CLAIMS

1. A therapeutic formulation suitable for intravenous administration to a subject comprising:

an aqueous solution;

a hydrophobic active agent dispersed to form a colloidal nano-dispersion of particles; and

at least one of a dispersion stabilizing agent and an opsonization reducer;

wherein the colloidal nano-dispersion of the active agent is dispersed into nano-dispersion particles having a mean size of less than 200-nm.

2. The formulation of claim 1, wherein the dispersion stabilizing agent is selected the group consisting of pegylated castor oil, Cremphor EL, Cremophor RH 40, Pegylated vitamin E, Vitamin E TPGS, and Dimyristoylphosphatidyl choline (DMPC).

3. The formulation of claim 2, wherein the dispersion stabilizing agent is DMPC.

4. The formulation of claim 1, wherein the opsonization reducer is selected from the group consisting of poloxamer and poloxamines.

5. The formulation of claim 4, wherein the opsonization reducer is poloxamer 188.

6. The formulation of claim 1, wherein the hydrophobic active agent is Coenzyme Q10 (CoQ10).

7. The formulation of any of the preceding claims wherein the hydrophobic active agent is CoQ10, the opsonization reducer is poloxamer 188 and the dispersion stabilizing agent is DMPC.

8. The formulation of claim 1, wherein the colloidal nano-dispersion is a suspension.

9. The formulation of claim 1, wherein the colloidal nano-dispersion is an emulsion.

10. The formulation of claim 1, wherein the active agent of the colloidal nano-dispersion is in a crystalline form.

11. The formulation of claim 1, wherein the active agent of the colloidal nano-dispersion is in a super-cooled melt form.

12. The formulation of claim 7, wherein the formulation has a weight-per-volume of the CoQ10, DMPC and poloxamer 188 of 4%, 3% and 1.5%, respectively.

13. The formulation of claim 7, wherein the formulation has a weight-per-volume of the CoQ10, DMPC and poloxamer 188 of 8%, 6% and 3%, respectively.

14. The formulation of claim 1, wherein the mean size of the nano-dispersion particles is between about 10-nm and about 200-nm.

15. The formulation of claim 1, wherein the mean size of the nano-dispersion particles is between about 10-nm and about 100-nm.

16. The formulation of claim 1, wherein the mean size of the nano-dispersion particles is between about 30-nm and about 80-nm.

17. The formulation of claim 1, wherein the mean size of the nano-dispersion particles is between about 35-nm and about 40-nm.

18. The formulation of claim 1, wherein the mean size of the nano-dispersion particles is less than about 45-nm.

19. A therapeutic formulation suitable for intravenous administration to a subject comprising:

an aqueous solution;

a hydrophobic active agent dispersed to form a colloidal nano-dispersion of particles; and

at least one of a dispersion stabilizing agent and an opsonization reducer;

wherein the colloidal nano-dispersion of the active agent is dispersed into liposomes having sizes of less than 200-nm.

20. The formulation of claim 19, wherein the liposomes are unilamellar.

21. The formulation of claim 19, wherein the liposomes are bi-layered multilamellar liposomes having an aqueous space between the bi-layers and a lipophilic space within the bi-layers.

22. The formulation of claim 21, wherein the hydrophobic active agent is entrapped within the lipophilic space of the bi-layers.

23. The formulation of claim 21, wherein the multilamellar liposome further includes a hydrophilic agent entrapped in the aqueous space between the bi-layers.

24. A therapeutic formulation suitable for intravenous administration to a subject comprising:

an aqueous solution;

a hydrophobic active agent dispersed to form a colloidal nano-dispersion of particles; and

DMPC and an opsonization reducer.

25. The formulation of claim 24, wherein the opsonization reducer is selected from the group consisting of poloxamer and poloxamines.

26. The formulation of claim 24, wherein the opsonization reducer is poloxamer 188.

27. The formulation of claim 24, wherein the hydrophobic active agent is Coenzyme Q10 (CoQ10).

28. The formulation of claim 24, wherein the hydrophobic active agent is Coenzyme Q10 (CoQ10) and the opsonization reducer is poloxamer 188.

29. The formulation of claim 28, wherein the formulation has a weight-per-volume of the CoQ10, DMPC and poloxamer 188 of 4%, 3% and 1.5%, respectively.

30. The formulation of claim 28, wherein the formulation has a weight-per-volume of the CoQ10, DMPC and poloxamer 188 of 8%, 6% and 3%, respectively.

31. The formulation of claim 24, wherein the colloidal nano-dispersion is a suspension.

32. The formulation of claim 24, wherein the colloidal nano-dispersion is an emulsion.

33. The formulation of claim 24, wherein the active agent of the colloidal nano-dispersion is in a crystalline form.

34. The formulation of claim 24, wherein the active agent of the colloidal nano-dispersion is in a super-cooled melt form.

35. A therapeutic formulation suitable for intravenous administration to a subject comprising:

an aqueous solution;

a hydrophobic active agent dispersed to form a colloidal nano-dispersion of particles; and

DMPC;

wherein the colloidal nano-dispersion of the active agent is dispersed into nano-dispersion particles having a mean size of less than 200-nm.

36. The formulation of claim 35, wherein the hydrophobic active agent is Coenzyme Q10 (CoQ10).

37. The formulation of claim 35, wherein the colloidal nano-dispersion is a suspension.

38. The formulation of claim 35, wherein the colloidal nano-dispersion is an emulsion.

39. The formulation of claim 35, wherein the active agent of the colloidal nano-dispersion is in a crystalline form.

40. The formulation of claim 35, wherein the active agent of the colloidal nano-dispersion is in a super-cooled melt form.

41. The formulation of claim 36, wherein the formulation has a weight-per-volume of the CoQ10 and DMPC of 4% and 3%, respectively.

42. The formulation of claim 36, wherein the formulation has a weight-per-volume of the CoQ10 and DMPC of 8% and 6%, respectively.

43. The formulation of claim 35, wherein the mean size of the nano-dispersion particles is between about 10-nm and about 200-nm.

44. The formulation of claim 35, wherein the mean size of the nano-dispersion particles is between about 10-nm and about 100-nm.

45. The formulation of claim 35, wherein the mean size of the nano-dispersion particles is between about 30-nm and about 80-nm.

46. The formulation of claim 35, wherein the mean size of the nano-dispersion particles is between about 35-nm and about 40-nm.

47. The formulation of claim 35, wherein the mean size of the nano-dispersion particles is less than about 45-nm.

48. A therapeutic formulation suitable for intravenous administration to a subject comprising:

an aqueous solution;

CoQ10 dispersed to form a colloidal nano-dispersion of particles;

a dispersion stabilizing agent selected from the group consisting of pegylated castor oil, Cremphor EL, Cremophor RH 40, Pegylated vitamin E, Vitamin E TPGS, and Dimyristoylphosphatidyl choline (DMPC); and

an opsonization reducer selected from the group consisting of poloxamer and poloxamines;

wherein the colloidal nano-dispersion of CoQ10 is dispersed into nano-dispersion particles having a mean size of between 10-nm and 100-nm.

49. A therapeutic formulation suitable for intravenous administration to a subject comprising:

an aqueous solution;

CoQ10 dispersed to form a colloidal nano-dispersion of particles;

DMPC;

and poloxamer 188;

wherein the colloidal nano-dispersion of CoQ10 is dispersed into nano-dispersion particles having a mean size of between 30-nm and 80-nm.

50. A method of preparing the therapeutic formulation of claim 1, wherein the method comprises dispersing the hydrophobic active agent by high pressure homogenization by:

adding hydrophobic active agent to a 65°C bath of water and mixing to form a hydrophobic active agent/water mixture;

adding a dispersion stabilizing agent to the hydrophobic active agent/water mixture and mix at 65°C to form a hydrophobic active agent/water/stabilizer mixture;

adding an opsonization reducer to form a hydrophobic active agent/water/stabilizer/reducer mixture;

pre-heating a Microfluidizer to 65°C; and

processing by mixing the hydrophobic active agent/water/stabilizer/reducer mixture in the Microfluidizer at 65°C such that a hydrophobic active agent colloidal nano-dispersion having a mean particle size less than 200-nm is formed.

51. A therapeutic formulation of claim 1, prepared by the method of claim 50.

52. The method of claim 50, wherein the dispersion stabilizing agent is selected from the group consisting of pegylated castor oil, Cremphor EL, Cremophor RH 40, Pegylated vitamin E, Vitamin E TPGS, and Dimyristoylphosphatidyl choline (DMPC).

53. The method of claim 52, wherein the dispersion stabilizing agent is DMPC.

54. The method of claim 50, wherein the oposonization reducer is selected from the group consisting of poloxamer and poloxamines.

55. The method of claim 54, wherein the opsonization reducer is poloxamer 188.

56. The method of claim 50, wherein the opsonization reducer is poloxamer 188 and the dispersion stabilizing agent is DMPC.

57. The method of claim 50, wherein the hydrophobic active agent is CoQ10.

58. The method of claim 50, wherein the hydrophobic active agent is CoQ10, the opsonization reducer is poloxamer 188 and the dispersion stabilizing agent is DMPC.

59. The method of claim 57 or 58, wherein the CoQ10 of the colloidal nano-dispersion is in the form of a super-cooled melt.

60. The method of claim 58, wherein the formulation has a weight-per-volume of the CoQ10, DMPC and poloxamer 188 of 4%, 3% and 1.5%, respectively.

61. The method of claim 58, wherein the formulation has a weight-per-volume of the CoQ10, DMPC and poloxamer 188 of 8%, 6% and 3%, respectively.

62. The method of claim 50, wherein a hydrophobic active agent colloidal nano-dispersion having a mean particle size of between 10-nm and 100-nm is formed.

63. The method of claim 50, wherein a hydrophobic active agent colloidal nano-dispersion having a mean particle size of between 35-nm and 40-nm is formed.

64. The method of claim 50, wherein a hydrophobic active agent colloidal nano-dispersion having a mean particle size of less than about 45-nm is formed.

65. The method of claim 50, further comprising the step of lyophilizing the colloidal nano-dispersion to crystallize the CoQ10 colloidal nano-dispersion particles.

66. The method of claim 65, further comprising the step of adding a lyoprotectant.

67. The method of claim 66, wherein the lyoprotectant is a nutritive sugar.

68. The method of claim 67, wherein the nutritive sugar is selected from the group consisting of lactose, mannose, maltose, galactose, fructose, sorbose, raffinose, neuraminic acid, glucosamine, galactosamine, N-methylglucosamine, mannitol, sorbitol, arginine, glycine and sucrose.

69. A method of treating or preventing an oncological disorder in a subject, comprising:

intravenously administering a therapeutic formulation as described in any one of claims 1-49 to the subject such that treatment or prevention of the oncological disorder occurs.

70. The method of claim 69, wherein the intravenous administration is via a dose selected for providing efficacy in the subject for the oncological disorder being treated.

71. The method of claim 69, wherein the oncological disorder is an aggressive or metastatic oncological disorder.

72. The method of claim 71, wherein the aggressive or metastatic oncological disorder is selected from the group consisting of pancreatic carcinoma, hepatocellular carcinoma, Ewing's sarcoma, metastatic breast cancer, metastatic melanoma, brain cancer (astrocytoma, glioblastoma), neuroendocrine cancer, colon cancer, lung cancer, osteosarcoma, androgen-independent prostate cancer, ovarian cancer and non-Hodgkin's Lymphoma.

73. The method of claim 69, wherein the oncological disorder is a non-aggressive oncological disorder.

74. The method of claim 73, wherein the non-aggressive oncological disorder is selected from the group consisting of non-metastatic breast cancer, androgen-dependent prostate cancer, small cell lung cancer and acute lymphocytic leukemia.

75. The method of claim 69, wherein the formulation comprises about 4% of Coenzyme Q10, 3% DMPC and 1.5% poloxamer 188.

76. A method for inhibiting tumor cell growth in a subject, comprising:

intravenously administering a therapeutic formulation as described in any one of claims 1-49 to the subject, such that tumor cell growth is inhibited.

77. The method of claim 76, wherein the intravenous administration is via a dose selected for providing efficacy in inhibiting tumor cell growth in the subject.

78. The method of claim 76, wherein the formulation comprises about 4% of Coenzyme Q10, 3% DMPC and 1.5% poloxamer 188.

Claims:

1. An invention not claimed in any divisional application.