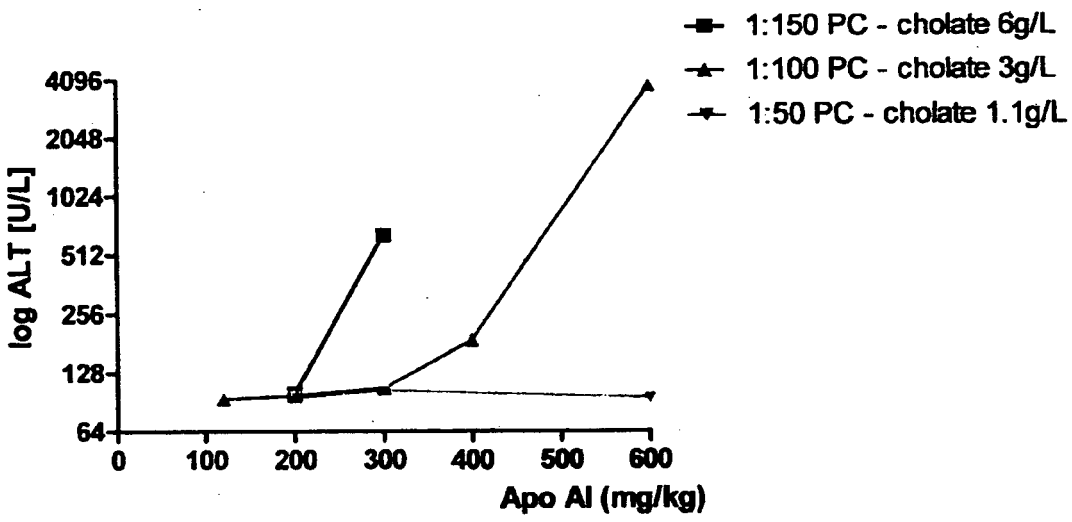

1:150 PC - cholate 6g/L
1:100 PC - cholate 3g/L
1:50 PC - cholate 1.1g/L
log ALT [U/L]
4096
2048
1024
512
256
128
64
0
100
200
300
400
500
600
Apo AI (mg/kg)

Figure 1

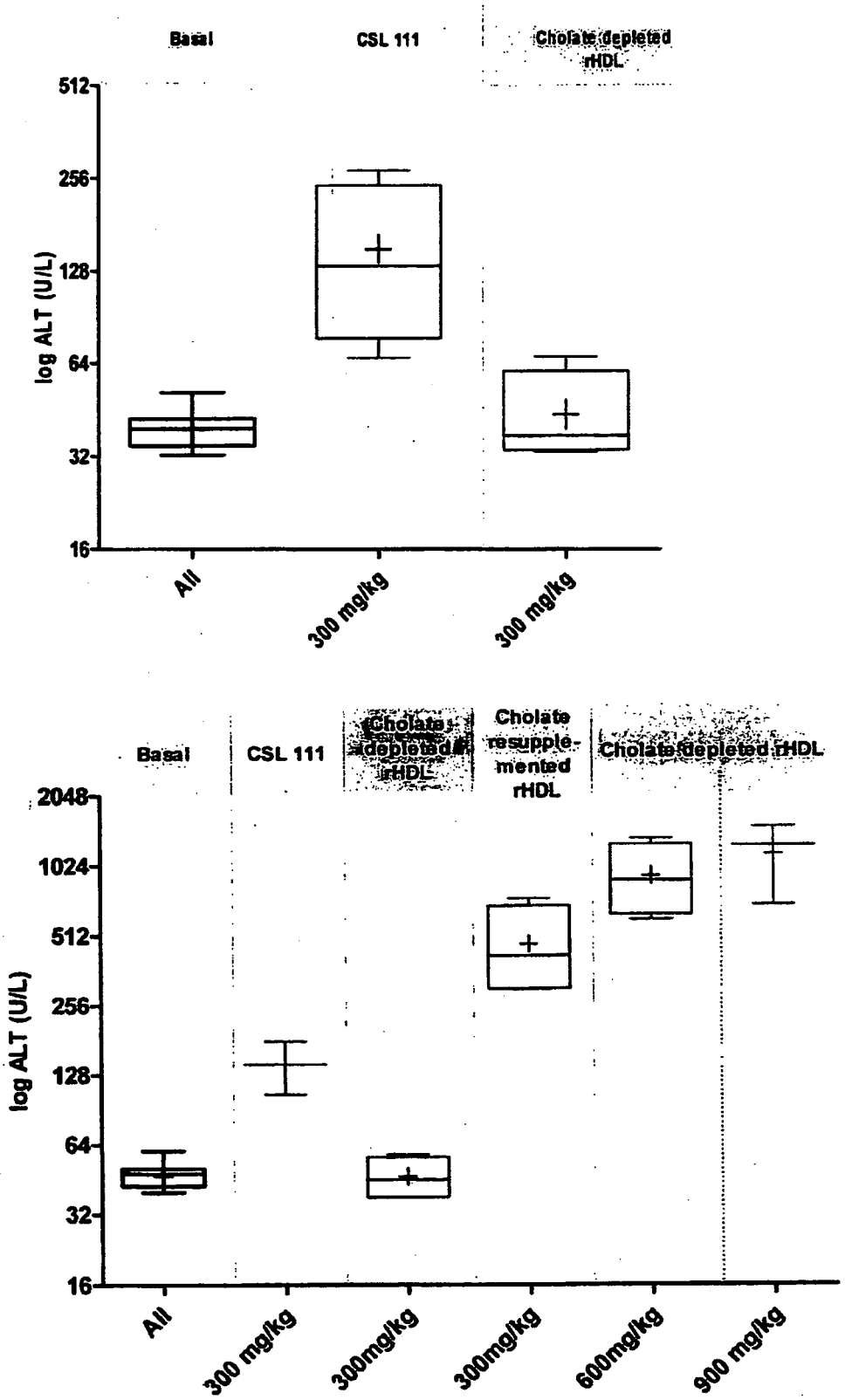

Basal
CSL 111
Cholate depleted rHDL
512
256
128
64
32
16
log ALT (U/L)
All
300 mg/kg
300 mg/kg
Basal
CSL 111
Cholate-depleted rHDL
Cholate resupplemented rHDL
Cholate depleted rHDL
2048
1024
512
256
128
64
32
16
log ALT (U/L)
All
300 mg/kg
300mg/kg
300mg/kg
600mg/kg
900 mg/kg

Figure 2

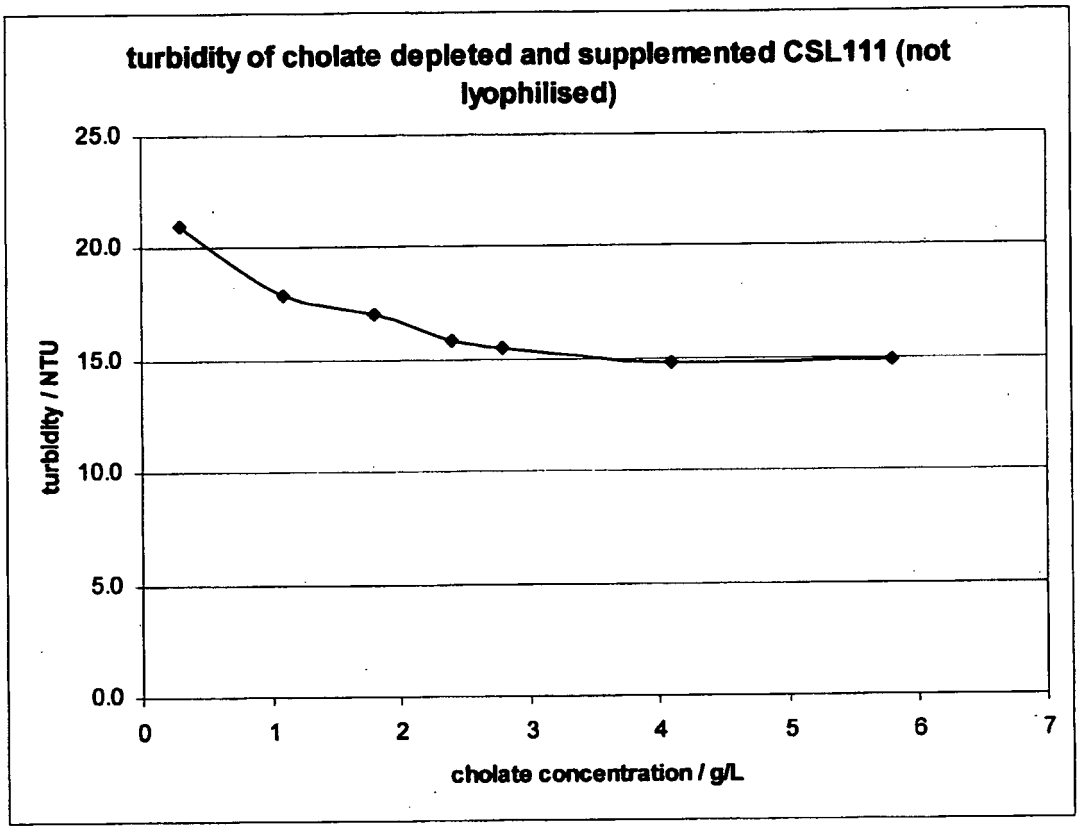

turbidity of cholate depleted and supplemented CSL111 (not lyophilised)
turbidity / NTU
25.0
20.0
15.0
10.0
5.0
0.0
0
1
2
3
4
5
6
7
cholate concentration / g/L

Figure 3

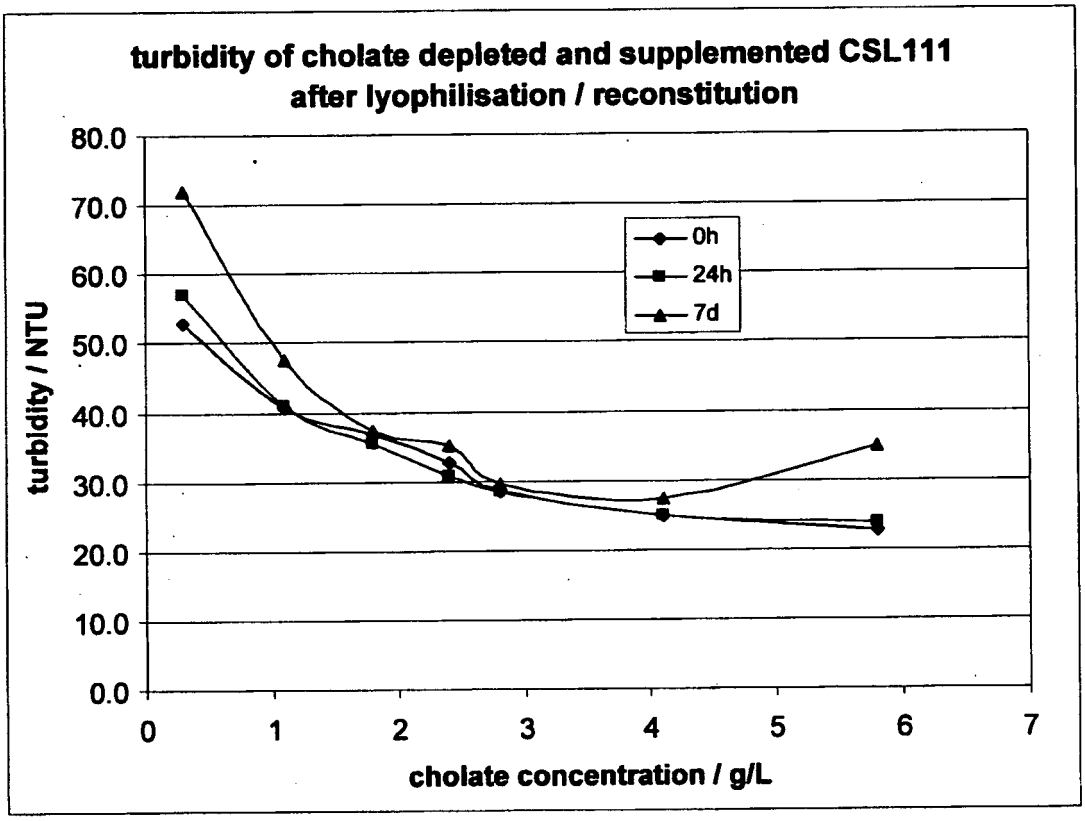

turbidity of cholate depleted and supplemented CSL111
after lyophilisation / reconstitution
turbidity / NTU
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
0
1
2
3
4
5
6
7
cholate concentration / g/L
0h
24h
7d

Figure 4

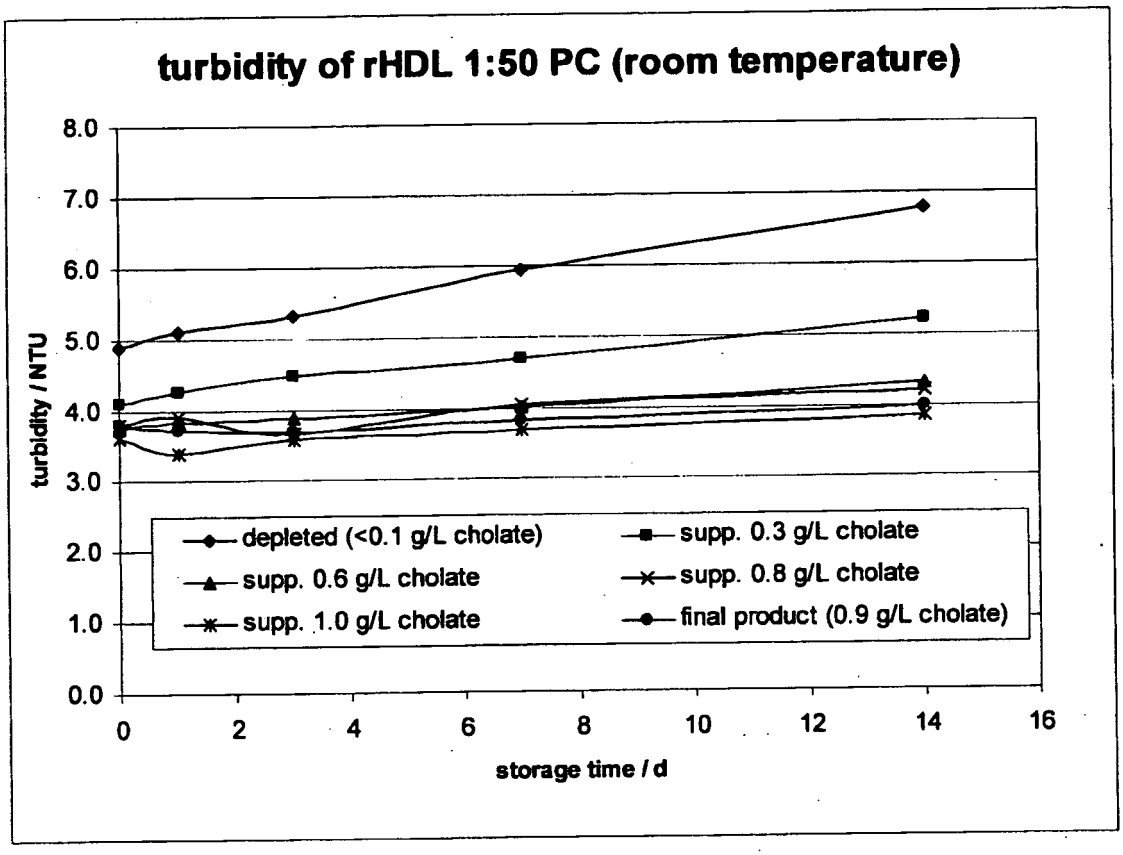

turbidity of rHDL 1:50 PC (room temperature)
turbidity / NTU
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0
2
4
6
8
10
12
14
16
storage time / d
depleted (<0.1 g/L cholate)
supp. 0.3 g/L cholate
supp. 0.6 g/L cholate
supp. 0.8 g/L cholate
supp. 1.0 g/L cholate
final product (0.9 g/L cholate)

Figure 5

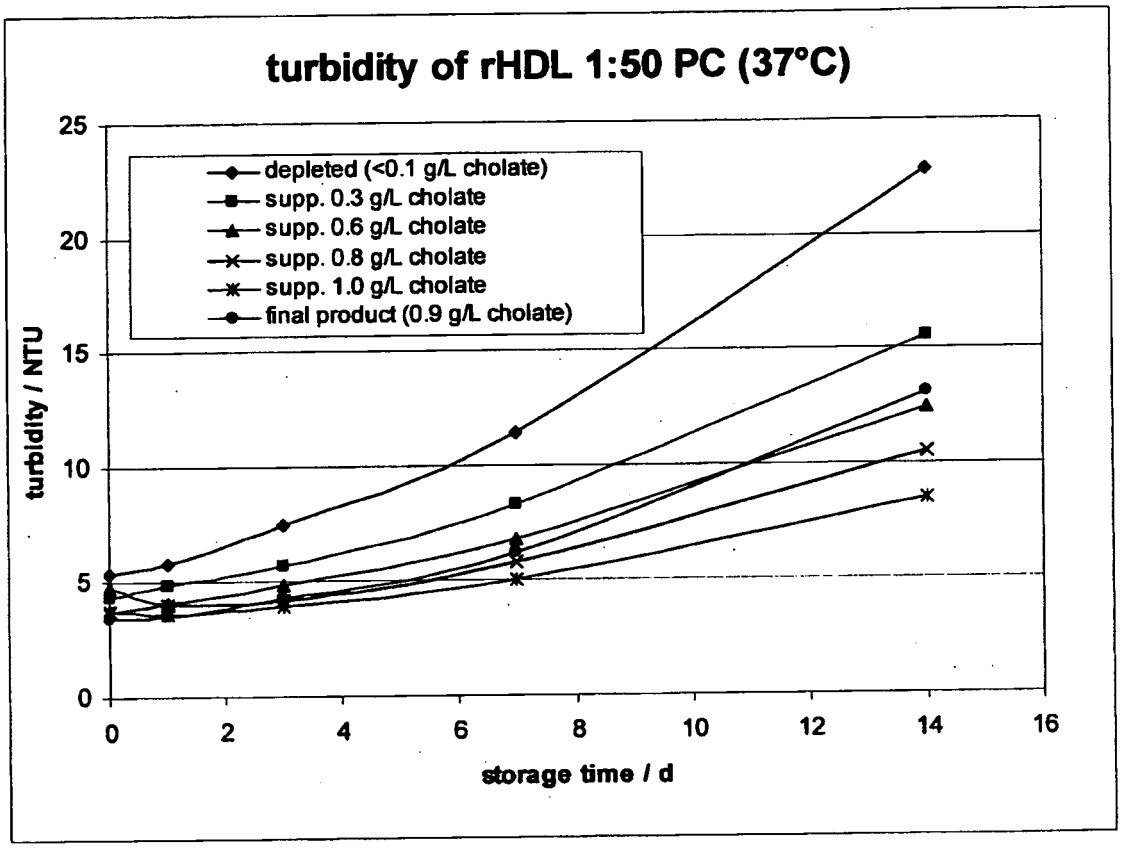

turbidity of rHDL 1:50 PC (37°C)
depleted (<0.1 g/L cholate)
supp. 0.3 g/L cholate
supp. 0.6 g/L cholate
supp. 0.8 g/L cholate
supp. 1.0 g/L cholate
final product (0.9 g/L cholate)
turbidity / NTU
storage time / d
0
5
10
15
20
25
0
2
4
6
8
10
12
14
16

Figure 6

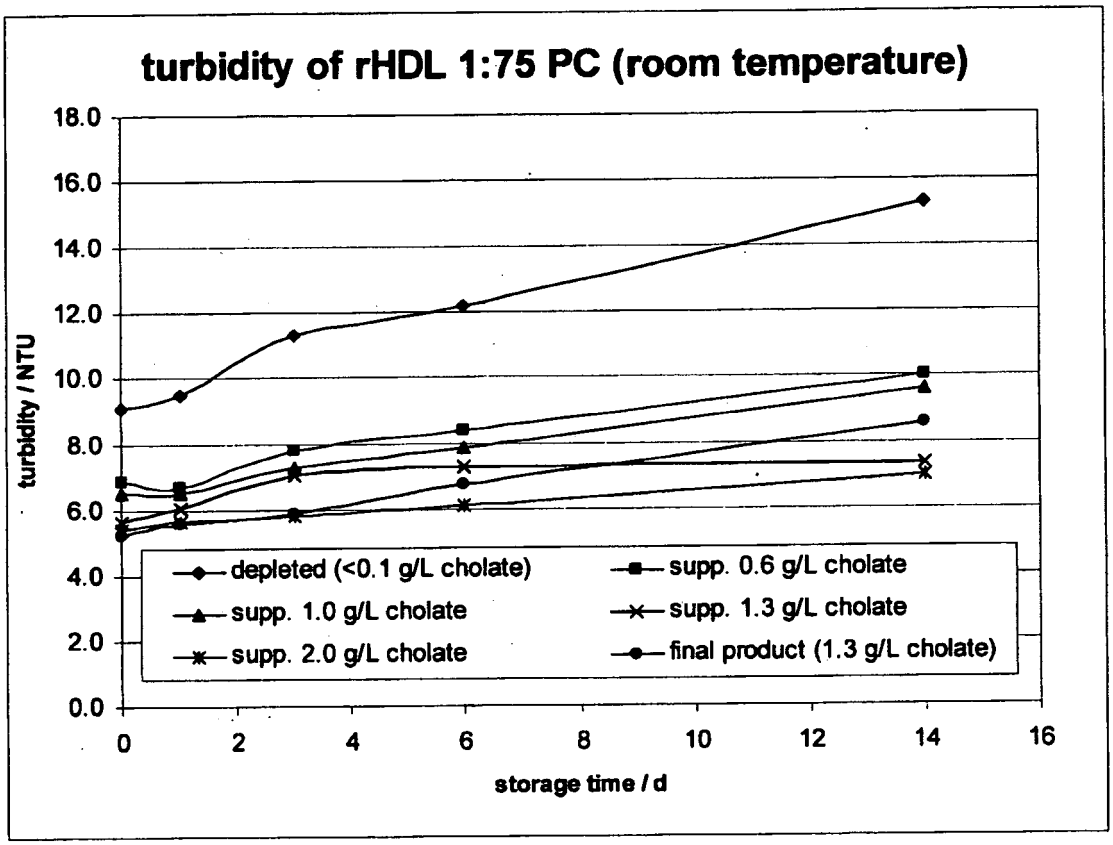

turbidity of rHDL 1:75 PC (room temperature)
turbidity / NTU
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
0
2
4
6
8
10
12
14
16
storage time / d
depleted (<0.1 g/L cholate)
supp. 0.6 g/L cholate
supp. 1.0 g/L cholate
supp. 1.3 g/L cholate
supp. 2.0 g/L cholate
final product (1.3 g/L cholate)

Figure 7

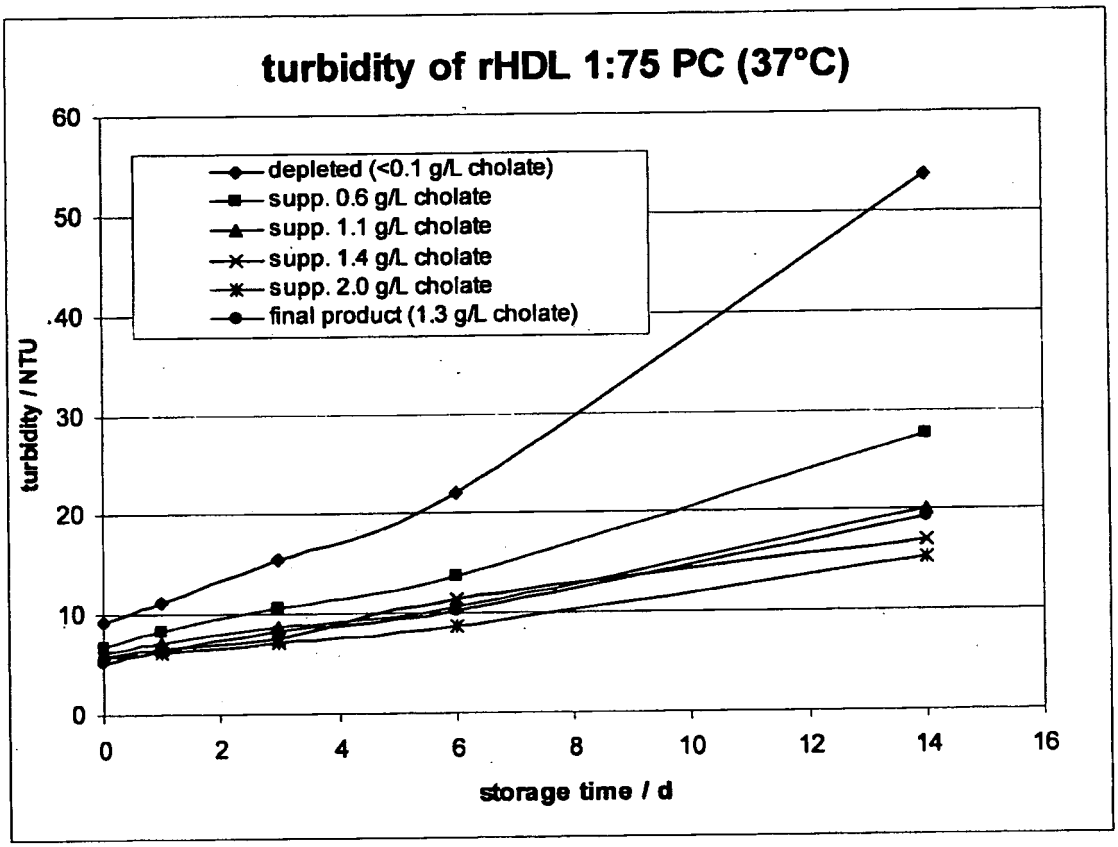

turbidity of rHDL 1:75 PC (37°C)
depleted (<0.1 g/L cholate)
supp. 0.6 g/L cholate
supp. 1.1 g/L cholate
supp. 1.4 g/L cholate
supp. 2.0 g/L cholate
final product (1.3 g/L cholate)
turbidity / NTU
storage time / d
0
10
20
30
40
50
60
0
2
4
6
8
10
12
14
16

Figure 8

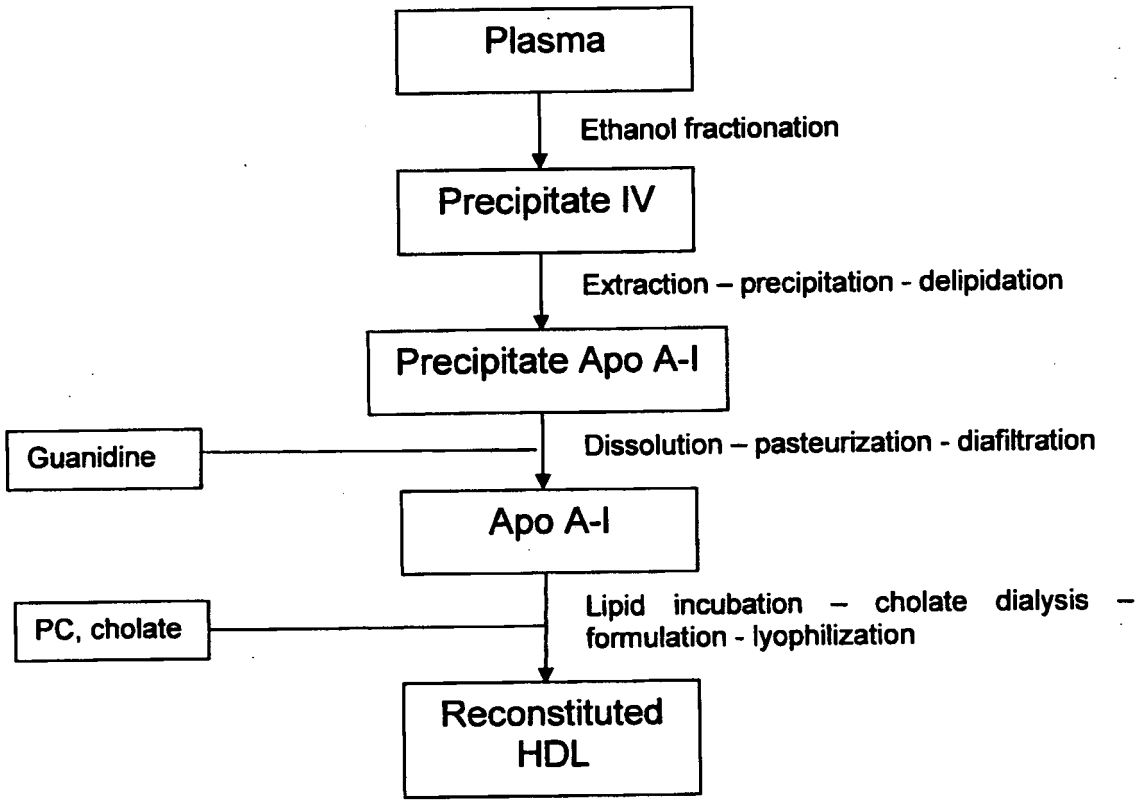

Plasma
Ethanol fractionation
Precipitate IV
Extraction – precipitation - delipidation
Precipitate Apo A-I
Guanidine
Dissolution – pasteurization - diafiltration
Apo A-I
PC, cholate
Lipid incubation – cholate dialysis – formulation - lyophilization
Reconstituted HDL

Figure 9