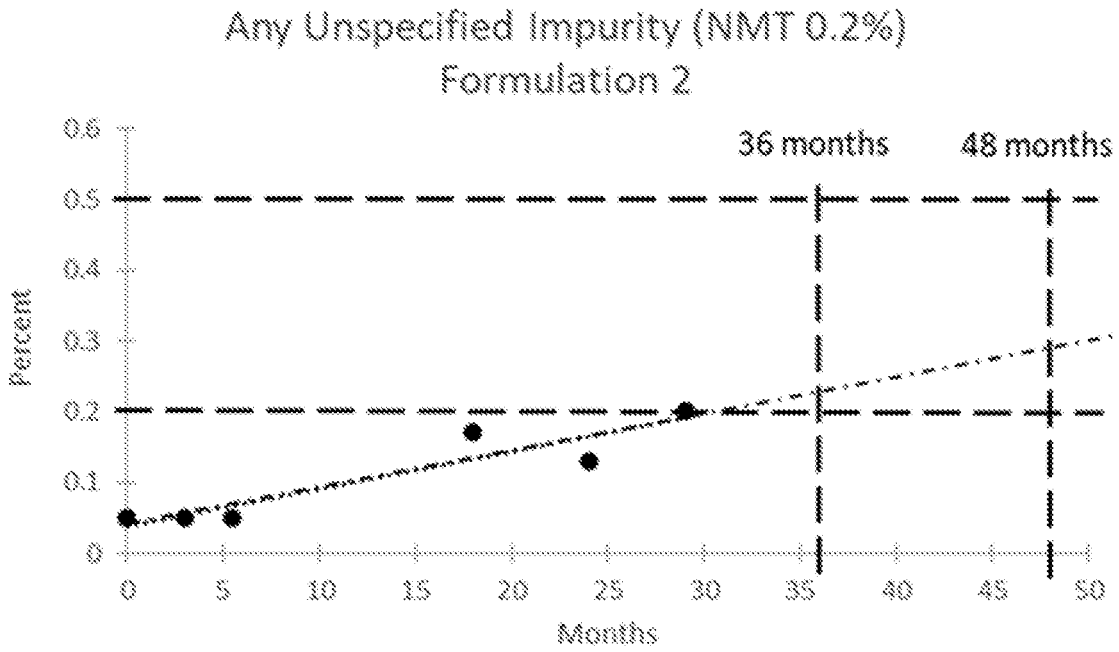


Figure 16

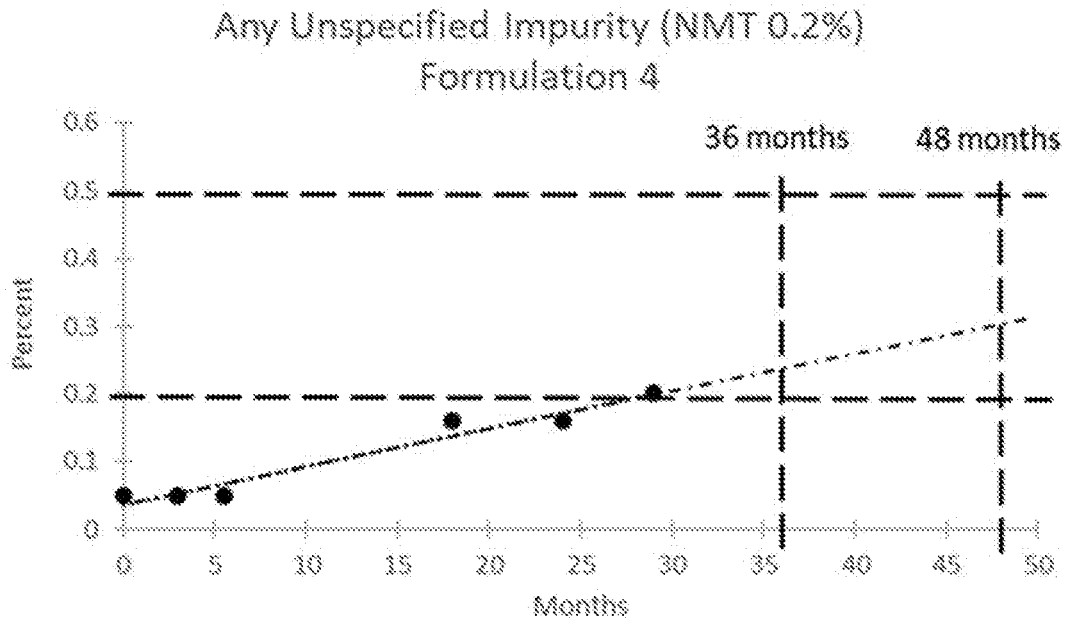


Figure 17

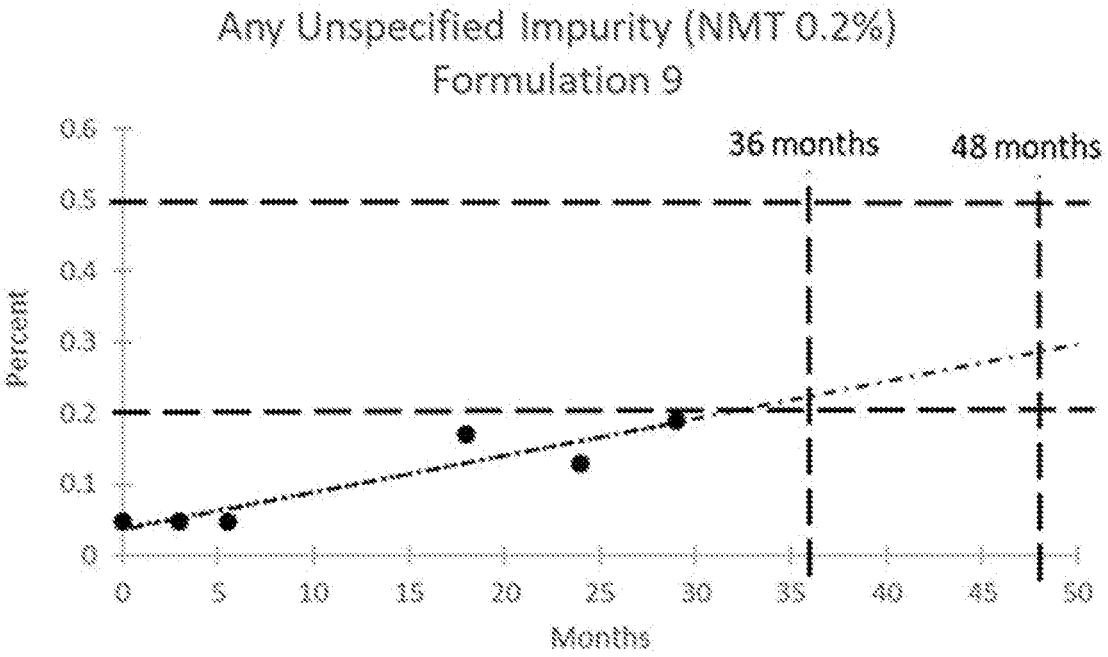


Figure 18

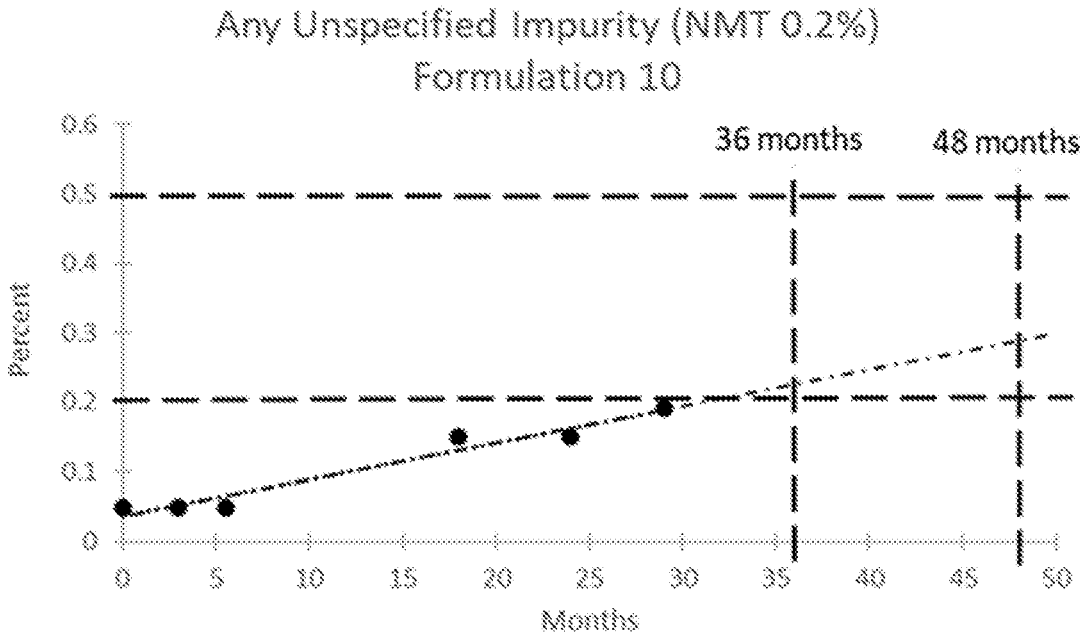


Figure 19

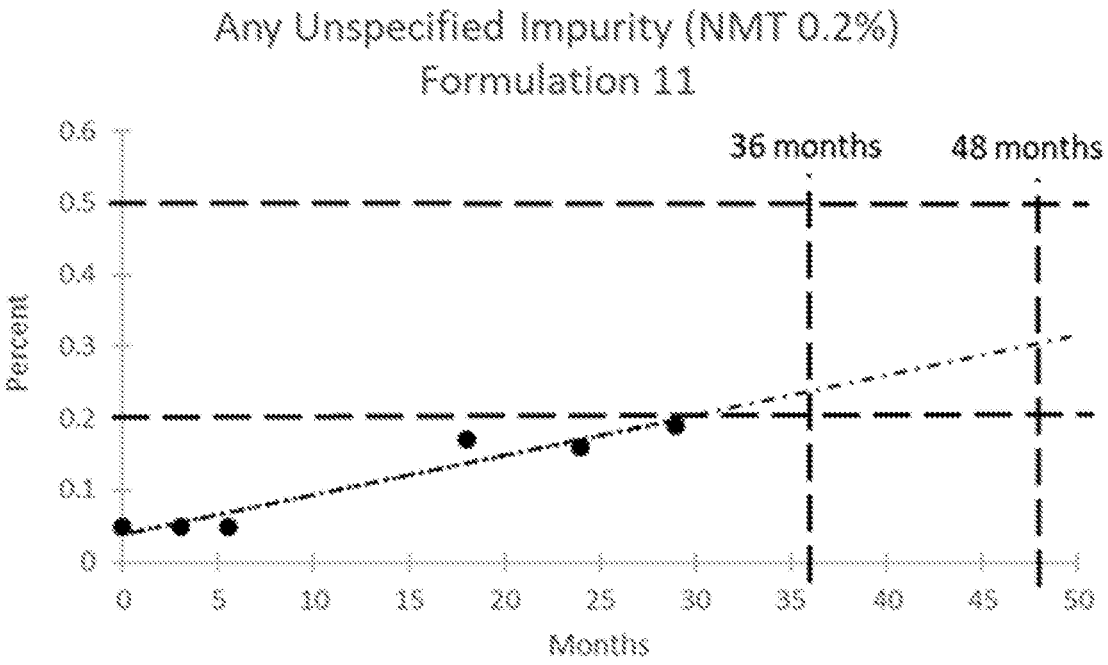


Figure 20

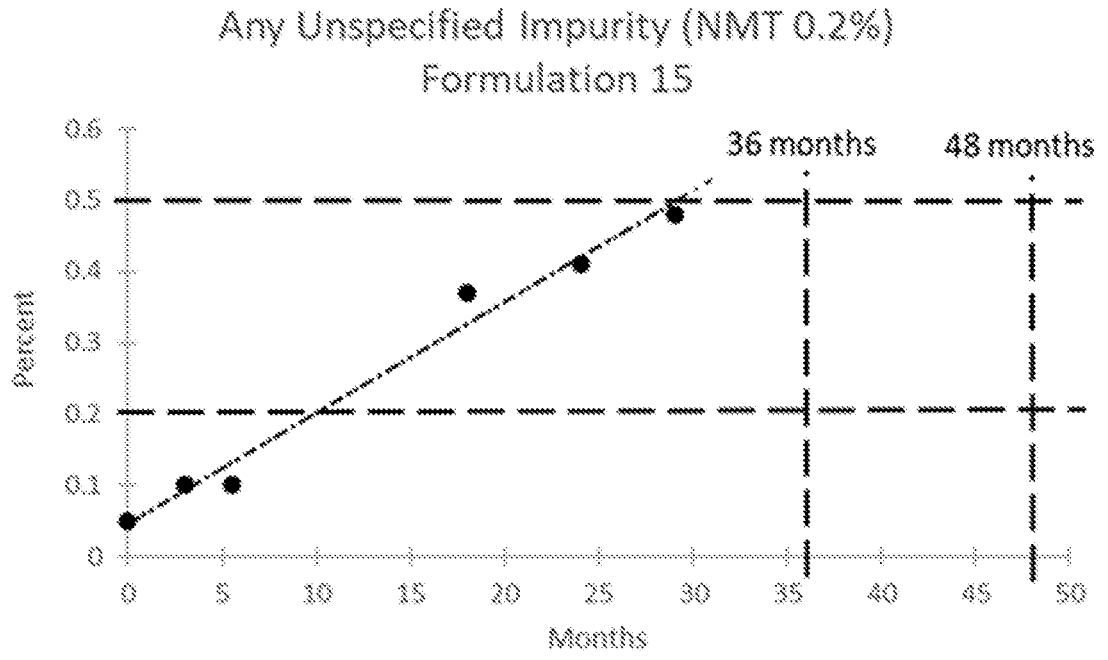


Figure 21

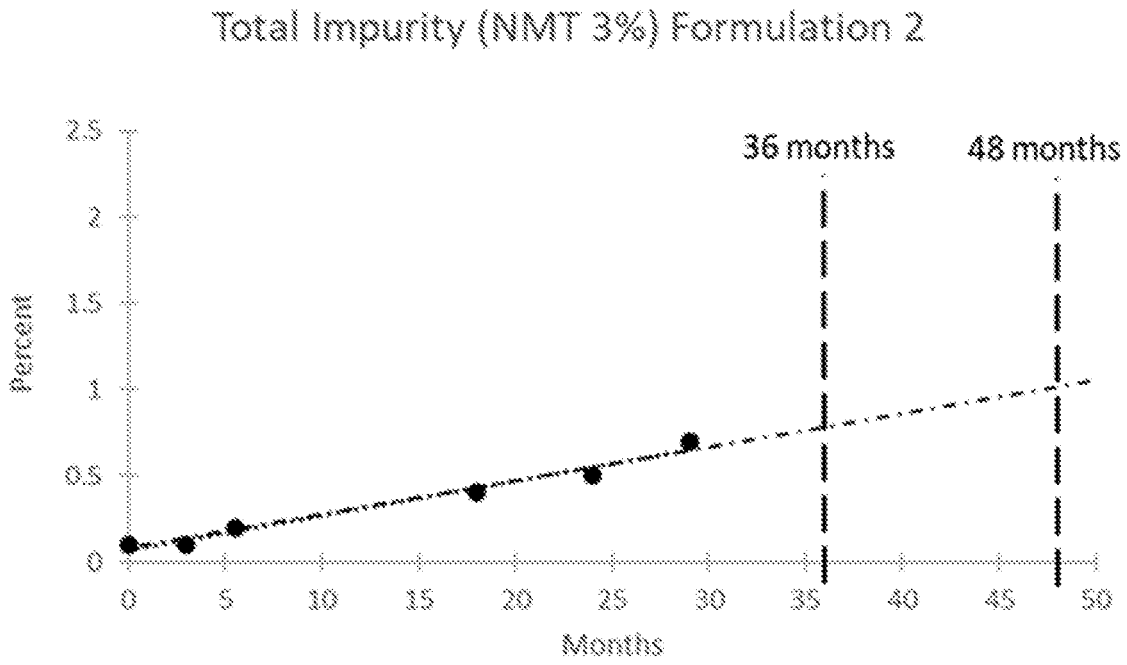


Figure 22

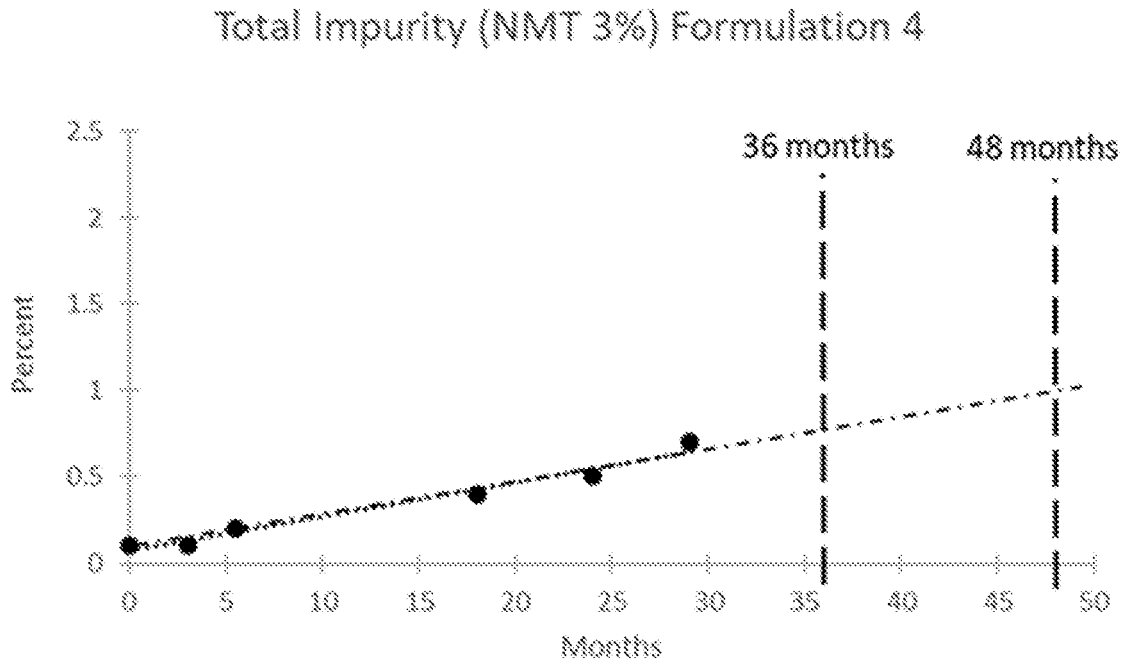


Figure 23

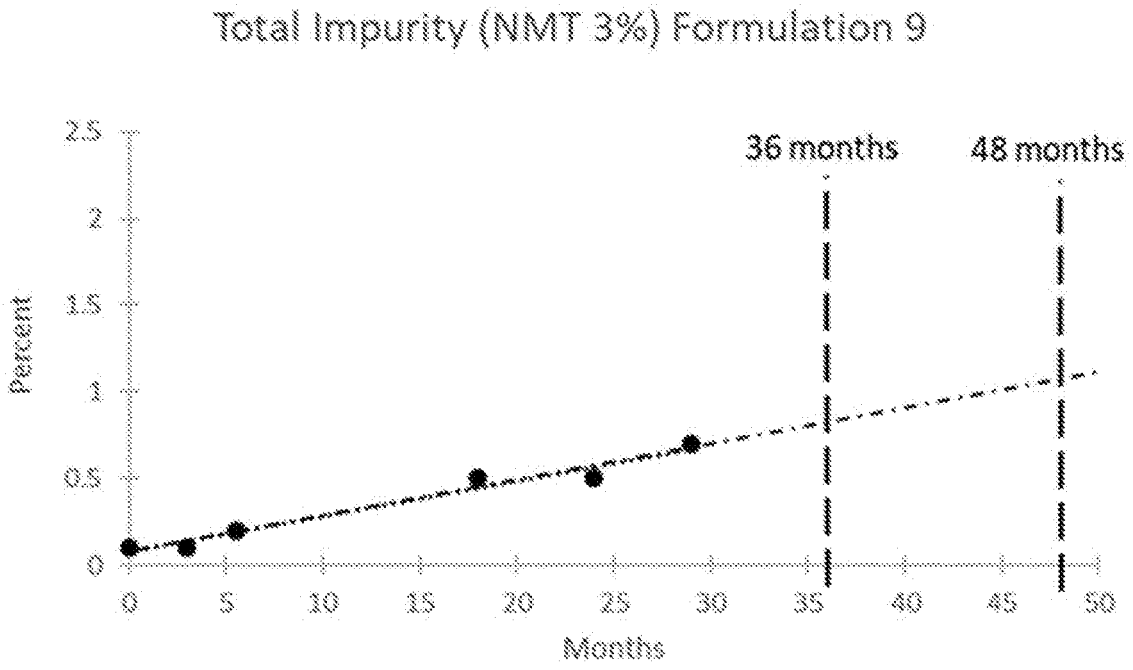


Figure 24

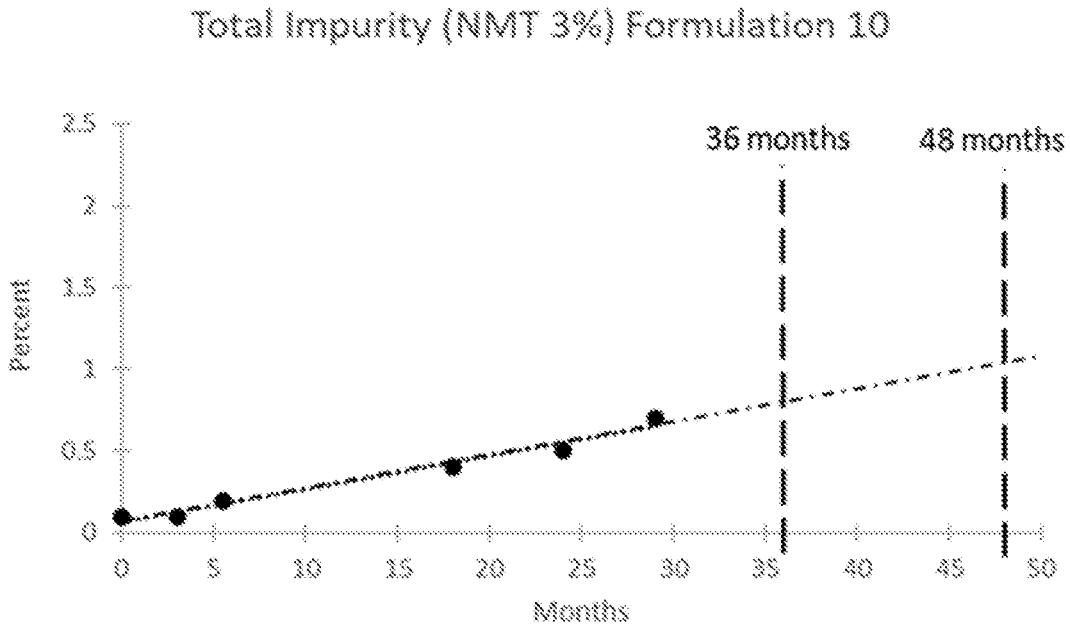


Figure 25

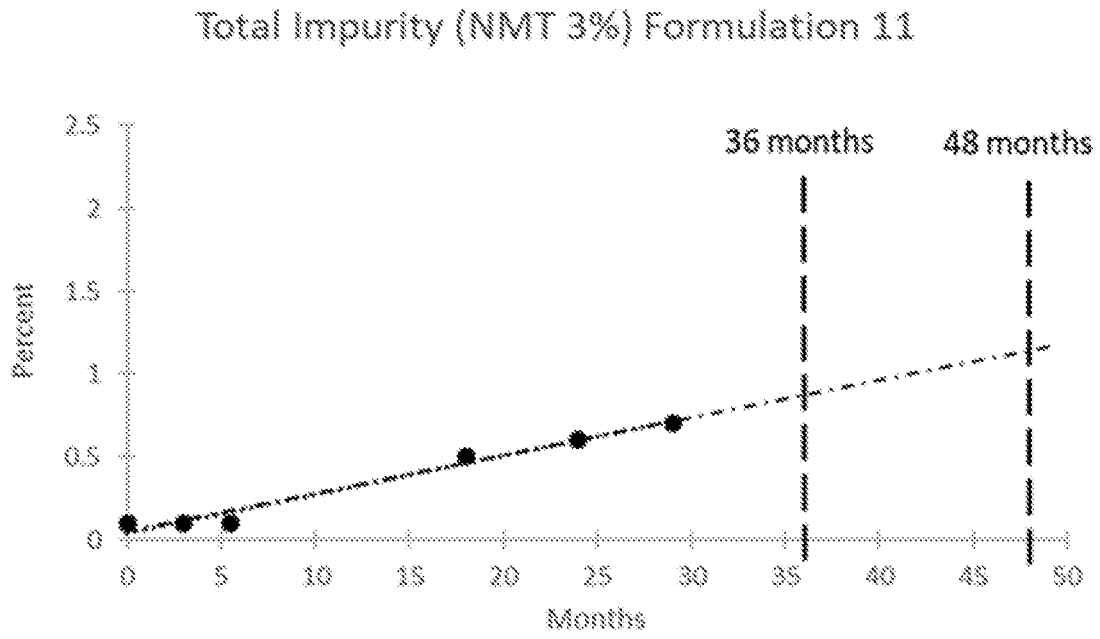


Figure 26

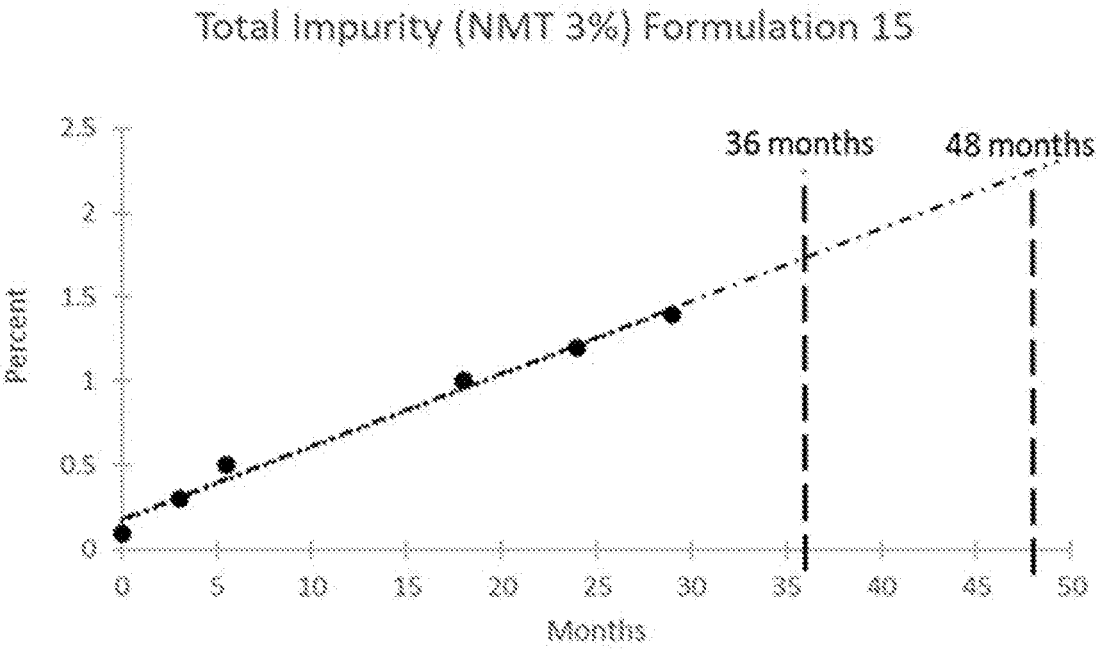
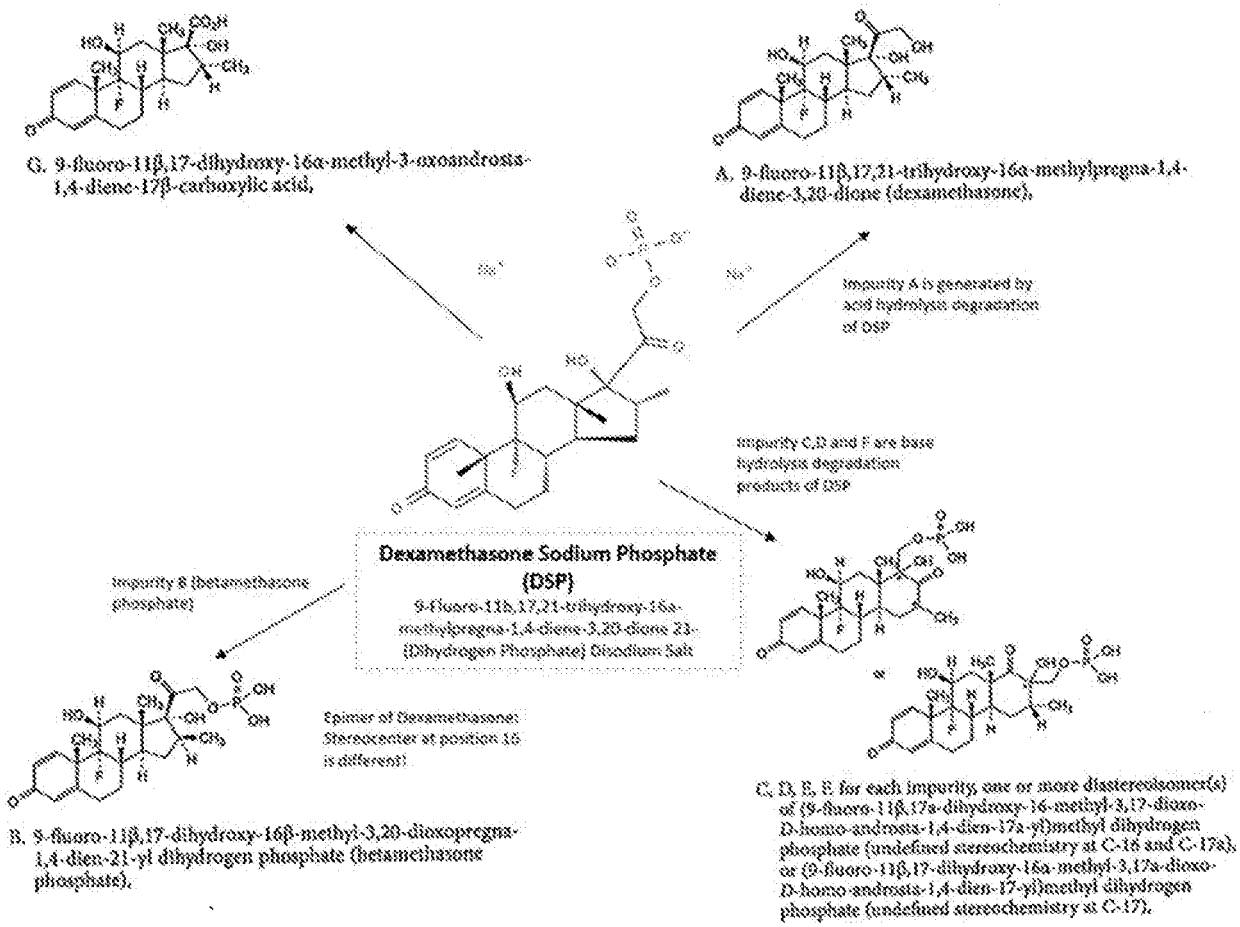
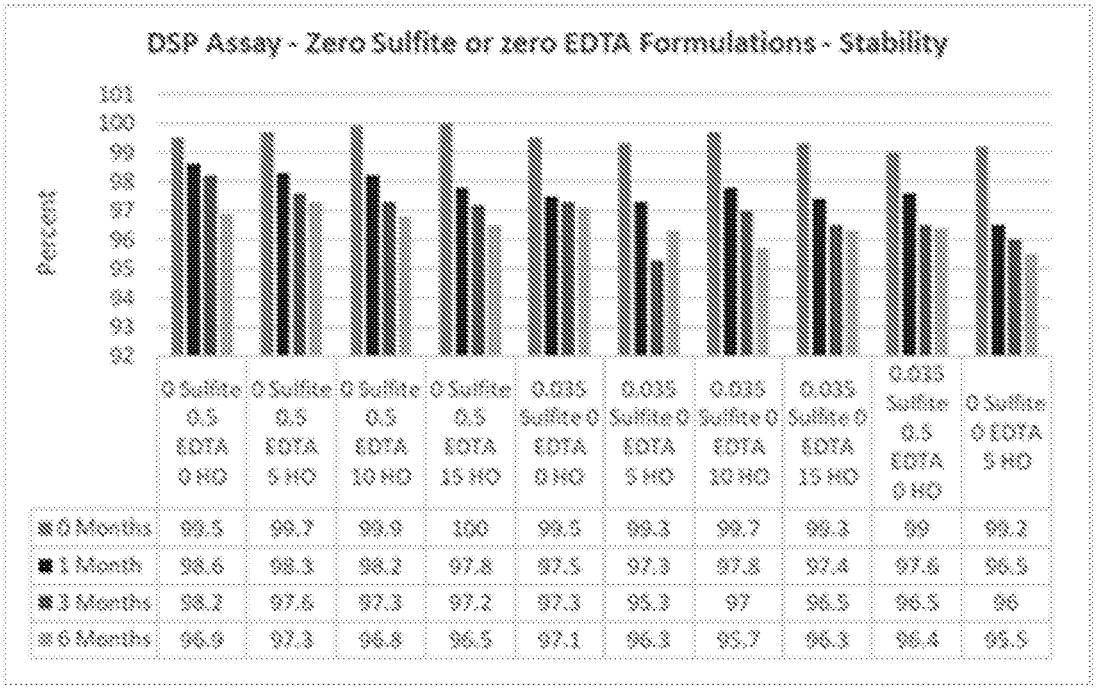


Figure 27



	Equivalent USP Impurity
Impurity A	Dexamethasone
Impurity B	Betamethasone sodium phosphate
Impurity C	USP Impurity a
Impurity D	USP Impurity b
Impurity E	USP Impurity c
Impurity F	USP Impurity d
Impurity G	USP Impurity f

Figure 28


DSP Assay - Zero Sulfite or zero EDTA Formulations - Stability
Percent
101
100
99
98
97
96
95
94
93
92
0 Sulfite 0.5 EDTA 0 HO
0 Sulfite 0.5 EDTA 5 HO
0 Sulfite 0.5 EDTA 10 HO
0 Sulfite 0.5 EDTA 15 HO
0.035 Sulfite 0 EDTA 0 HO
0.035 Sulfite 0 EDTA 5 HO
0.035 Sulfite 0 EDTA 10 HO
0.035 Sulfite 0 EDTA 15 HO
0.035 Sulfite 0.5 EDTA 0 HO
0 Sulfite 0 EDTA 5 HO
0 Months 99.5 99.7 99.9 100 99.5 99.3 99.7 99.3 99 99.2
1 Month 98.6 98.3 98.2 97.8 97.5 97.3 97.8 97.4 97.8 96.5
3 Months 98.2 97.6 97.3 97.2 97.3 95.3 97 96.5 96.5 96
6 Months 96.9 97.3 96.8 96.5 97.1 96.3 95.7 96.3 96.4 95.5

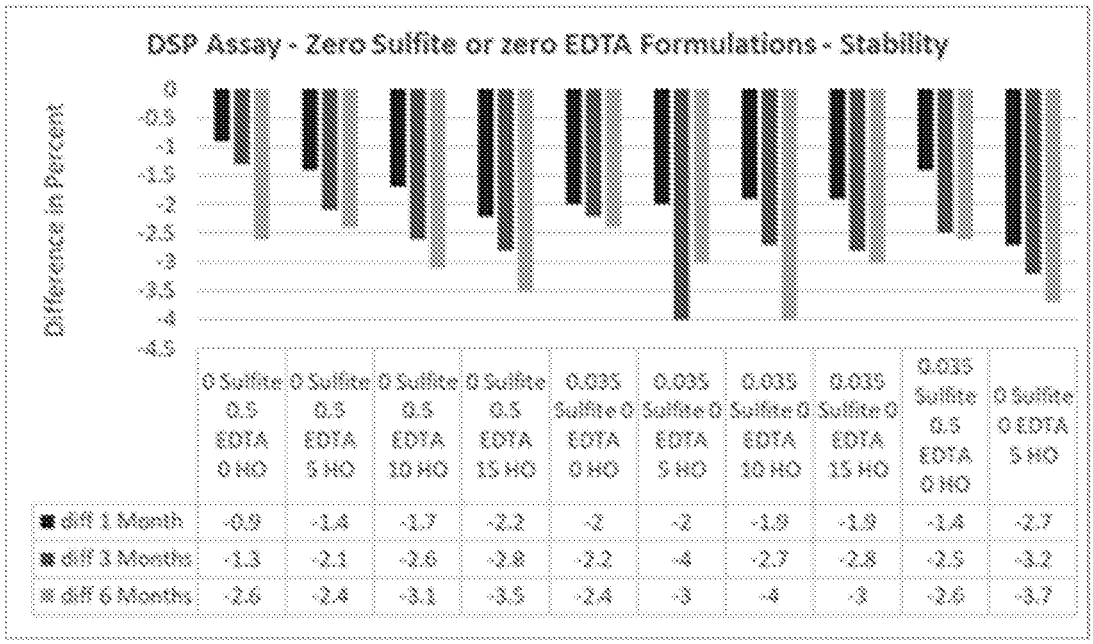

DSP Assay - Zero Sulfite or zero EDTA Formulations - Stability
Difference in Percent
0
-0.5
-1
-1.5
-2
-2.5
-3
-3.5
-4
-4.5
0 Sulfite 0.5 EDTA 0 HO
0 Sulfite 0.5 EDTA 5 HO
0 Sulfite 0.5 EDTA 10 HO
0 Sulfite 0.5 EDTA 15 HO
0.035 Sulfite 0 EDTA 0 HO
0.035 Sulfite 0 EDTA 5 HO
0.035 Sulfite 0 EDTA 10 HO
0.035 Sulfite 0 EDTA 15 HO
0.035 Sulfite 0.5 EDTA 0 HO
0 Sulfite 0 EDTA 5 HO
diff 1 Month -0.9 -1.4 -1.7 -2.2 -2 -2 -1.8 -1.8 -1.4 -2.7
diff 3 Months -1.3 -2.1 -2.6 -2.8 -2.2 -4 -2.7 -2.8 -2.5 -3.2
diff 6 Months -2.6 -2.4 -3.1 -3.5 -2.4 -3 -4 -3 -2.6 -3.7

Figure 29

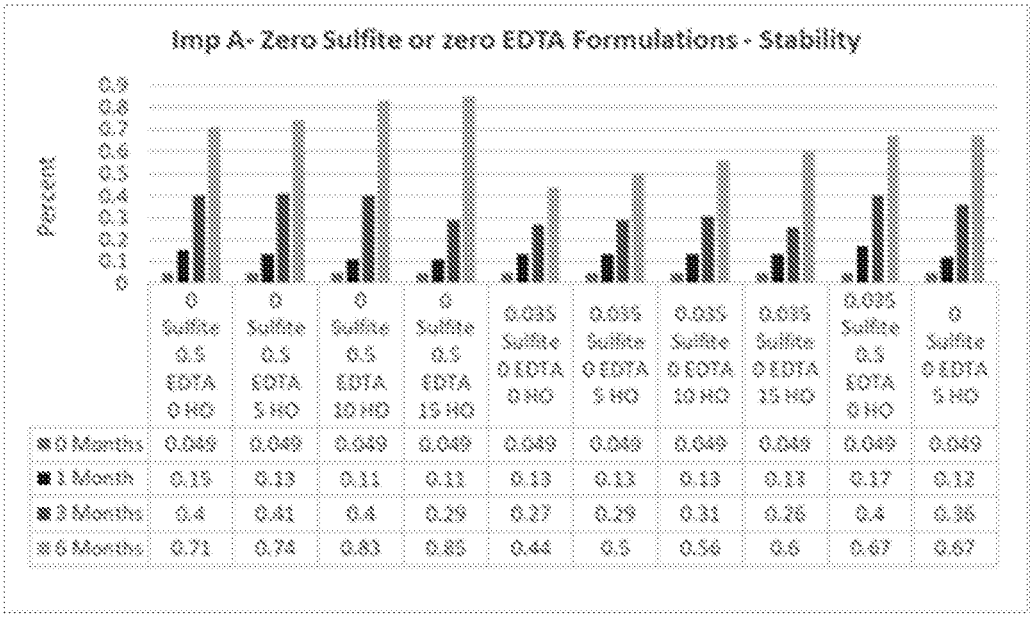


Figure 30

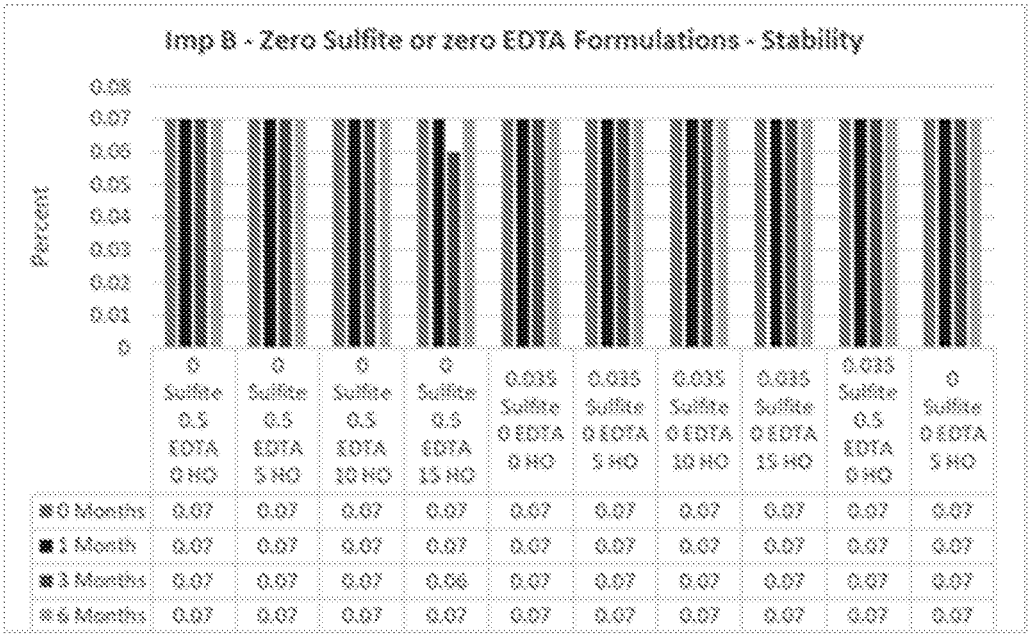


Figure 31

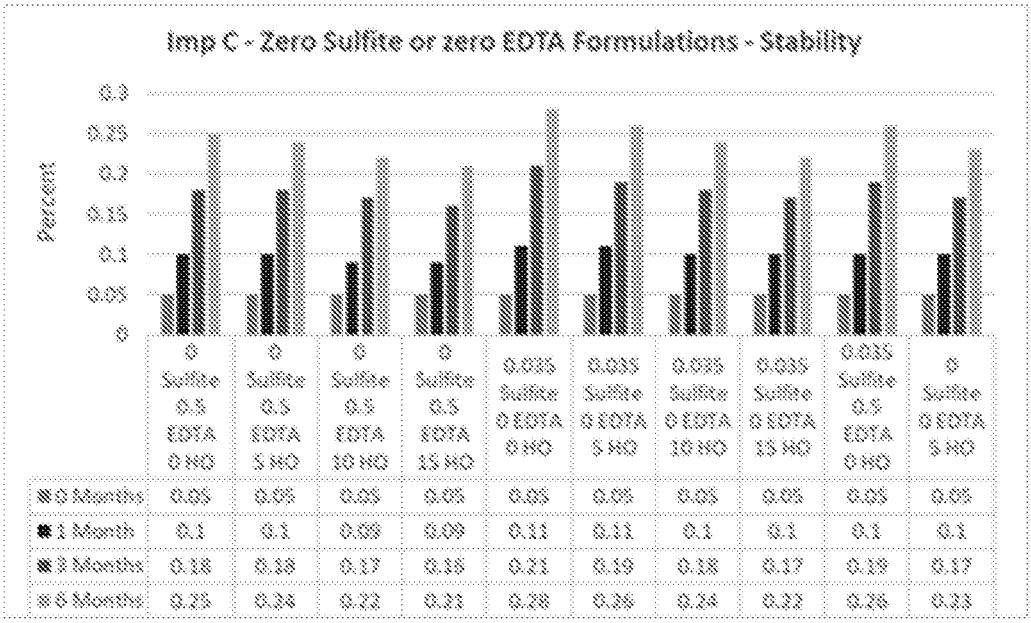


Figure 32

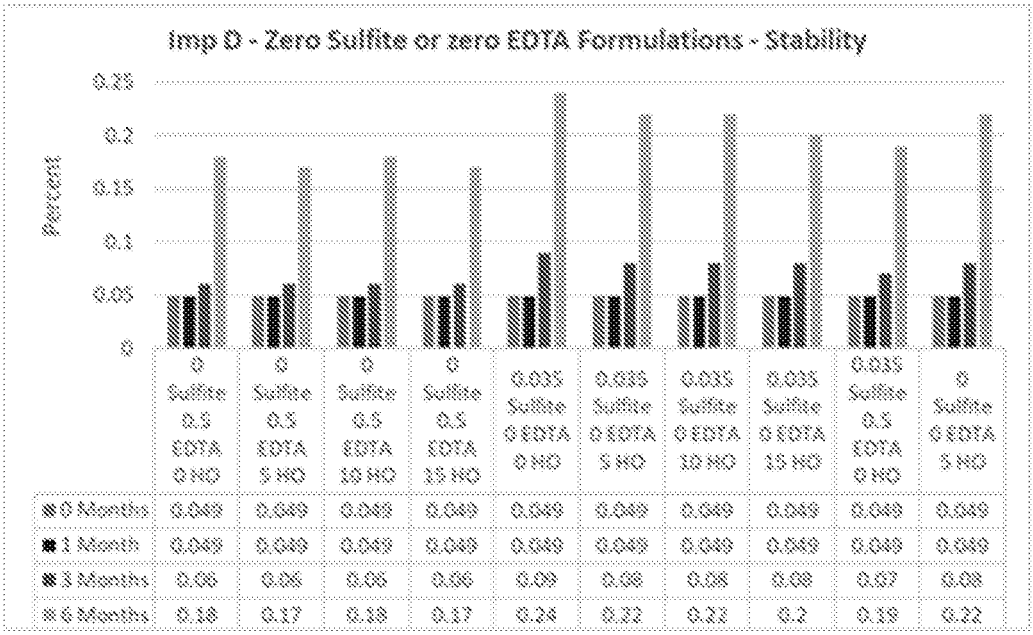


Figure 33

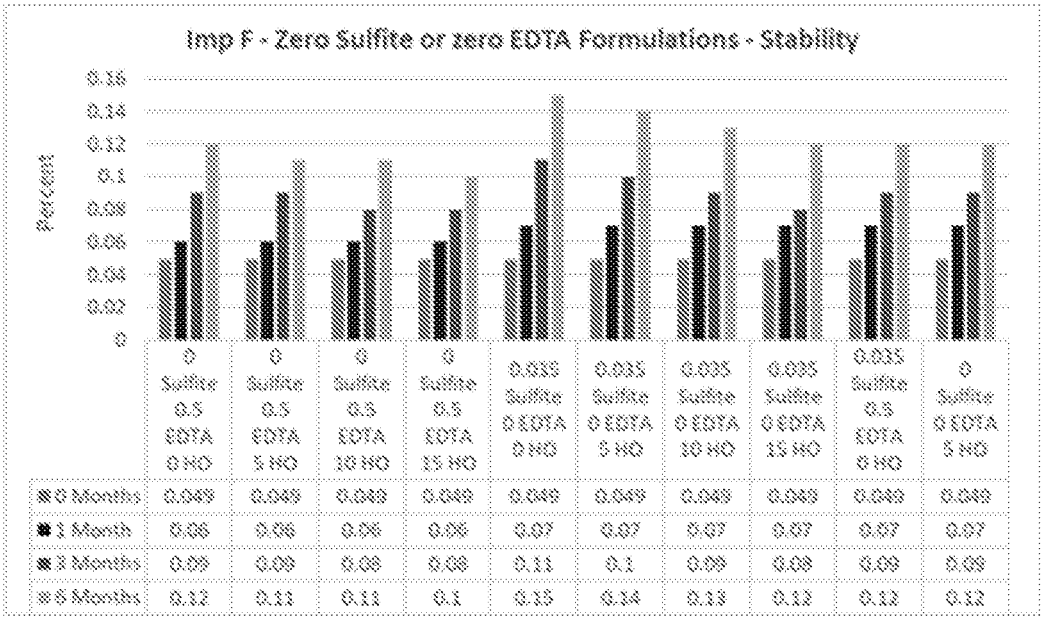


Figure 34

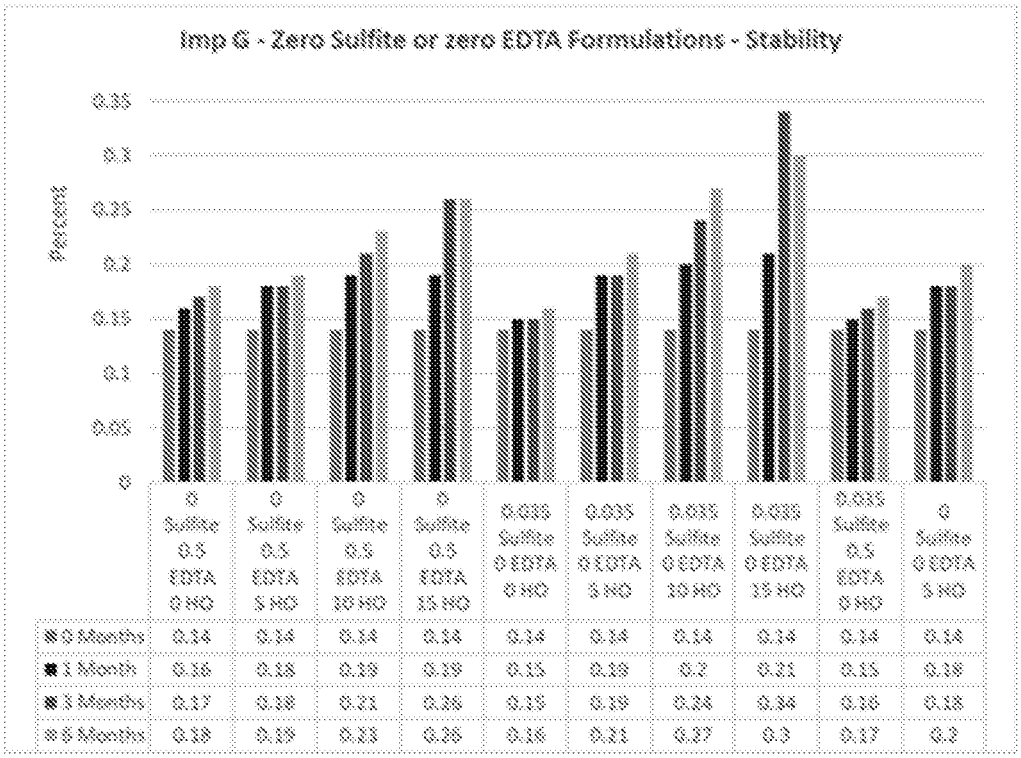


Figure 35

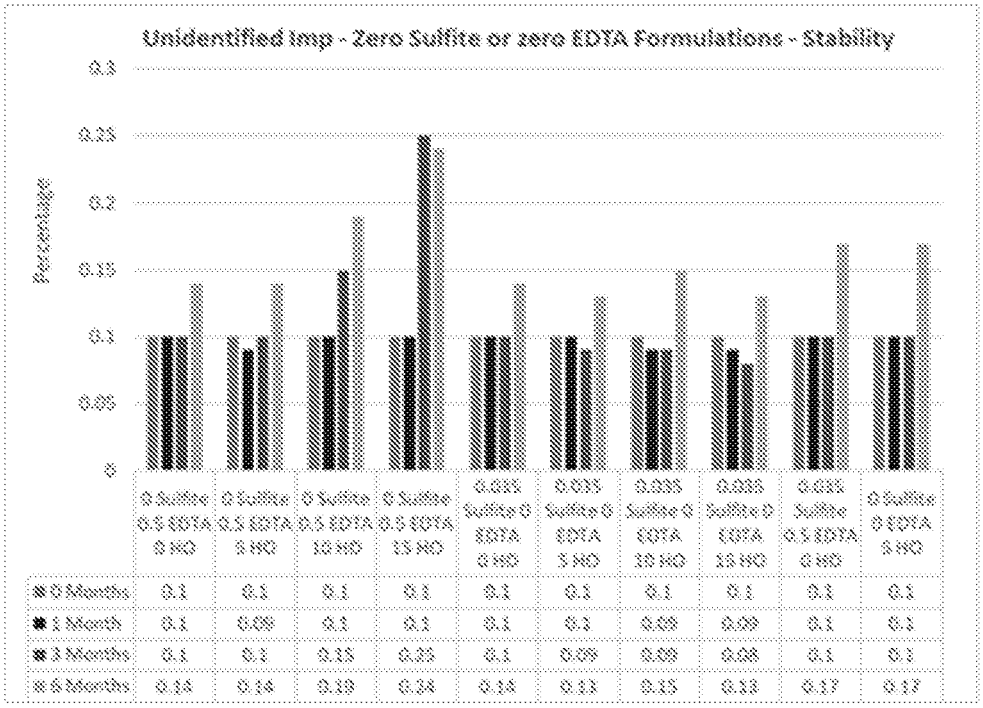


Figure 36

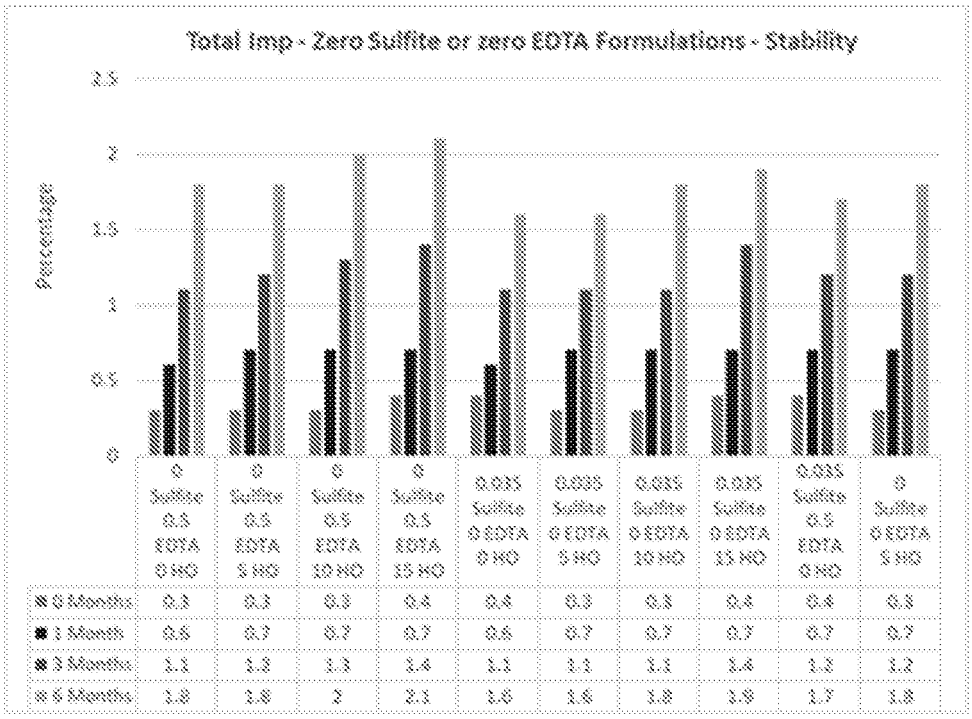


Figure 37

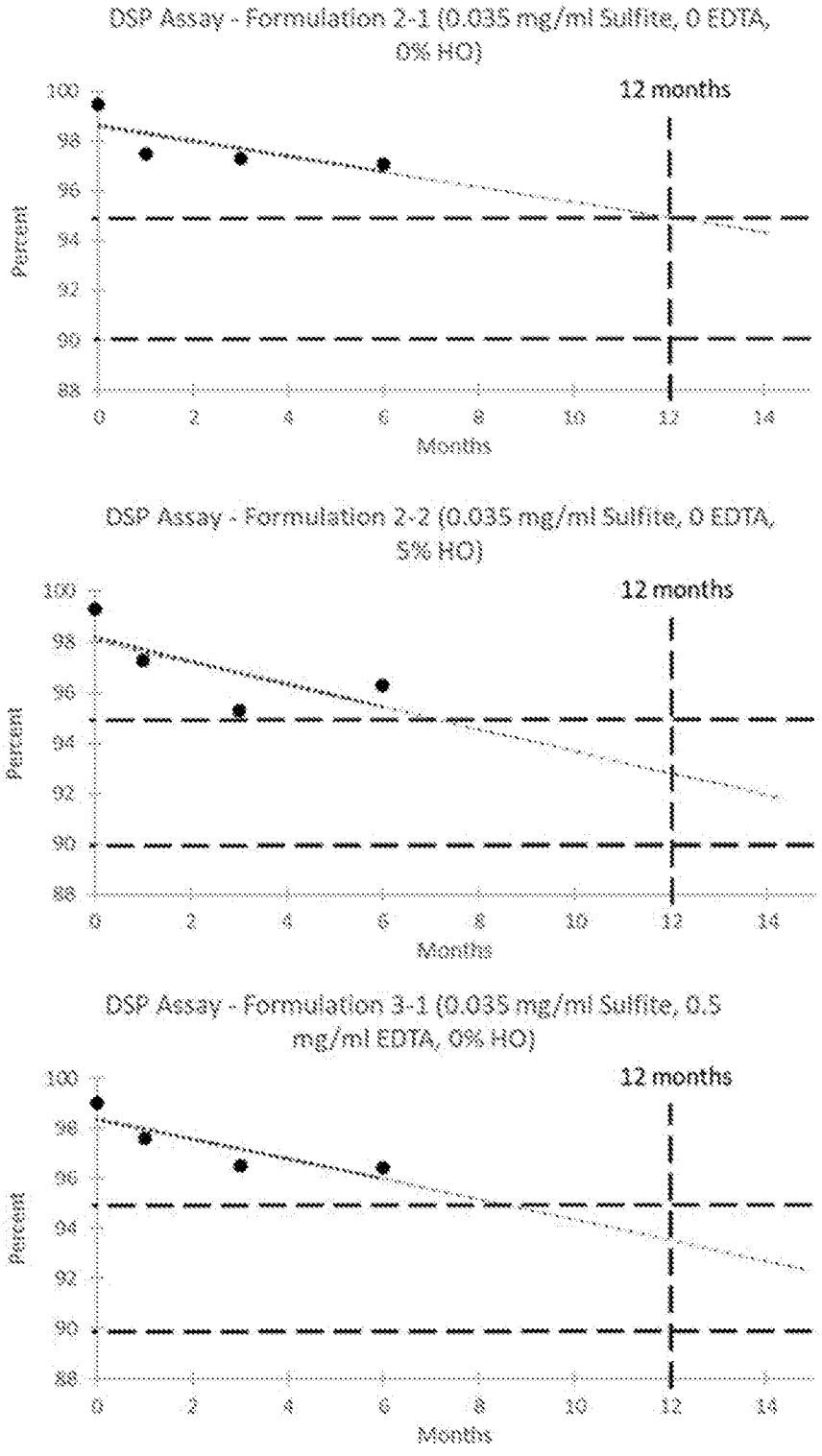

DSP Assay - Formulation 2-1 (0.035 mg/ml Sulfite, 0 EDTA, 0% HO)
12 months
Percent
Months
DSP Assay - Formulation 2-2 (0.035 mg/ml Sulfite, 0 EDTA, 5% HO)
12 months
Percent
Months
DSP Assay - Formulation 3-1 (0.035 mg/ml Sulfite, 0.5 mg/ml EDTA, 0% HO)
12 months
Percent
Months

Figure 38

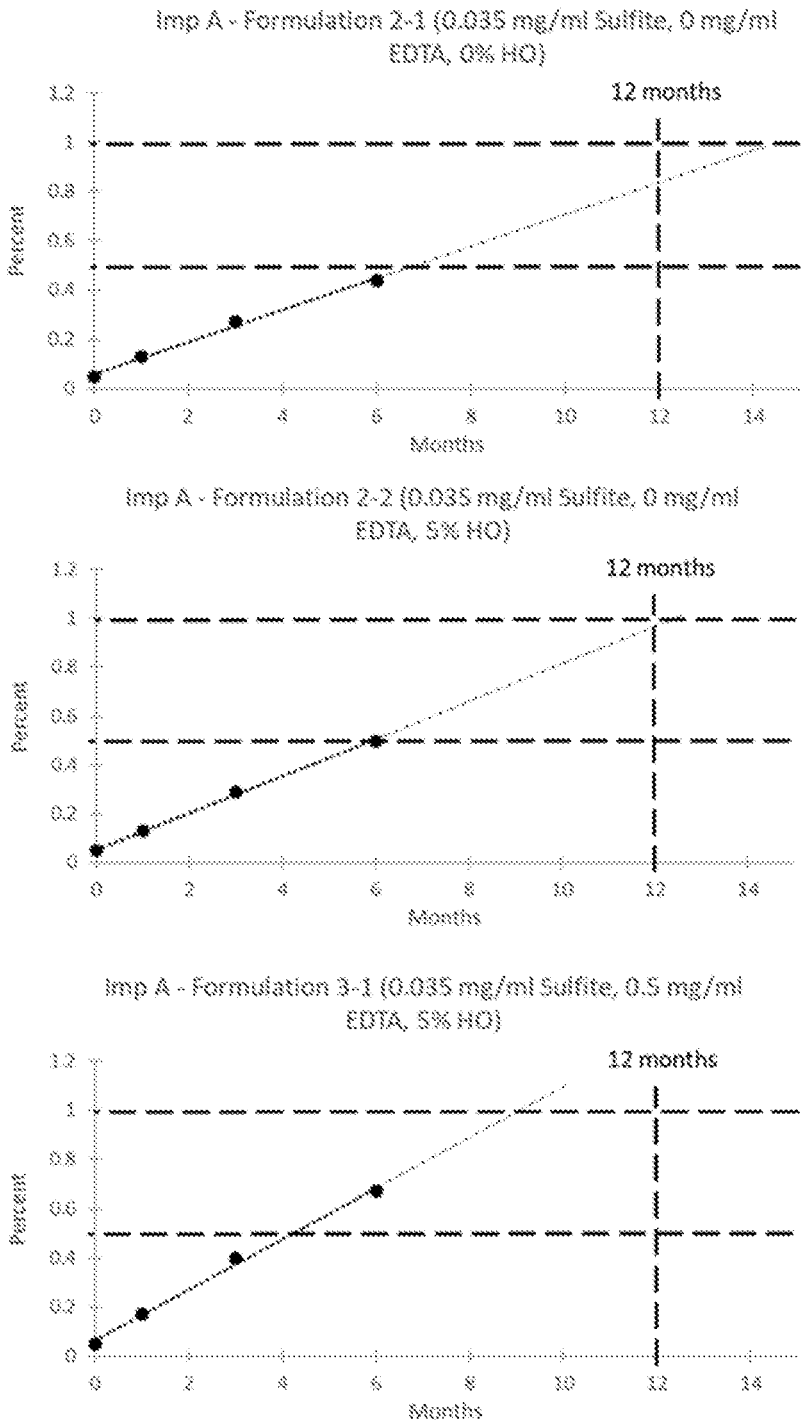

Imp A - Formulation 2-1 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 0% HO)
12 months
Percent
Months
Imp A - Formulation 2-2 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 5% HO)
12 months
Percent
Months
Imp A - Formulation 3-1 (0.035 mg/ml Sulfite, 0.5 mg/ml EDTA, 5% HO)
12 months
Percent
Months

Figure 39

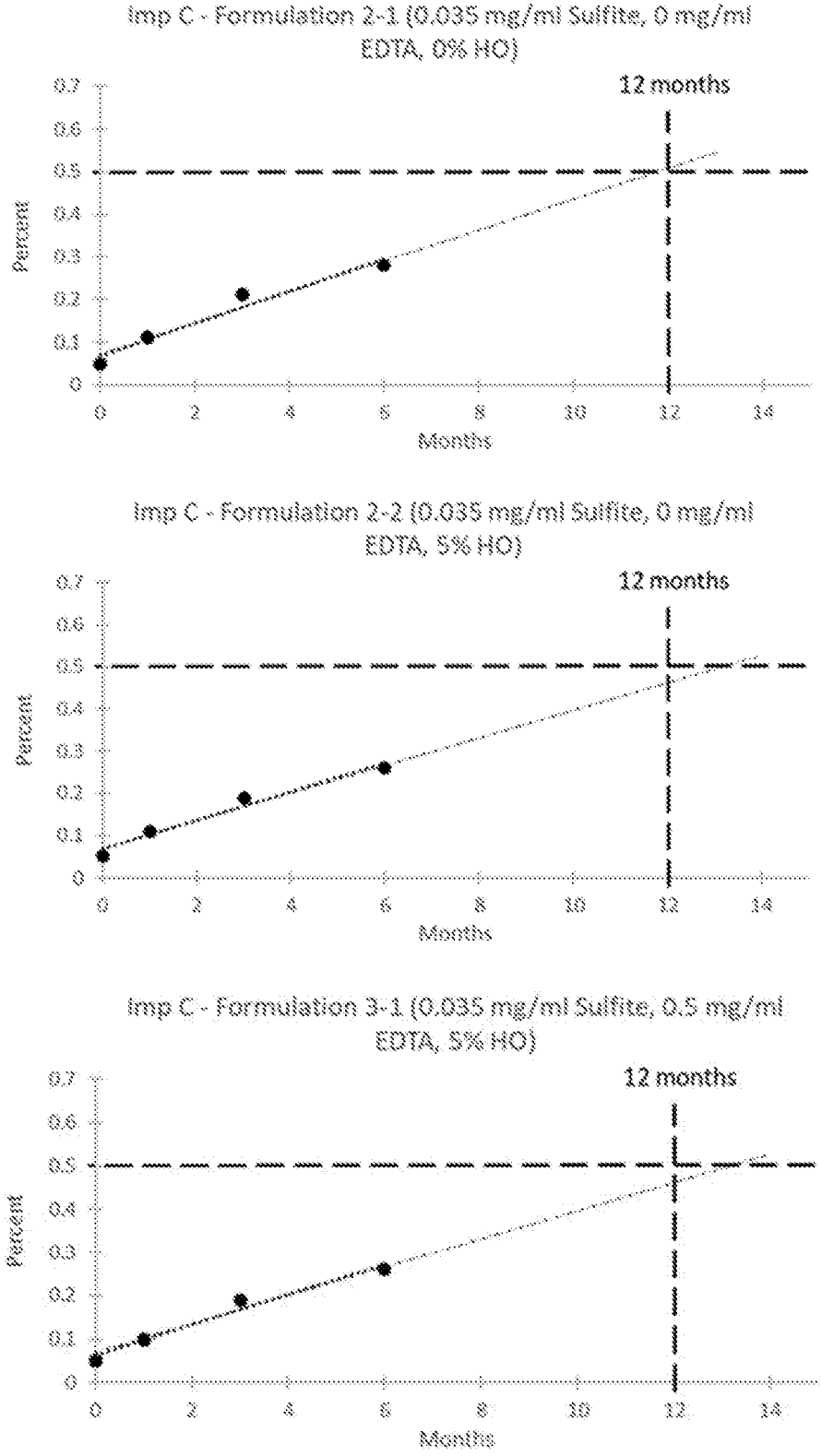

Imp C - Formulation 2-1 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 0% HO)
12 months
Percent
Months
Imp C - Formulation 2-2 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 5% HO)
12 months
Percent
Months
Imp C - Formulation 3-1 (0.035 mg/ml Sulfite, 0.5 mg/ml EDTA, 5% HO)
12 months
Percent
Months

Figure 40

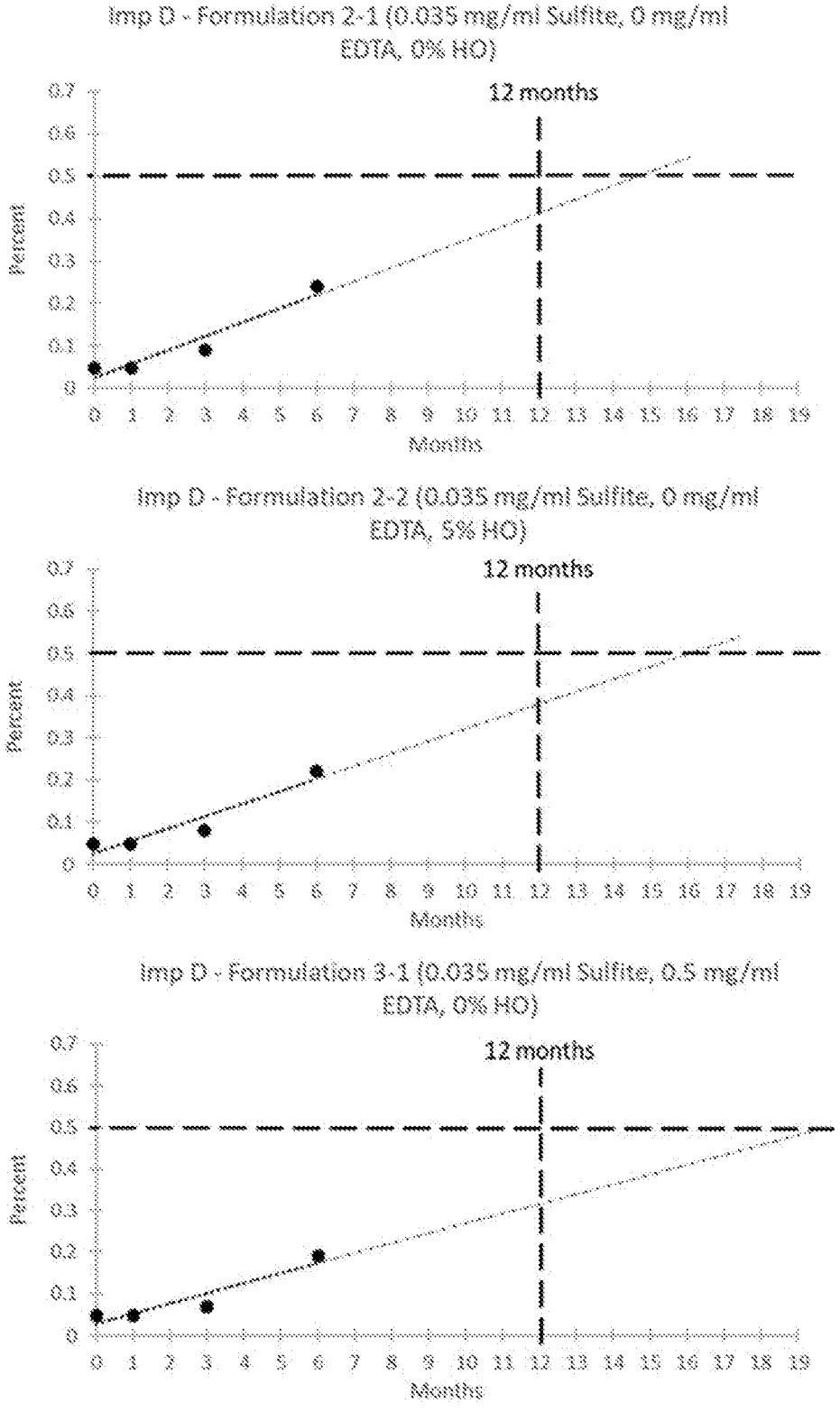

Imp D - Formulation 2-1 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 0% HO)
12 months
Percent
Months
Imp D - Formulation 2-2 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 5% HO)
12 months
Percent
Months
Imp D - Formulation 3-1 (0.035 mg/ml Sulfite, 0.5 mg/ml EDTA, 0% HO)
12 months
Percent
Months

Figure 41

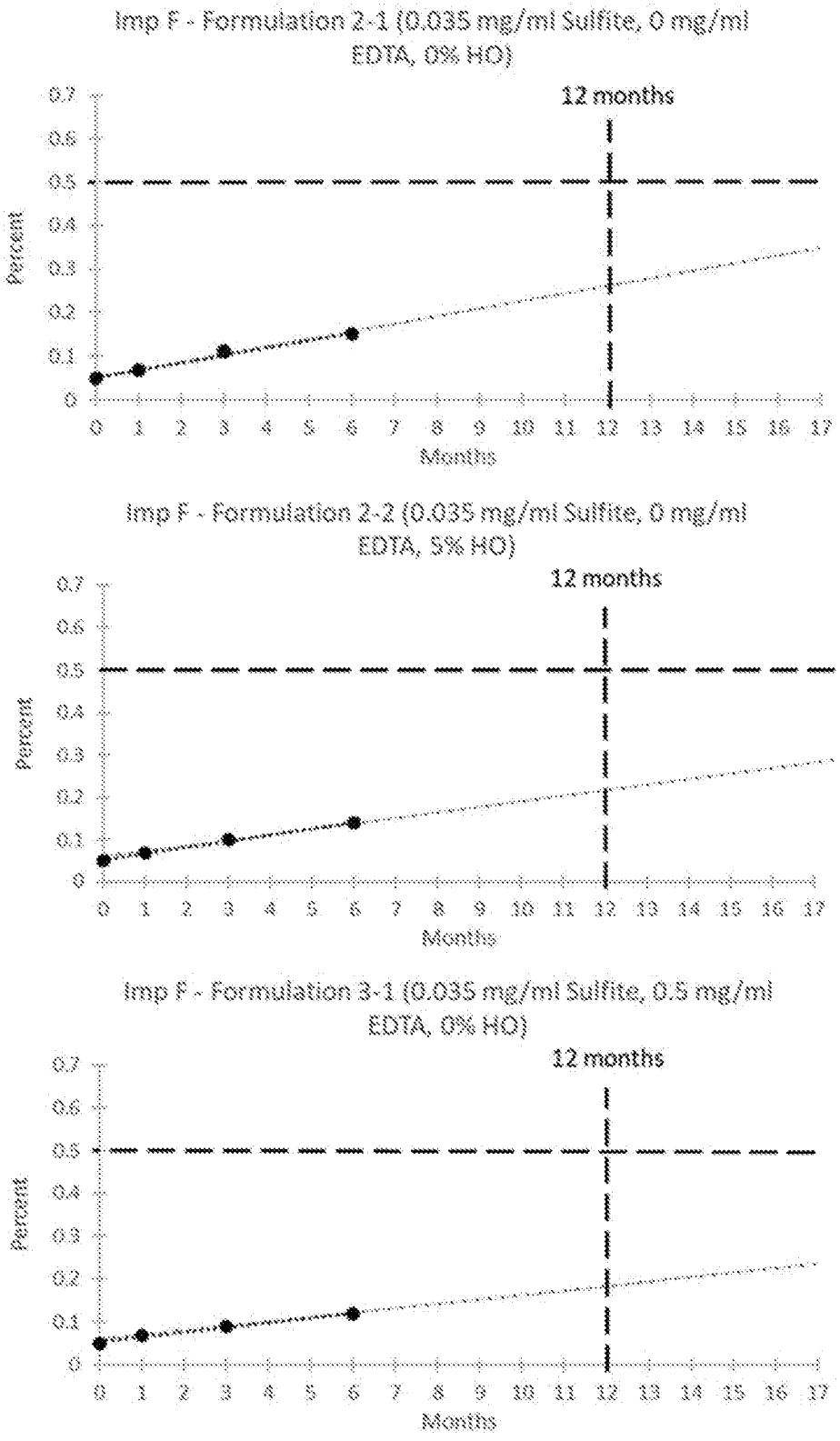

Imp F - Formulation 2-1 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 0% HO)
12 months
Percent
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17
Months
Imp F - Formulation 2-2 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 5% HO)
12 months
Percent
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17
Months
Imp F - Formulation 3-1 (0.035 mg/ml Sulfite, 0.5 mg/ml EDTA, 0% HO)
12 months
Percent
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17
Months

Figure 42

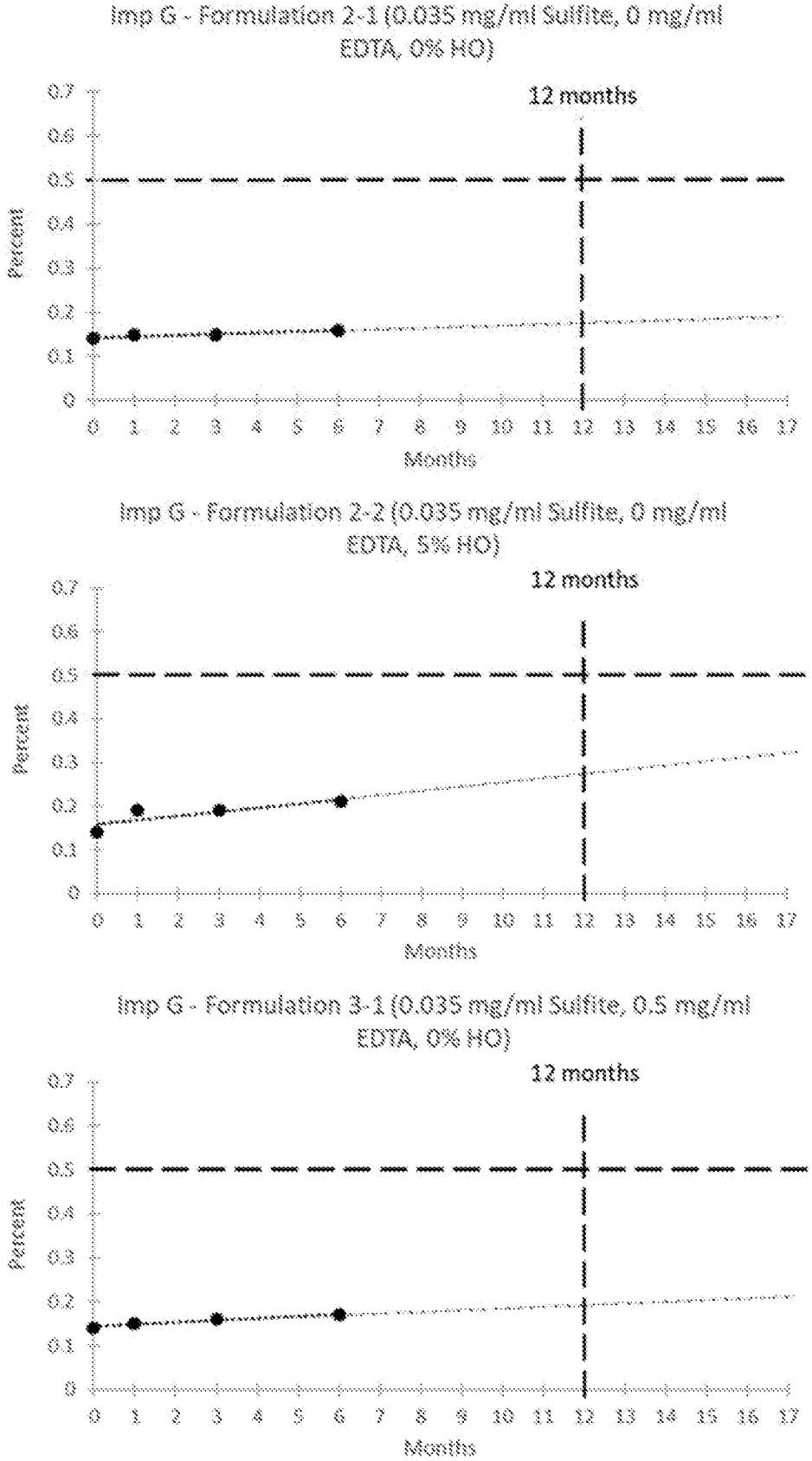

Imp G - Formulation 2-1 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 0% HO)
12 months
Percent
Months
Imp G - Formulation 2-2 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 5% HO)
12 months
Percent
Months
Imp G - Formulation 3-1 (0.035 mg/ml Sulfite, 0.5 mg/ml EDTA, 0% HO)
12 months
Percent
Months

Figure 43

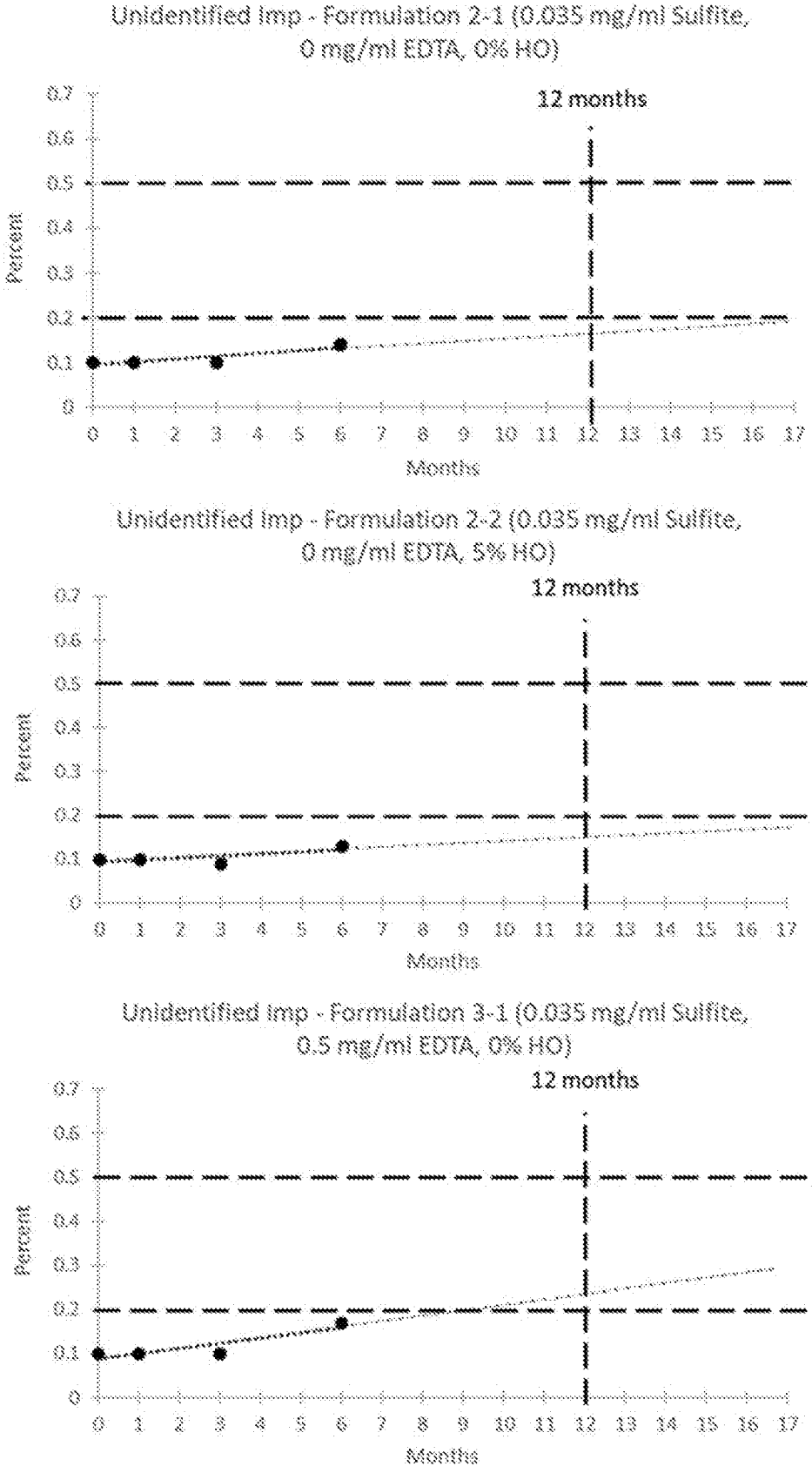

Unidentified Imp - Formulation 2-1 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 0% HO)
12 months
Percent
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17
Months
Unidentified Imp - Formulation 2-2 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 5% HO)
12 months
Percent
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17
Months
Unidentified Imp - Formulation 3-1 (0.035 mg/ml Sulfite, 0.5 mg/ml EDTA, 0% HO)
12 months
Percent
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17
Months

Figure 44

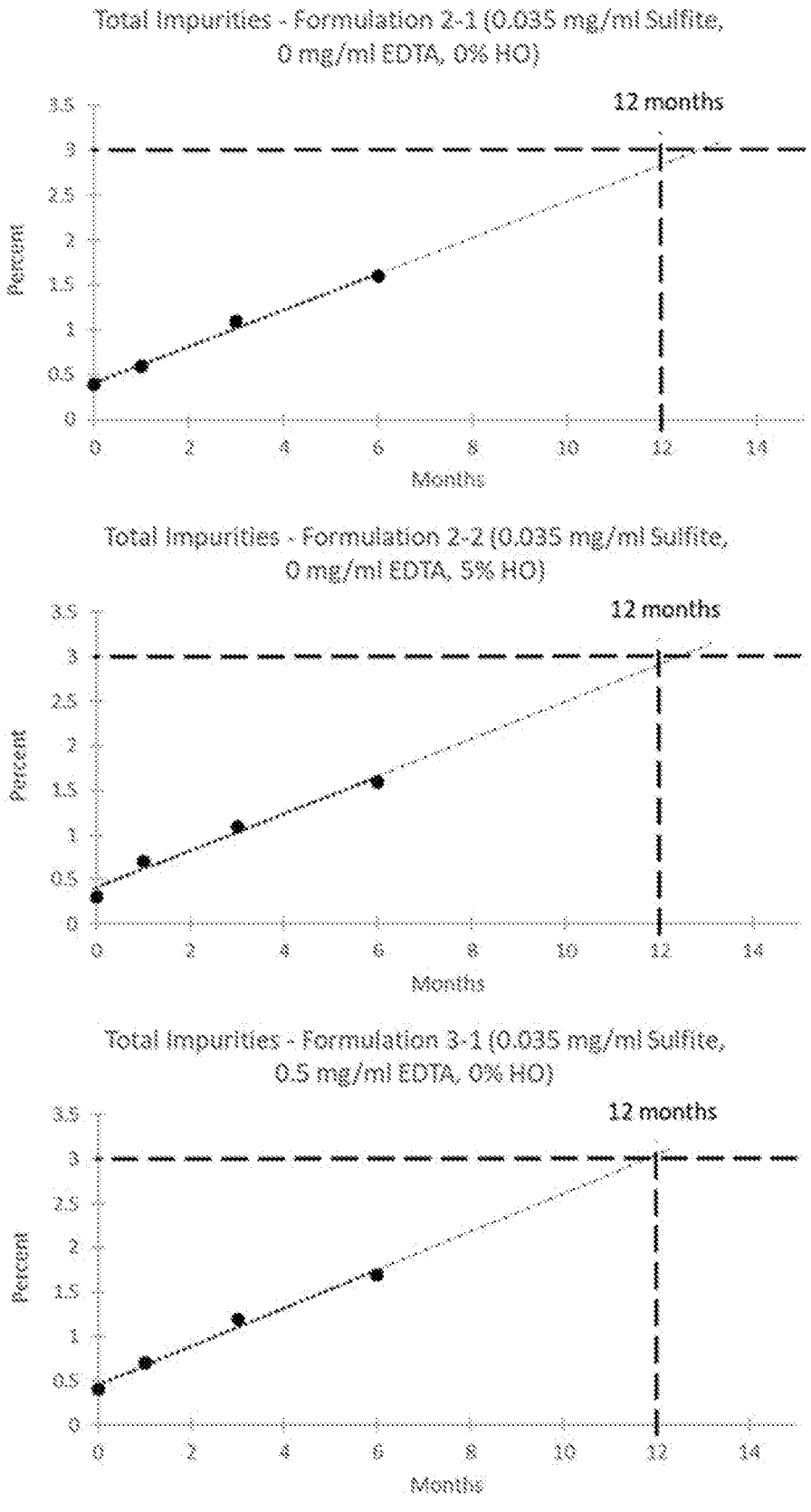
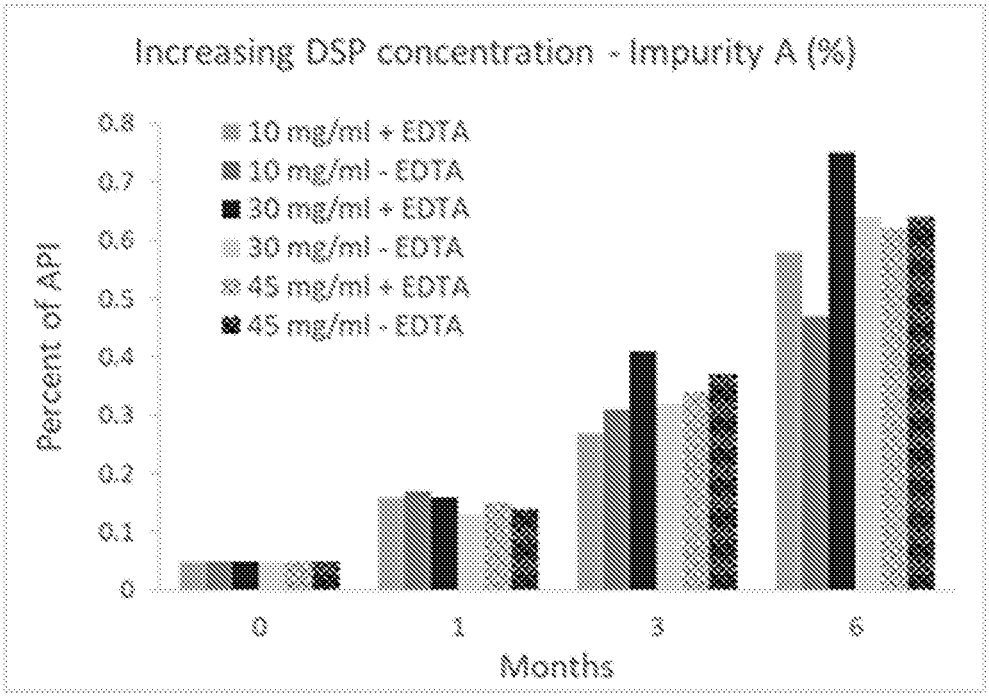

Total Impurities - Formulation 2-1 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 0% HO)
12 months
Percent
Months
Total Impurities - Formulation 2-2 (0.035 mg/ml Sulfite, 0 mg/ml EDTA, 5% HO)
12 months
Percent
Months
Total Impurities - Formulation 3-1 (0.035 mg/ml Sulfite, 0.5 mg/ml EDTA, 0% HO)
12 months
Percent
Months

Figure 45


Increasing DSP concentration - Impurity A (%)
Percent of API
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
10 mg/ml + EDTA
10 mg/ml - EDTA
30 mg/ml + EDTA
30 mg/ml - EDTA
45 mg/ml + EDTA
45 mg/ml - EDTA
0
1
3
6
Months

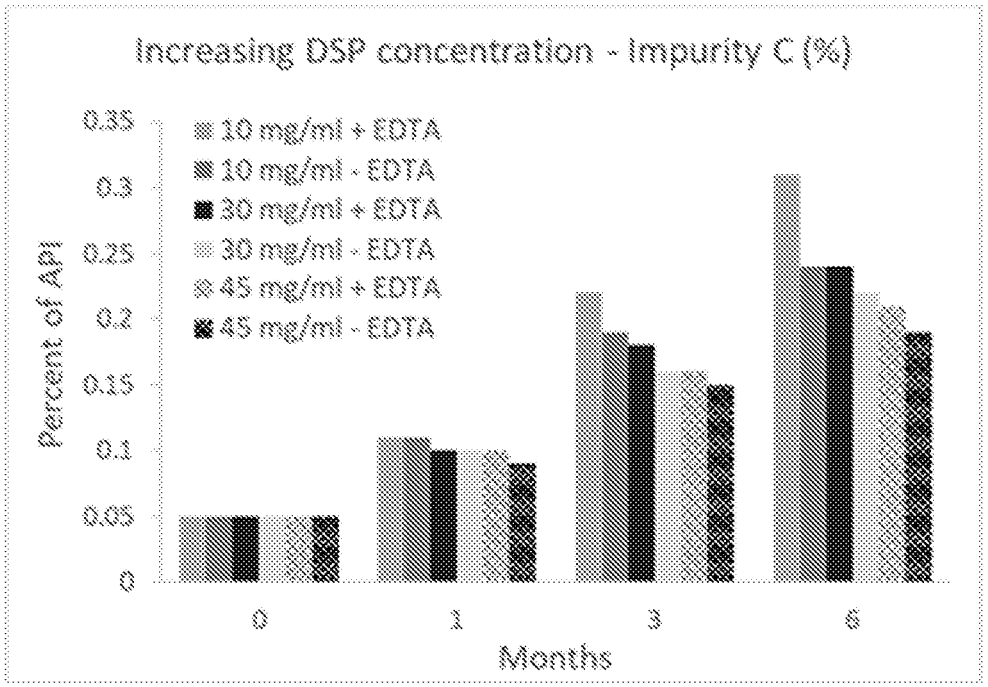
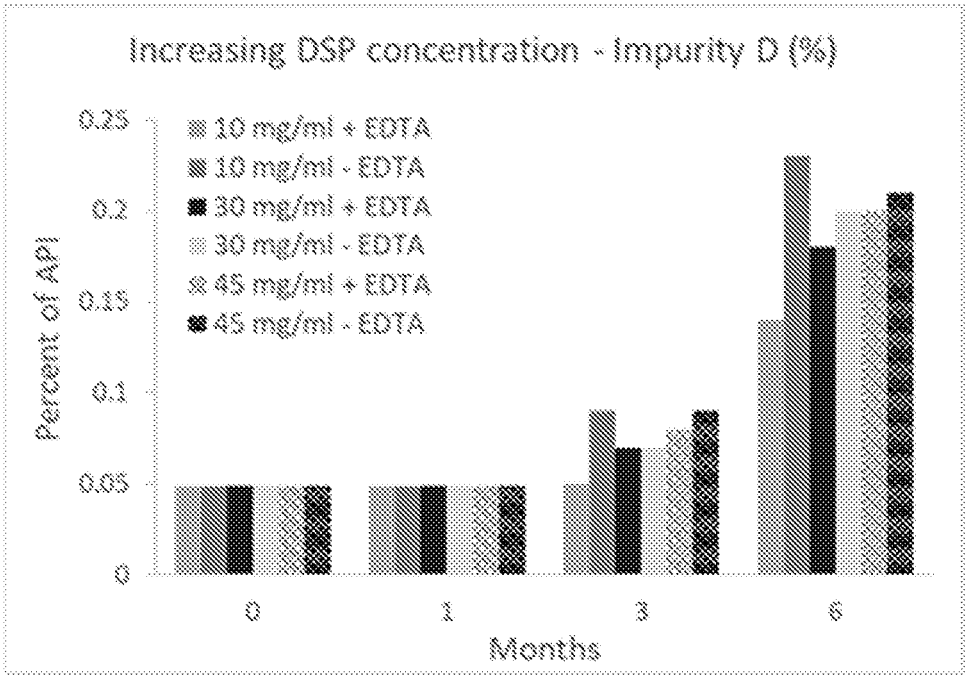

Increasing DSP concentration - Impurity C (%)
Percent of API
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
10 mg/ml + EDTA
10 mg/ml - EDTA
30 mg/ml + EDTA
30 mg/ml - EDTA
45 mg/ml + EDTA
45 mg/ml - EDTA
0
1
3
6
Months

Figure 46


Increasing DSP concentration - Impurity D (%)
10 mg/ml + EDTA
10 mg/ml - EDTA
30 mg/ml + EDTA
30 mg/ml - EDTA
45 mg/ml + EDTA
45 mg/ml - EDTA
Percent of API
0.25
0.2
0.15
0.1
0.05
0
0
1
3
6
Months

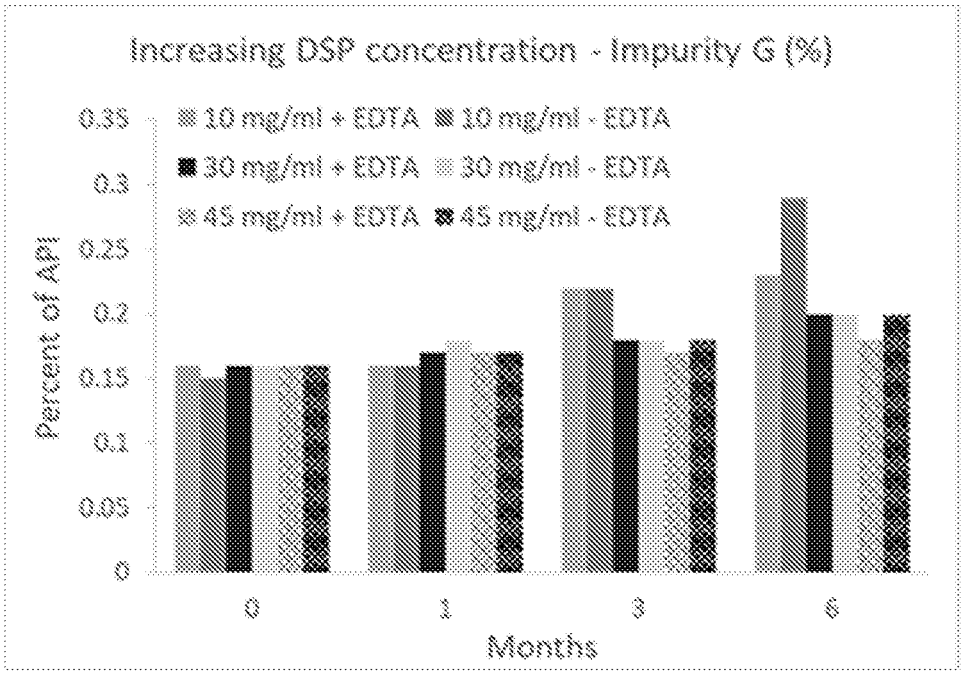
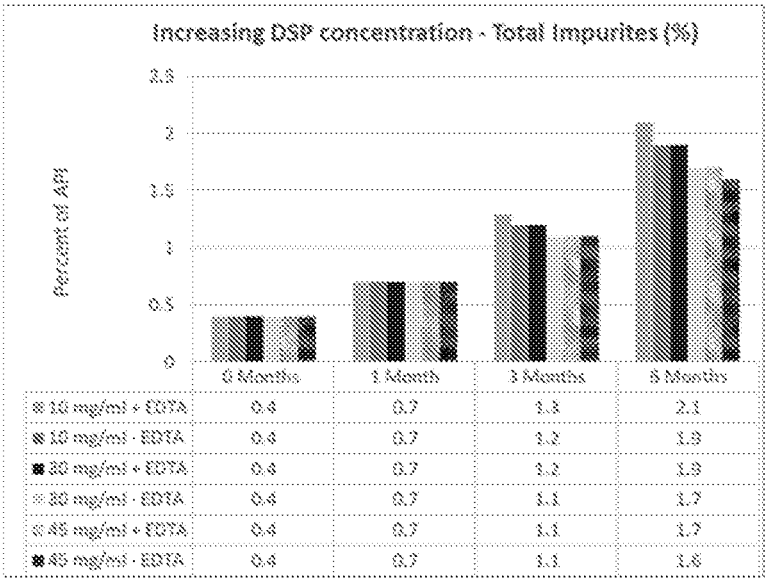
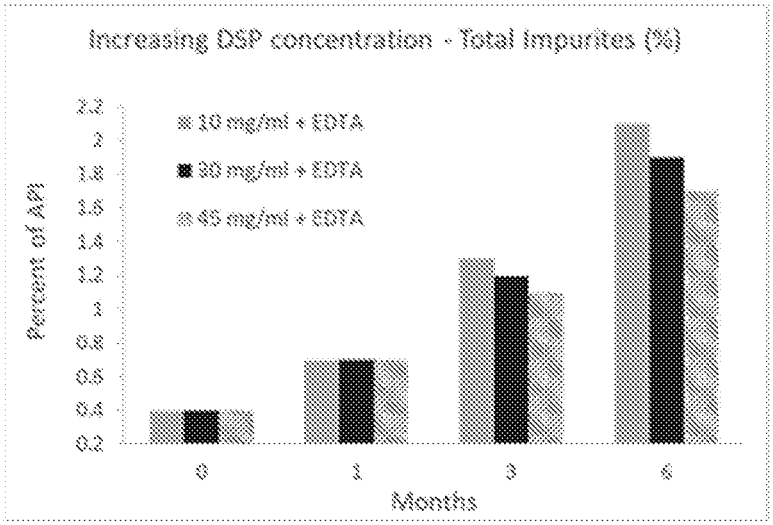
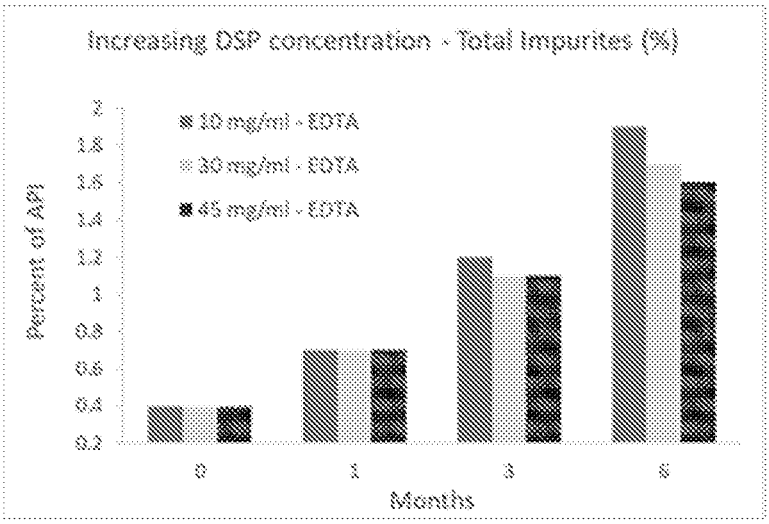

Increasing DSP concentration - Impurity G (%)
10 mg/ml + EDTA
10 mg/ml - EDTA
30 mg/ml + EDTA
30 mg/ml - EDTA
45 mg/ml + EDTA
45 mg/ml - EDTA
Percent of API
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
0
1
3
6
Months

Figure 47


Increasing DSP concentration - Total Impurites (%)
Percent of API
2.5
2
1.5
1
0.5
0
0 Months
1 Month
3 Months
6 Months
10 mg/ml + EDTA 0.4 0.7 1.3 2.1
10 mg/ml - EDTA 0.4 0.7 1.2 1.9
30 mg/ml + EDTA 0.4 0.7 1.2 1.9
30 mg/ml - EDTA 0.4 0.7 1.1 1.7
45 mg/ml + EDTA 0.4 0.7 1.1 1.7
45 mg/ml - EDTA 0.4 0.7 1.1 1.6


Increasing DSP concentration - Total Impurites (%)
Percent of API
10 mg/ml + EDTA
30 mg/ml + EDTA
45 mg/ml + EDTA
2.2
2
1.8
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
1
3
6
Months


Increasing DSP concentration - Total Impurites (%)
Percent of API
10 mg/ml - EDTA
30 mg/ml - EDTA
45 mg/ml - EDTA
2
1.8
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
1
3
6
Months