CLAIMS

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

an aqueous solution;

a hydrophobic active agent;

a dispersion stabilizing agent; and

an opsonization reducer selected from the group consisting of polyethylene glycols, polysaccharides, PEG-containing copolymers, poloxamines and poloxamers;

wherein the hydrophobic active agent is dispersed into a colloidal nano-dispersion of particles having a mean size of less than 200 nm as determined by photon correlation spectroscopy;

wherein the hydrophobic active agent is Coenzyme Q10 (CoQ10); and

wherein the dispersion stabilizing agent is dimyristoylphosphatidyl choline (DMPC).

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

3. The formulation of claim 1, wherein the opsonization reducer is poloxamer 188.

4. The formulation of claim 1, wherein the colloidal nano-dispersion is a suspension or an emulsion, or wherein the active agent of the colloidal nano-dispersion is in a crystalline form or in a super-cooled melt form.

5. The formulation of claim 3, wherein the formulation has a weight-per-volume of the CoQ10, DMPC and poloxamer 188 of 4%, 3% and 1.5%, respectively, or of 8%, 6% and 3%, respectively.

6. The formulation of claim 1, wherein the mean size of the nano-dispersion particles, as determined by photon correlation spectroscopy, is between about 10 nm and about 200 nm, preferably between about 10 nm and about 100 nm, more preferably between about 30 nm and about 80 nm, even more preferably between about 35 nm and about 40 nm, and in particular less than about 45 nm.

7. The formulation of claim 1, wherein the formulation has a weight-per-volume of the CoQ10 and DMPC of 4% and 3%, respectively or a weight-per-volume of the CoQ10 and DMPC of 8% and 6%, respectively.

8. The formulation according to claim 2, wherein the nano-dispersion particles have a mean size, as determined by photon correlation spectroscopy, of between 10 nm and 100 nm, preferably wherein the nano-dispersion particles have a mean size, as determined by photon correlation spectroscopy, of between 30 nm and 80 nm.

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

adding the DMPC to the hydrophobic active agent/water mixture and mixing at 65°C to form a hydrophobic active agent/water/DMPC mixture;

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

pre-heating a Microfluidizer to 65°C; and

processing by mixing the hydrophobic active agent/water/DMPC/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 as determined by photon correlation spectroscopy is formed.

10. A therapeutic formulation of claim 1, obtainable by the method of claim 9.

11. The method of claim 9, wherein the opsonization reducer is poloxamer 188.

12. The method of claim 9 or 11, wherein the CoQ10 of the colloidal nano-dispersion is in the form of a super-cooled melt.

13. The method of claim 9, further comprising the step of lyophilizing the colloidal nano-dispersion to crystallize the CoQ10 colloidal nano-dispersion particles, optionally further comprising the step of adding a lyoprotectant, wherein the lyoprotectant is preferably a nutritive sugar, wherein the nutritive sugar is preferably 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.

14. The therapeutic formulation as described in any one of claims 1-8 for use in a method, wherein the method is selected from the group consisting of

(i) treating or preventing an oncological disorder in a subject, comprising:

intravenously administering the therapeutic formulation as described in any one of claims 1-8 to the subject such that treatment or prevention of the oncological disorder occurs; and

(ii) inhibiting tumor cell growth in a subject, comprising:

intravenously administering the therapeutic formulation as described in any one of claims 1-8 to the subject, such that tumor cell growth is inhibited, wherein the intravenous administration is preferably via a dose selected for providing efficacy in the subject for the oncological disorder being treated and efficacy in inhibiting tumor cell growth in the subject, respectively.

15. The therapeutic formulation for use of claim 14, embodiment (i),

wherein the oncological disorder is an aggressive or metastatic oncological disorder, wherein the aggressive or metastatic oncological disorder is preferably 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; or

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

16. The therapeutic formulation for use of claim 14, wherein the formulation comprises about 4% of Coenzyme Q10, 3% DMPC and 1.5% poloxamer 188.

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

an aqueous solution;

a hydrophobic active agent; and

dimyristoylphosphatidyl choline (DMPC);

wherein the hydrophobic active agent is dispersed into a colloidal nano-dispersion of particles having a mean size of less than 200 nm as determined by photon correlation spectroscopy; and

wherein the hydrophobic active agent is Coenzyme Q10 (CoQ10).

18. The formulation of claim 17, wherein the colloidal nano-dispersion is a suspension or an emulsion, or wherein the active agent of the colloidal nano-dispersion is in a crystalline form or in a super-cooled melt form.

19. The formulation of claim 17, wherein the mean size of the nano-dispersion particles, as determined by photon correlation spectroscopy, is between about 10 nm and about 200 nm, preferably between about 10 nm and about 100 nm, more preferably between about 30 nm and about 80 nm, even more preferably between about 35 nm and about 40 nm, and in particular less than about 45 nm.

20. The formulation of claim 17, wherein the formulation has a weight-per-volume of the CoQ10 and DMPC of 4% and 3%, respectively, or a weight-per-volume of the CoQ10 and DMPC of 8% and 6%, respectively.

21. The therapeutic formulation as described in any one of claims 17-20 for use in a method, wherein the method is selected from the group consisting of

(i) treating or preventing an oncological disorder in a subject, comprising:

intravenously administering the therapeutic formulation as described in any one of claims 17-20 to the subject such that treatment or prevention of the oncological disorder occurs; and

(ii) inhibiting tumor cell growth in a subject, comprising:

intravenously administering the therapeutic formulation as described in any one of claims 17-20 to the subject, such that tumor cell growth is inhibited, wherein the intravenous administration is preferably via a dose selected for providing efficacy in the subject for the oncological disorder being treated and efficacy in inhibiting tumor cell growth in the subject, respectively.

22. The therapeutic formulation for use of claim 21, embodiment (i),

wherein the oncological disorder is an aggressive or metastatic oncological disorder, wherein the aggressive or metastatic oncological disorder is preferably 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; or

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