CLAIMS:

1. A non-aqueous, ethanol-free taxane liquid nanodispersion formulation comprising:

a taxane;

an oil;

a non-ionic surfactant;

a non-aqueous solvent; and

an organic acid component;

wherein the organic acid component is soluble in the non-aqueous solvent and the amount by weight of non-ionic surfactant is equal to or greater than the amount by weight of non-aqueous solvent or wherein the taxane is docetaxel and the organic acid component is soluble in the non-aqueous solvent and is substantially free of any conjugate base.

2. The nanodispersion formulation according to claim 1, wherein the taxane is present in an amount ranging from about 0.5 to about 5 wt%.

3. The nanodispersion formulation according to claim 1, wherein the taxane is present in about 2 wt%.

4. The nanodispersion formulation according to any one of claims 1-3, wherein the taxane is paclitaxel.

5. The nanodispersion formulation according to any one of claims 1-3, wherein the taxane is docetaxel.

6. The nanodispersion formulation according to claim 3, wherein the taxane is anhydrous docetaxel.

7. The nanodispersion formulation according to claim 3, wherein the taxane is docetaxel trihydrate.

8. The nanodispersion formulation according to any one of claims 1-7, wherein the oil is selected from the group consisting of synthetic oils, vegetable oils, tocopherols and combinations thereof.

9. The nanodispersion formulation according to claim 8, wherein the oil is selected from the group consisting of soybean oil, olive oil, sesame oil, corn oil, a medium chain triglyceride, a tocopherol or derivative thereof and combinations thereof.

10. The nanodispersion formulation according to any one of claims 1-9, wherein the oil is present in an amount ranging from about 1 to about 20 wt%.

11. The nanodispersion formulation according to claim 10, wherein the oil is soybean oil.

12. The nanodispersion formulation according to claim 11, wherein the soybean oil is present in an amount ranging from about 1 to about 5 wt%.

13. The nanodispersion formulation according to claim 10, wherein the oil is a medium chain triglyceride.

14. The nanodispersion formulation according to claim 13, wherein the medium chain triglyceride is present in an amount ranging from about 1 to about 5 wt%.

15. The nanodispersion formulation according to any one of claims 1-14, wherein the non-ionic surfactant is present in an amount ranging from about 40 to about 75 wt%.

16. The nanodispersion formulation according to claim 15, wherein the non-ionic surfactant is present in an amount ranging from about 50 to about 60 wt%.

17. The nanodispersion formulation according to any one of claims 1-16, wherein the non-ionic surfactant is polysorbate 80.

18. The nanodispersion formulation according to any one of claims 1-17, wherein the non-aqueous solvent is present in an amount ranging from about 20 to about 60 wt%.

19. The nanodispersion formulation according to claim 18, wherein the non-aqueous solvent is present in an amount ranging from about 35 to about 45 wt%.

20. The nanodispersion formulation according to any one of claims 1-19, wherein the non-aqueous solvent is polyethylene glycol.

21. The nanodispersion formulation according to claim 20, wherein the polyethylene glycol has a melting point of less than 0 °C.

22. The nanodispersion formulation according to any one of claims 1-21, wherein the organic acid component is present in an amount ranging from 0.3 to 3 wt%.

23. The nanodispersion formulation according to claim 22, wherein the organic acid component is present in an amount ranging from 0.5 to 1 wt%.

24. The nanodispersion formulation according to any one of claims 1-23, wherein the organic acid component is an organic acid.

25. The nanodispersion formulation according to claim 24, wherein the organic acid is selected from the group consisting of citric acid, lactic acid and acetic acid.

26. The nanodispersion formulation according to claim 25, wherein the organic acid is citric acid or lactic acid.

27. The nanodispersion formulation according to claim 26, wherein the citric acid or lactic acid is present in about 0.3 to about 1 wt%.

28. The nanodispersion formulation according to claim 26, wherein the citric acid or lactic acid is present in about 0.8 wt%.

29. The nanodispersion formulation according to any one of claims 1-23, wherein the organic acid component is an organic acid buffer.

30. The nanodispersion formulation according to claim 29, wherein the organic acid buffer is lactic acid buffer.

31. The nanodispersion formulation according to claim 30, wherein the lactic acid buffer is present in about 1 wt%.

32. The nanodispersion formulation according to any one of the above claims, wherein the amount by weight of oil is equal to or less than about 2.5 times the amount of taxane.

33. The nanodispersion formulation according to any one of the above claims, wherein the ratio by weight of taxane to oil is from about 1:0.5 to about 1:2.5.

34. A non-aqueous, ethanol-free docetaxel liquid nanodispersion formulation comprising:
docetaxel;
soybean oil in an amount ranging from about 1 to about 5 wt%;
polysorbate 80 in an amount ranging from about 50 to about 60 wt%;

polyethylene glycol in an amount ranging from about 35 to about 45 wt%; and

citric acid or lactic acid or lactic acid buffer in an amount ranging from 0.3 to 1 wt%;

wherein the amount by weight of non-ionic surfactant is about equal to or greater than the amount by weight of non-aqueous solvent.

35. The nanodispersion formulation according to claim 34, wherein the citric acid or lactic acid is present in an amount ranging from about 0.3 to about 1 wt% and wherein said citric acid is substantially citrate-free or said lactic acid is substantially lactate-free.

36. A non-aqueous, ethanol-free docetaxel liquid nanodispersion formulation comprising:

docetaxel;

a medium chain triglyceride in an amount ranging from about 1 to about 5 wt%;

polysorbate 80 in an amount ranging from about 50 to about 60 wt%;

polyethylene glycol in an amount ranging from about 35 to about 45 wt%; and

citric acid or lactic acid or lactic acid buffer in an amount ranging from 0.3 to 1 wt%;

wherein the amount by weight of non-ionic surfactant is about equal to or greater than the amount by weight of non-aqueous solvent.

37. The nanodispersion formulation according to claim 35, wherein the citric acid or lactic acid is present in an amount ranging from about 0.3 to about 1 wt% and wherein said citric acid is substantially citrate-free or said lactic acid is substantially lactate-free.

38. The nanodispersion formulation according to claims 34-37, wherein the docetaxel is anhydrous docetaxel.

39. The nanodispersion formulation according to claims 34-37, wherein the docetaxel is docetaxel trihydrate.

40. The nanodispersion formulation according to any one of claims 34-39, wherein the docetaxel is present in an amount ranging from about 0.5 to about 5 wt%.

41. The nanodispersion formulation according to claim 40, wherein the docetaxel is present in about 2 wt%.

42. The nanodispersion formulation according to any one of claims 34-41, wherein the polyethylene glycol has a melting point of less than 0 °C.

43. The nanodispersion formulation according to any one of claims 34-42, wherein the ratio by weight of docetaxel to oil is from 1:0.5 to 1:2.5.

44. The nanodispersion formulation according to any one of the above claims, wherein the ethanol-free taxane liquid nanodispersion formulation has a pH of less than about 3.5.

45. The nanodispersion formulation according to any one of the above claims, wherein the formulation is stable for more than 6 months at 40 °C.

46. The nanodispersion formulation according to any one of the above claims, wherein the formulation exhibits a taxane recovery rate of greater than 95% after 6 months at 40 °C.

47. The nanodispersion formulation according to any one of the above claims, wherein the formulation forms particles of less than about 20 nm when combined with an aqueous medium.

48. A method of administering an ethanol-free taxane liquid nanodispersion formulation to a subject, the method comprising:

(a) combining the ethanol-free taxane nanodispersion formulation according to any one of the above claims with an aqueous medium to provide an ethanol-free taxane diluted solution; and

(b) administering the ethanol-free taxane diluted solution to the subject.

49. The method of claim 48, wherein the taxane is docetaxel.

50. A kit comprising:

(a) a vial containing the ethanol-free taxane nanodispersion formulation according to any one of the above claims; and

(b) instructions for using the ethanol-free taxane nanodispersion formulation.

51. The kit according to claim 46, further comprising (c) an aqueous medium.

52. The kit of claim 50 or 51, wherein the taxane is docetaxel.

CLAIMS:

1. A non-aqueous, ethanol-free taxane liquid formulation comprising:

a taxane;

an oil;

a non-ionic surfactant;

a non-aqueous solvent; and

an organic acid component;

wherein the non-aqueous solvent is polyethylene glycol and wherein the non-aqueous solvent is present in an amount ranging from about 20 to about 60 wt%;

wherein the organic acid component is soluble in the non-aqueous solvent and the amount by weight of non-ionic surfactant is equal to or greater than the amount by weight of non-aqueous solvent.

2. The formulation according to claim 1, wherein the taxane is present in an amount ranging from about 0.5 to about 5 wt%.

3. The formulation according to claim 1, wherein the taxane is present in about 2 wt%.

4. The formulation according to claim 1, wherein the taxane is paclitaxel.

5. The formulation according to claim 1, wherein the taxane is docetaxel.

6. The formulation according to claim 3, wherein the taxane is anhydrous docetaxel.

7. The formulation according to claim 3, wherein the taxane is docetaxel trihydrate.

8. The formulation according to claim 1, wherein the oil is selected from the group consisting of synthetic oils, vegetable oils, tocopherols and combinations thereof.

9. The formulation according to claim 8, wherein the oil is selected from the group consisting of soybean oil, olive oil, sesame oil, corn oil, a medium chain triglyceride, a tocopherol or derivative thereof and combinations thereof.

10. The formulation according to claim 1, wherein the oil is present in an amount ranging from about 1 to about 20 wt%.

11. The formulation according to claim 10, wherein the oil is soybean oil.

12. The formulation according to claim 11, wherein the soybean oil is present in an amount ranging from about 1 to about 5 wt%.

13. The formulation according to claim 10, wherein the oil is a medium chain triglyceride.

14. The formulation according to claim 13, wherein the medium chain triglyceride is present in an amount ranging from about 1 to about 5 wt%.

15. The formulation according to claim 1, wherein the non-ionic surfactant is present in an amount ranging from about 40 to about 75 wt%.

16. The formulation according to claim 15, wherein the non-ionic surfactant is present in an amount ranging from about 50 to about 60 wt%.

17. The formulation according to claim 1, wherein the non-ionic surfactant is polysorbate 80.

18. The formulation according to claim 1, wherein the non-aqueous solvent is present in an amount ranging from about 35 to about 45 wt%.

19. The formulation according to claim 1, wherein the polyethylene glycol has a melting point of less than 0 °C.

20. The formulation according to claim 1, wherein the organic acid component is present in an amount ranging from 0.3 to 3 wt%.

21. The formulation according to claim 20, wherein the organic acid component is present in an amount ranging from 0.5 to 1 wt%.

22. The formulation according to claim 1, wherein the organic acid component is an organic acid.

23. The formulation according to claim 22, wherein the organic acid is selected from the group consisting of lactic acid and acetic acid.

24. The formulation according to claim 23, wherein the organic acid is lactic acid.

25. The formulation according to claim 24, wherein the lactic acid is present in about 0.8 wt%.

26. The formulation according to claim 1, wherein the organic acid component is an organic acid buffer.

27. The formulation according to claim 26, wherein the organic acid buffer is lactic acid buffer.

28. The formulation according to claim 27, wherein the lactic acid buffer is present in about 1 wt%.

29. The formulation according to claim 1, wherein the amount by weight of oil is equal to or less than about 2.5 times the amount of taxane.

30. The formulation according to claim 1, wherein the ratio by weight of taxane to oil is from about 1:0.5 to about 1:2.5.

31. A non-aqueous, ethanol-free docetaxel liquid formulation comprising:

docetaxel;

soybean oil in an amount ranging from about 1 to about 5 wt%;

polysorbate 80 in an amount ranging from about 50 to about 60 wt%;

polyethylene glycol in an amount ranging from about 35 to about 45 wt%; and

lactic acid or lactic acid buffer in an amount ranging from 0.3 to 1 wt%;

wherein the amount by weight of non-ionic surfactant is about equal to or greater than the amount by weight of non-aqueous solvent.

32. A non-aqueous, ethanol-free docetaxel liquid formulation comprising:

docetaxel;

a medium chain triglyceride in an amount ranging from about 1 to about 5 wt%;

polysorbate 80 in an amount ranging from about 50 to about 60 wt%;

polyethylene glycol in an amount ranging from about 35 to about 45 wt%; and

lactic acid or lactic acid buffer in an amount ranging from 0.3 to 1 wt%;

wherein the amount by weight of non-ionic surfactant is about equal to or greater than the amount by weight of non-aqueous solvent.

33. The formulation according to claim 31, wherein the docetaxel is anhydrous docetaxel.

34. The formulation according to claim 31, wherein the docetaxel is docetaxel trihydrate.

35. The formulation according to claim 31, wherein the docetaxel is present in an amount ranging from about 0.5 to about 5 wt%.

36. The formulation according to claim 35, wherein the docetaxel is present in about 2 wt%.

37. The formulation according to claim 31, wherein the polyethylene glycol has a melting point of less than 0 °C.

38. The formulation according to claim 31, wherein the ratio by weight of docetaxel to oil is from 1:0.5 to 1:2.5.

39. The formulation according to claim 1, wherein the ethanol-free taxane liquid formulation has a pH of less than about 3.5.

40. The formulation according to claim 1, wherein the formulation is stable for more than 6 months at 40 °C.

41. The formulation according to claim 1, wherein the formulation exhibits a taxane recovery rate of greater than 95% after 6 months at 40 °C.

42. The formulation according to claim 1, wherein the formulation forms particles of less than about 20 nm when combined with an aqueous medium.

43. A kit comprising:

(a) a vial containing the ethanol-free taxane formulation according to claim 1; and

(b) instructions for using the ethanol-free taxane formulation.

44. The kit according to claim 43, further comprising (c) an aqueous medium.

45. The formulation according to claim 18, wherein the non-aqueous solvent is polyethylene glycol having an average molecular weight of 1000 or less.

46. The non-aqueous, ethanol-free taxane liquid formulation of claim 1, wherein

the taxane is anhydrous docetaxel or a hydrate thereof;

the oil is soybean oil in an amount ranging from about 1 to about 5 wt%;

the non-ionic surfactant is polysorbate 80 in an amount ranging from about 50 to about 60 wt%; and

the non-aqueous solvent is polyethylene glycol having an average molecular weight of 1000 or less, and in an amount ranging from about 35 to about 45 wt%.

47. The formulation according to claim 46, wherein the formulation forms particles of less than about 20 nm when combined with an aqueous medium.