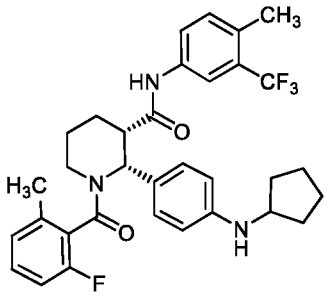
WHAT IS CLAIMED IS:

1. A solid solution capsule formulation comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C.

2. The solid solution capsule of claim **1**, wherein the vehicle comprises about 97 to 99% by weight of the total fill weight of said solid solution capsule.

3. The solid solution capsule of claim **1** wherein the vehicle comprises about 98% by weight of the total fill weight of said solid solution capsule.

4. The solid solution capsule of claim **1**, or claim **2**, comprising about 1 to 3% of Compound 1 by weight of the total fill weight of said solid solution capsule.

5. The solid solution capsule of claim **1**, claim **3**, comprising about 2% of Compound 1 by weight of the total fill weight of said solid solution capsule.

6. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises a 30:70 to 65:35 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

7. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises a 35:65 to 65:35 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

8. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises a 40:60 to 60:40 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

9. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises a 45:55 to 55:45 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

10. The solid solution capsule of any one of claims **1** to **5**, wherein the total weight of the vehicle comprises about a 50:50 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

11. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 comprises a polyoxyethylene derivative of a fatty acid containing from about 8 to 22 carbon atoms.

12. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 comprises a polyoxyethylene derivative of a fatty acid, wherein the fatty acid is ricinoleic acid.

13. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is a polyoxyethylene hydrogenated castor oil or a polyoxyethylene castor oil.

14. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate or macrogolglycerol ricinoleate.

15. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate.

16. The solid solution capsule of any one of claims **1** to **15**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1000, PEG-1500, PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000, PEG-8000, PEG-10000, PEG-20000, poloxamer 188, poloxamer 237, poloxamer 338 and poloxamer 407.

17. The solid solution capsule of any one of claims **1** to **15**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000.

18. The solid solution capsule of any one of claims **1** to **15**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.

19. The solid solution capsule of any one of claims **1** to **10**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate and the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.

20. The solid solution capsule of any one of claims **1** to **19**, wherein the total fill weight of said solid solution capsule is from about 130 mg to 900 mg.

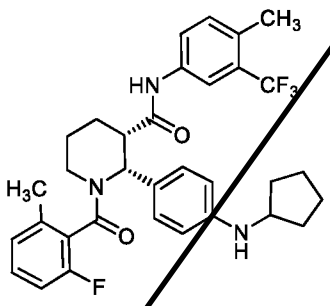
21. The solid solution capsule of any one of claims **1** to **19**, wherein the total fill weight of said solid solution capsule is about 500 mg.

22. The solid solution capsule of any one of claims **1** to **19**, wherein the capsule size is selected from the group consisting of #00, #0, #1, #2, #3, #4, or #5.

23. The solid solution capsule of any one of claims **1** to **19**, wherein the capsule size is #0.

24. The solid solution capsule of any one of claims **1** to **23**, wherein the capsule is a hard capsule.

25. A method of preparing a solid solution capsule comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C;

said method comprising

(a) melting the vehicle;

(b) combining the melted vehicle obtained in step (a) with Compound 1 to form a drug solution;

(c) encapsulating the drug solution in a capsule shell; and

(d) cooling the encapsulated drug solution to form a solid solution capsule comprising Compound 1.

26. The method of claim **25**, wherein step (a) comprises heating the vehicle to a temperature of about 50° to 85° C.

27. The method of claim **25**, wherein step (a) comprises

(i) heating at least one non-ionic surfactant having an HLB value of at least 10 to form a melted surfactant;

(ii) heating at least one water-soluble solubilizer to form a melted solubilizer; and

(iii) combining melted solubilizer with melted surfactant to form a melted vehicle.

28. The method of claim **27**, wherein step (i) comprises heating the at least one non-ionic surfactant having an HLB values of at least 10 to a temperature of about 50° to 70° C.

29. The method of claim **27** or claim **28**, wherein step (ii) comprises heating the at least one water-soluble solubilizer to a temperature of about 80 to 85 ° C.

30. The method of any one of claims **25** to **29**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is a polyoxyethylene hydrogenated castor oil or a polyoxyethylene castor oil.

31. The method of any one of claims **25** to **29**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate or macrogolglycerol ricinoleate.

32. The method of any one of claims **25** to **29**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycol hydroxystearate.

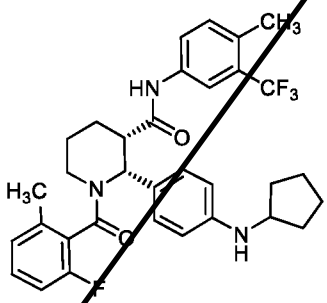
33. The method of any one of claims **25** to **29**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1500, PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000, poloxamer 188, poloxamer 237, poloxamer 338 and poloxamer 407.

34. The method of any one of claims **25** to **29**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, and PEG-6000.

35. The method of any one of claims **25** to **29**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.

36. The method of any one of claims **25** to **29**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate and at least one water-soluble solubilizer polyethylene glycol 4000 (PEG-4000).

37. A solid solution capsule comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C;

said solid solution capsule prepared according to the method of any one of claims **25** to **36**.

38. A method for treating an individual suffering from or susceptible to a disease or disorder involving pathologic activation of C5a receptors, comprising administering to the individual an effective amount of a solid solution capsule of any one of claims **1** to **24**.

39. The method of claim **38**, wherein the disease or disorder is an inflammatory disease or disorder.

40. The method of claim **39**, wherein the disease or disorder is selected from the group consisting of neutropenia, sepsis, septic shock, Alzheimer's disease, multiple sclerosis, stroke, inflammatory bowel disease, age-related macular degeneration, chronic obstructive pulmonary disorder, inflammation associated with burns, lung injury, osteoarthritis, atopic dermatitis, chronic urticaria, ischemia-reperfusion injury, acute respiratory distress syndrome, systemic inflammatory response syndrome, multiple organ dysfunction syndrome, tissue graft rejection, cancer and hyperacute rejection of transplanted organs.

41. The method of claim **38**, wherein the disease or disorder is a cardiovascular or cerebrovascular disorder.

42. The method of claim **41**, wherein the disease or disorder is selected from the group consisting of myocardial infarction, coronary thrombosis, vascular occlusion, post-surgical vascular reocclusion, artherosclerosis, traumatic central nervous system injury and ischemic heart disease.

43. The method of claim **38**, wherein the disease or disorder is an autoimmune disorder.

44. The method of claim **43**, wherein the disease or disorder is selected from the group consisting of rheumatoid arthritis, C3 glomerulopathy (C3G), hidradenitis suppurativa (HS), systemic lupus erythematosus, Guillain-Barre syndrome, pancreatitis, lupus nephritis, lupus glomerulonephritis, psoriasis, immunoglobulin A (IgA) nephropathy, Crohn's disease, vasculitis, irritable bowel syndrome, dermatomyositis, multiple sclerosis, bronchial asthma, pemphigus, pemphigoid, scleroderma, myasthenia gravis, autoimmune hemolytic and thrombocytopenic states, Goodpasture's syndrome, immunovasculitis, tissue graft rejection and hyperacute rejection of transplanted organs.

45. The method of claim **38**, wherein the disease or disorder is a pathologic sequelae associated with the group consisting of insulin-dependent diabetes, mellitus, lupus nephropathy, Heyman nephritis, membranous nephritis, glomerulonephritis, contact sensitivity responses, and inflammation resulting from contact of blood with artificial surfaces.

46. The method of claim **38**, wherein the disease or disorder is selected from the group consisting of anti-neutrophil cytoplasmic antibody associate (ANCA) vasculitis, C3 glomerulopathy, hidradenitis suppurativa, and lupus nephritis.

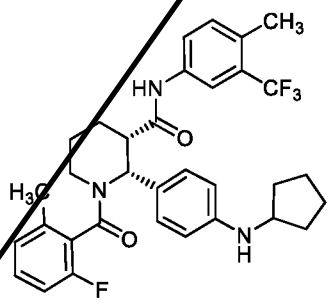
47. The method of claim **38**, wherein the disease or disorder is anti-neutrophil cytoplasmic antibody associate (ANCA) vasculitis.

48. The method of claim **38**, wherein the disease or disorder is C3 glomerulopathy.

49. The method of claim **38**, wherein the disease or disorder is hidradenitis suppurativa.

50. The method of claim **38**, wherein the disease or disorder is lupus nephritis.

51. A single unit dosage capsule comprising about 2.6 mg to 25.2 mg of Compound 1 as a free base, in its neutral form



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C.

52. The single unit dosage capsule of claim **51**, comprising about 2.6 mg to 18 mg of Compound 1 as a free base, in its neutral form.

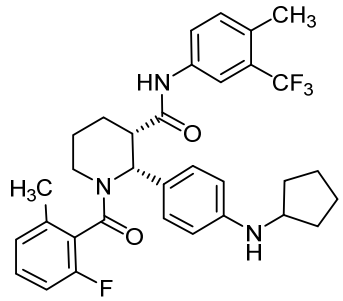
53. The single unit dosage capsule of claim **51**, comprising about 10 mg of Compound 1 as a free base, in its neutral form.

54. The single unit dosage capsule any one of claims **51** to **53**, wherein the total fill weight of said solid solution capsule is from about 130 mg to 900 mg.

55. A kit comprising one or more solid solution capsules of any one of claims **1** to **24**, or one or more single dosage units of any one of claims **51** to **54**.

CLAIMS:

1. A solid solution capsule formulation comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C.

2. The solid solution capsule of claim **1**, wherein:

(a) the vehicle comprises about 97 to 99% by weight of the total fill weight of said solid solution capsule, preferably wherein the vehicle comprises about 98% by weight of the total fill weight of said solid solution capsule; or

(b) the solid solution capsule comprises about 1 to 3% of Compound 1 by weight of the total fill weight of said solid solution capsule, preferably wherein the solid solution capsule comprises about 2% of Compound 1 by weight of the total fill weight of said solid solution capsule.

3. The solid solution capsule of claim **1** or **2**, wherein the total weight of the vehicle comprises a 30:70 to 65:35 ratio, preferably a 35:65 to 65:35 ratio of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

4. The solid solution capsule of claim **1** or **2**, wherein the total weight of the vehicle comprises a 40:60 to 60:40 ratio, preferably a 45:55 to 55:45 ratio of at least one non-

ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

5. The solid solution capsule of claim **1** or **2**, wherein the total weight of the vehicle comprises about a 50:50 ratio, of at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10 to at least one water-soluble solubilizer having a melting temperature at or above 37° C.

6. The solid solution capsule of any one of claims **1** to **5**, wherein:

(a) the at least one non-ionic surfactant having an HLB value of at least 10 comprises a polyoxyethylene derivative of a fatty acid containing from about 8 to 22 carbon atoms, preferably wherein the fatty acid is ricinoleic acid; or

(b) the at least one non-ionic surfactant having an HLB value of at least 10 is a polyoxyethylene hydrogenated castor oil or a polyoxyethylene castor oil; or

(c) the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate or macrogolglycerol ricinoleate.

7. The solid solution capsule of any one of claims **1** to **5**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate.

8. The solid solution capsule of any one of claims **1** to **7**, wherein:

(a) the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1000, PEG-1500, PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000, PEG-8000, PEG-10000, PEG-20000, poloxamer 188, poloxamer 237, poloxamer 338 and poloxamer 407, preferably selected from the group consisting of PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000.

9. The solid solution capsule of any one of claims **1** to **7**, wherein the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.

10. The solid solution capsule of any one of claims **1** to **5**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate and the at least one water-soluble solubilizer having a melting temperature at or above 37° C is PEG-4000.

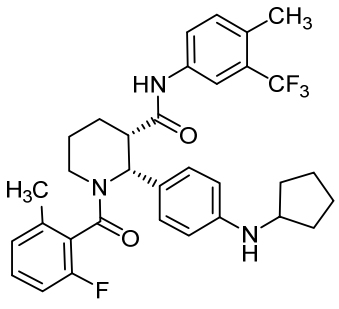
11. The solid solution capsule of any one of claims **1** to **10**, wherein:

(a) the total fill weight of said solid solution capsule is from about 130 mg to 900 mg, preferably about 500 mg; or

(b) the capsule size is selected from the group consisting of #00, #0, #1, #2, #3, #4, or #5, preferably wherein the capsule size is #0; or

(c) the capsule is a hard capsule.

12. A method of preparing a solid solution capsule comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C;

said method comprising

(a) melting the vehicle;

(b) combining the melted vehicle obtained in step (a) with Compound 1 to form a drug solution;

(c) encapsulating the drug solution in a capsule shell; and

(d) cooling the encapsulated drug solution to form a solid solution capsule comprising Compound 1.

13. The method of claim **12**, wherein:

1) step (a) comprises heating the vehicle to a temperature of about 50° to 85° C; or

2) step (a) comprises

(i) heating at least one non-ionic surfactant having an HLB value of at least 10 to form a melted surfactant;

(ii) heating at least one water-soluble solubilizer to form a melted solubilizer; and

(iii) combining melted solubilizer with melted surfactant to form a melted vehicle;

preferably wherein step (i) comprises heating the at least one non-ionic surfactant having an HLB values of at least 10 to a temperature of about 50° to 70° C, and/or step (ii) comprises heating the at least one water-soluble solubilizer to a temperature of about 80 to 85 ° C.

14. The method of claim **12** or **13**, wherein:

(a) the at least one non-ionic surfactant having an HLB value of at least 10 is a polyoxyethylene hydrogenated castor oil or a polyoxyethylene castor oil; or

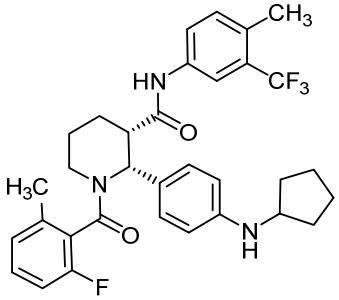
(b) the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate or macrogolglycerol ricinoleate., preferably macrogol-40-glycerol hydroxystearate; or

(c) the at least one water-soluble solubilizer having a melting temperature at or above 37° C is selected from the group consisting of PEG-1500, PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, PEG-6000, poloxamer 188, poloxamer 237, poloxamer 338 and

poloxamer 407,preferably selected from the group consisting of PEG-1540, PEG-2000, PEG-3000, PEG-3350, PEG-4000, and PEG-6000, more preferably being PEG-4000.

15. The method of claim **12** or **13**, wherein the at least one non-ionic surfactant having an HLB value of at least 10 is macrogol-40-glycerol hydroxystearate and the at least one water-soluble solubilizer is polyethylene glycol 4000 (PEG-4000).

16. A solid solution capsule comprising Compound 1 as a free base, in its neutral form or in the form of a pharmaceutically acceptable salt



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C;

said solid solution capsule obtainable according to the method of any one of claims **12** to **15**.

17. The solid solution capsule of any one of claims **1** to **11** or **16**, wherein Compound 1 is a free base, in its neutral form.

18. A solid solution capsule according to any one of claims **1** to **11** or **16** to **17** for use in a method for treating an individual suffering from or susceptible to a disease or disorder involving pathologic activation of C5a receptors, the method comprising an effective amount of the solid solution capsule to be administered to the individual.

19. The solid solution capsule for use of claim **18**, wherein:

(a) the disease or disorder is an inflammatory disease or disorder, preferably wherein the disease or disorder is selected from the group consisting of neutropenia, sepsis,

septic shock, Alzheimer's disease, multiple sclerosis, stroke, inflammatory bowel disease, age-related macular degeneration, chronic obstructive pulmonary disorder, inflammation associated with burns, lung injury, osteoarthritis, atopic dermatitis, chronic urticaria, ischemia-reperfusion injury, acute respiratory distress syndrome, systemic inflammatory response syndrome, multiple organ dysfunction syndrome, tissue graft rejection, cancer and hyperacute rejection of transplanted organs; or

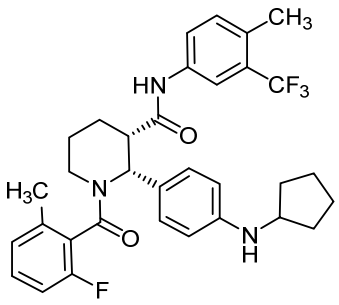
(b) the disease or disorder is a cardiovascular or cerebrovascular disorder, preferably wherein the disease or disorder is selected from the group consisting of myocardial infarction, coronary thrombosis, vascular occlusion, post-surgical vascular reocclusion, artherosclerosis, traumatic central nervous system injury and ischemic heart disease; or

(c) the disease or disorder is an autoimmune disorder, preferably wherein the disease or disorder is selected from the group consisting of rheumatoid arthritis, C3 glomerulopathy (C3G), hidradenitis suppurativa (HS), systemic lupus erythematosus, Guillain-Barre syndrome, pancreatitis, lupus nephritis, lupus glomerulonephritis, psoriasis, immunoglobulin A (IgA) nephropathy, Crohn's disease, vasculitis, irritable bowel syndrome, dermatomyositis, multiple sclerosis, bronchial asthma, pemphigus, pemphigoid, scleroderma, myasthenia gravis, autoimmune hemolytic and thrombocytopenic states, Goodpasture's syndrome, immunovasculitis, tissue graft rejection and hyperacute rejection of transplanted organs; or

(d) the disease or disorder is a pathologic sequelae associated with the group consisting of insulin-dependent diabetes, mellitus, lupus nephropathy, Heyman nephritis, membranous nephritis, glomerulonephritis, contact sensitivity responses, and inflammation resulting from contact of blood with artificial surfaces; or

(e) the disease or disorder is selected from the group consisting of anti-neutrophil cytoplasmic antibody associate (ANCA) vasculitis, C3 glomerulopathy, hidradenitis suppurativa, and lupus nephritis.

20. A single unit dosage capsule comprising about 2.6 mg to 25.2 mg of Compound 1 as a free base, in its neutral form



(Compound 1)

and a vehicle comprising

at least one non-ionic surfactant having a hydrophilic-lipophilic balance (HLB) value of at least 10, and

at least one water-soluble solubilizer having a melting point at or above 37° C.

21. The single unit dosage capsule of claim **20**, wherein:

(a) the single unit dosage capsule comprises about 2.6 mg to 18 mg, preferably about 10 mg, of Compound 1 as a free base, in its neutral form; and/or

(b) the total fill weight of said solid solution capsule is from about 130 mg to 900 mg.

22. A kit comprising one or more solid solution capsules of any one of claims **1** to **11, 16** or **17**, or one or more single dosage units of claim **20** or **21**.