SUMMARY

[06] Aspects of the present specification disclose a pharmaceutical composition comprising a therapeutic compound and a pharmaceutically-acceptable adjuvant. A therapeutic compound may have an anti-pain activity. Other aspects of the present specification disclose a pharmaceutical composition comprising a therapeutic compound disclosed herein, a pharmaceutically-acceptable solvent, and a pharmaceutically-acceptable adjuvant. In other aspects, the pharmaceutical compositions disclosed herein further comprise a pharmaceutically-acceptable stabilizing agent.

[06a] In one aspect, there is provided a pharmaceutical composition comprising:

a) a non-steroidal anti-pain drug (NSAID);

b) a pharmaceutically-acceptable lipid in an amount of at least 50% by weight of the pharmaceutical composition, the pharmaceutically-acceptable lipid comprising a pharmaceutically-acceptable fat in an amount of at least 30% by weight of the pharmaceutical composition and a pharmaceutically-acceptable monoglyceride or an acetylated monoglyceride in an amount of at least 20% by weight of the pharmaceutical composition; and

c) a pharmaceutically-acceptable polyethylene glycol (PEG) polymer in an amount less than about 15% by weight of the pharmaceutical composition;

wherein the pharmaceutical composition is formulated to be a solid at a temperature of about 15°C or lower.

[06b] In one aspect, there is provided use of a pharmaceutical composition according as defined herein in the manufacture of a medicament for the treatment of a severe pain condition

[07] Other aspects of the present specification disclose a method of preparing a pharmaceutical composition, the method comprising the step of contacting a therapeutic compound with a pharmaceutically-acceptable adjuvant under conditions which allow the formation of the pharmaceutical composition. Other aspects of the present specification disclose a method of preparing a pharmaceutical composition, the method comprising the steps: a) contacting a pharmaceutically-acceptable solvent with a therapeutic compound under conditions which allow the therapeutic compound to dissolve in the pharmaceutically-acceptable solvent, thereby forming a solution, wherein the therapeutic compound has an anti-pain activity, and b) contacting the solution formed in step (a) with a pharmaceutically-acceptable adjuvant under conditions which allow the formation of the pharmaceutical composition. In other aspects, the method of preparing disclosed herein further comprises c) removing the pharmaceutically-acceptable solvent from the pharmaceutical composition.

[08] Other aspects of the present specification disclose a pharmaceutical composition, the pharmaceutical composition made according to a method comprising the step of contacting a therapeutic compound with a pharmaceutically-acceptable adjuvant under conditions which allow the formation of the pharmaceutical composition. Other aspects of the present specification disclose a pharmaceutical composition, the pharmaceutical composition made according to a method comprising the steps: a)

contacting a pharmaceutically-acceptable solvent with a therapeutic compound under conditions which allow the therapeutic compound to dissolve in the pharmaceutically-acceptable solvent, thereby forming a solution, wherein the therapeutic compound has an anti-pain activity, and b) contacting the solution formed in step (a) with a pharmaceutically-acceptable adjuvant under conditions which allow the formation of the pharmaceutical composition. In other aspects, the method of making a pharmaceutical composition disclosed herein further comprises c) removing the pharmaceutically-acceptable solvent from the pharmaceutical composition.

[09] Other aspects of the present specification disclose a method of treating an individual with a severe pain condition, the method comprising the step of administering to the individual in need thereof a pharmaceutical composition disclosed herein, wherein administration results in a reduction in a symptom associated with the severe pain condition, thereby treating the individual.

[010] Other aspects of the present specification disclose a use of a pharmaceutical composition disclosed herein in the manufacture of a medicament for the treatment of a severe pain condition.

SUMMARY

[06] Aspects of the present specification disclose a pharmaceutical composition comprising a therapeutic compound and a pharmaceutically-acceptable adjuvant. A therapeutic compound may have an anti-pain activity. Other aspects of the present specification disclose a pharmaceutical composition comprising a therapeutic compound disclosed herein, a pharmaceutically-acceptable solvent, and a pharmaceutically-acceptable adjuvant. In other aspects, the pharmaceutical compositions disclosed herein further comprise a pharmaceutically-acceptable stabilizing agent.

[06a] In one aspect, there is provided an oral pharmaceutical composition comprising:

a) a non-steroidal anti-pain drug (NSAID);

b) a pharmaceutically-acceptable lipid in an amount of at least 50% by weight of the pharmaceutical composition, the pharmaceutically-acceptable lipid comprising a pharmaceutically-acceptable solid fat having a melting point of about 38°C to about 48°C in an amount of at least 30% by weight of the pharmaceutical composition and comprising one or more triglycerides and a pharmaceutically-acceptable liquid fat in an amount of at least 20% by weight of the pharmaceutical composition and comprising a monoglyceride or an acetylated monoglyceride and a diglyceride; and

c) a pharmaceutically-acceptable polyethylene glycol (PEG) polymer in an amount less than about 15% by weight of the pharmaceutical composition;

wherein the pharmaceutical composition is formulated to be a solid at a temperature of about 15°C or lower and has a melting point of 30°C or higher.

[07] Other aspects of the present specification disclose a method of preparing a pharmaceutical composition, the method comprising the step of contacting a therapeutic compound with a pharmaceutically-acceptable adjuvant under conditions which allow the formation of the pharmaceutical composition. Other aspects of the present specification disclose a method of preparing a pharmaceutical composition, the method comprising the steps: a) contacting a pharmaceutically-acceptable solvent with a therapeutic compound under conditions which allow the therapeutic compound to dissolve in the pharmaceutically-acceptable solvent, thereby forming a solution, wherein the therapeutic compound has an anti-pain activity, and b) contacting the solution formed in step (a) with a pharmaceutically-acceptable adjuvant under conditions which allow the formation of the pharmaceutical composition. In other aspects, the method of preparing disclosed herein further comprises c) removing the pharmaceutically-acceptable solvent from the pharmaceutical composition.

[08] Other aspects of the present specification disclose a pharmaceutical composition, the pharmaceutical composition made according to a method comprising the step of contacting a therapeutic compound with a pharmaceutically-acceptable adjuvant under conditions which allow the formation of the

[09] pharmaceutical composition. Other aspects of the present specification disclose a pharmaceutical composition, the pharmaceutical composition made according to a method comprising the steps: a) contacting a pharmaceutically-acceptable solvent with a therapeutic compound under conditions which allow the therapeutic compound to dissolve in the pharmaceutically-acceptable solvent, thereby forming a solution, wherein the therapeutic compound has an anti-pain activity, and b) contacting the solution formed in step (a) with a pharmaceutically-acceptable adjuvant under conditions which allow the formation of the pharmaceutical composition. In other aspects, the method of making a pharmaceutical composition disclosed herein further comprises c) removing the pharmaceutically-acceptable solvent from the pharmaceutical composition.

[010] Other aspects of the present specification disclose a method of treating an individual with a severe pain condition, the method comprising the step of administering to the individual in need thereof a pharmaceutical composition disclosed herein, wherein administration results in a reduction in a symptom associated with the severe pain condition, thereby treating the individual.

[011] Other aspects of the present specification disclose a use of an oral pharmaceutical composition disclosed herein in the manufacture of a medicament for the treatment of a severe pain condition.

CLAIMS

1. A pharmaceutical composition comprising:

   a) a non-steroidal anti-pain drug (NSAID);

   b) a pharmaceutically-acceptable lipid in an amount of at least 50% by weight of the pharmaceutical composition, the pharmaceutically-acceptable lipid comprising a pharmaceutically-acceptable fat in an amount of at least 30% by weight of the pharmaceutical composition and a pharmaceutically-acceptable monoglyceride or an acetylated monoglyceride in an amount of at least 20% by weight of the pharmaceutical composition; and

   c) a pharmaceutically-acceptable polyethylene glycol (PEG) polymer in an amount less than about 15% by weight of the pharmaceutical composition;

   wherein the pharmaceutical composition is formulated to be a solid at a temperature of about 15°C or lower.

2. The pharmaceutical composition according to Claim 1, wherein the NSAID comprises a non-selective cyclooxygenase inhibitor, a selective cyclooxygenase 1 inhibitor, a selective cyclooxygenase 2 inhibitor or any combination thereof.

3. The pharmaceutical composition according to Claim 1 or Claim 2, wherein the NSAID comprises a salicylate derivative NSAID, a p-amino phenol derivative NSAID, a propionic acid derivative NSAID, an acetic acid derivative NSAID, an enolic acid derivative NSAID, a fenamic acid derivative NSAID or a combination thereof.

4. The pharmaceutical composition according to Claim 3, wherein the propionic acid derivative NSAID comprises a pharmaceutically-acceptable form of an Alminoprofen, a Benoxaprofen, a Dexketoprofen, a Fenoprofen, a a Flurbiprofen, an Ibuprofen, an Indoprofen, a Ketoprofen, a Loxoprofen, a Naproxen, an Oxaprozin, a Pranoprofen, or a Suprofen.

5. The pharmaceutical composition according to Claim 4, wherein the propionic acid derivative NSAID is an Ibuprofen.

6. The pharmaceutical composition according to any one of Claims 1-5, wherein the pharmaceutically-acceptable fat is an amount of at least 35% by weight of the pharmaceutical composition.

7. The pharmaceutical composition according to any one of Claims 1-6, wherein the pharmaceutically-acceptable fat has a melting point of about 40°C to about 46°C.

8. The pharmaceutical composition according to any one of Claims 1-7, wherein the pharmaceutically-acceptable fat comprises a triglyceride or a triester of glycerol.

9. The pharmaceutical composition according to Claim 8, wherein the triglyceride comprises a mixture of saturated C_{10}-C_{18} triglycerides having a melting point of between 41°C to 45°C.

10. The pharmaceutical composition according to Claim 8 or Claim 9, wherein the triglyceride comprises a mixture of saturated C_{10}-C_{18} triglycerides having a melting point of about 43°C.

11. The pharmaceutical composition according to any one of Claims 1-10, wherein the pharmaceutically-acceptable monoglyceride or an acetylated monoglyceride comprises a glyceryl monolinoleate.

12. The pharmaceutical composition according to any one of Claims 1-11, wherein the pharmaceutically-acceptable PEG polymer is in an amount from about 8% to about 15% by weight of the pharmaceutical composition.

13. The pharmaceutical composition according to Claim 12, wherein the pharmaceutically-acceptable PEG polymer is in an amount from about 8% to about 12% by weight of the pharmaceutical composition.

14. The pharmaceutical composition according to any one of Claims 1-13, wherein the pharmaceutically-acceptable PEG polymer is less than about 2,000 g/mol.

15. The pharmaceutical composition according to Claim 14, wherein the pharmaceutically-acceptable PEG polymer comprises a PEG 100, a PEG 200, a PEG 300, a PEG 400, a PEG 500, a PEG 600, a PEG 700, a PEG 800, a PEG 900, a PEG 1000 or a combination thereof.

16. The pharmaceutical composition according to any one of Claims 1-15, further comprising a pharmaceutically-acceptable propylene glycol (PPG) polymer in an amount of about 5% to about 15% by weight of the pharmaceutical composition.

17. The pharmaceutical composition according to Claim 16, wherein the pharmaceutically-acceptable PPG polymer is in an amount from about 8% to about 15% by weight of the pharmaceutical composition.

18. The pharmaceutical composition according to Claim 17, wherein the pharmaceutically-acceptable PPG polymer is in an amount from about 8% to about 12% by weight of the pharmaceutical composition.

19. The pharmaceutical composition according to any one of Claims 16-19, wherein the pharmaceutically-acceptable PPG polymer is less than about 2,000 g/mol.

20. The pharmaceutical composition according to Claim 19, wherein the pharmaceutically-acceptable PEG polymer comprises a PPG 100, a PPG 200, a PPG 300, a PPG 400, a PPG 500, a PPG 600, a PPG 700, a PPG 800, a PPG 900, a PPG 1000 or a combination thereof.

21. Use of a pharmaceutical composition according as defined in any one of Claims 1-20 in the manufacture of a medicament for the treatment of a severe pain condition.

22. The use according to Claim 21, wherein the severe pain condition is an acute pain, a subacute pain, or a chronic pain.

23. The use according to Claim 21, wherein the severe pain condition is a nociceptive pain, a pathological pain, is a referred pain, a headache or a migraine.

24. The use according to Claim 23, wherein the nociceptive pain is a visceral pain, a deep somatic pain, a superficial somatic pain, or any combination thereof.

25. The use according to Claim 23, wherein the pathological pain is a neuropathic pain, a dysfunctional pain, or any combination thereof.

26. The use according to Claim 25, wherein the neuropathic pain is a central neuropathic pain, a peripheral neuropathic pain, a deafferentation pain, or any combination thereof.

27. The use according to Claim 26, wherein the peripheral neuropathic pain is a mononeuropathy, a mononeuropathic multiplex, a polyneuropathy, an autonomic neuropathy, neuralgia or a complex regional pain syndrome.

28. The use according to Claim 27, wherein the polyneuropathy is a distal axonopathy, a myelinopathy, or a neuronopathy.

29. The use according to Claim 23, wherein the headache is a muscular/myogenic headache, a vascular headache, a traction headache, inflammatory headache, a chronic sinusitis headache, a hormone headache, a rebound headache, an organic headache, or an ictal headache.

CLAIMS

1. An oral pharmaceutical composition comprising:

   a) a non-steroidal anti-pain drug (NSAID);

   b) a pharmaceutically-acceptable lipid in an amount of at least 50% by weight of the pharmaceutical composition, the pharmaceutically-acceptable lipid comprising a pharmaceutically-acceptable solid fat having a melting point of about 38°C to about 48°C in an amount of at least 30% by weight of the pharmaceutical composition and comprising one or more triglycerides and a pharmaceutically-acceptable liquid fat in an amount of at least 20% by weight of the pharmaceutical composition and comprising a monoglyceride or an acetylated monoglyceride and a diglyceride; and

   c) a pharmaceutically-acceptable polyethylene glycol (PEG) polymer in an amount less than about 15% by weight of the pharmaceutical composition;

   wherein the pharmaceutical composition is formulated to be a solid at a temperature of about 15°C or lower and has a melting point of 30°C or higher.

2. The pharmaceutical composition according to Claim 1, wherein the NSAID comprises a non-selective cyclooxygenase inhibitor, a selective cyclooxygenase 1 inhibitor, a selective cyclooxygenase 2 inhibitor or any combination thereof.

3. The pharmaceutical composition according to Claim 1 or Claim 2, wherein the NSAID comprises a salicylate derivative NSAID, a p-amino phenol derivative NSAID, a propionic acid derivative NSAID, an acetic acid derivative NSAID, an enolic acid derivative NSAID, a fenamic acid derivative NSAID or a combination thereof.

4. The pharmaceutical composition according to Claim 3, wherein the propionic acid derivative NSAID comprises a pharmaceutically-acceptable form of an Alminoprofen, a Benoxaprofen, a Dexketoprofen, a Fenoprofen, a a Flurbiprofen, an Ibuprofen, an Indoprofen, a Ketoprofen, a Loxoprofen, a Naproxen, an Oxaprozin, a Pranoprofen, or a Suprofen.

5. The pharmaceutical composition according to Claim 4, wherein the propionic acid derivative NSAID is an Ibuprofen.

6. The pharmaceutical composition according to any one of Claims 1-5, wherein the pharmaceutically-acceptable fat is an amount of at least 35% by weight of the pharmaceutical composition.

7. The pharmaceutical composition according to any one of Claims 1-6, wherein the pharmaceutically-acceptable fat has a melting point of about 40°C to about 46°C.

8. The pharmaceutical composition according to any one of Claims 1-7, wherein the pharmaceutically-acceptable fat comprises a triglyceride or a triester of glycerol.

9. The pharmaceutical composition according to Claim 8, wherein the triglyceride comprises a mixture of saturated C_{10}-C_{18} triglycerides having a melting point of between 41°C to 45°C.

10. The pharmaceutical composition according to Claim 8 or Claim 9, wherein the triglyceride comprises a mixture of saturated C_{10}-C_{18} triglycerides having a melting point of about 43°C.

11. The pharmaceutical composition according to any one of Claims 1-10, wherein the pharmaceutically-acceptable monoglyceride or an acetylated monoglyceride comprises a glyceryl monolinoleate.

12. The pharmaceutical composition according to any one of Claims 1-11, wherein the pharmaceutically-acceptable PEG polymer is in an amount from about 8% to about 15% by weight of the pharmaceutical composition.

13. The pharmaceutical composition according to Claim 12, wherein the pharmaceutically-acceptable PEG polymer is in an amount from about 8% to about 12% by weight of the pharmaceutical composition.

14. The pharmaceutical composition according to any one of Claims 1-13, wherein the pharmaceutically-acceptable PEG polymer is less than about 2,000 g/mol.

15. The pharmaceutical composition according to Claim 14, wherein the pharmaceutically-acceptable PEG polymer comprises a PEG 100, a PEG 200, a PEG 300, a PEG 400, a

PEG 500, a PEG 600, a PEG 700, a PEG 800, a PEG 900, a PEG 1000 or a combination thereof.

16. The pharmaceutical composition according to any one of Claims 1-15, further comprising a pharmaceutically-acceptable propylene glycol (PPG) polymer in an amount of about 5% to about 15% by weight of the pharmaceutical composition.

17. The pharmaceutical composition according to Claim 16, wherein the pharmaceutically-acceptable PPG polymer is in an amount from about 8% to about 15% by weight of the pharmaceutical composition.

18. The pharmaceutical composition according to Claim 17, wherein the pharmaceutically-acceptable PPG polymer is in an amount from about 8% to about 12% by weight of the pharmaceutical composition.

19. The pharmaceutical composition according to any one of Claims 16-19, wherein the pharmaceutically-acceptable PPG polymer is less than about 2,000 g/mol.

20. The pharmaceutical composition according to Claim 19, wherein the pharmaceutically-acceptable PEG polymer comprises a PPG 100, a PPG 200, a PPG 300, a PPG 400, a PPG 500, a PPG 600, a PPG 700, a PPG 800, a PPG 900, a PPG 1000 or a combination thereof.

21. Use of an oral pharmaceutical composition according as defined in any one of Claims 1-20 in the manufacture of a medicament for the treatment of a severe pain condition.

22. The use according to Claim 21, wherein the severe pain condition is an acute pain, a subacute pain, or a chronic pain.

23. The use according to Claim 21, wherein the severe pain condition is a nociceptive pain, a pathological pain, is a referred pain, a headache or a migraine.

24. The use according to Claim 23, wherein the nociceptive pain is a visceral pain, a deep somatic pain, a superficial somatic pain, or any combination thereof.

25. The use according to Claim 23, wherein the pathological pain is a neuropathic pain, a dysfunctional pain, or any combination thereof.

26. The use according to Claim 25, wherein the neuropathic pain is a central neuropathic pain, a peripheral neuropathic pain, a deafferentation pain, or any combination thereof.

27. The use according to Claim 26, wherein the peripheral neuropathic pain is a mononeuropathy, a mononeuropathic multiplex, a polyneuropathy, an autonomic neuropathy, neuralgia or a complex regional pain syndrome.

28. The use according to Claim 27, wherein the polyneuropathy is a distal axonopathy, a myelinopathy, or a neuronopathy.

29. The use according to Claim 23, wherein the headache is a muscular/myogenic headache, a vascular headache, a traction headache, inflammatory headache, a chronic sinusitis headache, a hormone headache, a rebound headache, an organic headache, or an ictal headache.