Fig. 1

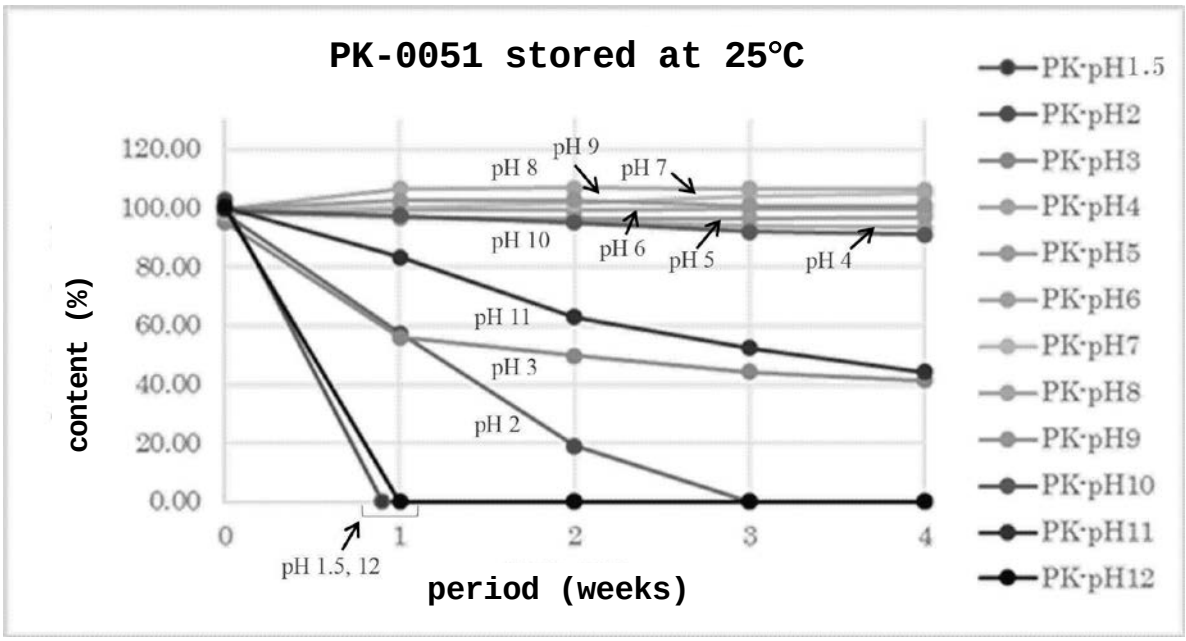

PK-0051 stored at 25℃
content (%)
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
1
2
3
4
period (weeks)
pH 1.5, 12
pH 2
pH 3
pH 4
pH 5
pH 6
pH 7
pH 8
pH 9
pH 10
pH 11
PK-pH1.5
PK-pH2
PK-pH3
PK-pH4
PK-pH5
PK-pH6
PK-pH7
PK-pH8
PK-pH9
PK-pH10
PK-pH11
PK-pH12

Fig. 2

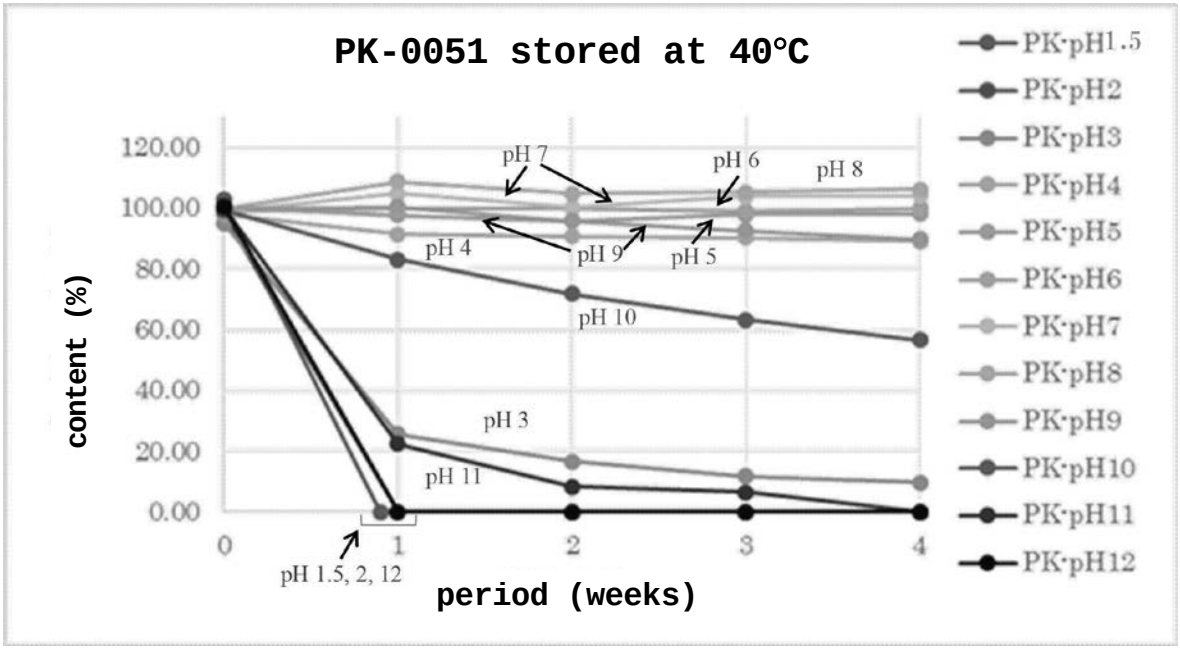

PK-0051 stored at 40℃
content (%)
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
1
2
3
4
period (weeks)
pH 1.5, 2, 12
pH 3
pH 4
pH 5
pH 6
pH 7
pH 8
pH 9
pH 10
pH 11
PK-pH1.5
PK-pH2
PK-pH3
PK-pH4
PK-pH5
PK-pH6
PK-pH7
PK-pH8
PK-pH9
PK-pH10
PK-pH11
PK-pH12

Fig. 3

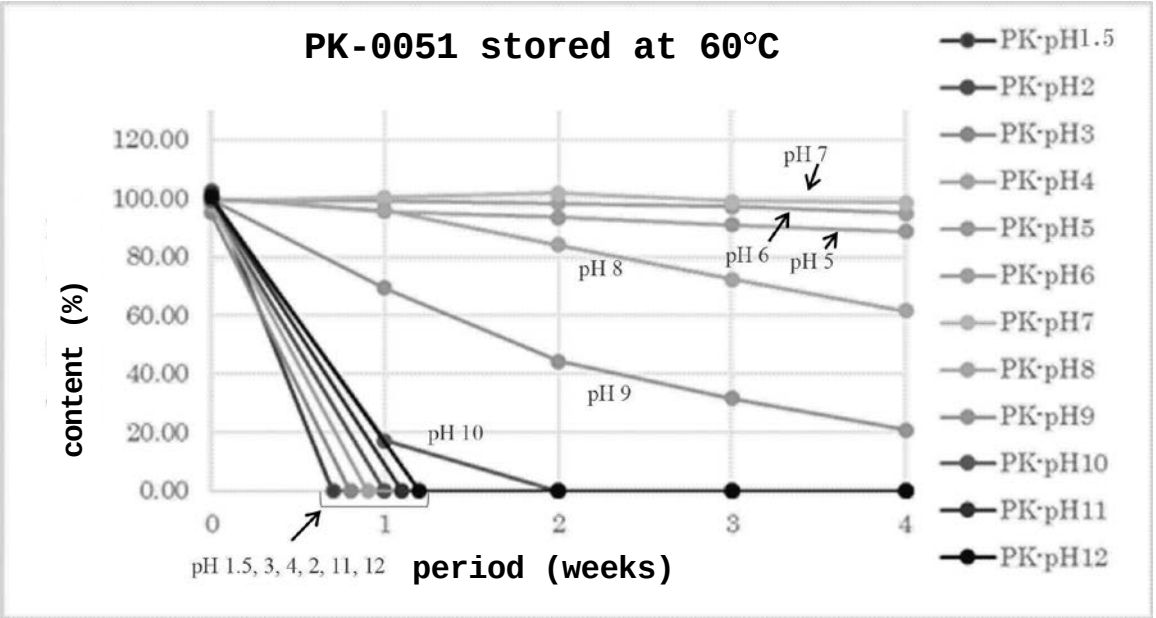

PK-0051 stored at 60°C
content (%)
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
1
2
3
4
pH 7
pH 6
pH 5
pH 8
pH 9
pH 10
pH 1.5, 3, 4, 2, 11, 12
period (weeks)
PK-pH1.5
PK-pH2
PK-pH3
PK-pH4
PK-pH5
PK-pH6
PK-pH7
PK-pH8
PK-pH9
PK-pH10
PK-pH11
PK-pH12

Fig. 4

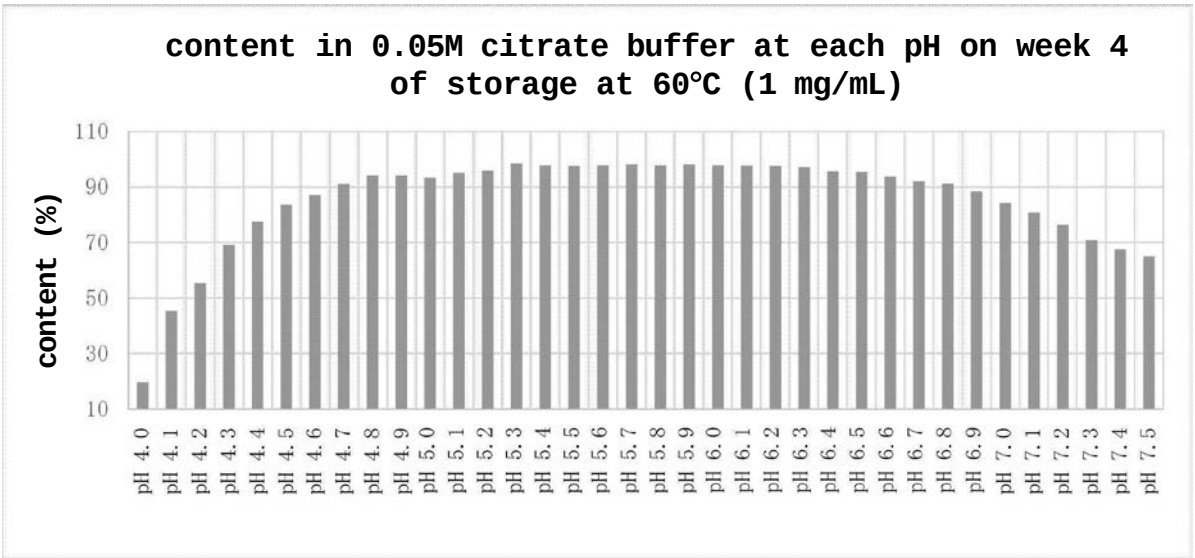

content in 0.05M citrate buffer at each pH on week 4 of storage at 60°C (1 mg/mL)
content (%)
110
90
70
50
30
10
pH 4.0
pH 4.1
pH 4.2
pH 4.3
pH 4.4
pH 4.5
pH 4.6
pH 4.7
pH 4.8
pH 4.9
pH 5.0
pH 5.1
pH 5.2
pH 5.3
pH 5.4
pH 5.5
pH 5.6
pH 5.7
pH 5.8
pH 5.9
pH 6.0
pH 6.1
pH 6.2
pH 6.3
pH 6.4
pH 6.5
pH 6.6
pH 6.7
pH 6.8
pH 6.9
pH 7.0
pH 7.1
pH 7.2
pH 7.3
pH 7.4
pH 7.5

Fig. 5

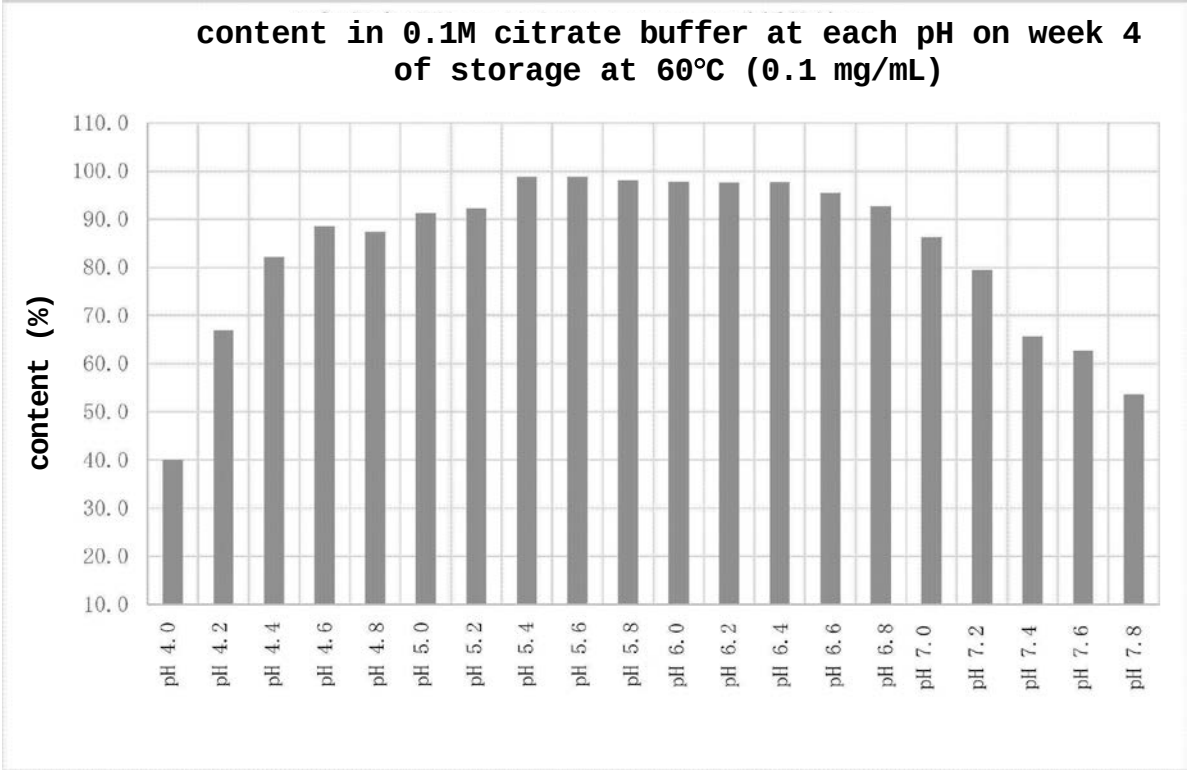

content in 0.1M citrate buffer at each pH on week 4 of storage at 60℃ (0.1 mg/mL)
content (%)
110.0
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
pH 4.0
pH 4.2
pH 4.4
pH 4.6
pH 4.8
pH 5.0
pH 5.2
pH 5.4
pH 5.6
pH 5.8
pH 6.0
pH 6.2
pH 6.4
pH 6.6
pH 6.8
pH 7.0
pH 7.2
pH 7.4
pH 7.6
pH 7.8

Fig. 6

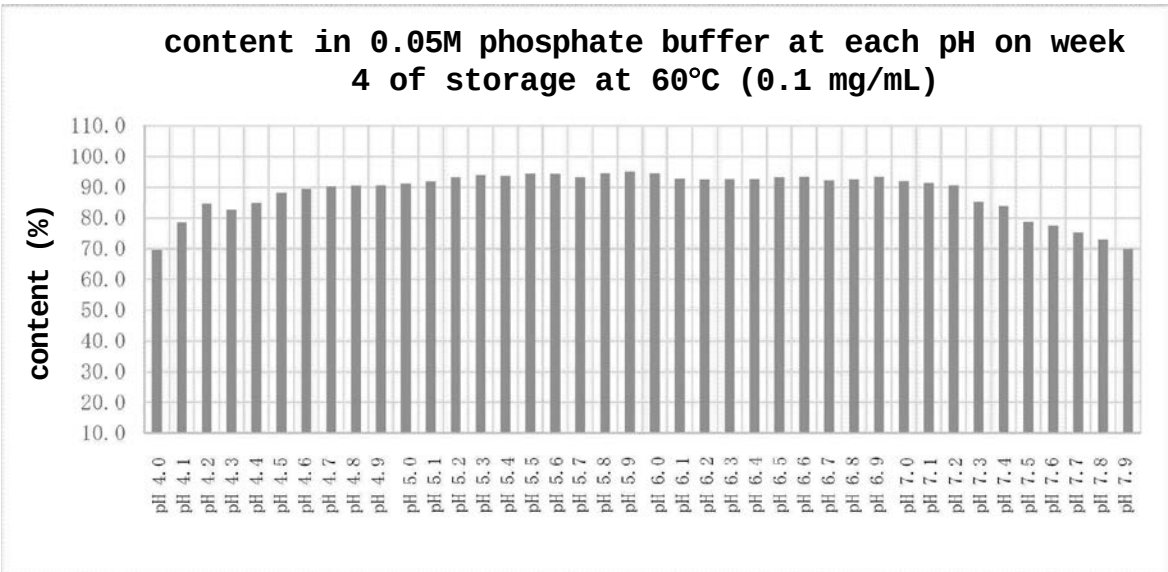

content in 0.05M phosphate buffer at each pH on week 4 of storage at 60℃ (0.1 mg/mL)
content (%)
110.0
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
pH 4.0
pH 4.1
pH 4.2
pH 4.3
pH 4.4
pH 4.5
pH 4.6
pH 4.7
pH 4.8
pH 4.9
pH 5.0
pH 5.1
pH 5.2
pH 5.3
pH 5.4
pH 5.5
pH 5.6
pH 5.7
pH 5.8
pH 5.9
pH 6.0
pH 6.1
pH 6.2
pH 6.3
pH 6.4
pH 6.5
pH 6.6
pH 6.7
pH 6.8
pH 6.9
pH 7.0
pH 7.1
pH 7.2
pH 7.3
pH 7.4
pH 7.5
pH 7.6
pH 7.7
pH 7.8
pH 7.9

Fig. 7

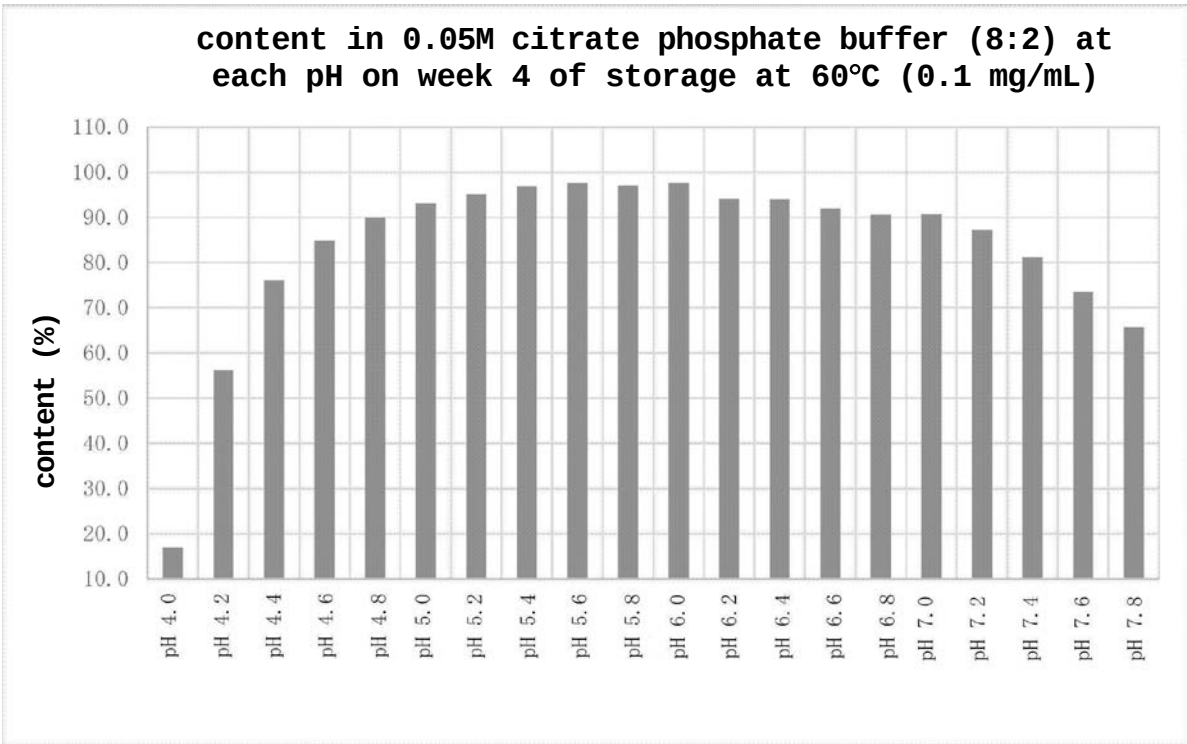

content in 0.05M citrate phosphate buffer (8:2) at each pH on week 4 of storage at 60℃ (0.1 mg/mL)
content (%)
110.0
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
pH 4.0
pH 4.2
pH 4.4
pH 4.6
pH 4.8
pH 5.0
pH 5.2
pH 5.4
pH 5.6
pH 5.8
pH 6.0
pH 6.2
pH 6.4
pH 6.6
pH 6.8
pH 7.0
pH 7.2
pH 7.4
pH 7.6
pH 7.8

Fig. 8

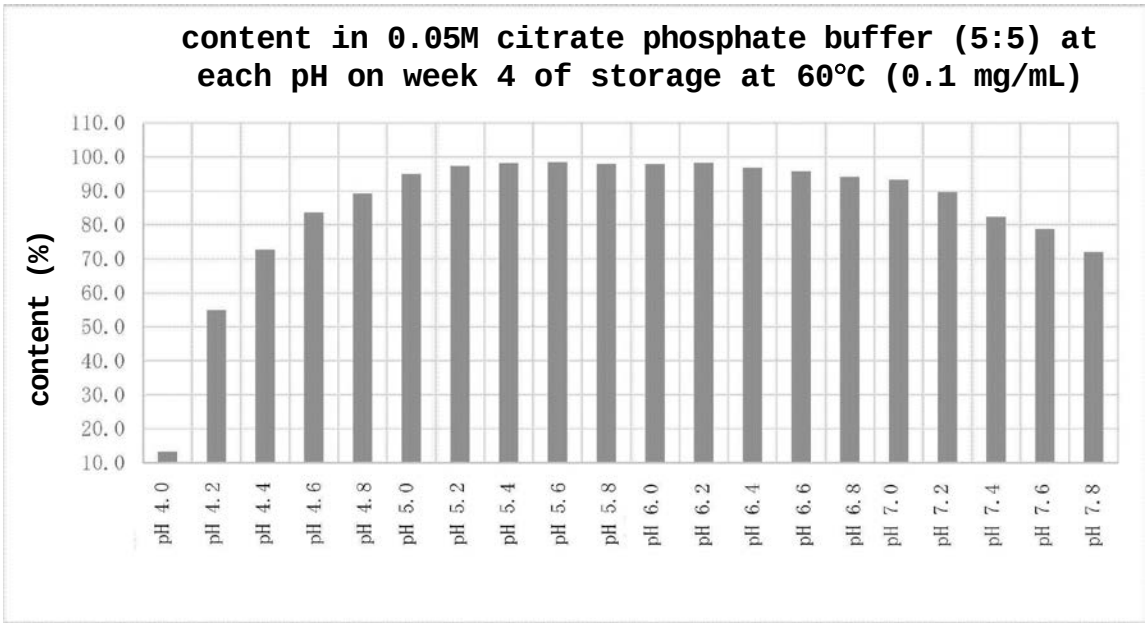

content in 0.05M citrate phosphate buffer (5:5) at each pH on week 4 of storage at 60℃ (0.1 mg/mL)
content (%)
110.0
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
pH 4.0
pH 4.2
pH 4.4
pH 4.6
pH 4.8
pH 5.0
pH 5.2
pH 5.4
pH 5.6
pH 5.8
pH 6.0
pH 6.2
pH 6.4
pH 6.6
pH 6.8
pH 7.0
pH 7.2
pH 7.4
pH 7.6
pH 7.8

Fig. 9

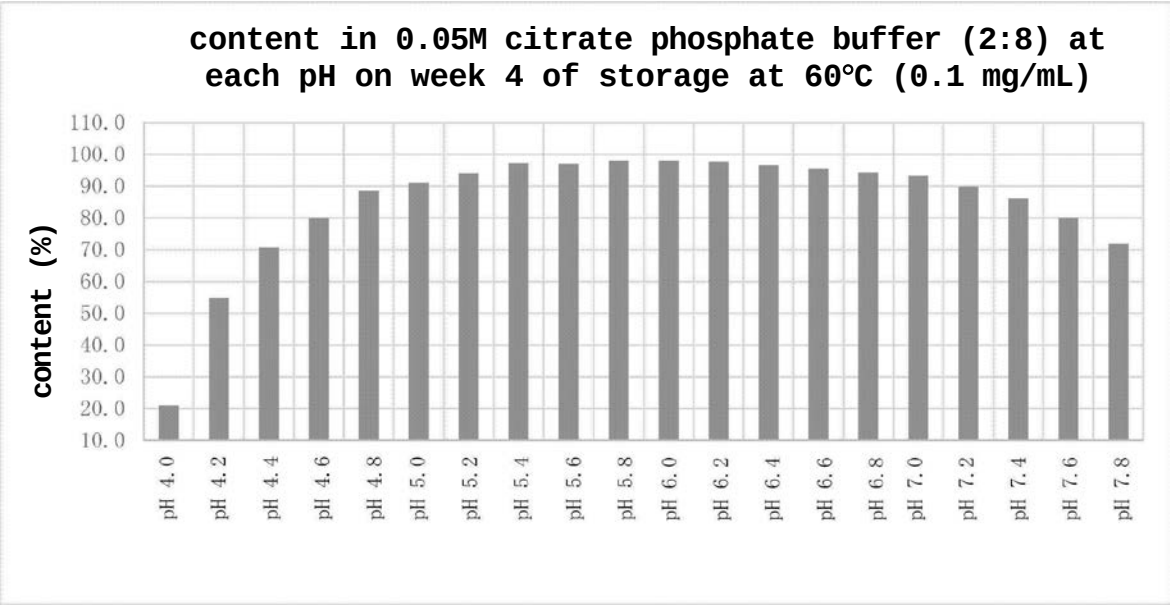

content in 0.05M citrate phosphate buffer (2:8) at each pH on week 4 of storage at 60℃ (0.1 mg/mL)
content (%)
110.0
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
pH 4.0
pH 4.2
pH 4.4
pH 4.6
pH 4.8
pH 5.0
pH 5.2
pH 5.4
pH 5.6
pH 5.8
pH 6.0
pH 6.2
pH 6.4
pH 6.6
pH 6.8
pH 7.0
pH 7.2
pH 7.4
pH 7.6
pH 7.8

Fig. 10

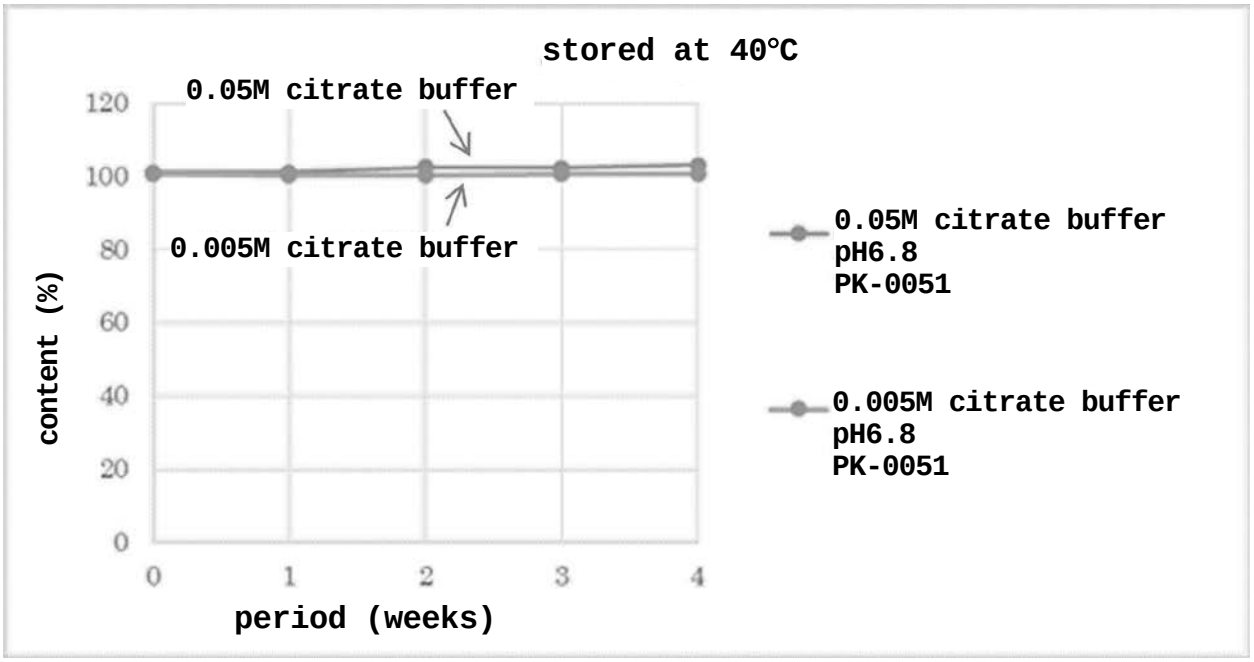

stored at 40℃
0.05M citrate buffer
0.005M citrate buffer
content (%)
120
100
80
60
40
20
0
0
1
2
3
4
period (weeks)
0.05M citrate buffer pH6.8 PK-0051
0.005M citrate buffer pH6.8 PK-0051

Fig. 11

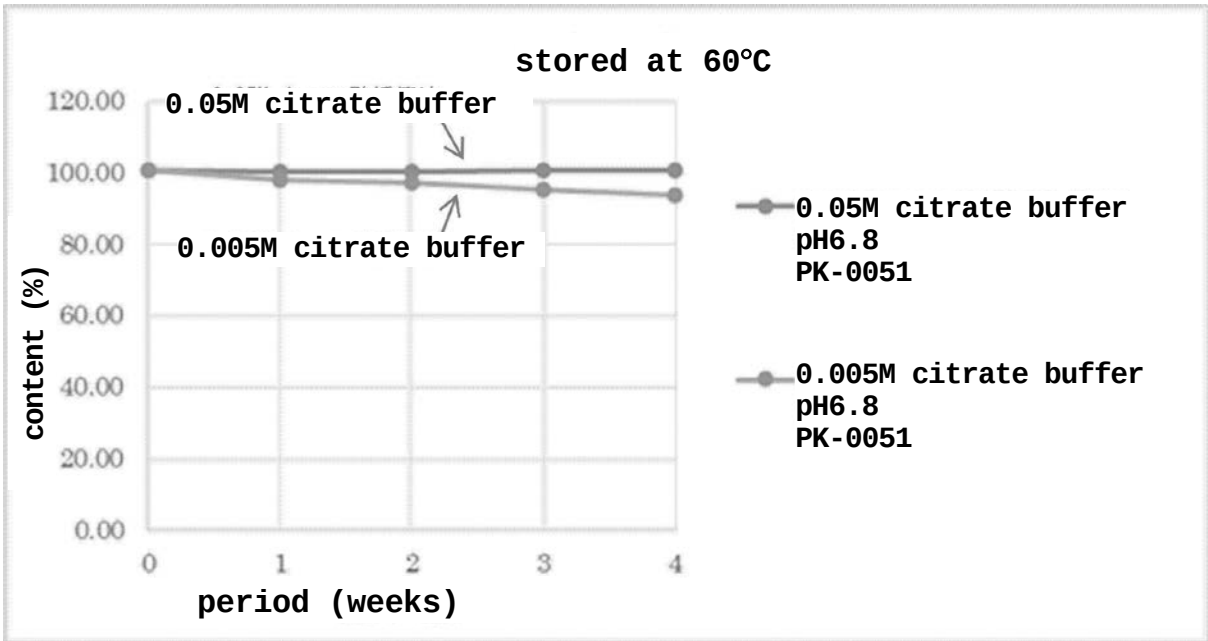

stored at 60°C
0.05M citrate buffer
0.005M citrate buffer
content (%)
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
1
2
3
4
period (weeks)
0.05M citrate buffer pH6.8 PK-0051
0.005M citrate buffer pH6.8 PK-0051

Fig. 12

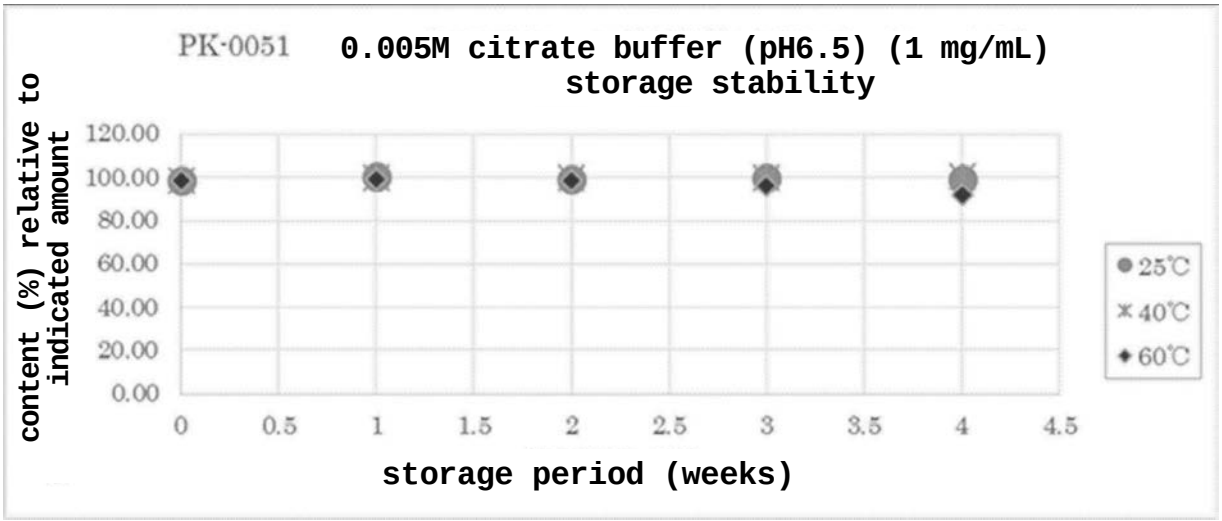

PK-0051
0.005M citrate buffer (pH6.5) (1 mg/mL)
storage stability
content (%) relative to indicated amount
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
storage period (weeks)
25℃
40℃
60℃

Fig. 13

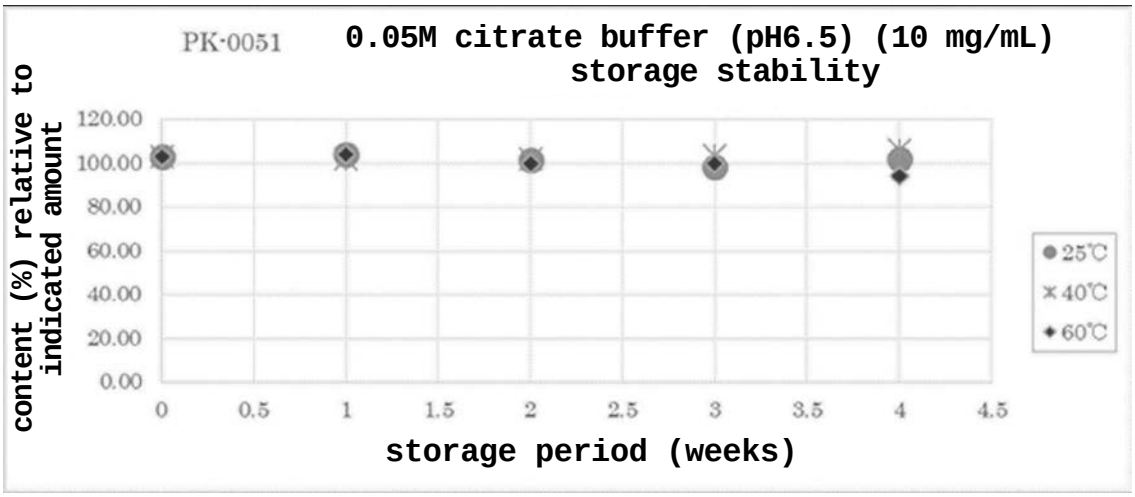

PK-0051
0.05M citrate buffer (pH6.5) (10 mg/mL)
storage stability
content (%) relative to indicated amount
120.00
100.00
80.00
60.00
40.00
20.00
0.00
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
storage period (weeks)
25℃
40℃
60℃

Fig. 14

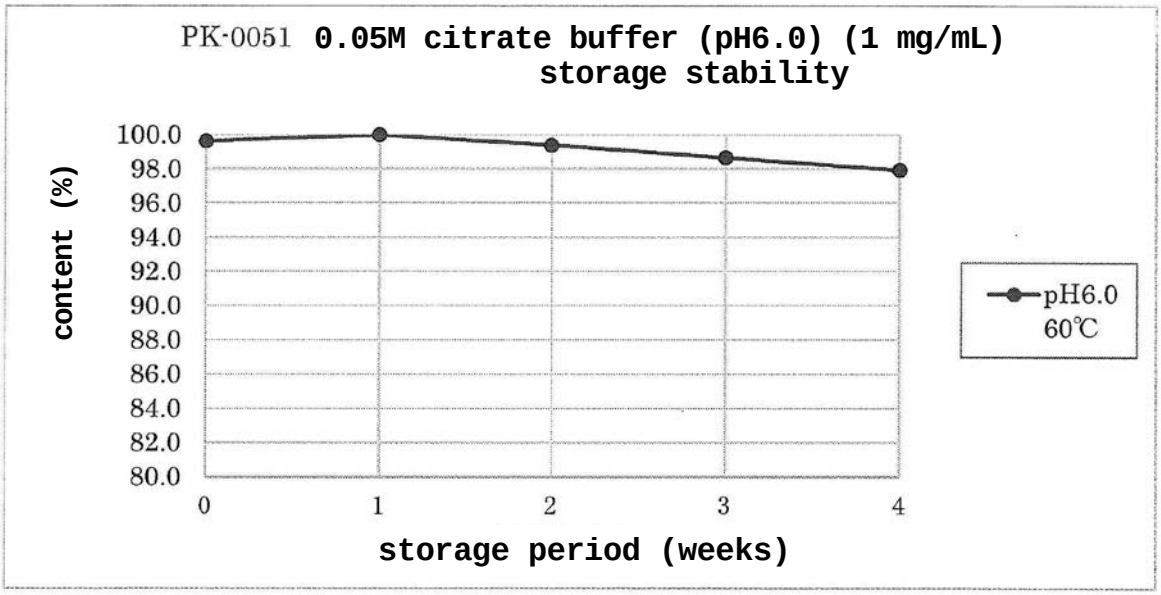

PK-0051 0.05M citrate buffer (pH6.0) (1 mg/mL)
storage stability
content (%)
100.0
98.0
96.0
94.0
92.0
90.0
88.0
86.0
84.0
82.0
80.0
0
1
2
3
4
storage period (weeks)
pH6.0
60℃

Fig. 15

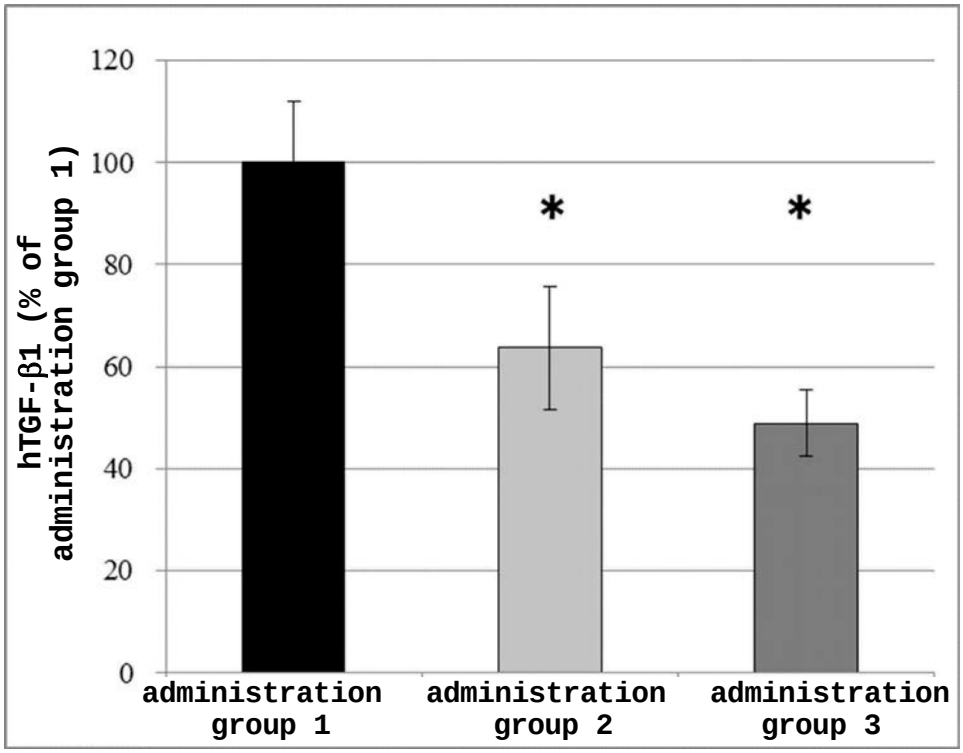

hTGF-β1 (% of administration group 1)
120
100
80
60
40
20
0
*
*
administration group 1
administration group 2
administration group 3

Fig. 16

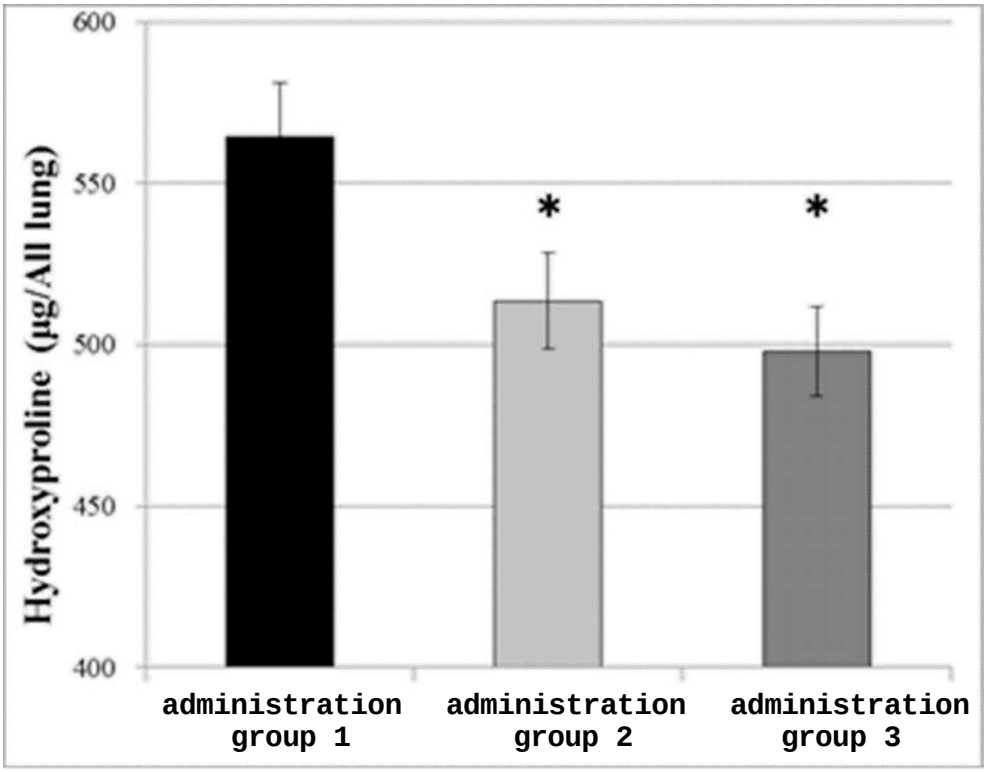

Hydroxyproline (μg/All lung)
600
550
500
450
400
*
*
administration group 1
administration group 2
administration group 3

Fig. 17

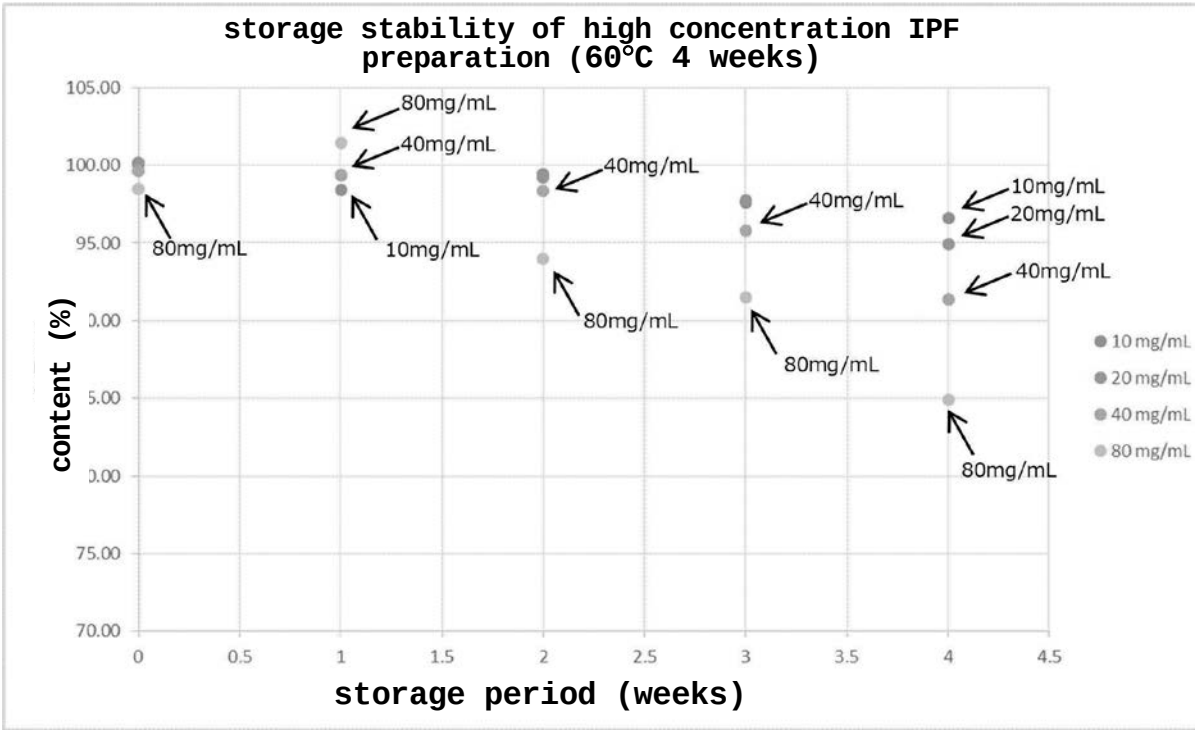

storage stability of high concentration IPF preparation (60°C 4 weeks)
content (%)
storage period (weeks)
105.00
100.00
95.00
75.00
70.00
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
80mg/mL
40mg/mL
10mg/mL
20mg/mL
10 mg/mL
20 mg/mL
40 mg/mL
80 mg/mL

Fig. 18

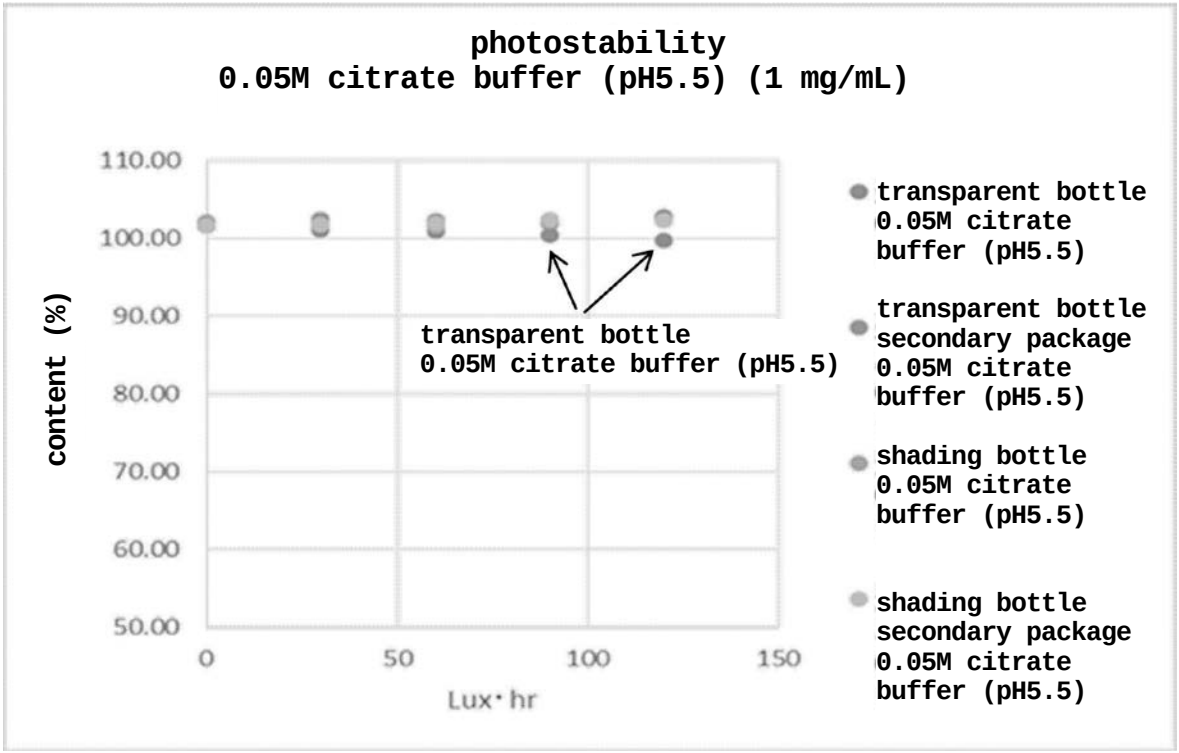

photostability
0.05M citrate buffer (pH5.5) (1 mg/mL)
content (%)
Lux·hr
110.00
100.00
90.00
80.00
70.00
60.00
50.00
0
50
100
150
transparent bottle
0.05M citrate buffer (pH5.5)
transparent bottle
0.05M citrate buffer (pH5.5)
transparent bottle secondary package
0.05M citrate buffer (pH5.5)
shading bottle
0.05M citrate buffer (pH5.5)
shading bottle secondary package
0.05M citrate buffer (pH5.5)

Fig. 19

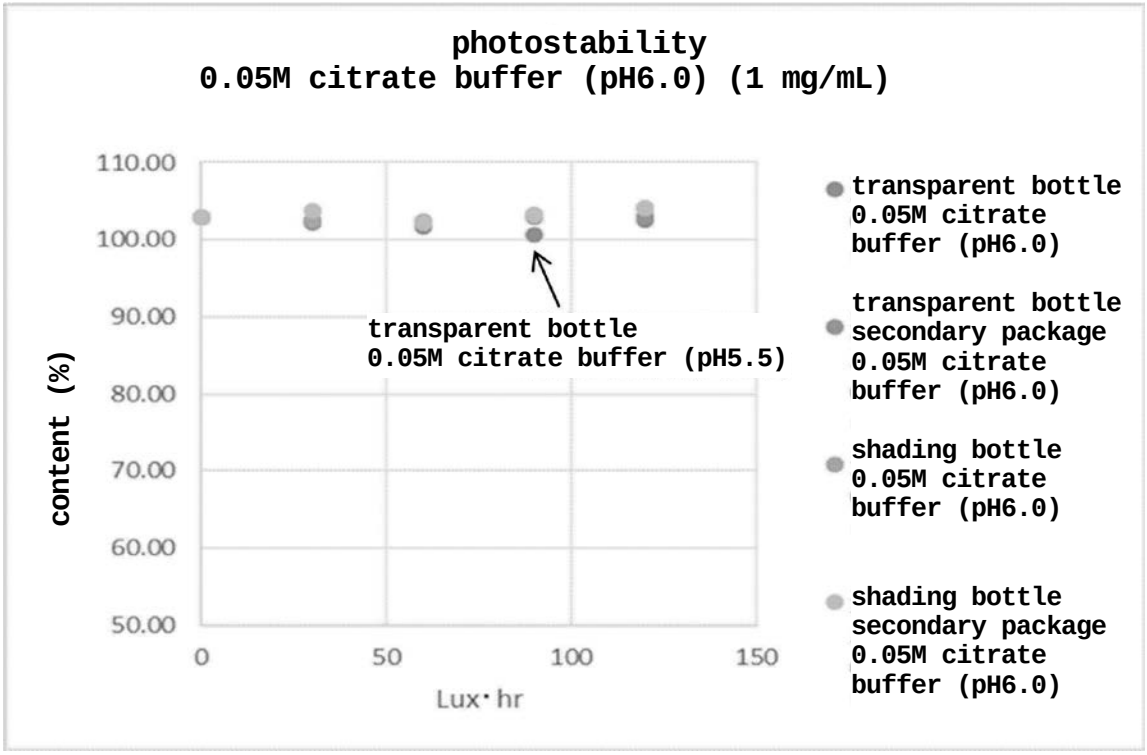

photostability
0.05M citrate buffer (pH6.0) (1 mg/mL)
content (%)
110.00
100.00
90.00
80.00
70.00
60.00
50.00
0
50
100
150
Lux·hr
transparent bottle
0.05M citrate buffer (pH5.5)
transparent bottle
0.05M citrate
buffer (pH6.0)
transparent bottle
secondary package
0.05M citrate
buffer (pH6.0)
shading bottle
0.05M citrate
buffer (pH6.0)
shading bottle
secondary package
0.05M citrate
buffer (pH6.0)

Fig. 20

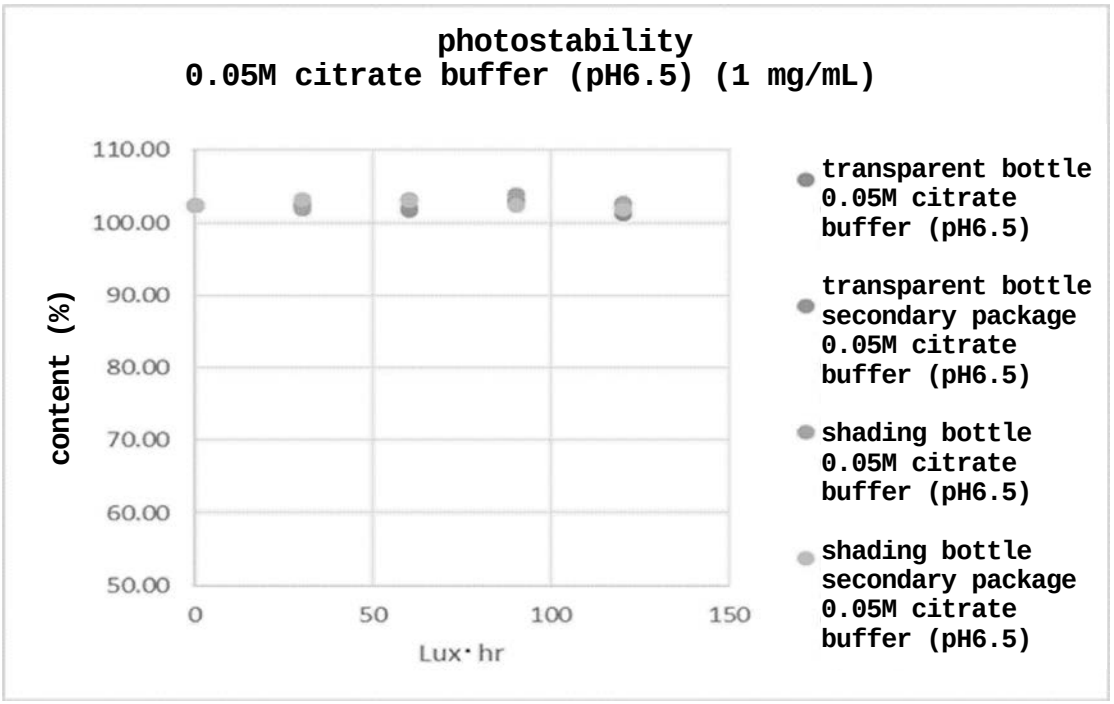

photostability
0.05M citrate buffer (pH6.5) (1 mg/mL)
content (%)
110.00
100.00
90.00
80.00
70.00
60.00
50.00
0
50
100
150
Lux·hr
transparent bottle
0.05M citrate
buffer (pH6.5)
transparent bottle
secondary package
0.05M citrate
buffer (pH6.5)
shading bottle
0.05M citrate
buffer (pH6.5)
shading bottle
secondary package
0.05M citrate
buffer (pH6.5)

Fig. 21

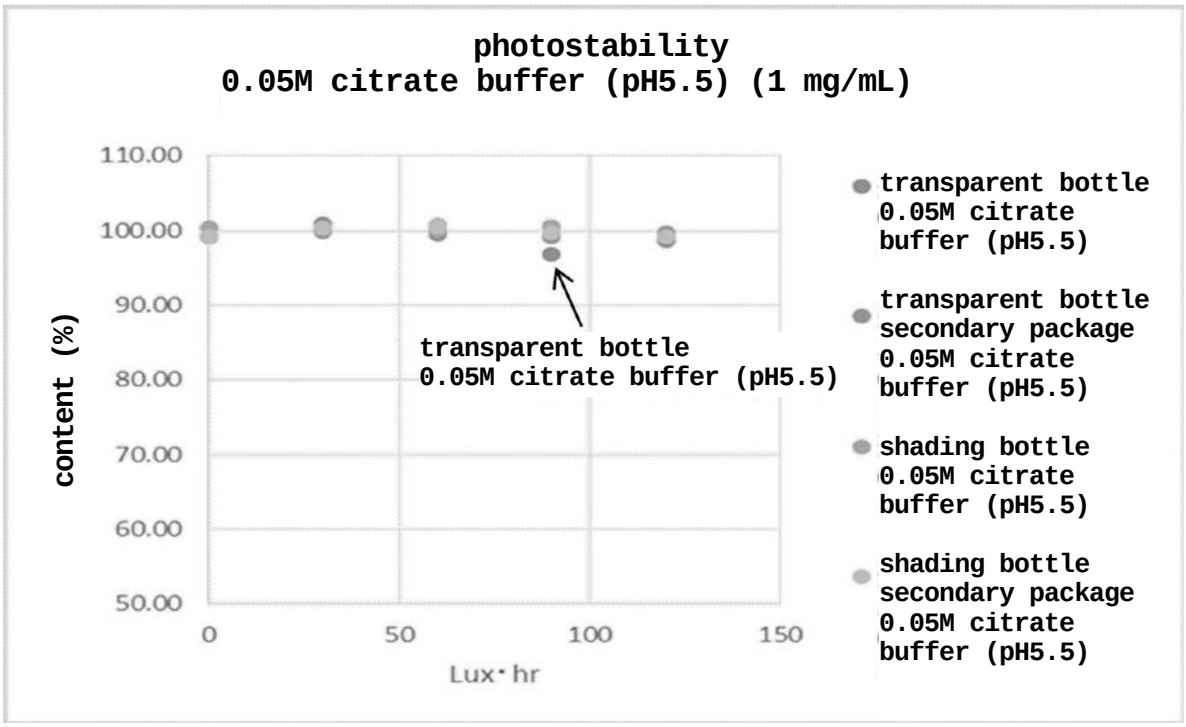

photostability
0.05M citrate buffer (pH5.5) (1 mg/mL)
content (%)
110.00
100.00
90.00
80.00
70.00
60.00
50.00
0
50
100
150
Lux·hr
transparent bottle
0.05M citrate buffer (pH5.5)
transparent bottle
0.05M citrate
buffer (pH5.5)
transparent bottle
secondary package
0.05M citrate
buffer (pH5.5)
shading bottle
0.05M citrate
buffer (pH5.5)
shading bottle
secondary package
0.05M citrate
buffer (pH5.5)

Fig. 22

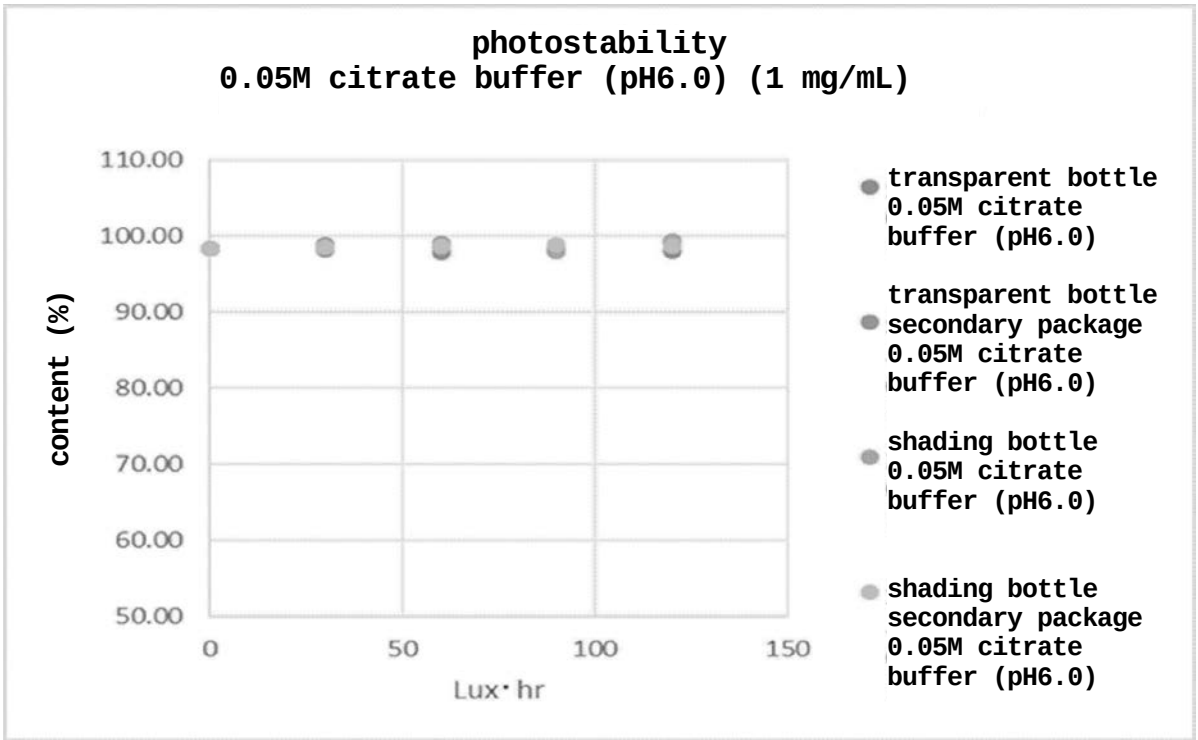
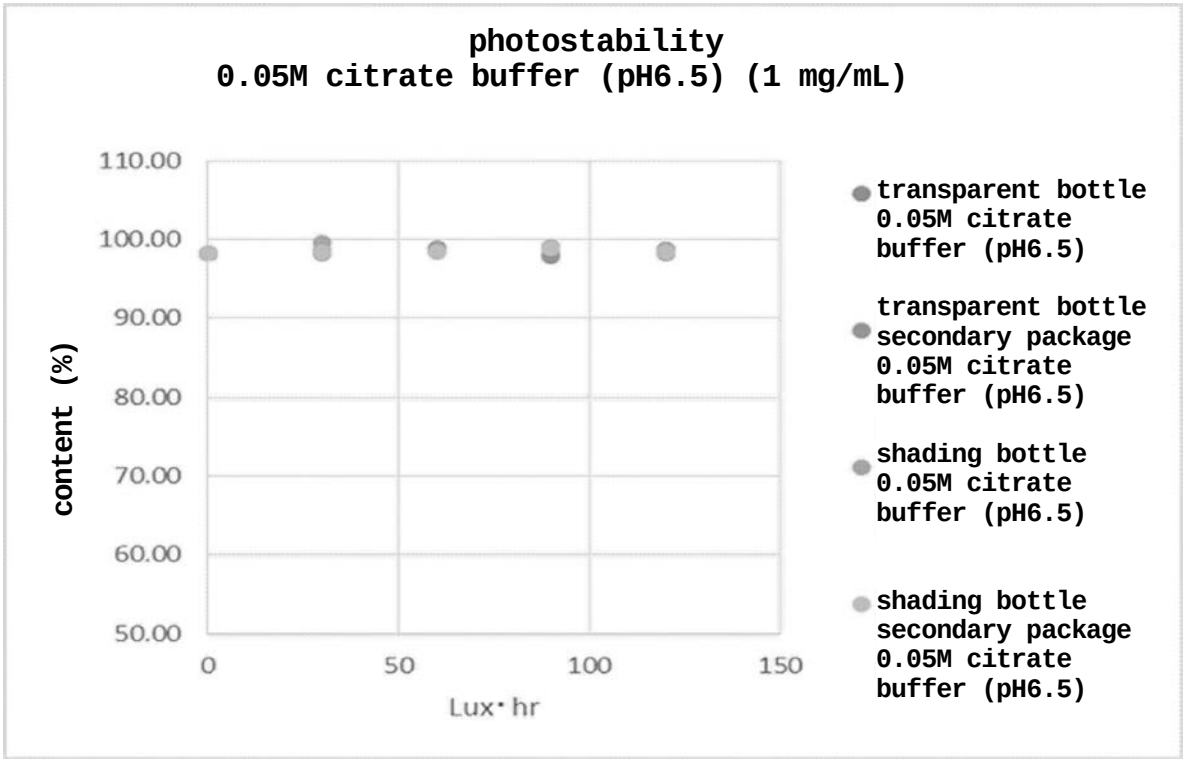

photostability
0.05M citrate buffer (pH6.0) (1 mg/mL)
content (%)
110.00
100.00
90.00
80.00
70.00
60.00
50.00
0
50
100
150
Lux·hr
transparent bottle
0.05M citrate
buffer (pH6.0)
transparent bottle
secondary package
0.05M citrate
buffer (pH6.0)
shading bottle
0.05M citrate
buffer (pH6.0)
shading bottle
secondary package
0.05M citrate
buffer (pH6.0)

Fig. 23


photostability
0.05M citrate buffer (pH6.5) (1 mg/mL)
content (%)
110.00
100.00
90.00
80.00
70.00
60.00
50.00
0
50
100
150
Lux·hr
transparent bottle 0.05M citrate buffer (pH6.5)
transparent bottle secondary package 0.05M citrate buffer (pH6.5)
shading bottle 0.05M citrate buffer (pH6.5)
shading bottle secondary package 0.05M citrate buffer (pH6.5)