What is claimed is:

1. An injectable composition or preparation, *e.g.*, an injectable composition of a pharmaceutical product, comprising:

a) a neutral diacyl lipid and/or a tocopherol;

b) a phospholipid:

c) an alcohol;

d) optionally, a polar solvent, *e.g.*, a buffer, optionally comprising an antioxidant; and

e) setmelanotide as the sole active pharmaceutical ingredient.

2. The injectable composition of claim 1, comprising a neutral diacyl lipid.

3. The injectable composition of claim 4, wherein the neutral diacyl lipid comprises diacyl glycerol.

4. The injectable composition of claim 4, wherein the neutral diacyl lipid comprises glycerol dioleate (GDO).

5. The injectable composition of claim 1, wherein the phospholipid comprises phosphatidylcholine (e.g., soybean phosphatidylcholine).

6. The injectable composition of claim 1, wherein the alcohol comprises ethanol.

7. The injectable composition of claim 6, wherein the ethanol is provided in an amount that is sufficiently great that it provides a solubility of setmelanotide of at least 10 mg/g, 20mg/g or 30mg/g.

8. The injectable composition of claim 6, wherein the amount, by weight % of ethanol is greater than 1% by weight, *e.g.*, between 1-20% by weight.

9. The injectable composition of claim 6, wherein the amount of ethanol is sufficiently low that injection can be made easily and comfortably by operation of a device, *e.g.*, a syringe, by a subject, *e.g.*, a subject described herein.

10. The injectable composition of claim 6, wherein the amount, by weight % of ethanol is less than 20%, 15%, or 10%.

11. The injectable composition of claim 6, wherein, the amount of ethanol is sufficiently great that the composition has a viscosity low enough to be comfortably delivered with a device, *e.g.*, a syringe with a narrow needle, *e.g.*, a 27 Gauge needle.

12. The injectable composition of claim 6, wherein the amount of ethanol is sufficiently low that, upon injection, the initial burst of drug, *e.g.*, initial release, after subcutaneous injection gives a ratio of maximum concentration (C_{max}) in plasma to minimum concentration (C_{min}) in plasma before a next dose is administered, of less than 8, (*e.g.*, less than 7, 6.5, 6, 5.5, 5, 4.5, 4, 3.5, 3, 2.5, 2 or lesser).

13. The injectable composition of claim 6, wherein, the amount of ethanol is sufficiently low that, upon injection, the pharmaceutical product provides a low initial release of setmelanotide.

14. The injectable composition of claim 13, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 6 hours) after dosing, which is less than 10% or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

15. The injectable composition of claim 13, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 12 hours) after dosing, which is less than 10-20% or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

16. The injectable composition of claim 13, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 24 hours) after dosing, which is less than 20-30%, or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

17. The injectable compositions of claim 9, wherein the device can be a single use device, or a multi-use device.

18. The injectable composition of claim 9, wherein the device is chosen from: a manual syringe, (*e.g.*, a syringe comprising a needle (*e.g.*, a needle with a suitable diameter, *e.g.*, a 27 Gauge needle)), or an auto-injector (*e.g.*, a spring-loaded syringe, or a pen injector).

19. The injectable composition of claim 1, wherein the polar solvent, *e.g.*, buffer, comprises citrate buffer, optionally wherein the pH of the buffer is 6.4.

20. The injectable composition of claim 1, wherein the polar solvent, *e.g.*, buffer, comprises citrate acid monohydrate.

21. The injectable composition of claim 1, wherein the polar solvent, *e.g.*, buffer, comprises an additional component, *e.g.*, an antioxidant, or a chemical or physical stabilizing agent.

22. The injectable composition of claim 21, wherein the antioxidant is EDTA.

23. The injectable composition of claim 1, wherein the polar solvent, *e.g.*, buffer, comprises citric acid monohydrate, disodium EDTA, and water.

24. The injectable composition of claim 1, wherein setmelanotide is present as a chloride salt.

25. The injectable composition of claim 1, wherein the pharmaceutical product optionally comprises an anti-microbial or microbial-static agent, *e.g.*, bacteriostatic agent or preservative.

26. The injectable composition of claim 1, wherein the ratio, by weight, of a:b is 70:30 to 40:60.

27. The injectable composition of claim 1, wherein the ratio, by weight, of a:b is 70:30, 65:45, 60:40, 55:45, 50:50, 45:55 or 40:60

28. The injectable composition of claim 1, wherein component a, is 20-80%, 30-70%, 33-60%, or 38-43% by weight of the total weight of components a, b, and c solution.

29. The injectable composition of claim 1, wherein component b, is 20-80%, 30-70%, 33-60%, or 38-43% by weight of the total weight of components a, b, and c solution

30. The injectable composition of claim 1, wherein component c, *e.g.*, ethanol, is 0.5-50%, 2-30%, or 5-20% by weight of the total weight of components a, b, and c solution.

31. The injectable composition of claim 1, wherein,

the neutral diacyl lipid comprises glycerol dioleate;

the phospholipid comprises phosphatidylcholine;

the alcohol comprises ethanol; and

the polar solvent, *e.g.*, buffer, comprises a citrate buffer.

32. The injectable composition of claim 1, wherein,

the neutral diacyl lipid comprises glycerol dioleate;

the phospholipid comprises soybean phosphatidylcholine;

the alcohol comprises ethanol; and

the polar solvent, *e.g.*, buffer, comprises a citrate buffer at pH 6.4 comprising EDTA.

33. The injectable composition of claim 1, comprising, per one milliliter of composition:

420 +/- 20% mg glycerol dioleate (GDO);

420 +/- 20% mg soybean phosphatidylcholine;

105 +/- 20% mg ethanol;

20 +/- 20% mg citrate buffer; and

30 +/- 20% mg setmelanotide.

34. The injectable composition of claim 1, comprising, per one milliliter of composition:

420 +/- 10% mg glycerol dioleate (GDO);

420 +/- 10% mg soybean phosphatidylcholine;

105 +/- 10% mg ethanol;

20 +/- 10% mg citrate buffer; and

30 +/- 10% mg setmelanotide.

35. The injectable composition of claim 1, comprising, per one milliliter of composition:

420 +/- 5% mg glycerol dioleate (GDO);

420 +/- 5% mg soybean phosphatidylcholine;

105 +/- 5% mg ethanol;

20 +/- 5% mg citrate buffer; and

30 +/- 5% mg setmelanotide.

36. The injectable composition of claim 1, comprising, per one milliliter of composition:

420 +/- 2% mg glycerol dioleate (GDO);

420 +/- 2% mg soybean phosphatidylcholine;

105 +/- 2% mg ethanol;

20 +/- 2% mg citrate buffer; and

30 +/- 2% mg setmelanotide.

37. The injectable composition of claim 1, comprising, per one milliliter of composition

419.8 mg glycerol dioleate (GDO);

419.8 mg soybean phosphatidylcholine;

105 mg ethanol;

20 mg citrate buffer; and

30 mg setmelanotide.

38. The injectable composition of claim 1, comprising:

neutral diacyl lipid of component a at 20-80%, 30-70%, 33-60%, or 38-43% by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition;

phospholipid of component b at is 20-80%, 30-70%, 33-60%, or 38-43% by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition;

alcohol of component c at 0.1 -35%, 5 -20%, 8-15 %, or 9-11 % by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition;

polar solvent of component d, *e.g.*, buffer, at 0.5-10%, 1-5%, or 1-3% by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition; and

setmelanotide, at 0.1 -10%, 0.2 -8%, 0.5-6%, 1-4% by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition.

39. The injectable composition of claim 1, comprising:

neutral diacyl lipid at 42% +/-10, 42% +/-5, 42% +/-2, or 42 % +/-1 by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition;

phospholipid at 42% +/-10, 42% +/-5, 42% +/-2, or 42 % +/-1 by weight, of components a, b, and c; components a, b, c, and d; components a, b, c, d, and e; or of the composition;

alcohol at 10% +/-8, 10% +/-6, 10% +/-5, or 10 % +/-1 by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition;

polar solvent, *e.g.*, buffer, at 2% +/-1, 2% +/-0.5, 2% +/-0.25, or 2 % +/-0.1 by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition; and

setmelanotide at 3% +/-1.5, 3% +/-1, or 3% +/-0.5, by weight, of components a, b, and c; components a, b, c, and d; or components a, b, c, d, and e of the composition.

40. The injectable composition of claim 1, which, upon contact with an aqueous environment, *e.g.*, injection, *e.g.*, subcutaneous injection, into a subject, forms or is capable of forming, at least one liquid crystalline structure.

41. The injectable composition of claim 1, wherein the viscosity is:

(i) low enough to be comfortably delivered with a device, *e.g.*, a syringe with a narrow needle, *e.g.*, a 27 Gauge needle;

(ii) low enough that, upon injection, the initial burst, *e.g.*, initial release, of setmelanotide;, from the pharmaceutical product after subcutaneous injection gives a ratio of maximum concentration (C_{max}) in plasma to minimum concentration (C_{min}) in plasma before a next dose is administered, of less than 8, (*e.g.*, less than 7, 6.5, 6, 5.5, 5, 4.5, 4, 3.5, 3, 2.5, 2 or lesser); or

(iii) low enough that, upon injection, the pharmaceutical product provides a low initial release of setmelanotide.

42. The injectable composition of claim 1, wherein when injected into a subject:

(i) the initial burst, *e.g.*, initial release, of setmelanotide, from the pharmaceutical product after subcutaneous injection gives a ratio of maximum concentration (C_{max}) in plasma to minimum concentration (C_{min}) in plasma before a next dose is administered, of less than 8, (*e.g.*, less than 7, 6.5, 6, 5.5, 5, 4.5, 4, 3.5, 3, 2.5, 2 or lesser); or

(ii) the pharmaceutical product provides a low initial release of setmelanotide.

43. The injectable composition of claim 41, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 6 hours) after dosing, which is less than 10% or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

44. The injectable composition of claim 41, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 12 hours) after dosing, which is less than 10-20% or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

45. The injectable composition of claim 41, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 24 hours) after dosing, which is less than 20-30%, or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

46. A unit dosage form comprising the composition of claim 1.

47. The unit dosage form of claim 46, comprising at least 2, 1.8, 1.6, 1.4, 1.2, 1, 0.8, 0.6, 0.4, or 0.2 mL of the composition.

48. The unit dosage form of claim 46, disposed in a liquid tight enclosure, *e.g.*, a vial or a cartridge.

49. The injetable unit dosage form of claim 46, disposed in an injection device, *e.g.*, a single use device, or a multi-use device.

50. The unit dosage form of claim 49, wherein the device is chosen from: a manual syringe, (*e.g.*, a syringe comprising a needle (*e.g.*, a needle with a suitable diameter, *e.g.*, a 27 Gauge needle), or an auto-injector (*e.g.*, a spring-loaded syringe, or a pen injector).

51. The unit dosage form of claim 46, containing 10-70; 20-60, 25-50; 25-40; 25-35 mg of setmelanotide.

52. The unit dosage form of claim 46, containing 50 +/-20% ; 40 +/-20%; or 30 +/-20%, mg of setmelanotide.

53. The unit dosage form of claim 46, containing 50 +/-10%; 40 +/-10%; or 30 +/-10%, mg of setmelanotide.

54. The unit dosage form of claim 46, containing 50 +/-5%; 40 +/-5%; or 30 +/-5%, mg of setmelanotide.

55. The unit dosage form of claim 46, containing 40, 35 or 30, mg of setmelanotide.

56. The unit doasge of claim 46, wherein the composition is suitable for injection, *e.g.*, subcutaneous injection or intramuscular injection.

57. The unit dosage form of claim 46, wherein the viscosity is:

(i) low enough to be comfortably delivered with a device, *e.g.*, a syringe with a narrow needle, *e.g.*, a 27 Gauge needle;

(ii) low enough that, upon injection, the initial burst, *e.g.*, initial release, of setmelanotide from the pharmaceutical product after subcutaneous injection gives a ratio of maximum concentration (C_{max}) in plasma to minimum concentration (C_{min}) in plasma before a next dose is administered, of less than 8, (*e.g.*, less than 7, 6.5, 6, 5.5, 5, 4.5, 4, 3.5, 3, 2.5, 2 or lesser); or

(iii) low enough that, upon injection, the pharmaceutical product provides a low initial release of setmelanotide.

58. The unit dosage form of claim 46, wherein when injected into a subject:

(i) the initial burst, *e.g.*, initial release, of setmelanotide from the pharmaceutical product after subcutaneous injection gives a ratio of maximum concentration (C_{max}) in plasma to minimum concentration (C_{min}) in plasma before a next dose is administered, of less than 8, (*e.g.*, less than 7, 6.5, 6, 5.5, 5, 4.5, 4, 3.5, 3, 2.5, 2 or lesser); or

(ii) the pharmaceutical product provides a low initial release of setmelanotide.

59. The unit dosage form of claim 46, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 6 hours) after dosing, which is less than 10% or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

60. The unit dosage form of claim 58, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 12 hours) after dosing, which is less than 10-20% or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

61. The unit dosage form of claim 58, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 24 hours) after dosing, which is less than 20-30%, or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

62. A method of making a preparation or composition, *e.g.*, a pharmaceutical composition, formulated for injection, comprising setmelanotide as sole active pharmaceutical ingredient, *e.g.*, a preparation or composition having a controlled level of EtOH, comprising:

i) providing a mixture of setmelanotide, a first amount of EtOH, and one or more of components:

a) a neutral diacyl lipid and/or a tocopherol;

b) a phospholipid;

c) an alcohol; and

d) a polar solvent, *e.g.*, a buffer; and

ii) adding a second amount of EtOH,

thereby making a preparation or composition, *e.g.*, a pharmaceutical composition, formulated for injection, comprising setmelanotide as sole active pharmaceutical ingredient.

63. The method of claim 62, wherein providing comprises forming the mixture.

64. The method of claim 62, wherein addition of the second amount of EtOH results in an amount of EtOH that meets a reference value, *e.g.*, falls within a range of values, *e.g.*, falls within a range defined by a lower and an upper value, *e.g.*, an upper and lower value for weight % EtOH, *e.g.*, weight % of 10-0.5.

65. The method of claim 64, wherein the reference value is a value within the range of 5 to 20; 8.5 to 12.5; and 9 to 11 weight % EtOH, *e.g.*, weight % of 10.

66. The method of claim 64, wherein the reference value is a value within the range of 9 to 11 weight % EtOH, *e.g.*, weight % of 10.

67. The method of claim 62, comprising determining the amount of EtOH in the mixture by suitable analytical determination.

68. The method of claim 67, comprising, responsive to the determination, selecting an amount of EtOH to add to the mixture, *e.g.*, an amount that will achieve the reference value.

69. The method of claim 68, comprising adding the selected amount of EtOH to the mixture to form an EtOH-replenished mixture.

70. The method of claim 69, wherein the selected amount is added to the mixture as a single aliquot or as a plurality of aliquots of the same, or different, amounts.

71. The method of claim 62, wherein less than 48 hours, less than 24 hours, or less than 4 hours elapses between forming the mixture and determining the amount of EtOH in the mixture, selecting an amount of EtOH to add, or adding the second amount.

72. The method of claim 62, comprising providing the amount of the components added to the mixture.

73. The method of claim 72, wherein providing comprises weighing the amount of components added to the mixture.

74. The method of claim 62, comprising providing a value for the amount of EtOH in the mixture and determining the amount of EtOH that needs to be added to meet the reference for amount of EtOH.

75. The method of claim 62, wherein after forming the mixture, EtOH is lost from the mixture, *e.g.*, by evaporation, *e.g.*, evaporation into the headspace of a container, *e.g.*, a mixing vessel.

76. The method of claim 62, wherein after the second amount is added to the mixture, determining the amount of EtOH in the EtOH-replenished mixture.

77. The method of claim 76, comprising, responsive to the determination, selecting an amount of EtOH to add to the EtOH-replenished mixture.

78. The method of claim 77, comprising adding the selected amount of EtOH to the EtOH-replenished mixture to form a twice-replenished mixture.

79. The method of of claim 62, further comprising providing a second a preparation or composition, *e.g.*, a pharmaceutical product, formulated for injection, comprising setmelanotide as sole active pharmaceutical ingredient.

80. The method of of claim 62, comprising:

making a mixture comprising setmelanotide, EtOH, a neutral diacyl lipid and/or a tocopherol and a phospholipid,

wherein one or both of neutral diacyl lipid and/or a tocopherol and phospholipid, are added after setmelanotide and the EtOH are combined,

thereby making a setmelanotide composition or preparation, *e.g.*, a pharmaceutical product, formulated for injection.

81. The method of of claim 62, comprising:

making a mixture comprising setmelanotide, water or a polar solvent, *e.g.*, a buffer, a neutral diacyl lipid and/or a tocopherol and a phospholipid,

wherein one or both of neutral diacyl lipid and/or a tocopherol and phospholipid, are added after setmelanotide and water or the polar solvent, *e.g.*, the buffer, are combined,

thereby making a setmelanotide composition or preparation, *e.g.*, a pharmaceutical product, formulated for injection.

82. The method of of claim 62, wherein the order of formation of the mixture is:

i) setmelanotide is contacted with EtOH (and optionally water or a polar solvent, *e.g.*, a buffer);

ii) the phospholipid is added to the mixture resulting from i); and

iii) the neutral diacyl lipid and/or a tocopherol is added to the mixture resulting from ii).

83. A method of making a pharmaceutical product formulated for injection comprising setmelanotide as sole active pharmaceutical ingredient, component a, component b, component d, and a predetermined amount of alcohol, comprising

combining (in any order) setmelanotide, component a, component b, component d and alcohol, to mixture, and

comparing a value for alcohol content in the mixture with a reference value for alcohol content,

thereby making a pharmaceutical product formulated for injection comprising setmelanotide as sole active pharmaceutical ingredient, component a, component b, component d, and a predetermined amount of alcohol.

84. The method of claim 83, comprising:

responsive to the value or comparison, increasing or decreasing the amount of alcohol in the mixture to provide a formulation having a predetermined amount of alcohol.

85. The method of claim 83, comprising adding an addition amount of alcohol to the mixture.

86. The method of claim 85, wherein the addition amount of alcohol is greater than the predetermined amount of alcohol.

87. A method of making a pharmaceutical product formulated for injection comprising setmelanotide as sole active pharmaceutical ingredient, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, comprising:

combining (in any order) setmelanotide, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4) and alcohol, to mixture, and

comparing a value for alcohol content in the mixture with a reference value for alcohol content,

thereby making a pharmaceutical product formulated for injection comprising setmelanotide as sole active pharmaceutical ingredient, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol.

88. The method of claim 87, comprising adding an addition amount of alcohol to the mixture.

89. The method of claim 88, wherein the addition amount of alcohol is greater than the predetermined amount of alcohol.

90. The method of claim 87, wherein, the predetermined amount is 5-20, 10-20, 15-20, 5-15, 5-10, 5-15, or 10-15% by weight.

91. The method of claim 87, wherein, the predetermined amount is 10 +/- 5 % by weight.

92. The method of claim 87, wherein, the predetermined amount is 10 +/- 4 % by weight.

93. The method of claim 87, wherein, the predetermined amount is 10 +/- 3 % by weight.

94. The method of claim 87, wherein, the predetermined amount is 10 +/- 2 % by weight.

95. The method of claim 87, wherein, the predetermined amount is 10 +/- 1 % by weight.

96. The method of claim 87, wherein, the predetermined amount is 10 +/- 0.5 % by weight.

97. The method of claim 87, wherein the method comprises producing a plurality of batches of the formulation.

98. The method of claim 97, wherein each batch of the plurality of batches has an alcohol content within 2, 1, or 0.5% by weight of the other batch(es) in the plurality.

99. The method of claim 97, wherein each batch of the plurality of batches has an alcohol content within 2, 1, or 0.5% by weight of a reference value.

100. The method of claim 99, wherein, the reference value is a value within the range of:

5-20, 10-20, 15-20, 5-15, 5-10, 5-15, or 10-15% by weight;
10 +/- 5 % by weight;
10 +/- 4% by weight;
10 +/- 3 % by weight;
10 +/- 2 % by weight;
10 +/- 1 % by weight; or
10 +/- 0.5 % by weight.

101. The method of claim 99, wherein the reference value is a value within the range of 10 +/- 2 % by weight and each batch of the plurality of batches has an alcohol content within 1, or 0.5% by weight of the reference value.

102. The method of claim 99, wherein the reference value is 10 % by weight and each batch of the plurality of batches has an alcohol content within 0.5% by weight of the reference value.

103. The method of claim 99, wherein each batch of the plurality of batches has an alcohol content that is sufficiently great that the composition has a viscosity low enough to be comfortably delivered with a device, *e.g.*, a syringe with a narrow needle, *e.g.*, a 27 Gauge needle.

104. The method of claim 99, wherein each batch of the plurality of batches, has an alcohol content that is sufficiently low that, upon injection, the initial burst of setmelanotide, *e.g.*, initial release, after subcutaneous injection gives a ratio of maximum concentration (C_{max}) in plasma to minimum concentration (C_{min}) in plasma before a next dose is administered, of less than 8, (*e.g.*, less than 7, 6.5, 6, 5.5, 5, 4.5, 4, 3.5, 3, 2.5, 2 or lesser).

105. The method of claim 99, wherein each batch of the plurality of batches, has an alcohol content that is sufficiently low that, upon injection, the pharmaceutical product provides a low initial release of setmelanotide.

106. The method of claim 105, wherein the low initial release is measured by the partial area under the drug concentration curve during the first hours (*e.g.*, first 6 hours) after dosing, which is less than 10% or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

107. The method of claim 105, wherein the low initial release is measured by the partial area under the setmelanotide concentration curve during the first hours (*e.g.*, first 12 hours) after dosing, which is less than 10-20% or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

108. The method of claim 105, wherein the low initial release is measured by the partial area under the setmelanotide concentration curve during the first hours (*e.g.*, first 24 hours) after dosing, which is less than 20-30%, or lesser, relative to the area under the drug concentration time curve of a 7 day, steady state dosing interval.

109. The method of claim 103, wherein the device can be a single use device, or a multi-use device.

110. The method of claim 103, wherein the device is chosen from: a manual syringe, (*e.g.*, a syringe comprising a needle (*e.g.*, a needle with a suitable diameter, *e.g.*, a 27 Gauge needle), or an auto-injector (*e.g.*, a spring-loaded syringe, or a pen injector).

111. The method of claim 87, wherein, the predetermined amount of alcohol is added as a single aliquot.

112. The method of claim 87, wherein the predetermined amount of alcohol is added as a plurality of aliquots.

113. The method of claim 87, wherein at least a portion of the process after addition of alcohol is performed in a closed vessel.

114. The method of claim 87, wherein the process after addition of alcohol is performed in a closed vessel.

115. The method of claim 87, wherein at least a portion of the process prior to addition of alcohol is performed in a closed vessel.

116. The method of claim 87, wherein the process prior to addition of alcohol is performed in a closed vessel.

117. A method of making a pharmaceutical product formulated for injection comprising setmelanotide as sole active pharmaceutical ingredient comprising:

(i) providing a mixture comprising setmelanotide and alcohol (a setmelanotide-alcohol mixture), *e.g.*, in contact with, *e.g.*, dissolved or dispersed in an alcohol, *e.g.*, ethanol; and

(ii) combining the setmelanotide-alcohol mixture with an amount of component a, b, and d, or all of components a, b, and d.

118. The method of claim 117, wherein step (i), (ii), or (i) and (ii) are performed in a closed vessel.

119. A method of making a pharmaceutical product formulated for injection comprising setmelanotide as sole active pharmaceutical ingredient comprising:

(i) providing a mixture comprising setmelanotide and alcohol (a setmelanotide-alcohol mixture), *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in an alcohol, *e.g.*, ethanol; and

(ii) combining setmelanotide-alcohol mixture with an amount of component a (e.g, GDO), component b (*e.g.*, soybean PC), and component d (*e.g.*, citrate buffer at pH 6.4), or all of components a, b, and d.

120. The method of claim 119, wherein step (i), (ii), or (i) and (ii) are performed in a closed vessel.

121. A method of making a preparation of setmelanotide as sole active pharmaceutical ingredient formulated for injection, or evaluating a candidate preparation, *e.g.*, for a quality control or release specification, comprising:

providing a value for the amount of EtOH in a candidate preparation of setmelanotide; and

comparing the value with a reference value for amount of EtOH;

thereby making a preparation of setmelanotide as sole active pharmaceutical ingredient formulated for injection.

122. The method of claim 121, further comprising, responsive to the comparison, selecting the candidate preparation of setmelanotide.

123. The method of claim 121, wherein the reference value comprises a range defined by a lower and an upper value, *e.g.*, an upper and lower value for weight % EtOH, *e.g.*, weight % of 10.

124. The method of claim 123, wherein meeting the reference value comprises falling within the range.

125. The method of claims 121, wherein the reference value is a value within the range of 5 to 20; 8.5 to 12.5; and 9 to 11 weight % EtOH, *e.g.*, weight % of 10.

126. The method of claim 125, wherein the reference value is a value within the range of 9 to 11 weight % EtOH, *e.g.*, weight % of 10.

127. The method of claim 121, comprising

providing a value for the amount of EtOH in a second candidate preparation of setmelanotide as sole active pharmaceutical ingredient formulated for injection; and

comparing the value with a reference value for amount of EtOH.

128. The method of claim 121, comprising

providing a value for the amount of EtOH in N candidate preparations of setmelanotide as sole active pharmaceutical ingredient formulated for injection, wherein N is equal to or greater than 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 50, 100, or 1,000; and

comparing the value with a reference value for amount of EtOH.

129. The method of claim 128, wherein the amount of EtOH in each of the plurality of preparations is within 5, 2, 1, or 0.5% of one another.

130. The method of claim 128, wherein the amount of EtOH in each of the plurality of preparations is within 2% of one another.

131. The method of claim 128, wherein the amount of EtOH in each of the plurality of preparations is within 0.5% of one another.

132. The method of claim 128, wherein a first preparation and a second preparation of the plurality are made within 10, 20, 30, 60, 180, or 365 days of one another.

133. The method of claim 128, wherein a second preparation is made less than 10, 20, 30, 60, 180, or 365 days after the first preparation.

134. A method of making a composition or preparation formulated for injection comprising setmelanotide as the sole active pharmaceutical ingredient, *e.g.*, a pharmaceutical product,

comprising:

making a mixture comprising setmelanotide, EtOH, a neutral diacyl lipid and/or a tocopherol and a phospholipid,

wherein one or both of neutral diacyl lipid and/or a tocopherol and phospholipid, are added after component (e) comprising setmelanotide and the EtOH are combined,

thereby making a composition or preparation formulated for injection setmelanotide as the sole active pharmaceutical ingredient, *e.g.*, a pharmaceutical product.

135. The method of claim 134, wherein one or both of neutral diacyl lipid and/or a tocopherol and a phospholipid are added after at least 10, 25, 50, 75, or all of the setmelanotide is allowed to go into solution.

136. The method of vclaim 134, wherein the order of formation of the mixture is:

i) setmelanotide is contacted with EtOH (and optionally water or buffer);

ii) phospholipid is added to the mixture resulting from i); and

iii) neutral diacyl lipid and/or a tocopherol is added to the mixture resulting from ii).

137. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection comprising the following steps in order:

(i) providing a mixture comprising setmelanotide and alcohol (setmelanotide-alcohol mixture), *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in an alcohol, *e.g.*, ethanol; and

(ii) combining the setmelanotide-alcohol mixture with an amount of one or more of components a, b and d,

thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, *e.g.*, a pharmaceutical comprising setmelanotide as sole active pharmaceutical ingredient comprising a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

138. A method of making a pharmaceutical product of comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection comprising the following steps in order:

(i) providing a mixture comprising setmelanotide and alcohol, *e.g.*, comprising setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol; and

(ii) combining the mixture with an amount of component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), and component d (*e.g.*, citrate buffer at pH 6.4), or an amount of all of components a, b, and d;

thereby making a a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, *e.g.*, a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection comprising a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

139. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection comprising the following steps in order:

(i) providing a mixture comprising setmelanotide, alcohol and component d, *e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol, and a buffer; and

(ii) combining the mixture with an amount of one or more of components a and b;

thereby making a pharmaceutical product) comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, *e.g.*, a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection comprising a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

140. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection comprising the following steps in order:

(i) providing a mixture comprising setmelanotide, alcohol and component d, *e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4, *e.g.*, comprising setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol, and a citrate buffer at pH 6.4; and

(ii) combining the mixture with an amount of component a (*e.g.*, GDO), and component b (*e.g.*, soybean PC), or an amount of all of components a and b;

thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, *e.g.*, a pharmaceutical product setmelanotide

as sole active pharmaceutical ingredient formulated for injection comprising a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

141. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a, component b, component d, and a predetermined amount of alcohol, comprising

combining, in a specified order, setmelanotide, component a, component b, component d and an addition amount of alcohol, wherein the addition amount of alcohol results in a predetermined amount of alcohol in the pharmaceutical product, and wherein the specified order comprises the following steps in order:

(i) providing a mixture comprising setmelanotide and an addition amount of alcohol, *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol; and

(ii) combining the mixture with an amount of components a, b, and d or all of components a, b, and d;

wherein (i), (ii) or (i) and (ii) are performed in a closed vessel, thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a, component b, component d, and a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

142. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection; component a, component b, component d, and a predetermined amount of alcohol, comprising

combining, in a specified order, setmelanotide, component a, component b, component d and an addition amount of alcohol, wherein the addition amount of alcohol results in a predetermined amount of alcohol in the pharmaceutical product, and wherein the specified order comprises the following steps in order:

(i) providing a mixture comprising setmelanotide and an addition amount of alcohol (a setmelanotide-alcohol mixture), *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol; and

(ii) combining the setmelanotide-alcohol mixture with an amount of components a, b, and d or all of components a, b, and d;

wherein (i), (ii) or (i) and (ii) are performed in a closed vessel, thereby making a pharmaceutical product comprising setmelanotide, component a, component b, component d, and a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

143. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, comprising

combining, in a specified order, setmelanotide, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and an addition amount of alcohol, wherein the addition amount of alcohol results in a predetermined amount of alcohol in the pharmaceutical product, wherein the specified order comprises the following steps in order:

(i) providing a mixture comprising setmelanotide and an addition amount of alcohol, *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol; and

(ii) combining the mixture with an amount of component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), and component d (*e.g.*, citrate buffer at pH 6.4), or all of components a, b, and d;

wherein (i), (ii) or (i) and (ii) are performed in a closed vessel, thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

144. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, comprising

combining, in a specified order, setmelanotide; component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and an addition amount of alcohol, wherein the addition amount of alcohol results in a

predetermined amount of alcohol in the pharmaceutical product, wherein the specified order comprises the following steps in order:

(i) providing a mixture comprising setmelanotide and an addition amount of alcohol (a setmelanotide moiety-alcohol mixture), *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol; and

(ii) combining the setmelanotide-alcohol mixture with an amount of component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), and component d (*e.g.*, citrate buffer at pH 6.4), or all of components a, b, and d;

wherein (i), (ii) or (i) and (ii) are performed in a closed vessel, thereby making a pharmaceutical product comprising setmelanotide, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

145. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a, component b, component d, and a predetermined amount of alcohol, comprising

combining, in a specified order, setmelanotide, component a, component b, component d and an addition amount of alcohol, wherein the addition amount of alcohol results in a predetermined amount of alcohol in the pharmaceutical product, wherein the specified order comprises the following steps in order:

(i) providing a mixture comprising setmelanotide, an addition amount of alcohol and component d, *e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4, *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol and a citrate buffer at pH 6.4; and

(ii) combining the component (e)-alcohol-buffer mixture with an amount of components a and b or all of components a and b;

wherein (i), (ii) or (i) and (ii) are performed in a closed vessel, thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a, component b, component d, and a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

146. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a, component b, component d, and a predetermined amount of alcohol, comprising

combining, in a specified order, the setmelanotide, component a, component b, component d and an addition amount of alcohol, wherein the addition amount of alcohol results in a predetermined amount of alcohol in the pharmaceutical product, wherein the specified order comprises the following steps in order:

(i) providing a mixture comprising a setmelanotide, an addition amount of alcohol and component d, *e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4 (a setmelanotide-alcohol-buffer mixture), *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol and a citrate buffer at pH 6.4; and

(ii) combining setmelanotide-alcohol-buffer mixture with an amount of components a and b or all of components a and b;

wherein (i), (ii) or (i) and (ii) are performed in a closed vessel, thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a, component b, component d, and a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

147. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, comprising

combining, in a specified order, setmelanotide, component a, component b, component d and an addition amount of alcohol, wherein the addition amount of alcohol results in a predetermined amount of alcohol in the pharmaceutical product, wherein the specified order comprises the following steps in order:

(i) providing a mixture comprising setmelanotide, an addition amount of alcohol and component d, *e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4, *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol and a citrate buffer at pH 6.4; and

(ii) combining the mixture with an amount of component a (*e.g.*, GDO), and component b (*e.g.*, soybean PC) or all of components a and b;

wherein (i), (ii) or (i) and (ii) are performed in a closed vessel, thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

148. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, comprising

combining, in a specified order, the setmelanotide, component a, component b, component d and an addition amount of alcohol, wherein the addition amount of alcohol results in a predetermined amount of alcohol in the pharmaceutical product, wherein the specified order comprises the following steps in order:

(i) providing a mixture comprising the setmelanotide, an addition amount of alcohol and component d, *e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4 (a setmelanotide-alcohol-buffer mixture), *e.g.*, setmelanotide in contact with, *e.g.*, dissolved or dispersed in, an alcohol, *e.g.*, ethanol and a citrate buffer at pH 6.4; and

(ii) combining the setmelanotide-alcohol-buffer mixture with an amount of component a (*e.g.*, GDO), and component b (*e.g.*, soybean PC) or all of components a and b;

wherein (i), (ii) or (i) and (ii) are performed in a closed vessel, thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, component a (*e.g.*, GDO), component b (*e.g.*, soybean PC), component d (*e.g.*, a polar solvent, *e.g.*, a buffer, *e.g.*, a citrate buffer at pH 6.4), and a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

149. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection comprising the following steps in order:

i) combining an amount of one or more of (*e.g.*, all of) components a, b, c and d;

ii) providing to this mixture component (e) comprising setmelanotide; and

iii) mixing the mixture of (i) and (ii) for a specified amount of time to dissolve or disperse setmelanotide,

thereby making a pharmaceutical product setmelanotide as sole active pharmaceutical ingredient formulated for injection, *e.g.*, a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, comprising a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

150. The method of claim 149, wherein the mixing is performed for at least 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30 hours.

151. The method of claim 149, wherein the mixing is performed for 1-30 hours,

152. The method of claim 149, wherein the mixing is performed for no more than 30, 40, or 50 hours.

153. A method of making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection comprising the following steps in order:

i) combining an amount of one or more of (*e.g.*, all of) components a, b, d setmelanotide;

ii) providing to this mixture a predetermined amount of component c; and

iii) mixing the mixture of (i) and (ii) for a specified amount of time to dissolve or disperse setmelanotide;

thereby making a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, *e.g.*, a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, comprising a predetermined amount of alcohol, *e.g.*, 10 wt. % alcohol, *e.g.*, ethanol.

154. The method of claim 153, wherein the mixing is performed for at least 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30 hours.

155. The method of claim 153, wherein the mixing is performed for 1-30 hours.

156. The method of claim 153, wherein the mixing is performed for no more than 30, 40, or 50 hours.

157. A plurality of preparations, *e.g.*, a first preparation, a second preparation, a third preparation or more, of a pharmaceutical product comprising setmelanotide as sole active pharmaceutical ingredient formulated for injection, each preparation of the plurality having an amount of EtOH that falls within a predetermined range, *e.g.*, a plurality of preparations made by the method of claim 62.

158. The plurality of preparations of claim 157, wherein the amount of EtOH in each of the plurality of preparations is within 2, 1, or 0.5% by weight of one another.

159. The plurality of preparations of claim 157, wherein the amount of EtOH in each of the plurality of preparations is within the range of 10% +/-5, 10% +/-4, 10% +/-3, 10 % +/-2, or 10%+/-1 by weight of one another.

160. The plurality of preparations of claim 157, wherein a first preparation and a second preparation of the plurality are made within 10, 20, 30, 60, 180, or 365 days of one another.

161. The plurality of preparations of claim 157, wherein a second preparation is made less than 10, 20, 30, 60, 180, or 365 days of the first preparation.

162. Use of an injectable composition of claim 1 comprising setmelanotide as sole active pharmaceutical ingredient in the manufacture of a medicament, wherein said medicament is to be administered via injection to a subject.

163. The use of claim 162, wherein the subject has, or is at risk of having a disorder responsive to modulation of melanocortin-4 receptor (MC4R).

164. The use of claim 163, wherein the disorder is chosen from: type 1 diabetes, type 2 diabetes, obesity, insulin resistance, metabolic syndrome, male erectile dysfunction, female sexual

disorder, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, disorders of substance abuse, including alcoholism, feeding disorders, cachexia, inflammation or anxiety, Prader-Willi Syndrome, Bardet-Biedl syndrome, and Alström syndrome.

165. The use of claim 164, wherein the disorder is obesity.

166. The use of claim 164, wherein the disorder is type 1 diabetes.

167. The use of claim 164, wherein the disorder is type 2 diabetes.

168. The use of claim 164, wherein the disorder is Prader-Willi Syndrome.

169. The use of claim 164, wherein the disorder is Bardet-Biedl syndrome.

170. The use of claim 164, wherein the disorder is Alström syndrome.