CLAIMS

1. A pharmaceutical composition comprising: a) a therapeutic compound, wherein the therapeutic compound has an anti-pain activity; and b) a pharmaceutically-acceptable adjuvant.

2. The pharmaceutical composition according to Claim 1, wherein the composition further comprises a pharmaceutically-acceptable solvent.

3. A pharmaceutical composition comprising: a) a therapeutic compound, wherein the therapeutic compound has an anti-pain activity; b) a pharmaceutically-acceptable solvent; and c) a pharmaceutically-acceptable adjuvant.

4. A pharmaceutical composition comprising: a) a therapeutic compound, wherein the therapeutic compound has an anti-pain activity; b) a pharmaceutically-acceptable solvent; and c) a pharmaceutically-acceptable adjuvant, wherein the ratio of the pharmaceutically-acceptable solvent to pharmaceutically-acceptable adjuvant is in a range from about 0:1 to about 1:25.

5. The pharmaceutical composition according to Claim 2 or 3, wherein the ratio of the pharmaceutically-acceptable solvent to pharmaceutically-acceptable adjuvant is in a range from about 0:1 to about 1:25.

6. The pharmaceutical composition according to any one of Claims 1-5, wherein the anti-pain activity reduces a severe pain response, a nociceptive pain response, reduces a pain response mediated by a nociceptive receptor, a somatic pain response, a visceral pain response, a pathological pain response, a neuropathic pain response, a central neuropathic pain response, a peripheral neuropathic pain response, a mononeuropathic pain response, a mononeuropathic multiplex pain response, a polyneuropathic pain response, an autonomic neuropathic pain response, a neuralgia pain response, a complex regional pain syndrome pain response, a referred pain response, a deafferentation pain response, a dysfunctional pain response, a headache pain response, or a migraine pain response.

7. The pharmaceutical composition according to any one of Claims 1-6, wherein the therapeutic compound has a logP value indicating that the compound is soluble in an organic solvent.

8. The pharmaceutical composition according to any one of Claims 1-7, wherein the therapeutic compound has a logP value of more than 1.0.

9. The pharmaceutical composition according to any one of Claims 1-8, wherein the therapeutic compound has a polar surface area that is hydrophobic.

10. The pharmaceutical composition according to any one of Claims 1-9, wherein the therapeutic compound has a polar surface area that is less than 8.0 nm^2.

11. The pharmaceutical composition according to any one of Claims 1-10, wherein the therapeutic compound comprises a non-steroidal anti-pain drug (NSAID), a PPARγ agonist, a nuclear receptor binding agent, a fibrate, a statin, a tocotrienol, a niacin, a bile acid sequestrants (resin), a cholesterol absorption inhibitor, a pancreatic lipase inhibitor, a sympathomimetic amine, or an anti-hyperlipidemic agent, or an ester thereof.

12. The pharmaceutical composition according to Claims 1-11, wherein the pharmaceutically-acceptable solvent is less than about 20% (v/v).

13. The pharmaceutical composition according to Claims 1-12, wherein the pharmaceutically-acceptable solvent comprises a pharmaceutically-acceptable polar aprotic solvent, a pharmaceutically-acceptable polar protic solvent, a pharmaceutically-acceptable non-polar solvent, or a combination thereof.

14. The pharmaceutical composition according to Claims 1-13, wherein the pharmaceutically-acceptable solvent comprises a pharmaceutically-acceptable alcohol, a pharmaceutically-acceptable ester of pharmaceutically-acceptable alcohol and an acid, a pharmaceutically-acceptable glycol ether, a pharmaceutically-acceptable diol, a pharmaceutically-acceptable propylene glycol, a pharmaceutically-acceptable dipropylene glycol, a pharmaceutically-acceptable polypropylene glycol (PPG) polymer, a pharmaceutically-acceptable polyethylene glycol (PEG) polymer, a pharmaceutically-acceptable glyceride, or any combination thereof.

15. The pharmaceutical composition according to Claims 1-14, wherein the pharmaceutically-acceptable solvent is a liquid at 20°C or wherein the pharmaceutically-acceptable solvent is a solid at 20°C.

16. The pharmaceutical composition according to Claims 1-15, wherein the adjuvant is at least 80% (v/v).

17. The pharmaceutical composition according to Claims 1-16, wherein the pharmaceutically-acceptable adjuvant is a liquid at 20°C or wherein the pharmaceutically-acceptable adjuvant is a solid at 20°C.

18. The pharmaceutical composition according to Claims 1-17, wherein the pharmaceutically-acceptable adjuvant comprises a pharmaceutically-acceptable lipid.

19. The pharmaceutical composition according to Claim 18, wherein the pharmaceutically-acceptable lipid comprises a saturated fatty acid, an unsaturated fatty acid, a pharmaceutically-acceptable oil, a pharmaceutically-acceptable glycerolipid, a pharmaceutically-acceptable glycol fatty acid ester, a pharmaceutically-acceptable polyether fatty acid ester, a mixture of pharmaceutically-acceptable lipids, or any combination thereof.

20. The pharmaceutical composition according to Claims 1-19, wherein the pharmaceutical composition further comprises a pharmaceutically-acceptable stabilizing agent.

21. The pharmaceutical composition according to Claim 20, wherein the pharmaceutically-acceptable stabilizing agent comprises water, a sacrificial acid comprising a fatty acid component and acetic acid, ethyl acetate, a sodium acetate/acetic acid, a monoglyceride, an acetylated monoglyceride, a diglyceride, an acetylated diglyceride, a fatty acid, a fatty acid salt, or a combination thereof.

22. The pharmaceutical composition according to Claims 1-21, wherein the pharmaceutical composition does not comprise a pharmaceutically-acceptable emulsifying agent.

23. 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.

24. A method of preparing a pharmaceutical composition as defined by Claims 1-23, 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 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.

25. A method of preparing a pharmaceutical composition as defined by any one of Claims 1-23, 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 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, wherein the ratio of the pharmaceutically-acceptable solvent to pharmaceutically-acceptable adjuvant is in a range from about 0:1 to about 1:25.

26 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 as defined by any one of Claims 1-23, wherein administration results in a reduction in a symptom associated with the severe pain condition, thereby treating the individual.

27. Use of a pharmaceutical composition as defined by any one of Claims 1-23 in the manufacture of a medicament for the treatment of a chronic inflammation.

28. Use of a pharmaceutical composition as defined by any one of Claims 1-23 for the treatment of a severe pain condition.

29. The method according to Claim 26 or the use according to Claim 27 or 28, wherein the severe pain condition is an acute pain, a subacute pain, or a chronic pain.

30. The method according to Claim 26 or the use according to Claim 27 or 28, wherein the severe pain condition is a nociceptive pain.

31. The method or use according to Claim 30, wherein the nociceptive pain is a visceral pain, a deep somatic pain, a superficial somatic pain, or any combination thereof.

32. The method according to Claim 26 or the use according to Claim 27 or 28, wherein the severe pain condition is a pathological pain.

33. The method or use according to Claim 32, wherein the pathological pain is a neuropathic pain, a dysfunctional pain, or any combination thereof.

34. The method or use according to Claim 33, wherein the neuropathic pain is a central neuropathic pain, a peripheral neuropathic pain, a deafferentation pain, or any combination thereof.

35. The method or use according to Claim 34, wherein the peripheral neuropathic pain is a mononeuropathy, a mononeuropathic multiplex, a polyneuropathy, or an autonomic neuropathy.

36. The method or use according to Claim 35, wherein the polyneuropathy is a distal axonopathy, a myelinopathy, or a neuronopathy.

37. The method or use according to Claim 34, wherein the peripheral neuropathic pain is a neuralgia or a complex regional pain syndrome.

38. The method according to Claim 26 or the use according to Claim 27 or 28, wherein the severe pain condition is a referred pain.

39. The method according to Claim 26 or the use according to Claim 27 or 28, wherein the severe pain condition is a headache.

40. The method or use according to Claim 39, 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.

41. The method according to Claim 26 or the use according to Claim 27 or 28, wherein the severe pain condition is a migraine.

42. The method according to Claims 26 or 29-41 or the use according to Claims 27-41, wherein upon administration to an individual, the pharmaceutical composition comprising the therapeutic compound as defined by any one of Claims 1-23 results in a bio-distribution of the therapeutic compound different than a bio-distribution of the therapeutic compound included in the same pharmaceutical composition, except without the pharmaceutically-acceptable adjuvant.

43. The method according to Claims 26 or 29-42 or the use according to Claims 27-42, wherein upon administration to an individual, the amount of the therapeutic compound of the pharmaceutical composition as defined by any one of Claims 1-23 delivered to a macrophage is at least 5% of the total amount of the therapeutic compound contained in the administered pharmaceutical composition.

44. The method according to Claims 26 or 29-43 or the use according to Claims 27-43, wherein upon administration to an individual, the pharmaceutical composition as defined by any one of Claims 1-23 reduces intestinal irritation by at least 5% when compared to the pharmaceutical composition as defined by any one of Claims 1-23, except without the pharmaceutically-acceptable adjuvant.

45. The method according to Claims 26 or 29-44 or the use according to Claims 27-44, wherein upon administration to an individual, the pharmaceutical composition as defined by any one of Claims 1-23 reduces gastric irritation by at least 5% when compared to the pharmaceutical composition as defined by any one of Claims 1-23, except without the pharmaceutically-acceptable adjuvant.

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.