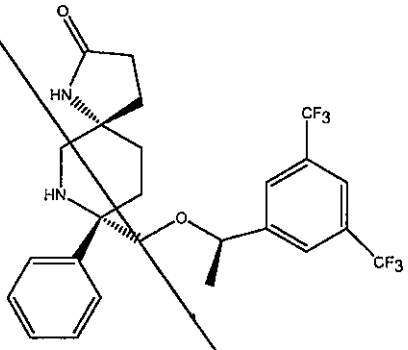
WHAT IS CLAIMED:

1. A pharmaceutical composition suitable for intravenous administration comprising:

a) a compound of Formula I



or a pharmaceutically acceptable salt thereof and

b) a pharmaceutically acceptable vehicle.

2. The composition according to claim 1 wherein the pharmaceutically acceptable vehicle is selected from the group consisting of cremophors, emulsions, microemulsions, micelles, negatively charged micelles, oil loaded micelles, intralipids, HSA, liposomes and negatively and positively charged amino acids.

3. The composition according to claim 1 wherein the pharmaceutically acceptable vehicle is selected from the group consisting of water soluble organic solvents, non-ionic surfactants, water insoluble lipids, organic lipids/semisolids and phospholipids.

4. The composition according to claim 2 wherein the pharmaceutically acceptable vehicle is in the form of an oil-loaded micelle.

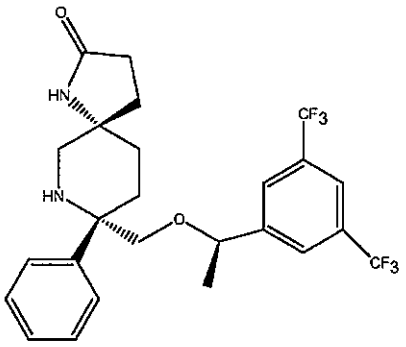
5. The composition according to claim 4 wherein the oil-loaded micelle comprises Solutol in combination with a long-chain and medium chain triglyceride.

6. The composition according to claim 2 wherein the pharmaceutically acceptable vehicle is in the form of an emulsion.

7. The composition according to claim 6 wherein the emulsion comprises a long chain triglyceride and a short chain triglyceride.

8. A pharmaceutical composition comprising:

a) a compound of Formula I



or a pharmaceutically acceptable salt thereof;

b) macrogol 15-hydroxystearate in an amount of from about 0.50% to about 10.0% by weight of the total composition;

c) a medium chain triglyceride in an amount of from about 0.10% to about 2.5% by weight of the total composition;

d) a long chain triglyceride in an amount of from about 0.10% to about 1.5% by weight of the total composition; and

e) at least one buffer, wherein the weight ratio of macrogol 15-hydroxystearate:medium chain triglyceride:long chain triglyceride in the composition is about 5-100:1-5:1, and wherein the pH of the composition is from about 6.5 to about 8.0.

9. The pharmaceutical composition of claim 8, wherein the medium chain triglyceride is selected from the group consisting of caprylic acid triglyceride, capric acid triglyceride, caprylic/capric acid triglyceride, trigylceride from coconut oil, caprylic/caprylic/lauric triglyceride, caprylic/caprylic/linoleic triglyceride, caprylic/caprylic/stearic triglyceride and combinations of two or more thereof.

10. The pharmaceutical composition of claim 8, wherein the long chain triglyceride is selected from the group consisting of soybean oil, corn oil, cottonseed oil, olive oil, peanut oil, safflower oil, sesame oil, shark liver oil, ethyl oleate, castor oil, monounsaturated omega-9 fatty acid and combinations of two or more thereof.

11. The pharmaceutical composition of claim 8, wherein the macrogol 15-hydroxystearate is present in an amount of from about 0.5% to about 10.0% by weight of the total composition; the medium chain triglyceride is present in an amount of from about 0.15% to about 1.5% by

weight of the total composition; and the long chain triglyceride is present in an amount of from about 0.10% to about 1.2% by weight of the total composition.

12. The pharmaceutical composition of claim 8, wherein the macrogol 15-hydroxystearate is present in an amount of from about 0.88% to about 4.84% by weight of the total composition; the medium chain triglyceride is present in an amount of from about 0.20% to about 1.20% by weight of the total composition; and the long chain triglyceride is present in an amount of from about 0.10% to about 0.75% by weight of the total composition.

13. The pharmaceutical composition of claim 8, wherein the medium chain triglyceride is caprylic/capric acid triglyceride and the long chain triglyceride is refined soybean oil.

14. The pharmaceutical composition of claim 8, wherein the pharmaceutically acceptable salt is a hydrochloride salt.

15. The pharmaceutical composition of claim 8, wherein the compound of Formula 1 is present in a concentration of from 1 mg/ml to 15 mg/ml.

16. The pharmaceutical composition of claim 15, wherein the compound of Formula I is present in a concentration of from 2 mg/ml to 10 mg/ml.

17. The pharmaceutical composition of claim 16, wherein the compound of formula I is present in a concentration of 2 mg/ml.

18. The pharmaceutical composition of claim 8, wherein the pH of the composition is from about 7 to about 8.

19. The pharmaceutical composition of claim 18, wherein the pH of the composition is about 7.5.

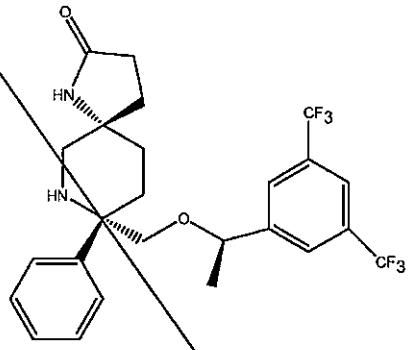
20. The pharmaceutical composition of claim 8, wherein the composition further comprises a tonicity adjuster and/or a pH adjuster.

21. The pharmaceutical composition of claim 8, wherein the at least one buffer is a phosphate buffer.

22. The pharmaceutical composition of claim 21, wherein the phosphate buffer is sodium phosphate buffer.

23. A pharmaceutical composition comprising:

(a) a compound of Formula I



or a pharmaceutically acceptable salt thereof;

(b) macrogol 15-hydroxystearate in an amount of about 4.4% by weight of the total composition;

(c) at least one medium chain triglyceride in an amount of about 1.1% by weight of the total composition;

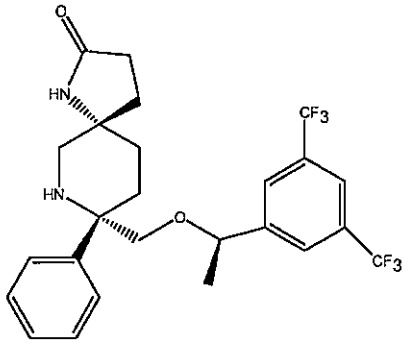
(d) refined soybean oil in an amount of about 0.66% by weight of the total composition; and

(e) a phosphate buffer, wherein the pH of the composition is about 7.5.

24. The pharmaceutical composition of claim 23, wherein the compound of Formula I is present in a concentration of from 1 mg/ml to 15 mg/ml.

25. A pharmaceutical composition comprising:

(a) a compound of Formula I



or a pharmaceutically acceptable salt thereof;

(b) macrogol 15-hydroxystearate in an amount of about 0.88% by weight of the total composition;

(c) at least one medium chain triglyceride in an amount of about 0.22% by weight of the total composition;

(d) refined soybean oil in an amount of about 0.12% by weight of the total composition; and

(e) a phosphate buffer, wherein the pH of the composition is about 7.5.

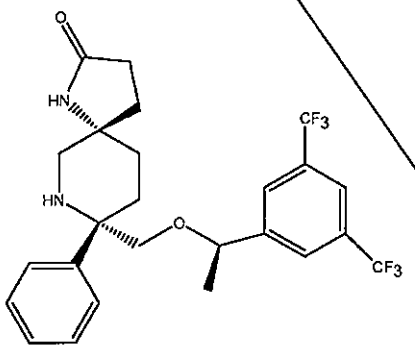
26. The pharmaceutical composition of claim 25, wherein the compound of Formula I is present in a concentration of from 1 mg/ml to 15 mg/ml.

27. A process for making a pharmaceutical composition comprising:

a) heating (i) melted macrogol 15-hydroxystearate, (ii) a medium chain triglyceride and (iii) a long chain triglyceride to form a composition;

b) adding water to the composition to form a microemulsion composition;

c) adding to the microemulsion composition a compound of Formula I



or a pharmaceutically acceptable salt thereof; and

d) adding at least one buffer and adjusting the pH from about 6.5 to about 8.0 to form a pharmaceutical composition, wherein the macrogol 15-hydroxystearate is present in an amount of about 0.50% to about 10.0% by weight of the total pharmaceutical composition, the medium chain triglyceride is present in an amount of about 0.10% to about 2.5% by weight of the total pharmaceutical composition, and the long chain triglyceride is present in an amount of from about 0.10% to about 1.5% by weight of the total pharmaceutical composition, and wherein the weight ratio of macrogol 15-hydroxystearate:medium chain triglyceride:long chain triglyceride in the composition is about 5-100:1-5:1.

28. The process of claim 27, wherein the medium chain triglyceride is selected from the group consisting of caprylic acid triglyceride, capric acid triglyceride, caprylic/capric acid triglyceride, trigylceride from coconut oil, caprylic/caprylic/lauric triglyceride, caprylic/caprylic/linoleic triglyceride, caprylic/caprylic/stearic triglyceride and combinations of two or more thereof.

29. The process of claim 27, wherein the long chain triglyceride is selected from the group consisting of soybean oil, corn oil, cottonseed oil, olive oil, peanut oil, safflower oil, sesame oil, shark liver oil, ethyl oleate, castor oil, monounsaturated omega-9 fatty acid and combinations of two or more thereof.

30. The process of claim 27, wherein the medium chain triglyceride is caprylic/capric acid triglyceride and the long chain triglyceride is soybean oil.

31. The process of claim 27, wherein the melted macrogol 15-hydroxystearate is obtained by heating the macrogol 15-hydroxystearate at a temperature of from 60°C to 65°C.

32. The process of claim 27, wherein in step (b) the mixture is heated at a temperature of about 60°C.

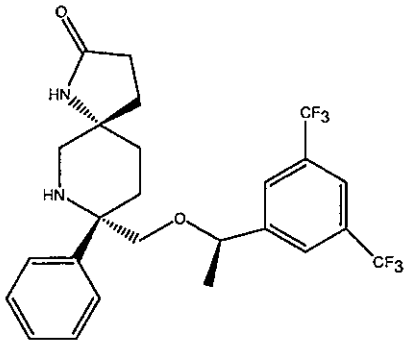
33. The process of claim 27, wherein the compound of Formula I is present in the pharmaceutical composition in a concentration from 1 mg/ml to 15 mg/ml.

34. The process of claim 27, wherein in step (c) the pH is adjusted to about 7.5.

35. The process of claim 27, further comprising adding a tonicity adjuster to the microemulsion composition.

36. A pharmaceutical composition comprising:

a) compound of Formula I



or a pharmaceutically acceptable salt thereof; and

b) pegylated hydroxystearate in an amount of from about 0.88% to about 5% by weight of the total composition, wherein the pegylated hydroxystearate is substantially free from free polyethylene glycol, and wherein the pH of the composition is from about 6.5 to about 8.0.

37. A method for treating nausea and/or emesis in a patient in need of treatment, the method comprising intravenously administering by infusion to the patient an effective amount of the pharmaceutical composition of claims 1, 8, 23, 25 or 36, wherein hemolysis in the patient is minimized.

38. The method of claim 37, wherein the nausea and/or vomiting are induced by chemotherapy or are post-operative nausea and/or vomiting.

39. The method of claim 37, wherein the patient is a primate or a companion animal.

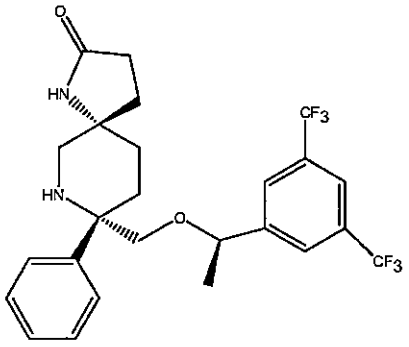
40. The method of claim 39, wherein the primate is a human.

41. The method of claim 37, wherein the compound of Formula I or pharmaceutically acceptable salt thereof is present in a concentration of from 1 mg/ml to 15 mg/ml.

42. The method of claim 41, wherein the composition is intravenously administered by infusion for a period of 15 to 90 minutes.

43. The method of claim 37, wherein the total daily dose of the compound of Formula I or pharmaceutically acceptable salt thereof is from 1 mg/kg to 9 mg/kg patient body weight.

44. A method for minimizing hemolysis in a patient following intravenous administration of a compound of the formula I or a pharmaceutically acceptable salt thereof,



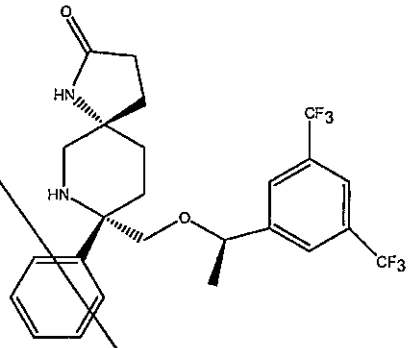
the method comprising intravenously administering by infusion to the patient an effective amount of the pharmaceutical composition of claims 1, 8, 23, 25 or 36.

45. The method of claim 44, wherein the patient is a primate or a companion animal.

46. The method of claim 45, wherein the primate is a human.

47. A pharmaceutical composition which comprises:

a) a compound of Formula I

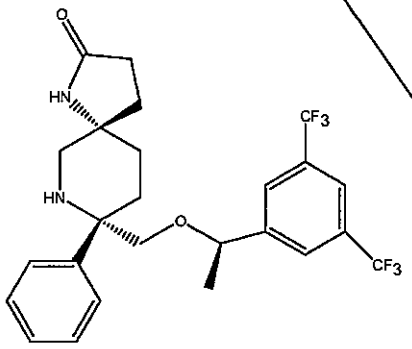


or a pharmaceutically acceptable salt thereof; and

b) a phospholipid.

48. A pharmaceutical composition which comprises:

a) a compound of Formula I

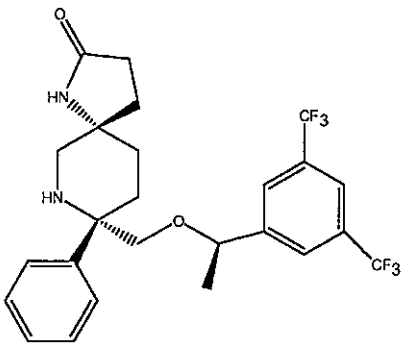


or a pharmaceutically acceptable salt thereof; and

b) a long chain fatty acid or long chain triglyceride.

49. A pharmaceutical composition which comprises:

a) a compound of Formula I

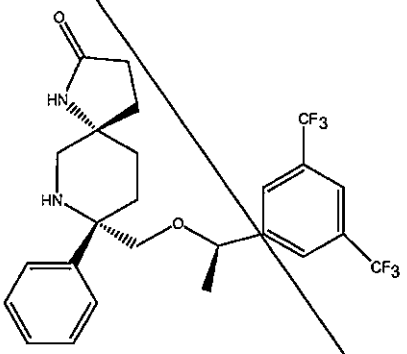


or a pharmaceutically acceptable salt thereof; and

b) a medium chain triglyceride or fatty acid.

50. A pharmaceutical composition which comprises:

a) a compound of Formula I



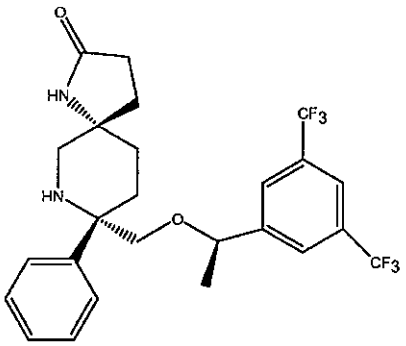
or a pharmaceutically acceptable salt thereof; and

b) a medium chain triglyceride and/or long chain fatty acid or triglyceride; and

c) a phospholipid.

51. A pharmaceutical composition which comprises:

a) a compound of Formula I



or a pharmaceutically acceptable salt thereof; and

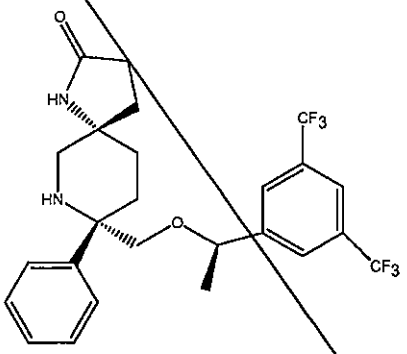
b) a medium chain triglyceride and/or long chain fatty acid or triglyceride; and

c) a phospholipid and

d) glycerin.

52. A pharmaceutical composition which comprises:

a) a compound of Formula I



or a pharmaceutically acceptable salt thereof; and

a) a medium chain triglyceride and/or long chain fatty acid or triglyceride; and

b) a phospholipid;

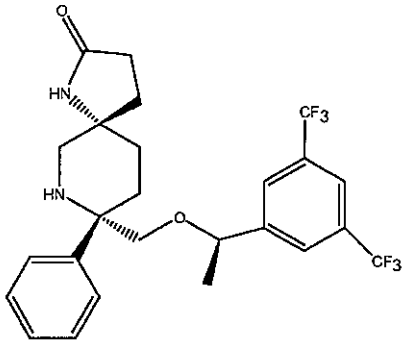
c) glycerin and

d) ethanol.

53. The composition according to claim 52 wherein the weight percentage of component b) based upon the total weight of the composition is about 10%.

54. A pharmaceutical composition which comprises:

a) a compound of Formula I



or a pharmaceutically acceptable salt thereof; and

b) 10% of a medium chain triglyceride and/or long chain fatty acid or triglyceride; and

c) 1.2 % of a phospholipid and

d) 2.25% of glycerin.

55. A combination comprising a pharmaceutically effective amount of a formulation according to claim 1 and at least one additional active pharmaceutical ingredient selected from the group consisting of an antidepressant, an anti-nausea or anti-emetic medication, a chemotherapeutic agent or an anti-inflammatory agent.

56. The combination according to claim 55 wherein the antidepressant is selected from an SSRI.

57. The combination according to claim 55 wherein the anti-nausea/anti-emetic medication is selected from a 5-HT_3 receptor antagonist.

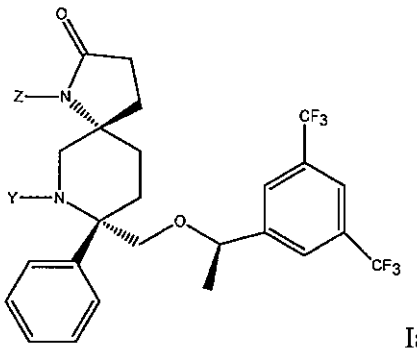
58. A method of treating acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy comprising administration of an intravenous formulation of a compound of formula I in combination with at least one additional antiemetic agent.

59. A method of treating acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy comprising administration of an intravenous formulation of a compound of formula I in combination with at least one additional antiemetic agent.

60. A method of treating emesis in a patient in need of treatment thereof comprising administration of a pharmaceutically effective amount of a composition according to claim 53.

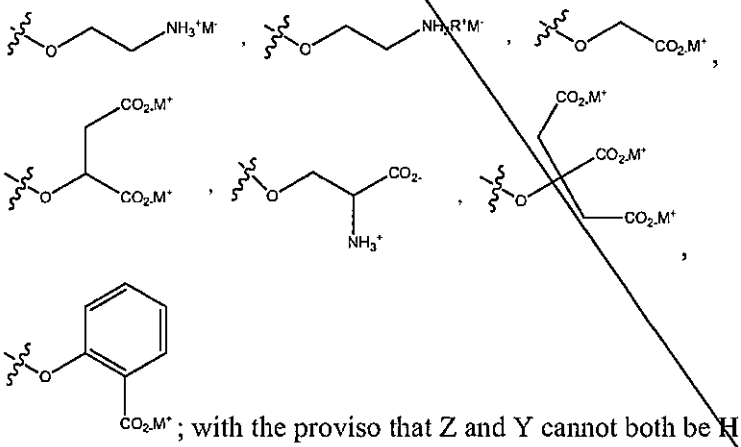
61. The method according to claim 60 wherein the composition is administered as a bolus dose.

62. A compound of Formula Ia and pharmaceutically acceptable salts thereof:



Ia

wherein Z and Y are independently selected from the group consisting of H, $-PO(OH)O^-M^+$, $-PO(O^-)_2M^+$, $-PO(O^-)_2D^{2+}$, $-[C(R^1)(R^2)]_n-PO(OH)O^-M^+$, $-[C(R^1)(R^2)]_n-PO(O^-)_2M^+$, $-[C(R^1)(R^2)]_n-PO(O^-)_2D^{2+}$, $-C(O)[C(R^1)(R^2)]_m-OPO(O^-)_2M^+$, $-C(O)[C(R^1)(R^2)]_oNR^1R^2$, $-C(O)[C(R^1)(R^2)]_pCO_2.M^+$, $-SO_3.M^+$, $-[C(R^1)(R^2)]_qSO_3.M^+$ and $-[C(R^1)(R^2)]_rOC(O)OR^3$, wherein R^3 is selected from the group consisting of



; with the proviso that Z and Y cannot both be H; M^+ is selected from a monovalent cation; D^+ is selected from a divalent cation; R^1 and R^2 are independently selected from H or C_{1-6}alkyl; n is 1-4; m, o, and p are independently selected from 0-4; and R is selected from C_{1-6}alkyl.

63. The compound according to claim 62 wherein Z is selected from H and Y is selected from any one of the groups shown above for Z and Y exclusive of H.

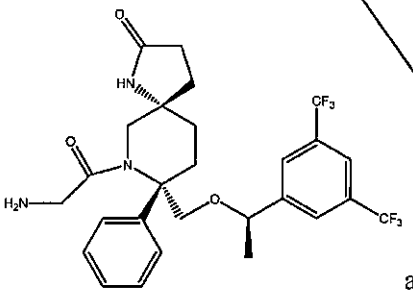
64. The compound according to claim 62 wherein M^+ is selected from ammonium salts, alkali metal salts such as sodium, alkaline earth metal salts such as calcium and magnesium, salts

with organic bases such as N-methyl-D-glucamine or dicyclohexylamine or amino acid salts such as arginine or lysine.

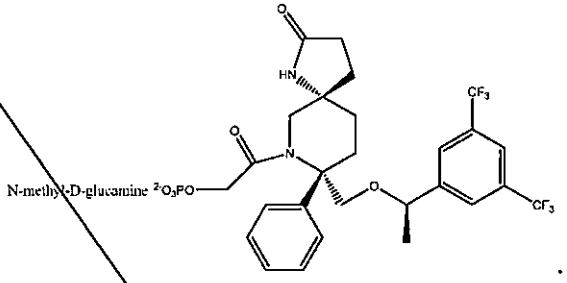
65. A method of treating acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy comprising administration of an intravenous formulation of a compound of formula Ia in combination with at least one additional antiemetic agent.

66. A method of treating acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy comprising administration of an intravenous formulation of a compound of formula Ia in combination with at least one additional antiemetic agent.

67. The compound according to claim 62 having the formula:



and



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68. An intravenous formulation comprising a compound of formula Ia according to claim 62.

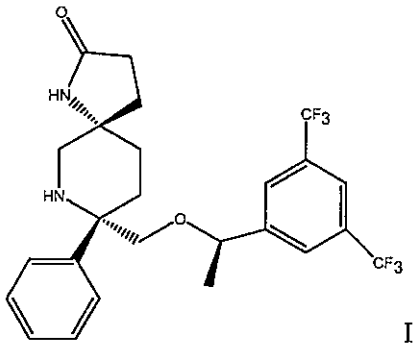
69. A method of treating a patient in need of treatment thereof for CINV comprising administering an intravenous formulation according to claim 1 wherein the formulation is administered at one dose per chemotherapeutic treatment cycle.

70. A pharmaceutical intravenous formulation comprising a compound of formula I or a pharmaceutically acceptable salt thereof wherein the $T_{1/2}$ for the active ingredient is about 180 hrs and wherein upon administration the blood concentration (ng/mL) for doses ranging from about 50 to about 200 mg and directly after administration ranges from about 280 ng/mL to about 850 ng/mL.

71. A micelle formulation suitable for intravenous administration comprising a compound of formula I or pharmaceutically acceptable salts thereof.

72. An emulsion formulation suitable for intravenous administration comprising a compound of formula I or a pharmaceutically acceptable salt thereof.

73. A pharmaceutical composition comprising a compound of formula I



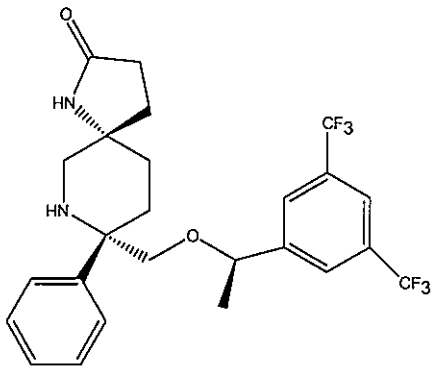
I

or pharmaceutically acceptable salts thereof and a non-ionic solubilizer.

Claims

1. A pharmaceutical composition comprising:

a) a compound of Formula I



or a pharmaceutically acceptable salt thereof;

b) macrogol 15-hydroxystearate in an amount of from about 0.50% to about 10.0% by weight of the total composition;

c) a medium chain triglyceride in an amount of from about 0.10% to about 2.5% by weight of the total composition;

d) a long chain triglyceride in an amount of from about 0.10% to about 1.5% by weight of the total composition; and

e) at least one buffer, wherein the weight ratio of macrogol 15-hydroxystearate:medium chain triglyceride:long chain triglyceride in the composition is about 5-100:1-5:1, and wherein the pH of the composition is from about 6.5 to about 8.0.

2. The pharmaceutical composition of claim 1, wherein the medium chain triglyceride is selected from the group consisting of caprylic acid triglyceride, capric acid triglyceride, caprylic/capric acid triglyceride, trigylceride from coconut oil, caprylic/caprylic/lauric triglyceride, caprylic/caprylic/linoleic triglyceride, caprylic/caprylic/stearic triglyceride and combinations of two or more thereof.

3. The pharmaceutical composition of claim 1, wherein the long chain triglyceride is selected from the group consisting of soybean oil, corn oil, cottonseed oil, olive oil, peanut oil,

safflower oil, sesame oil, shark liver oil, ethyl oleate, castor oil, monounsaturated omega-9 fatty acid and combinations of two or more thereof.

4. The pharmaceutical composition of claim 1, wherein the macrogol 15-hydroxystearate is present in an amount of from about 0.5% to about 10.0% by weight of the total composition; the medium chain triglyceride is present in an amount of from about 0.15% to about 1.5% by weight of the total composition; and the long chain triglyceride is present in an amount of from about 0.10% to about 1.2% by weight of the total composition.

5. The pharmaceutical composition of claim 1, wherein the macrogol 15-hydroxystearate is present in an amount of from about 0.88% to about 4.84% by weight of the total composition; the medium chain triglyceride is present in an amount of from about 0.20% to about 1.20% by weight of the total composition; and the long chain triglyceride is present in an amount of from about 0.10% to about 0.75% by weight of the total composition.

6. The pharmaceutical composition of claim 1, wherein the medium chain triglyceride is caprylic/capric acid triglyceride and the long chain triglyceride is refined soybean oil.

7. The pharmaceutical composition of claim 1, wherein the pharmaceutically acceptable salt is a hydrochloride salt.

8. The pharmaceutical composition of claim 1, wherein the compound of Formula I or pharmaceutically acceptable salt thereof is present in a concentration of from 1 mg/ml to 15 mg/ml.

9. The pharmaceutical composition of claim 8, wherein the compound of Formula I or pharmaceutically acceptable salt thereof is present in a concentration of from 2 mg/ml to 10 mg/ml.

10. The pharmaceutical composition of claim 9, wherein the compound of Formula I or pharmaceutically acceptable salt thereof is present in a concentration of 2 mg/ml.

11. The pharmaceutical composition of claim 1, wherein the pH of the composition is from about 7 to about 8.

12. The pharmaceutical composition of claim 11, wherein the pH of the composition is about 7.5.

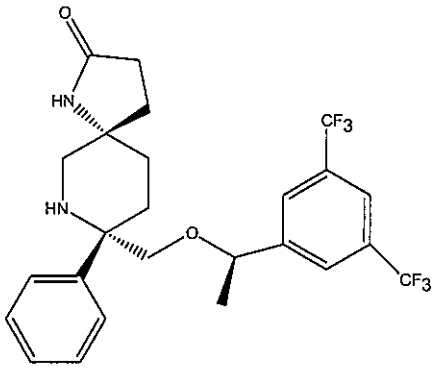
13. The pharmaceutical composition of claim 1, wherein the composition further comprises a tonicity adjuster and/or a pH adjuster.

14. The pharmaceutical composition of claim 1, wherein the at least one buffer is a phosphate buffer.

15. The pharmaceutical composition of claim 14, wherein the phosphate buffer is sodium phosphate buffer.

16. A pharmaceutical composition comprising:

(a) a compound of Formula I



or a pharmaceutically acceptable salt thereof;

(b) macrogol 15-hydroxystearate in an amount of about 4.4% by weight of the total composition;

(c) at least one medium chain triglyceride in an amount of about 1.1% by weight of the total composition;

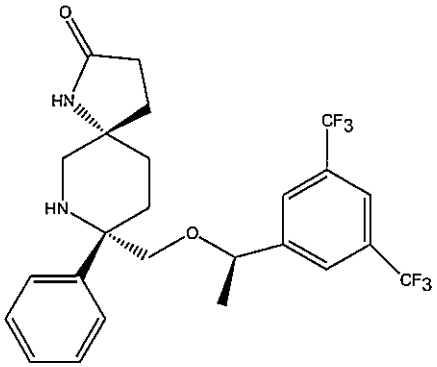
(d) refined soybean oil in an amount of about 0.66% by weight of the total composition; and

(e) a phosphate buffer, wherein the pH of the composition is about 7.5.

17. The pharmaceutical composition of claim 16, wherein the compound of Formula I or pharmaceutically acceptable salt thereof is present in a concentration of from 1 mg/ml to 15 mg/ml.

18. A pharmaceutical composition comprising:

(a) a compound of Formula I



or a pharmaceutically acceptable salt thereof;

(b) macrogol 15-hydroxystearate in an amount of about 0.88% by weight of the total composition;

(c) at least one medium chain triglyceride in an amount of about 0.22% by weight of the total composition;

(d) refined soybean oil in an amount of about 0.12% by weight of the total composition; and

(e) a phosphate buffer, wherein the pH of the composition is about 7.5.

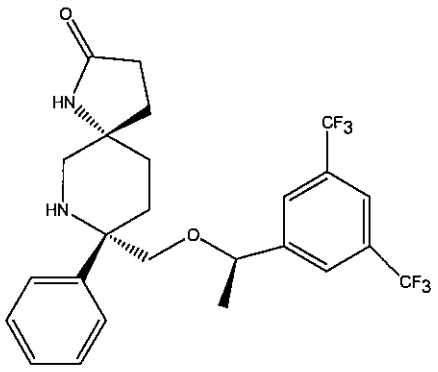
19. The pharmaceutical composition of claim 18, wherein the compound of Formula I or pharmaceutically acceptable salt thereof is present in a concentration of from 1 mg/ml to 15 mg/ml.

20. A process for making a pharmaceutical composition comprising:

a) heating (i) melted macrogol 15-hydroxystearate, (ii) a medium chain triglyceride and (iii) a long chain triglyceride to form a composition;

b) adding water to the composition to form a microemulsion composition;

c) adding to the microemulsion composition a compound of Formula I



or a pharmaceutically acceptable salt thereof; and

d) adding at least one buffer and adjusting the pH from about 6.5 to about 8.0 to form a pharmaceutical composition, wherein the macrogol 15-hydroxystearate is present in an amount of about 0.50% to about 10.0% by weight of the total pharmaceutical composition, the medium chain triglyceride is present in an amount of about 0.10% to about 2.5% by weight of the total pharmaceutical composition, and the long chain triglyceride is present in an amount of from about 0.10% to about 1.5% by weight of the total pharmaceutical composition, and wherein the weight ratio of macrogol 15-hydroxystearate:medium chain triglyceride:long chain triglyceride in the composition is about 5-100:1-5:1.

21. The process of claim 20, wherein the medium chain triglyceride is selected from the group consisting of caprylic acid triglyceride, capric acid triglyceride, caprylic/capric acid triglyceride, trigylceride from coconut oil, caprylic/caprylic/lauric triglyceride, caprylic/caprylic/linoleic triglyceride, caprylic/caprylic/stearic triglyceride and combinations of two or more thereof.

22. The process of claim 20, wherein the long chain triglyceride is selected from the group consisting of soybean oil, corn oil, cottonseed oil, olive oil, peanut oil, safflower oil, sesame oil, shark liver oil, ethyl oleate, castor oil, monounsaturated omega-9 fatty acid and combinations of two or more thereof.

23. The process of claim 20, wherein the medium chain triglyceride is caprylic/capric acid triglyceride and the long chain triglyceride is soybean oil.

24. The process of claim 20, wherein the melted macrogol 15-hydroxystearate is obtained by heating the macrogol 15-hydroxystearate at a temperature of from 60°C to 65°C.

25. The process of claim 20, wherein in step (b) the mixture is heated at a temperature of about 60°C.

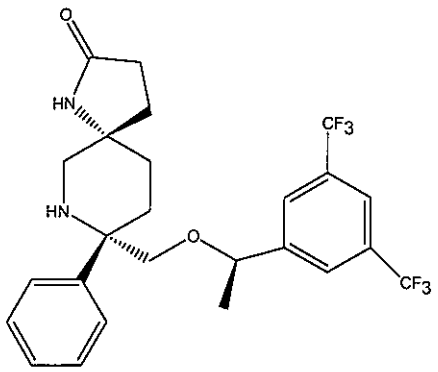
26. The process of claim 20, wherein the compound of Formula I or pharmaceutically acceptable salt thereof is present in the pharmaceutical composition in a concentration from 1 mg/ml to 15 mg/ml.

27. The process of claim 20, wherein in step (c) the pH is adjusted to about 7.5.

28. The process of claim 20, further comprising adding a tonicity adjuster to the microemulsion composition.

29. A pharmaceutical composition comprising:

a) compound of Formula I



or a pharmaceutically acceptable salt thereof; and

b) pegylated hydroxystearate in an amount of from about 0.88% to about 5% by weight of the total composition, wherein the pegylated hydroxystearate is substantially free from free polyethylene glycol, and wherein the pH of the composition is from about 6.5 to about 8.0.

30. Use of a pharmaceutical composition according to any one of claims 1, 16, 18, or 29 in the manufacture of a medicament for treating nausea and/or emesis, wherein the medicament is formulated for intravenous infusion.

31. The use of claim 30, wherein the nausea and/or emesis is induced by chemotherapy or is post-operative nausea and/or vomiting.

32. The use of claim 30, wherein the patient is a primate or a companion animal.

33. The use of claim 32, wherein the primate is a human.

34. The use of claim 30, wherein the compound of Formula I or pharmaceutically acceptable salt thereof is present in a concentration of from 1 mg/ml to 15 mg/ml.

35. The use of claim 34, wherein the composition is intravenously administered by infusion for a period of 15 to 90 minutes.

36. The use of claim 30, wherein the total daily dose of the compound of Formula I or pharmaceutically acceptable salt thereof is from 1 mg/kg to 9 mg/kg patient body weight.

37. Use of a pharmaceutical composition according to any one of claims 1, 16, 18, or 29 in the manufacture of a medicament for minimizing hemolysis in a patient following intravenous administration of said compound or pharmaceutically acceptable salt thereof, wherein the medicament is formulated for intravenous infusion.

38. The use of claim 37, wherein the patient is a primate or a companion animal.

39. The use of claim 38, wherein the primate is a human.