Drawings

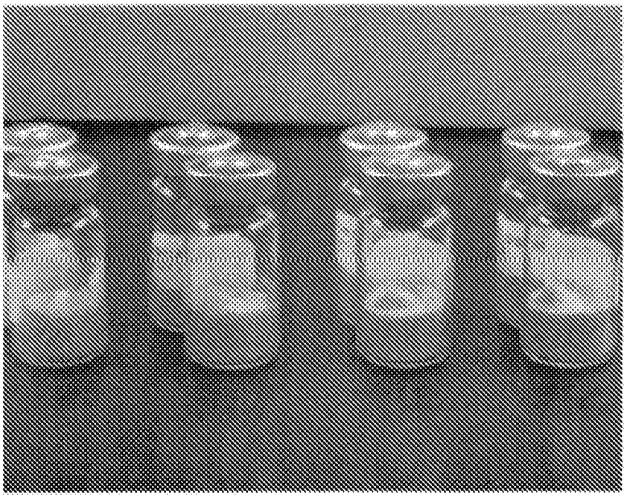


Fig. 1 lyophilization of forms R, A, O and C in order as depicted from left to right.

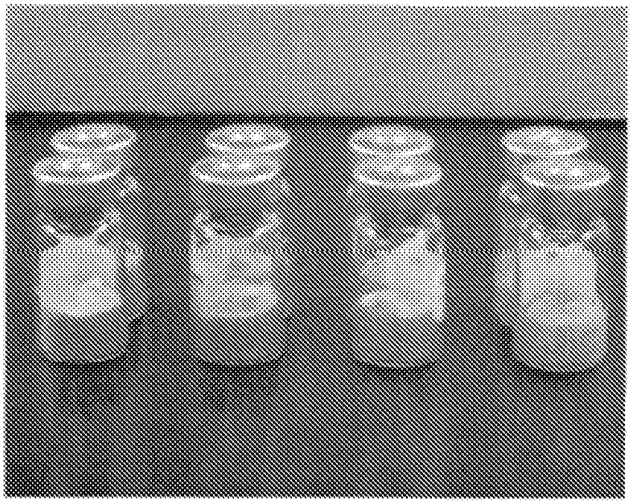


Fig. 2 lyophilization of forms G, Q, S and T in order as depicted from left to right.

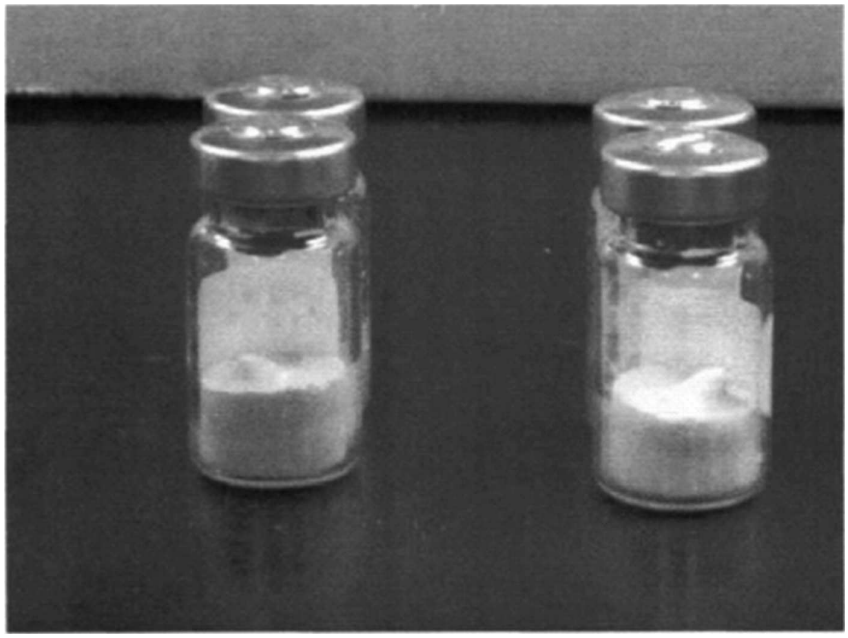
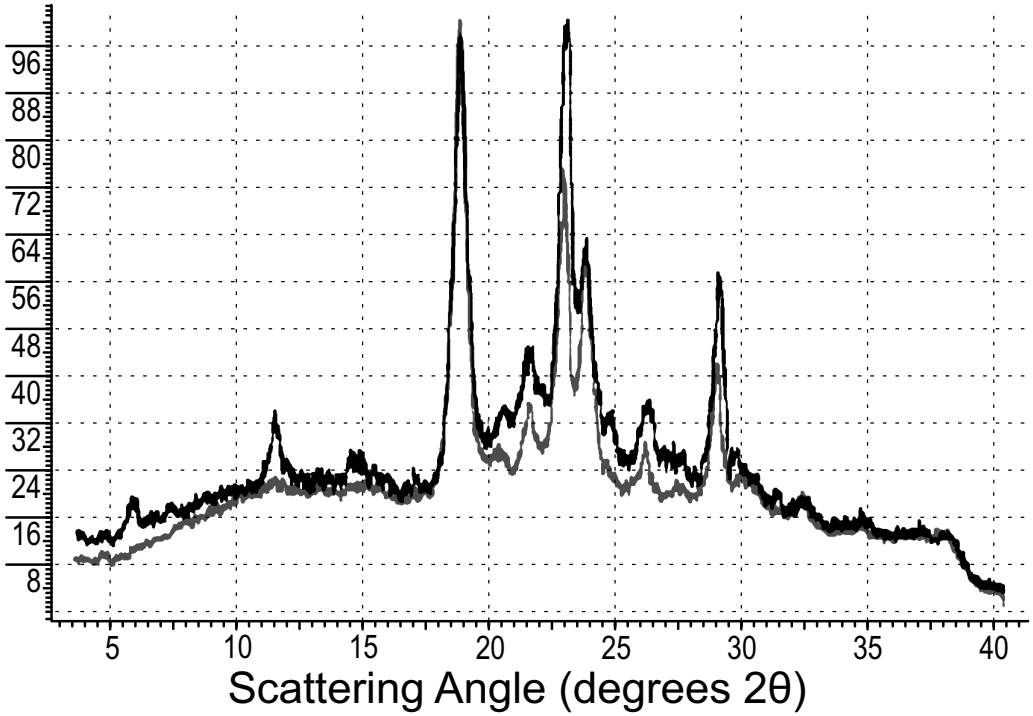
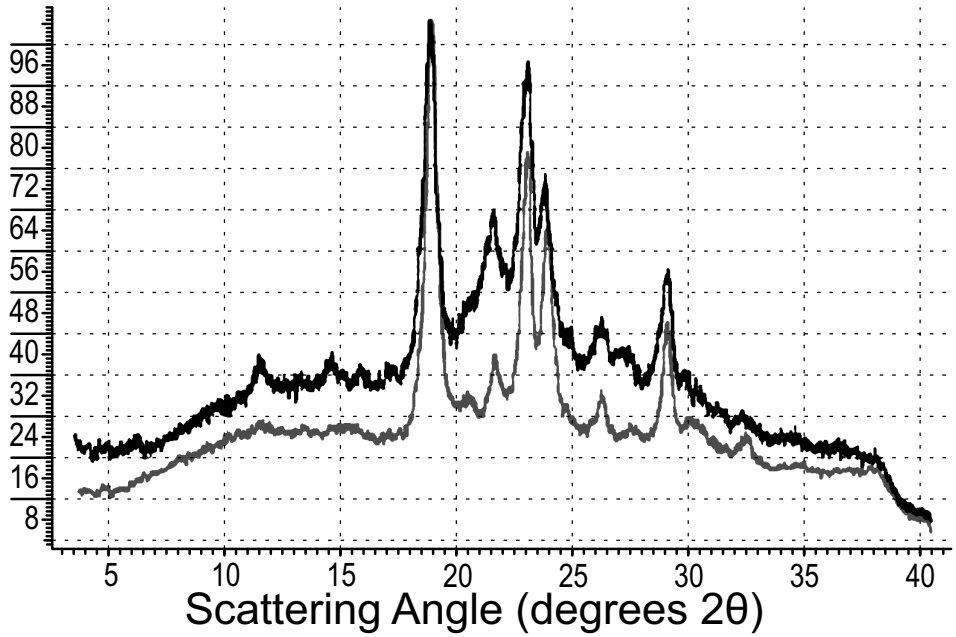


Fig. 3 lyophilization of forms U and V in order as depicted from left to right.



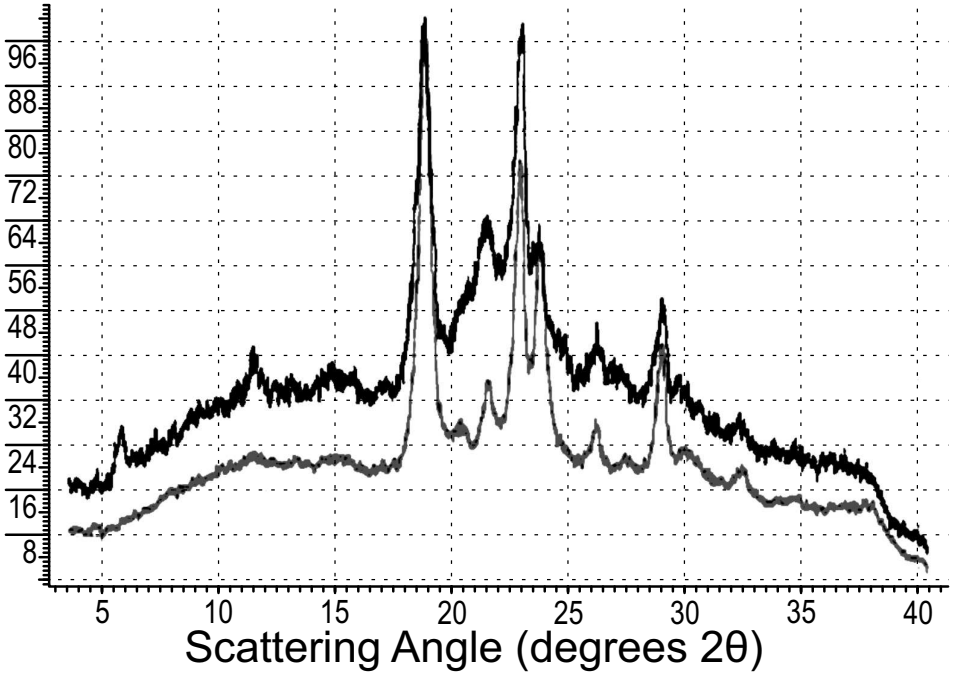
XRPD pattern obtained for "Form A 40 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 4



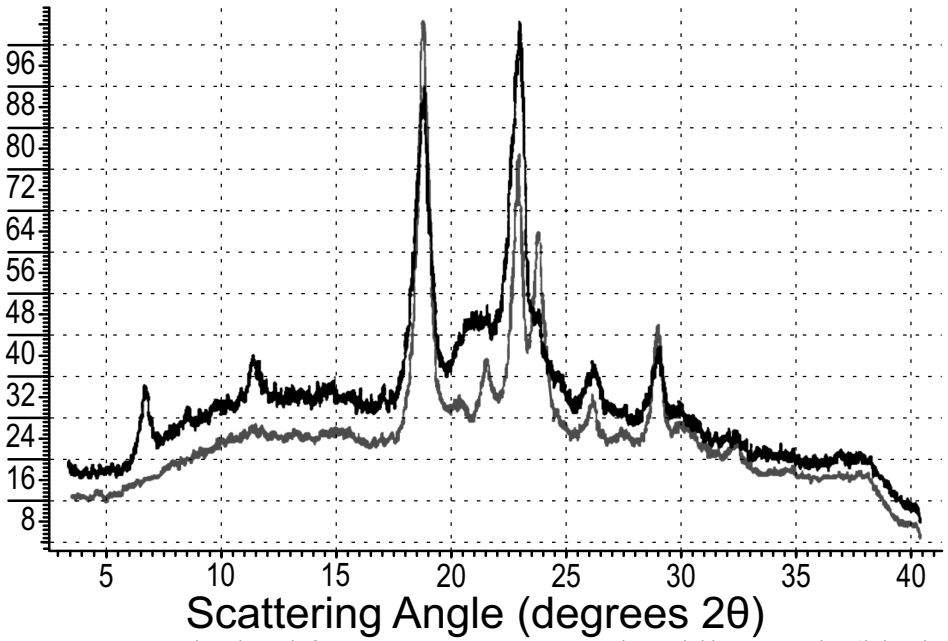
XRPD pattern obtained for "Form C 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 5



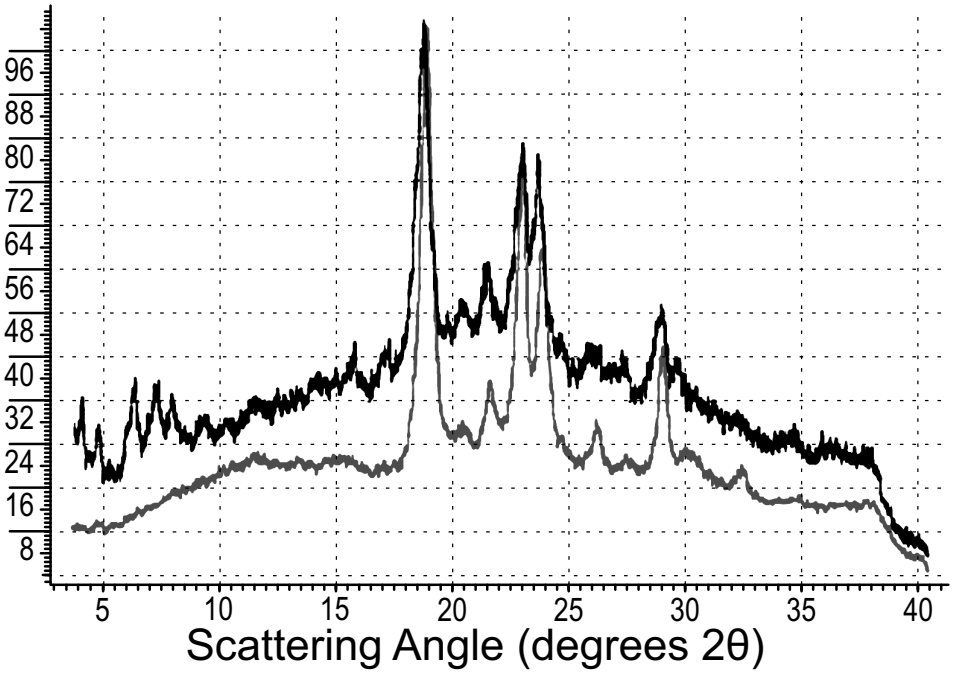
XRPD pattern obtained for "Form G 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 6



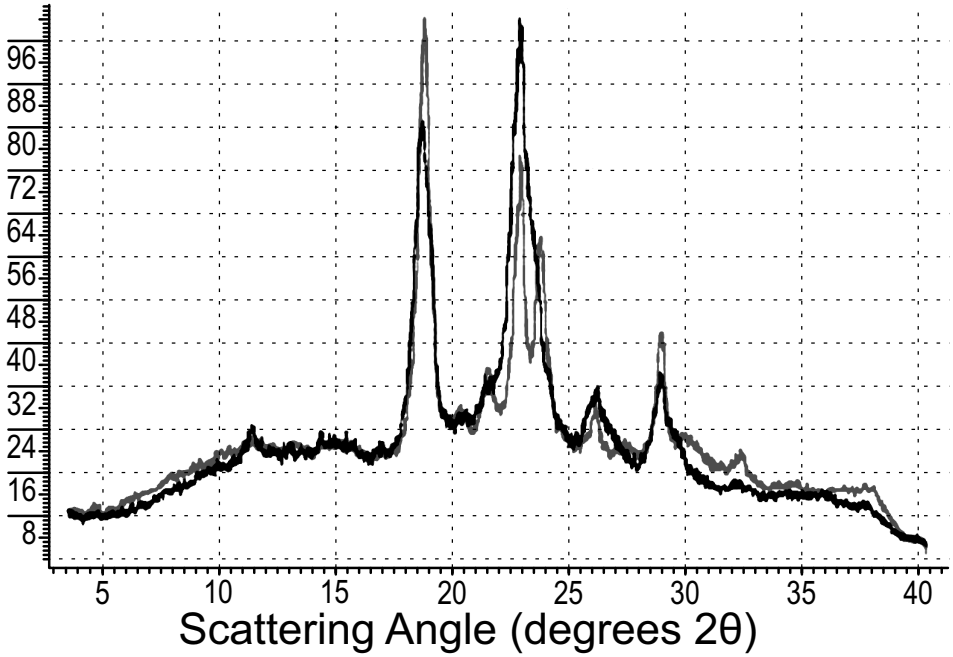
XRPD pattern obtained for "Form O 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 7



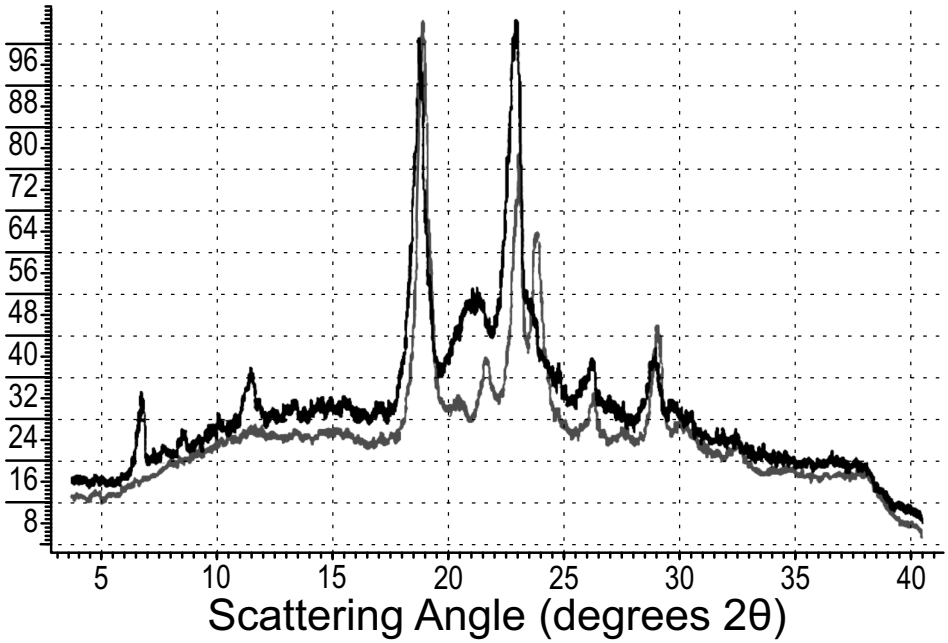
XRPD pattern obtained for "Form Q 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 8



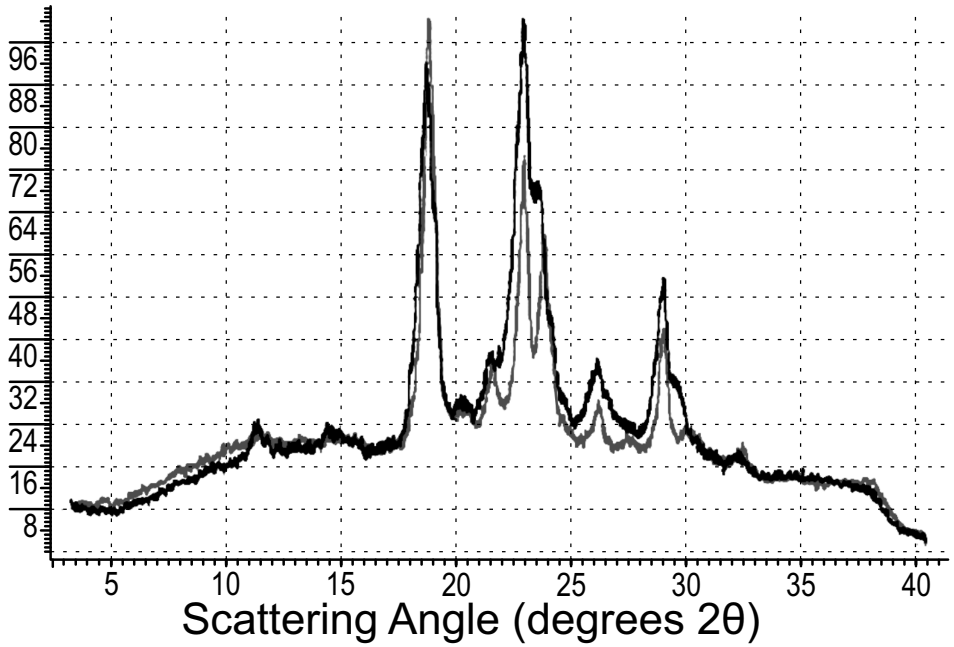
XRPD pattern obtained for "Form R 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 9



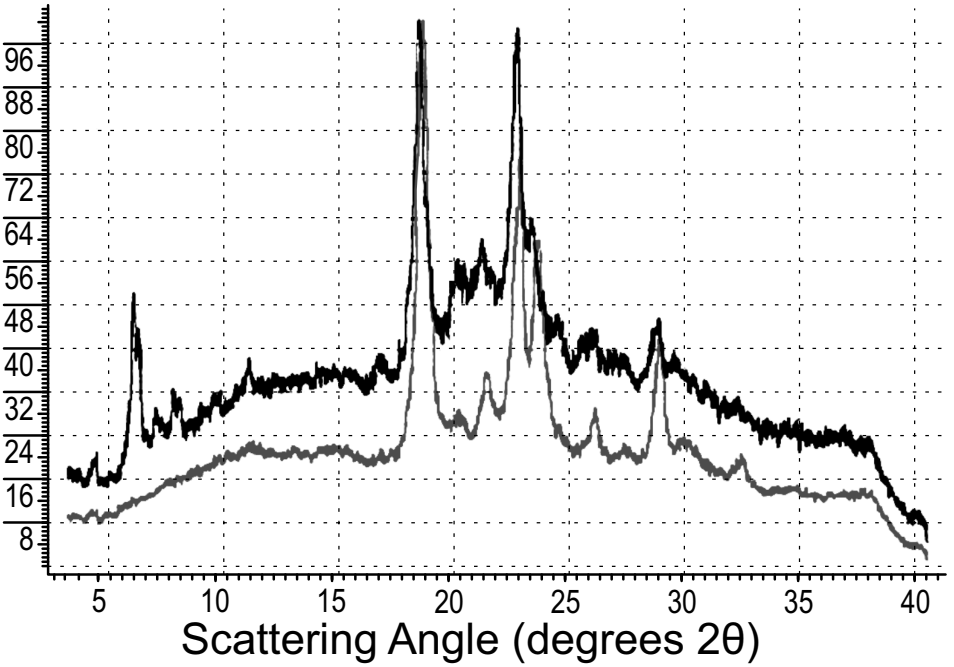
XRPD pattern obtained for "Form S 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 10



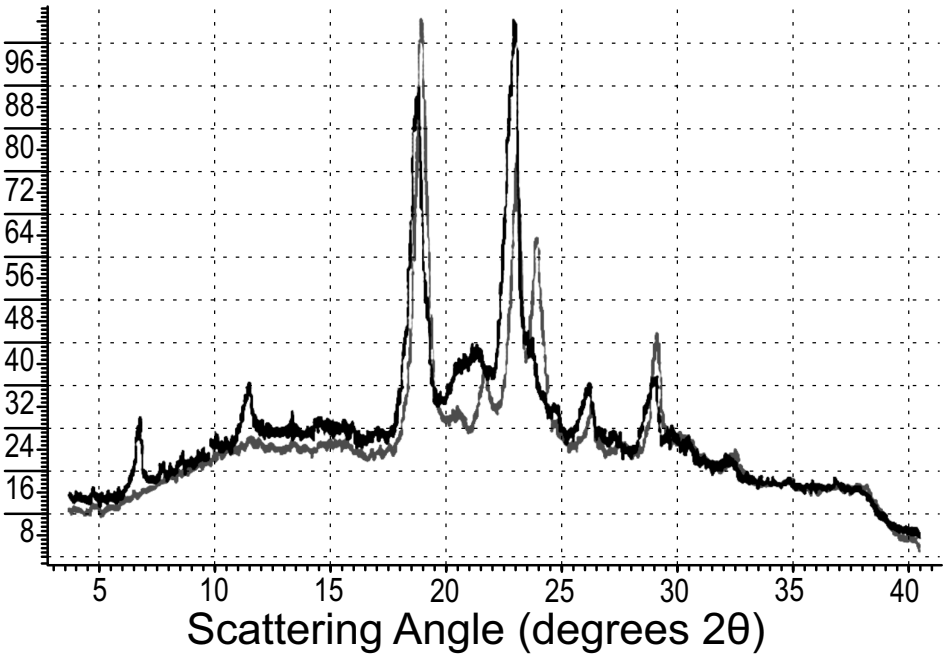
XRPD pattern obtained for "Form T 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 11



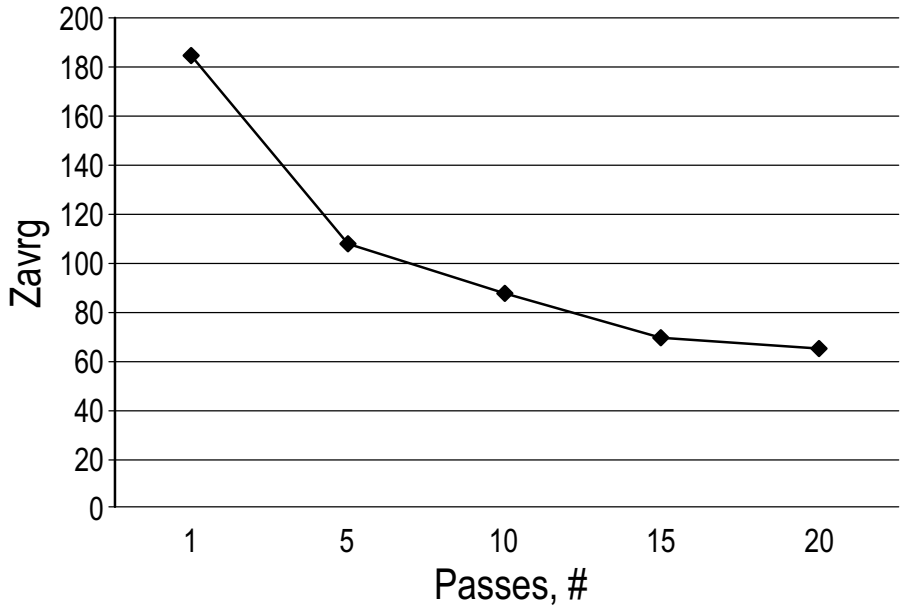
XRPD pattern obtained for "Form U 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 12



XRPD pattern obtained for "Form V 20 pass" lyophile sample (black trace) and XRPD pattern of CoQ10 bulk drug substance (red trace). The pattern has been normalized so that the intensity of the most intense peak equals 100%.

Fig. 13



Effect of number of passes on particle size.
5g of Cytotech31510, 3g of DMPC, and 92 ml of water.
The MFz model - M-110P. Processing chamber - F12Y.
Maximum pressure - 25,000 PSI.

Fig. 14

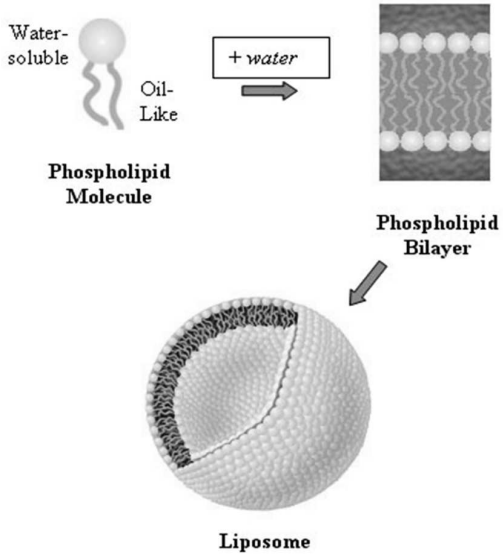


Fig. 15

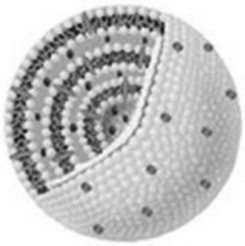


Fig. 16

Figure 2. Effect of number of passes on the particle size.
The MFz model - M-110P.Processing chamber - F12Y.

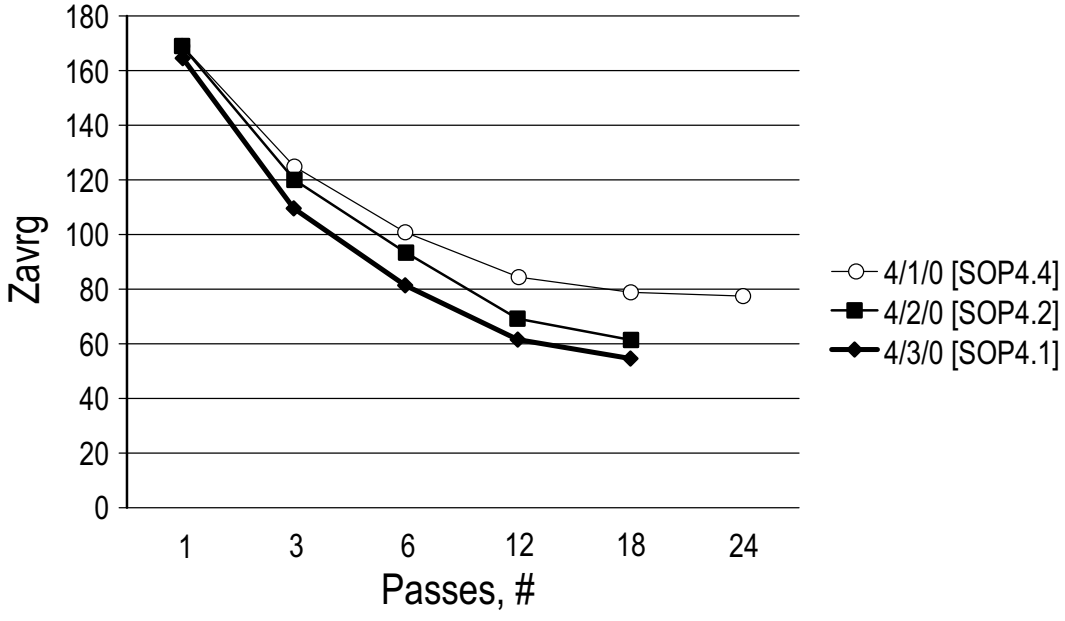


Fig. 17

Figure 3. Effect of number of passes on the particle size.
The MFz model - M-110P.Processing chamber - F12Y.

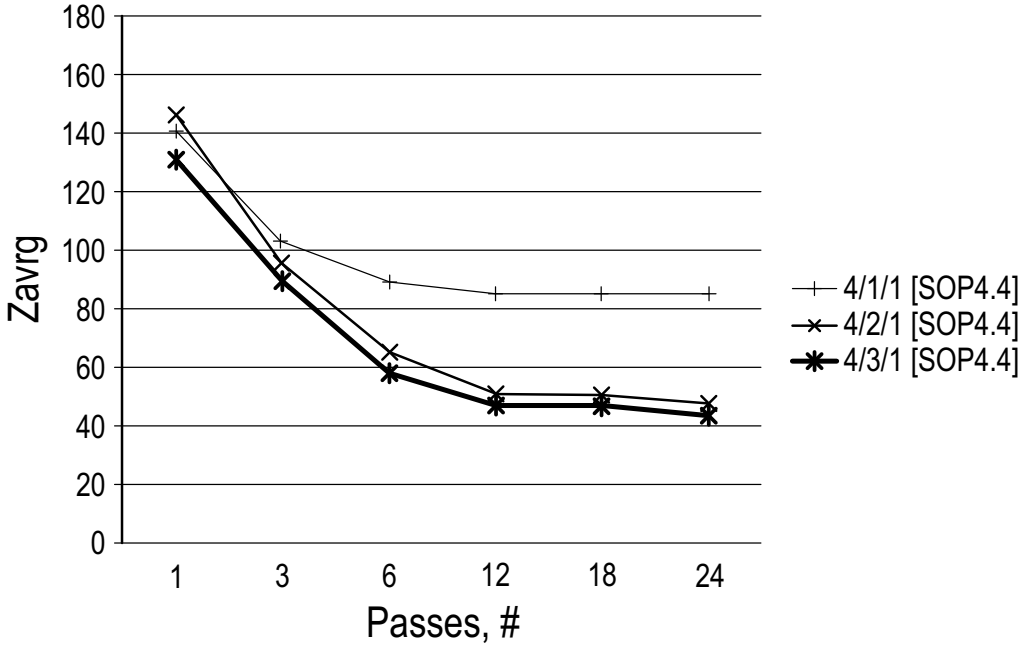


Fig. 18

Figure 4. Effect of number of passes on the particle size.
The MFz model - M-110P.Processing chamber - F12Y.

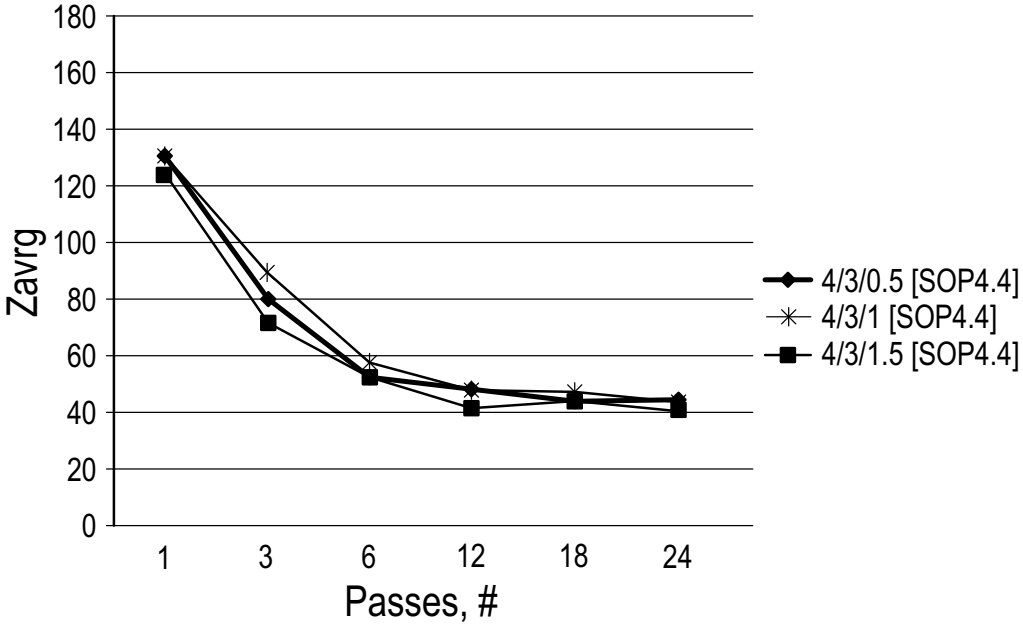


Fig. 19

Figure 5. Effect of number of passes on the particle size.
The MFz model - M-110P.Processing chamber - F12Y.

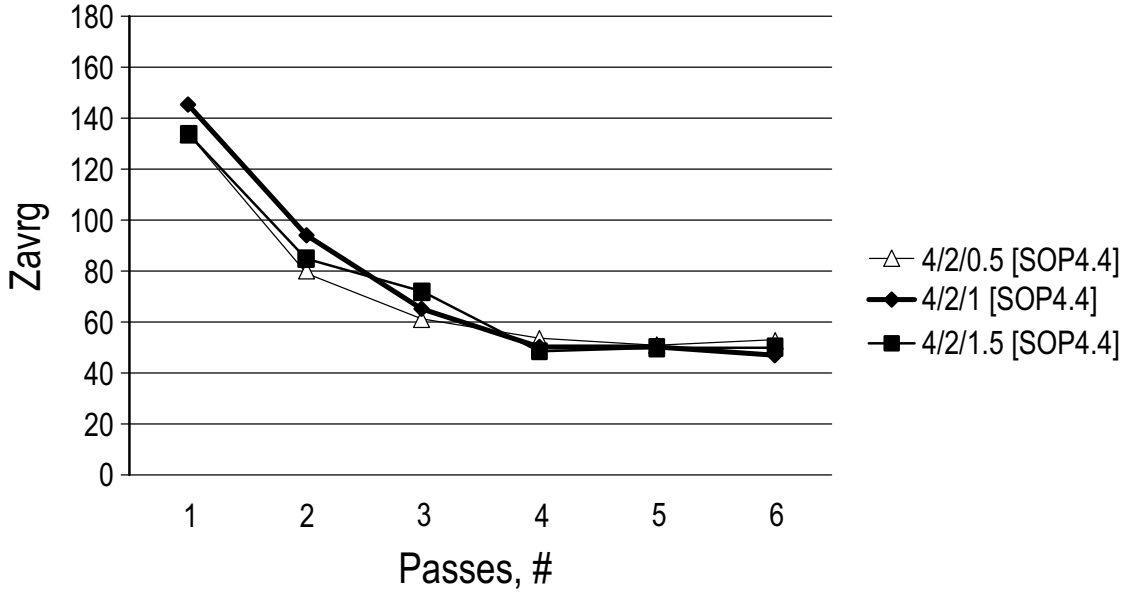


Fig. 20

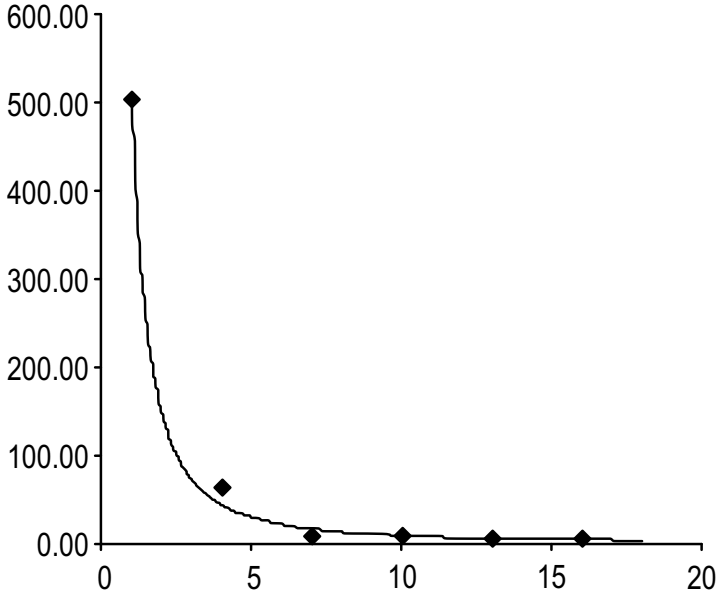


Fig. 21

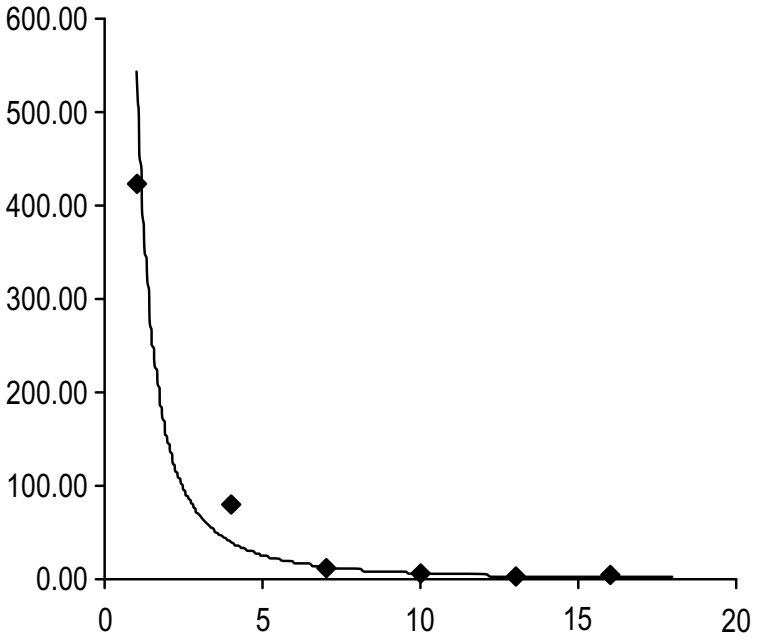


Fig. 22

Efficacy by treatment group:

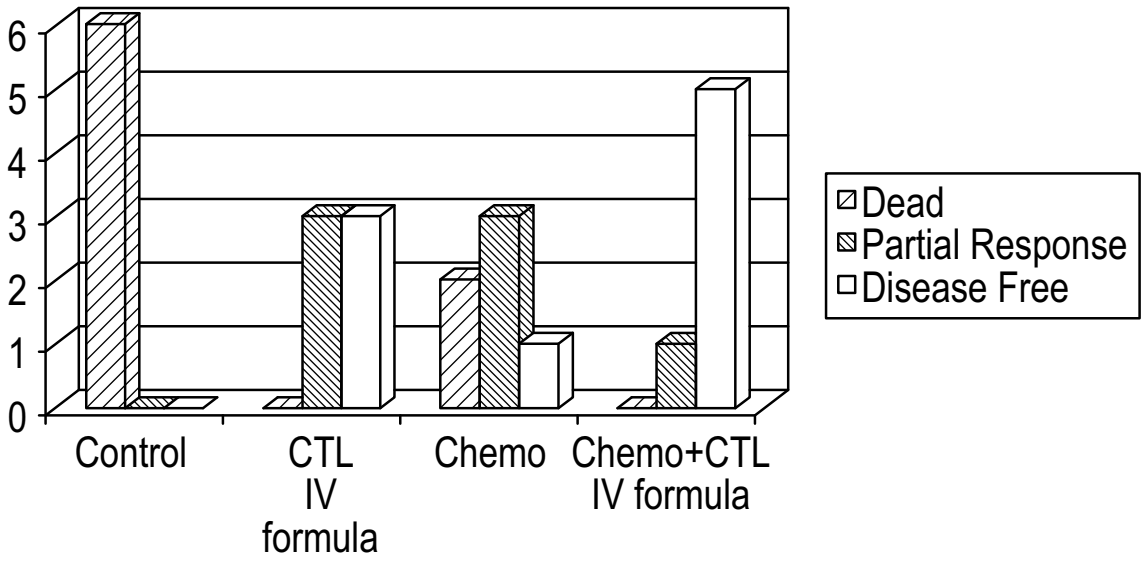


Fig. 23

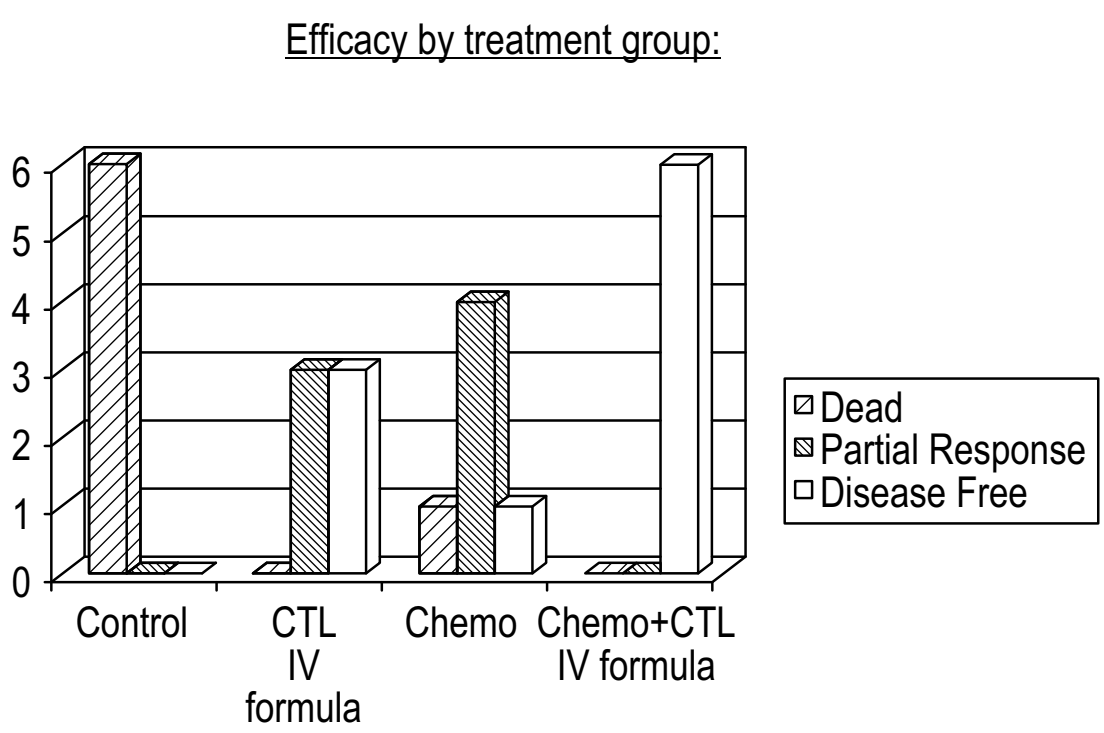

Efficacy by treatment group:
6
5
4
3
2
1
0
Control
CTL IV formula
Chemo
Chemo+CTL IV formula
Dead
Partial Response
Disease Free

Fig. 24

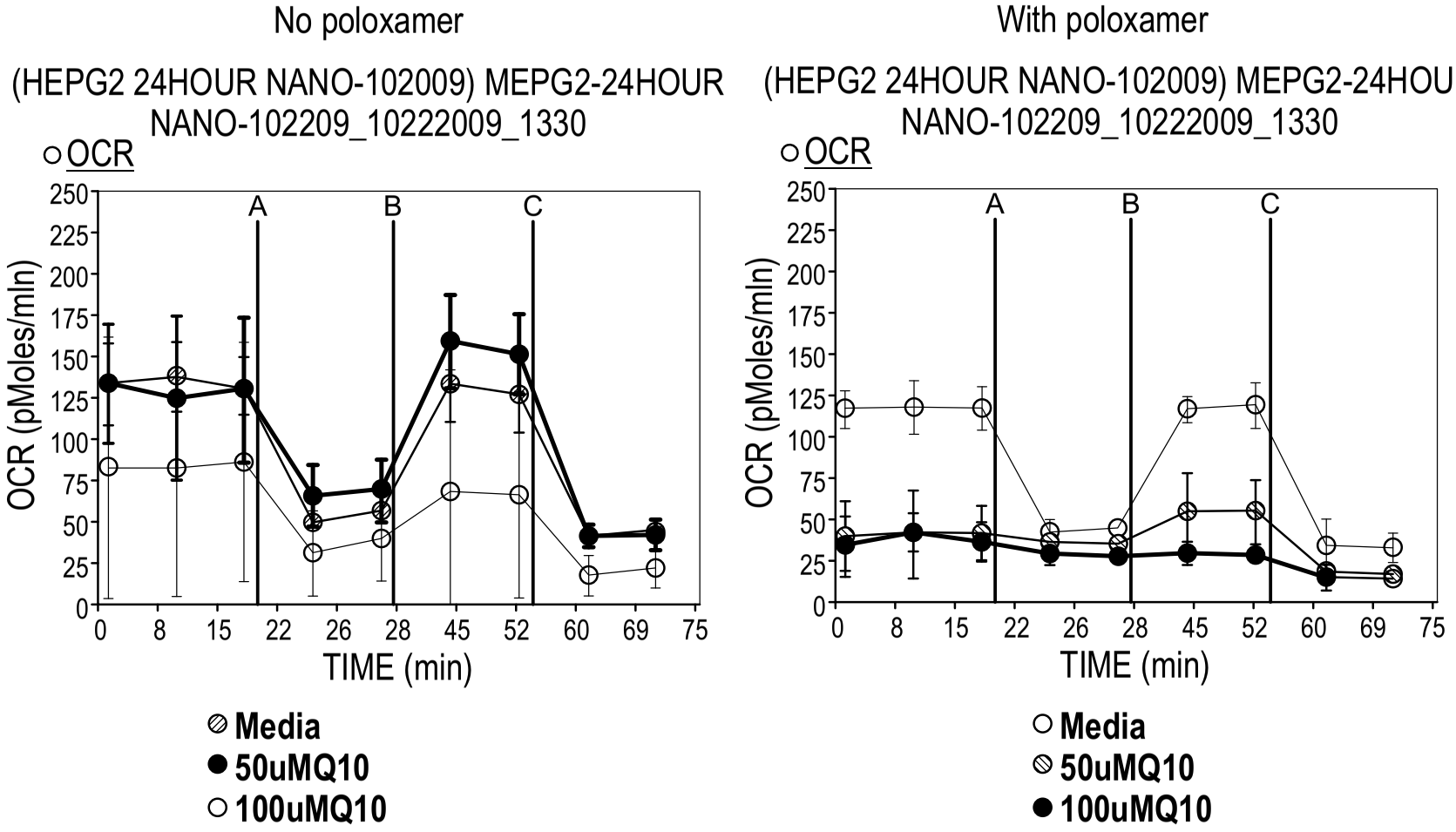


Fig. 25 - Effect of IV formulation on OCR in HepG2 cells.

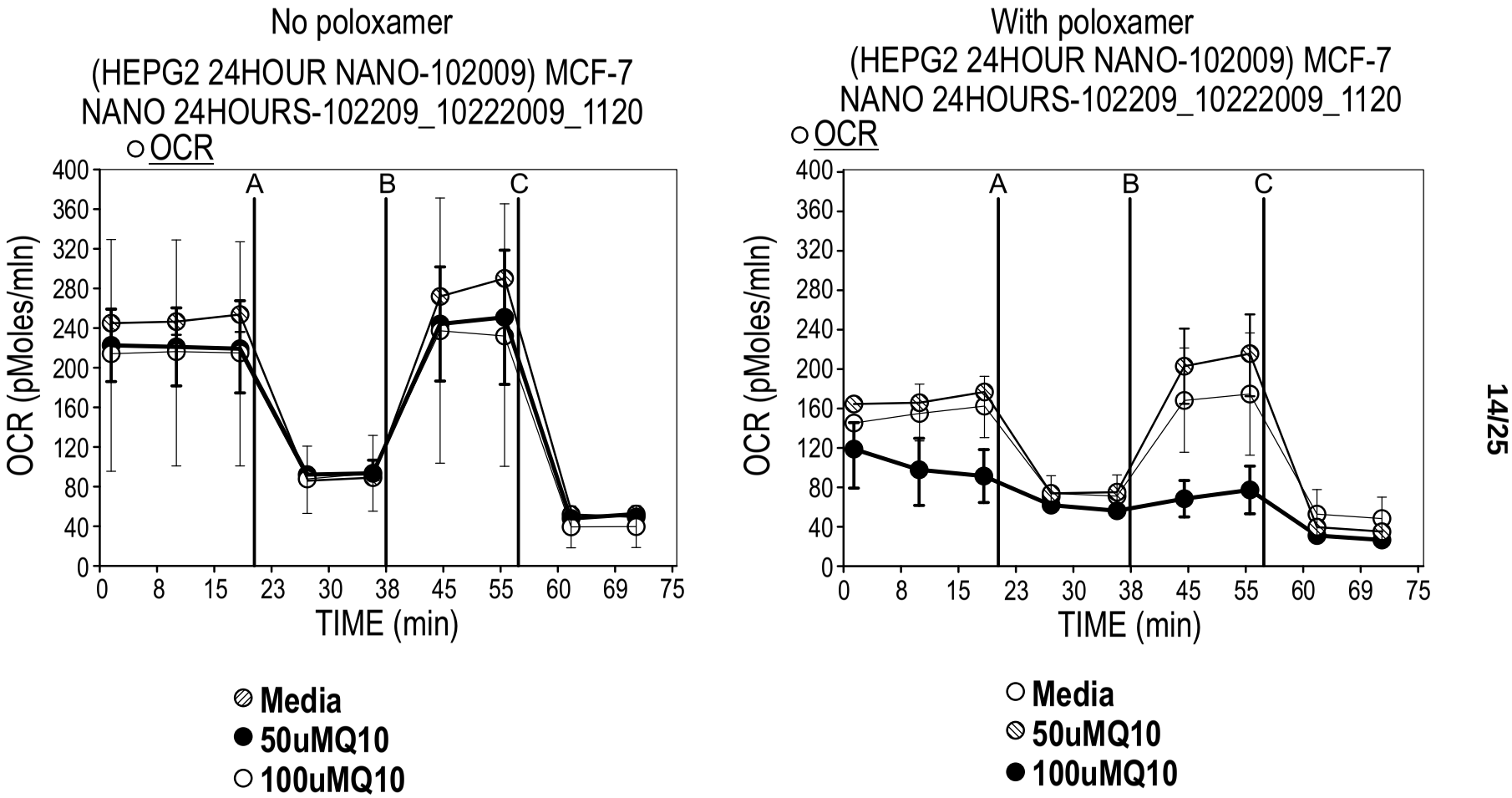


Fig. 26 - Effect of IV formulation on OCR in MCF-7 cells.

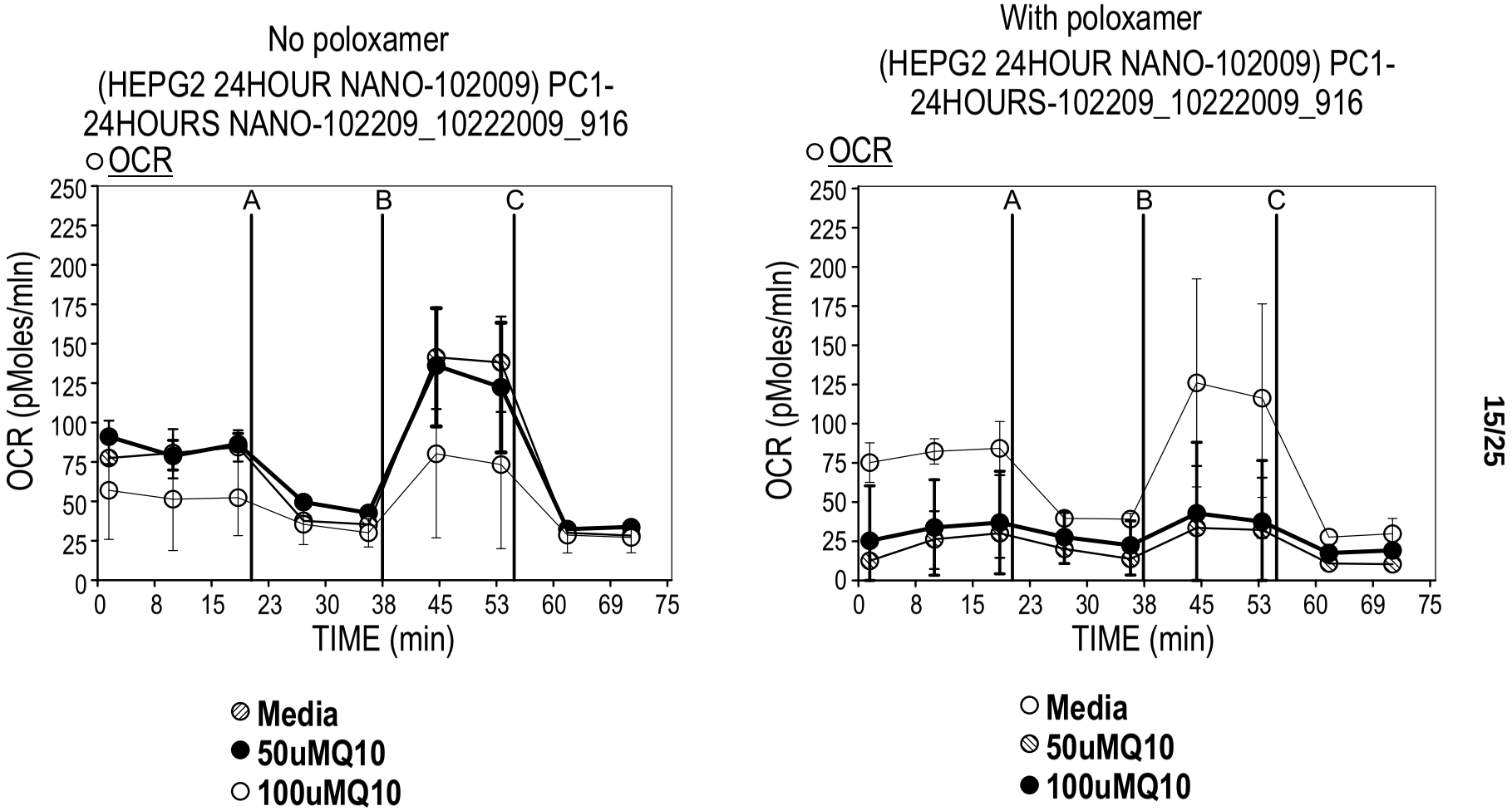


Fig. 27 - Effect of IV formulation on OCR in PC-3 cells.

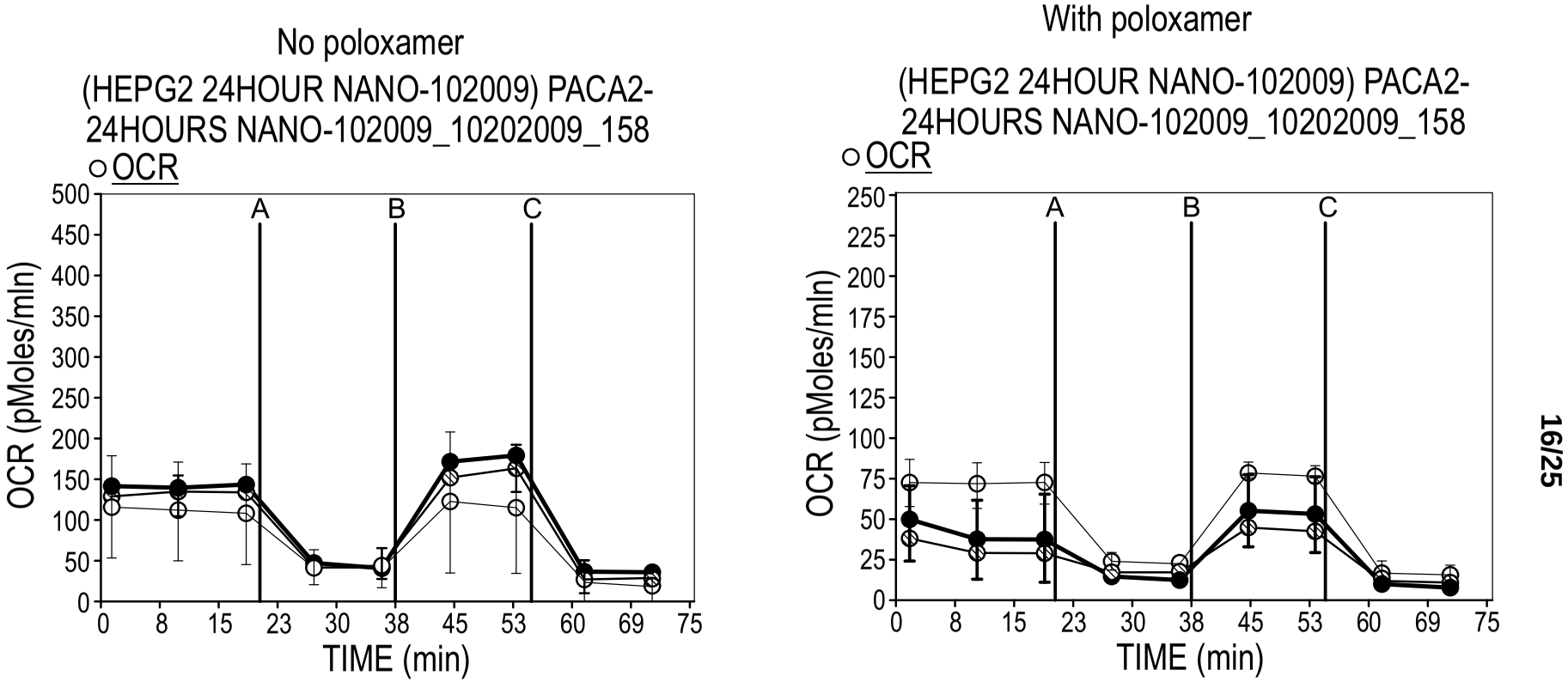


Fig. 28 - Effect of IV formulation on OCR in PaCa2 cells.

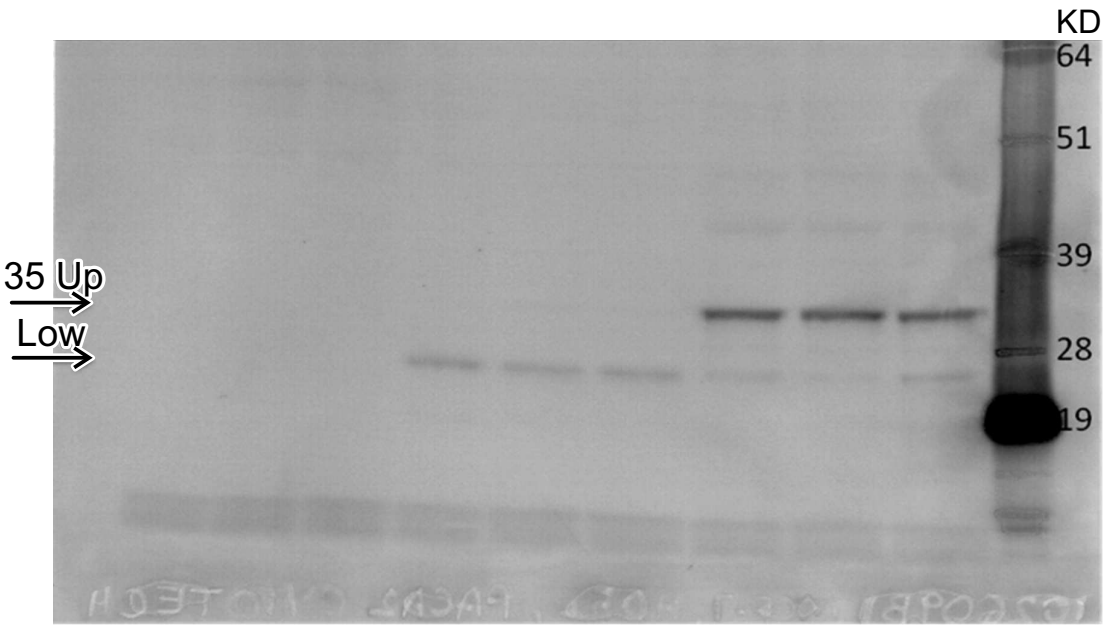


Fig. 29

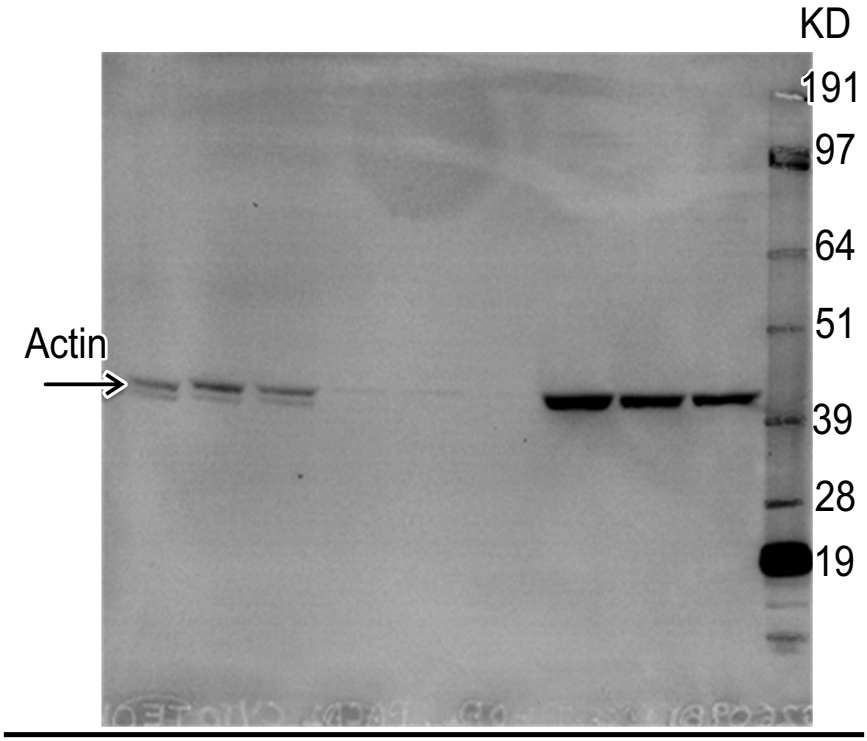


Fig. 30

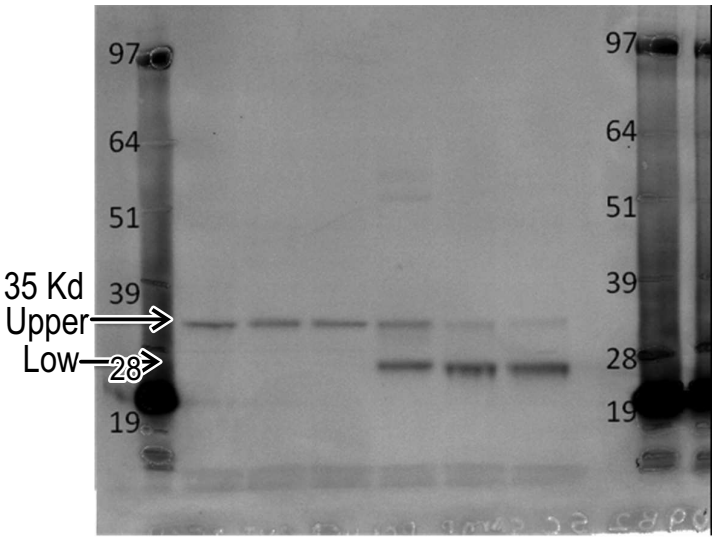


Fig. 31

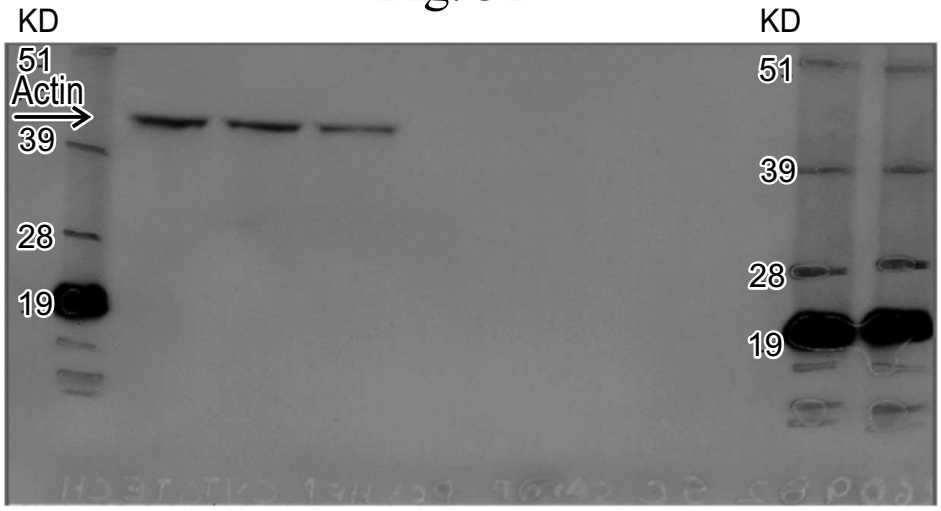


Fig. 32

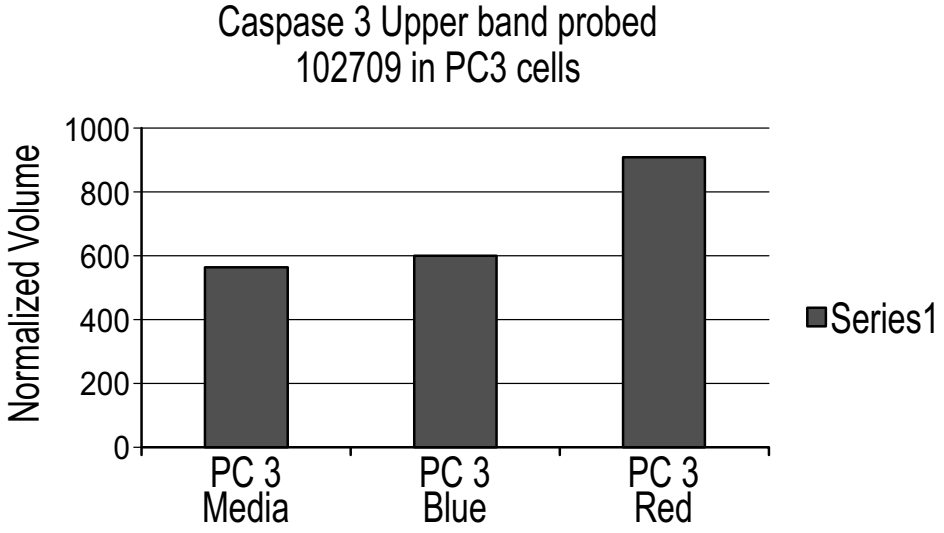


Fig. 33

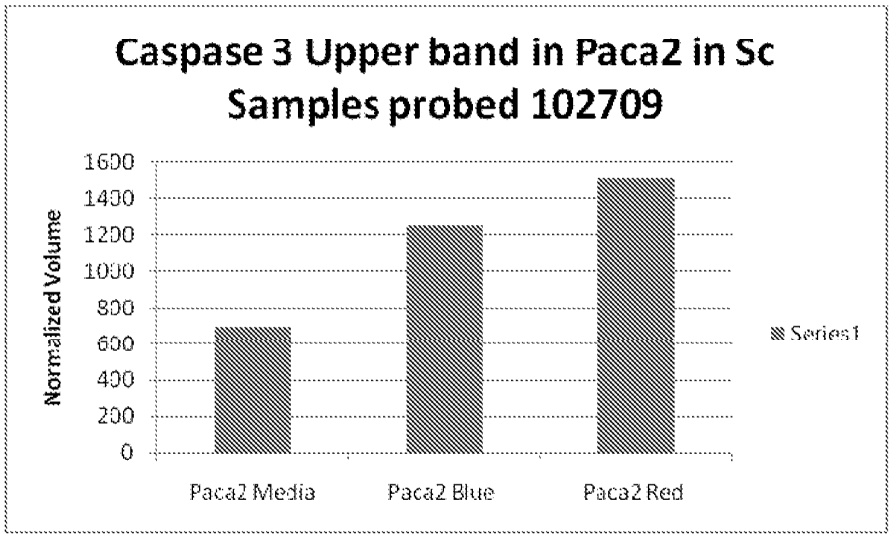

Caspase 3 Upper band in Paca2 in Sc Samples probed 102709
Normalized Volume
1600
1400
1200
1000
800
600
400
200
0
Paca2 Media
Paca2 Blue
Paca2 Red
Series1

Fig. 34

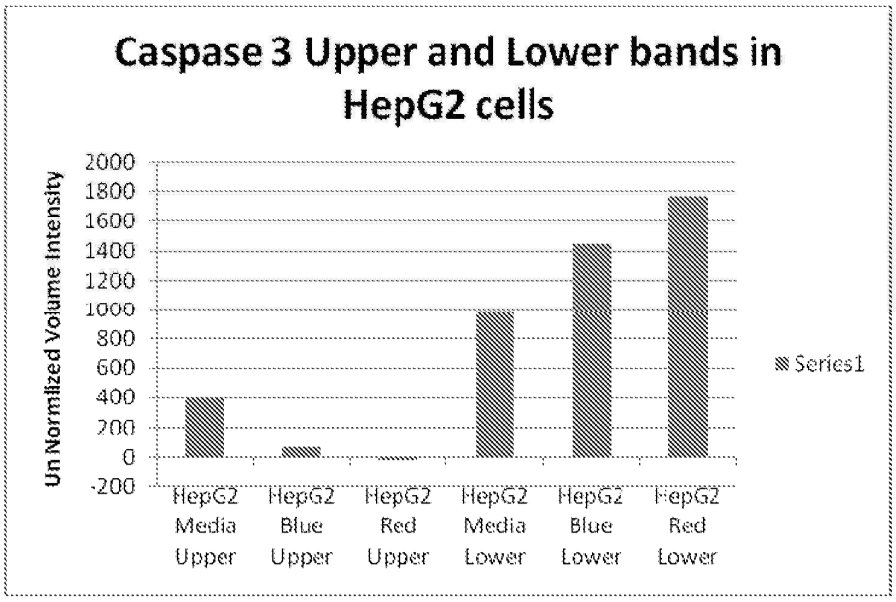

Caspase 3 Upper and Lower bands in HepG2 cells
Un Normlized Volume Intensity
2000
1800
1600
1400
1200
1000
800
600
400
200
0
-200
HepG2 Media Upper
HepG2 Blue Upper
HepG2 Red Upper
HepG2 Media Lower
HepG2 Blue Lower
HepG2 Red Lower
Series1

Fig. 35

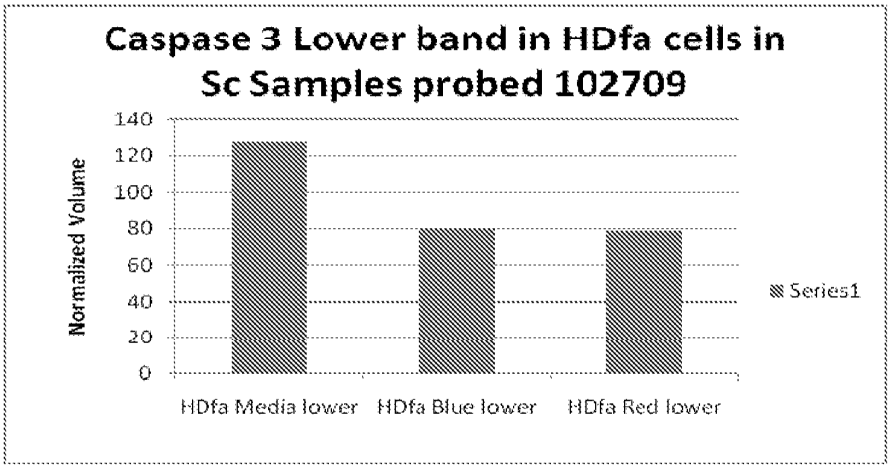
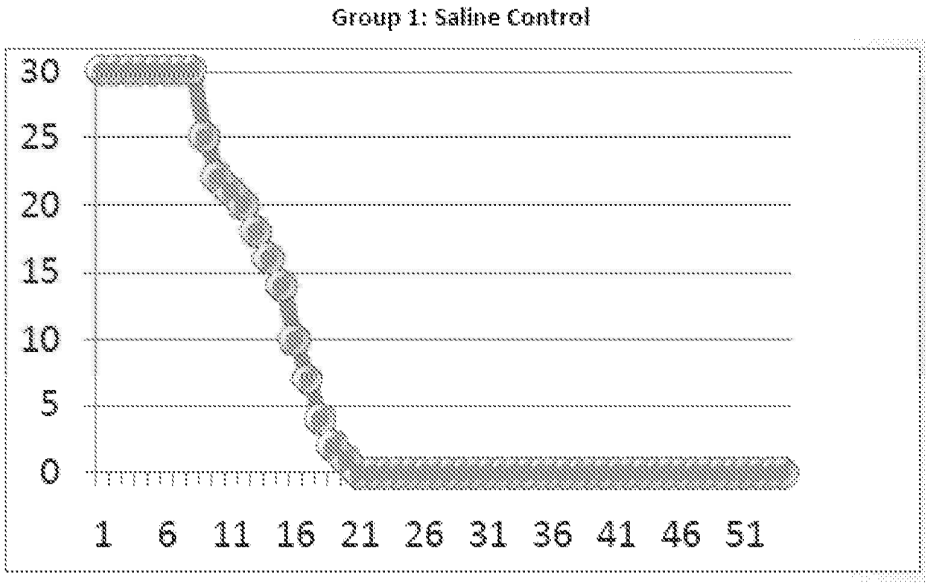


Fig. 36



As can be seen, all animals were dead by approximately day 21.

Fig. 37

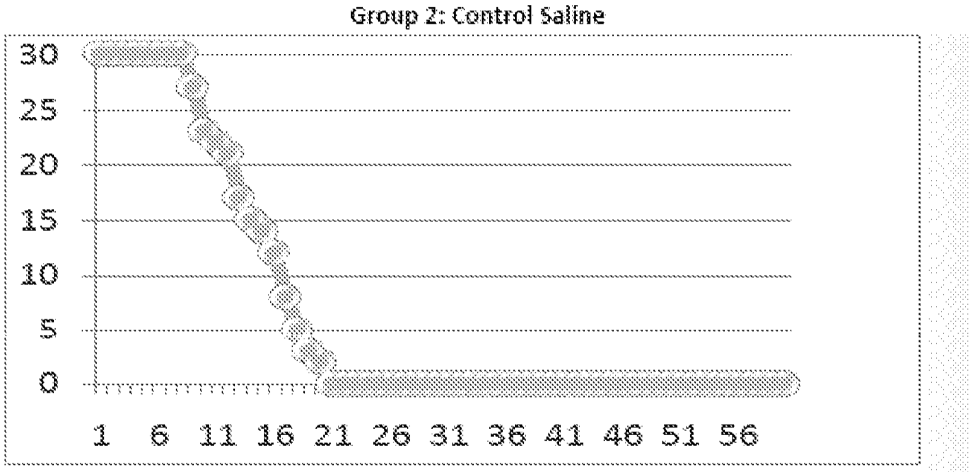
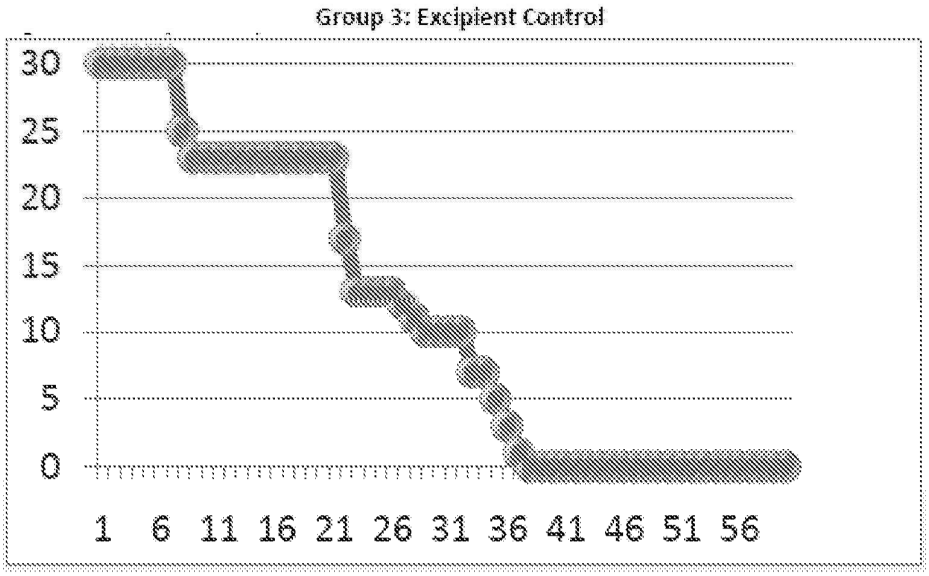
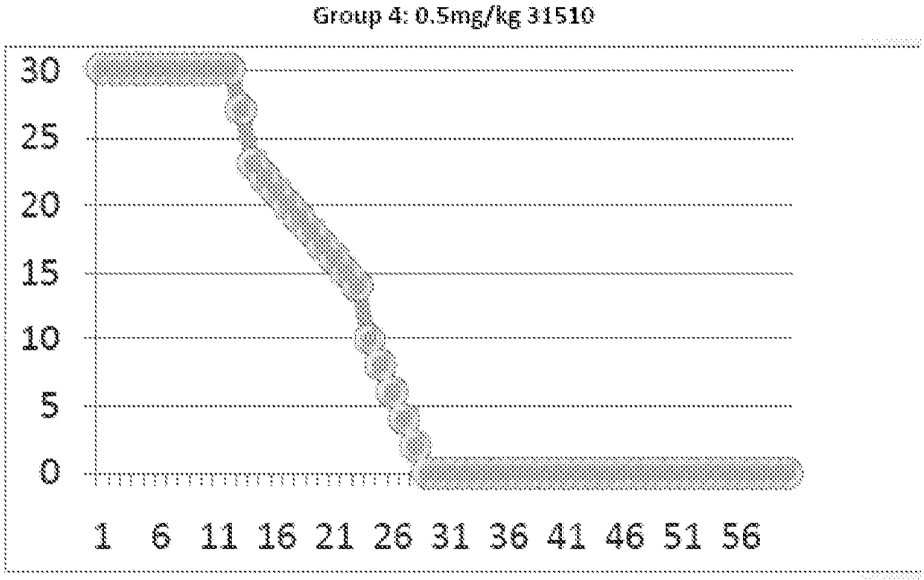


Fig. 38



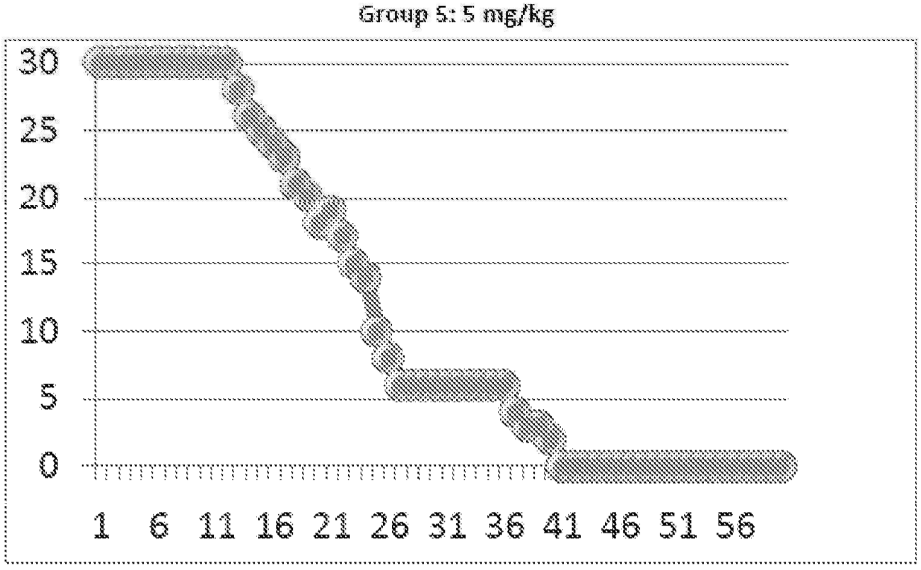
There was a prolongation of life by approximately 15 days by the excipient control. This does not indicate a therapeutic effect per se, rather, a palliative effect parallel to what is observed in humans with life prolongation.

Fig. 39



At 0.5 mg/kg 31510, there was an increase in survival days by 10 days.

Fig. 40



In this group there was a statistically significant prolongation of life or approximately 20 days. Animals were found in better health, with less signs of moribundity.

Fig. 41

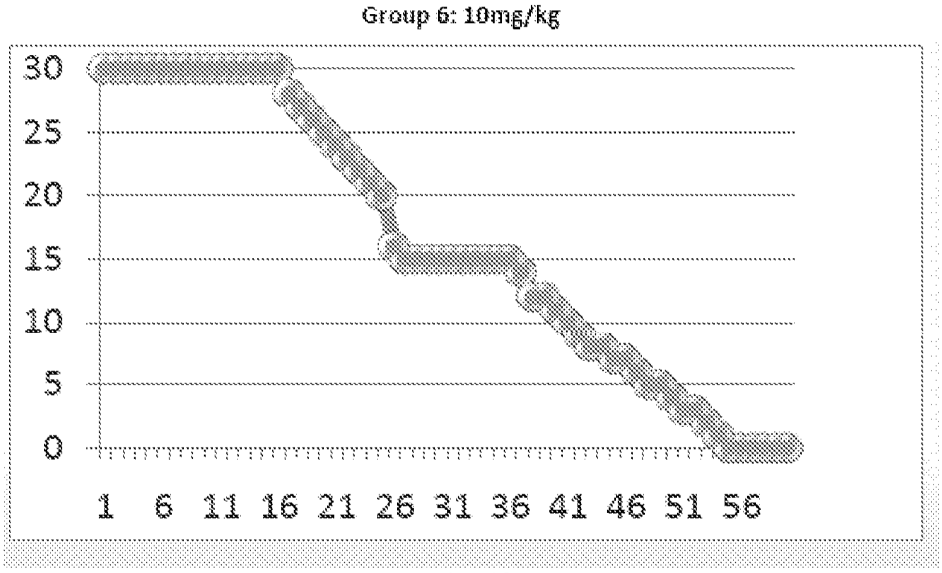
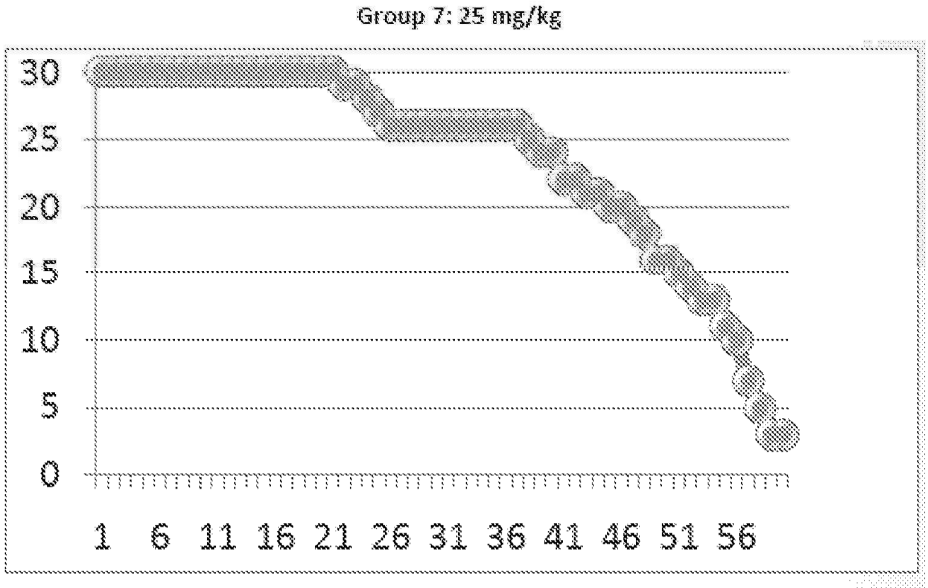
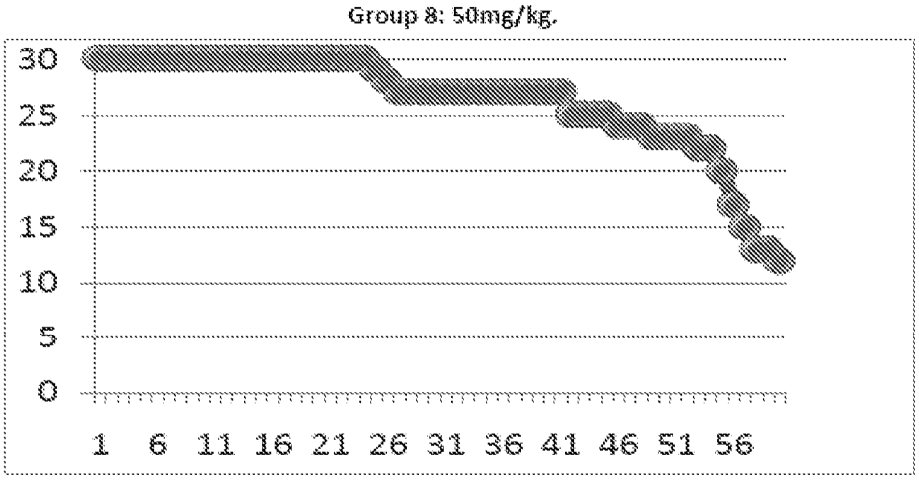


Fig. 42



The results with this dosage are truly impressive. Survival was enhanced significantly. The three surviving animals sacrificed on day 60, each had a small tumor.

Fig. 43



Thus far, these are the most striking findings. Deaths at day 31 were minimal and prolongation of life was statistically significant. Moreover, at this dose survival rates at day 60 were significantly increased, with approximately 60% of animals alive and only four animals exhibiting visible tumors.

Fig. 44

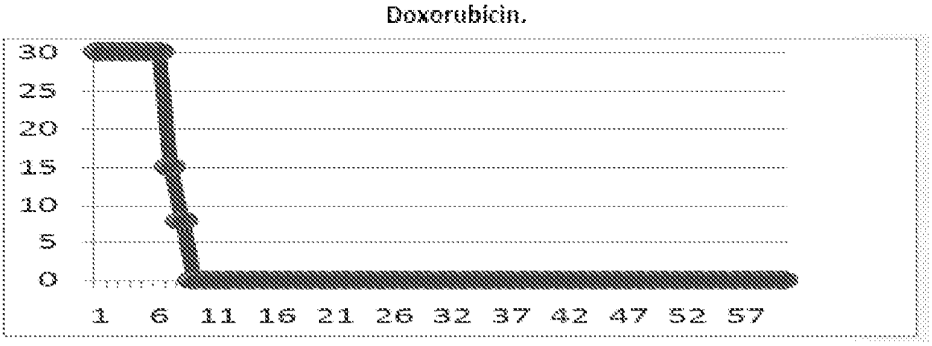


Fig. 45

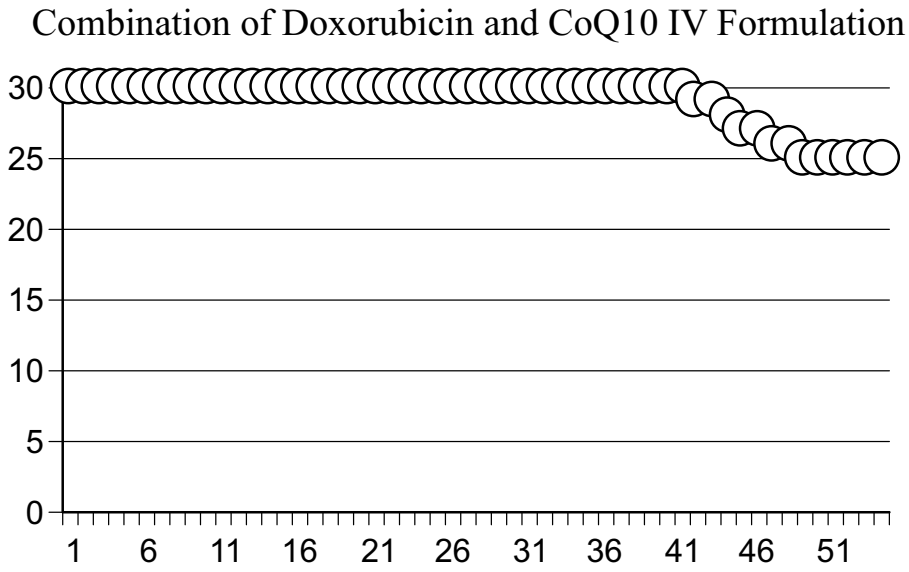

Combination of Doxorubicin and CoQ10 IV Formulation
30
25
20
15
10
5
0
1
6
11
16
21
26
31
36
41
46
51

Fig. 46

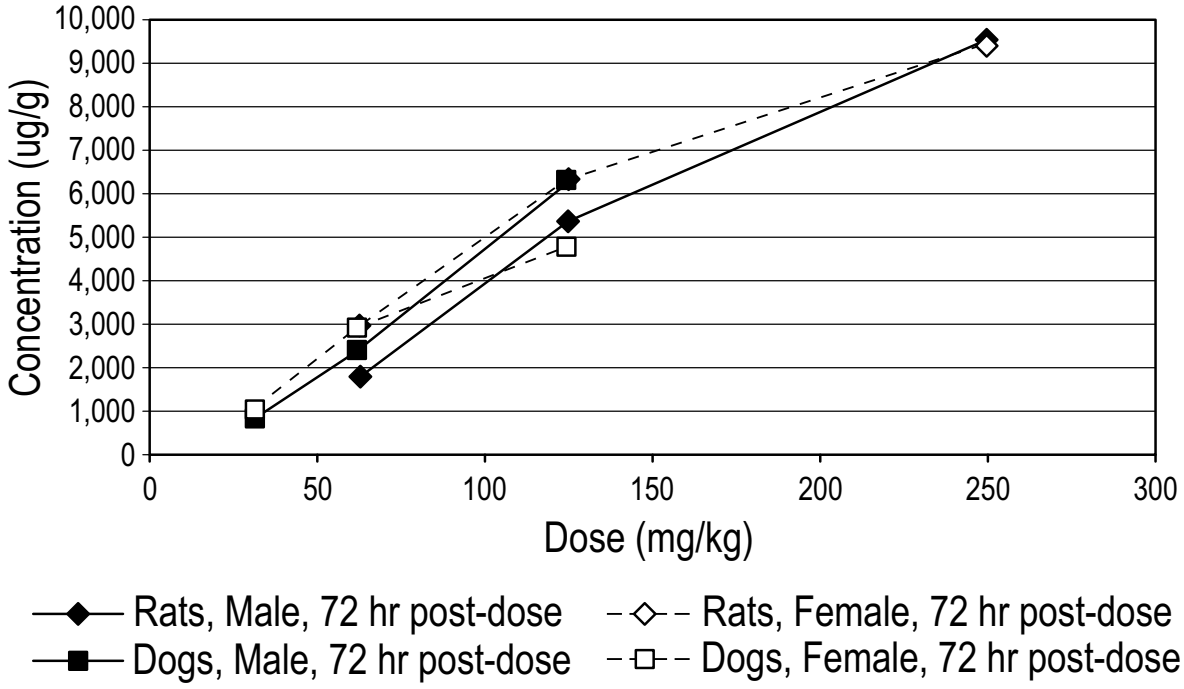

Concentration (ug/g)
10,000
9,000
8,000
7,000
6,000
5,000
4,000
3,000
2,000
1,000
0
0
50
100
150
200
250
300
Dose (mg/kg)
Rats, Male, 72 hr post-dose
Rats, Female, 72 hr post-dose
Dogs, Male, 72 hr post-dose
Dogs, Female, 72 hr post-dose

Fig. 47