CLAIMS

1. An oral prolonged release pharmaceutical composition comprising at least:

a) at least one prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof; and wherein

c) the pharmaceutical composition after storage under stressed conditions has less than 4 % of total substances related to oxycodone or a pharmaceutically acceptable salt or derivative thereof and/or related to naloxone or a pharmaceutically acceptable salt or derivative thereof.

2. An oral prolonged release pharmaceutical composition comprising at least:

a) at least one prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof; and wherein

c) the pharmaceutical composition after storage under stressed conditions has less than 0.5 % of known oxycodone or a pharmaceutically acceptable salt or derivative thereof related substances or known naloxone or a pharmaceutically acceptable salt or derivative thereof related substances.

3. Pharmaceutical composition according to claim 1 or 2, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 to 15 mg, preferably 1 to 9 mg of oxycodone HCl and naloxone or a pharmaceutically

acceptable salt thereof in an amount equivalent to 0.5 to 7.5 mg, preferably 0.5 to 4.5 mg of naloxone HCl.

4. Pharmaceutical composition according to claim 1, 2 or 3, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a ratio of 2:1 by weight.

5. Pharmaceutical composition according to claim 1, 2, 3 or 4, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1.25 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 7.5 mg of oxycodone HCl and naloxone in an amount equivalent to 3.75 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 12.5 mg of oxycodone HCl and naloxone in an amount equivalent to 6.25 mg of naloxone HCl or oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of oxycodone HCl and naloxone in an amount equivalent to 7.5 mg of naloxone HCl.

6. Pharmaceutical composition according to any of claims 1 to 5, wherein the at least one prolonged release material and oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof are combined to form a prolonged release matrix.

7. Pharmaceutical composition according to claim 6, wherein the prolonged release material is selected from the group comprising hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, natural and synthetic oils and waxes.

8. Pharmaceutical composition according to claim 7, wherein the prolonged release material is a cellulose ether, a (meth)acrylic based (co)polymer and/or a fatty alcohol.

9. Pharmaceutical composition according to any of claims 6, 7 or 8, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose as prolonged release material;
b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein
c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

10. Pharmaceutical composition according to any of claims 6, 7 or 8, comprising at least:

a) at least one fatty alcohol as prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

11. Pharmaceutical composition according to any of claims 6, 7 or 8, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose and at least one fatty alcohol as prolonged release materials;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release materials to form a prolonged release matrix.

12. Pharmaceutical composition according to any of claims 6, 7, 8, 9, 10 or 11 wherein the pharmaceutical composition comprises additionally at least one filler, at least one lubricant and at least one binder.

13. Pharmaceutical composition according to claim 12, wherein said filler is lactose monohydrate.

14. Pharmaceutical composition according to claim 12, wherein magnesium stearate and/or talc are used as lubricants.

15. Pharmaceutical composition according to claim 12, wherein hydroxypropyl cellulose, povidone, co-povidone, hydroxypropylmethyl cellulose polyvinyl pyrrolidone vinyl alcohol (PVPVA), microcrystalline cellulose, polyethylene glycols (PEGs), gelatine, starch or glycerol esters of fatty acids is used as binder.

16. Pharmaceutical composition according to claim 12, wherein the prolonged release pharmaceutical composition does not comprise hydroxypropyl cellulose as a binder.

17. Pharmaceutical composition according to claim 12, wherein the prolonged release pharmaceutical composition comprises hydroxypropyl cellulose as a binder.

18. Pharmaceutical composition according to any of claims 1 to 17, wherein the composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 500 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min: 10 to 30 % by weight of the pharmaceutically active agents,
at 2 h: 40 to 60% by weight of the pharmaceutically active agents,
at 10 h: more than 80% by weight of the pharmaceutically active agents.

19. Pharmaceutical composition according to claim 1 or 2, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 to 160 mg, preferably 16 to 160 mg of oxycodone HCl and naloxone or a pharmaceutically

acceptable salt thereof in an amount equivalent to 5 to 80, preferably 8 to 80 mg of naloxone HCl.

20. Pharmaceutical composition according to claim 1, 2 or 19, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a ratio of 2:1 by weight.

21. Pharmaceutical composition according to any of claims 1, 2, 19 or 20, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 40 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 60 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 40 mg of naloxone HCl and oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 160 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of naloxone HCl.

22. Pharmaceutical composition according to any of claims 1, 2, 19, 20 or 21, wherein the at least one prolonged release material and oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof are combined to form a prolonged release matrix.

23. Pharmaceutical composition according to claim 22, wherein the prolonged release material is selected from the group comprising hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, natural and synthetic oils and waxes.

24. Pharmaceutical composition according to claim 22, wherein the prolonged release material is a cellulose ether, a (meth)acrylic based (co)polymer and/or a fatty alcohol.

25. Pharmaceutical composition according to any of claims 22, 23 or 24, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose as prolonged release material;
b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein
c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

26. Pharmaceutical composition according to any of claims 22, 23 or 24, comprising at least:

a) at least one fatty alcohol as prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

27. Pharmaceutical composition according to any of claims 22, 23 or 24, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose and at least one fatty alcohol as prolonged release materials;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release materials to form a prolonged release matrix.

28. Pharmaceutical composition according to any of claims 22, 23, 24, 25, 26 or 27, wherein the pharmaceutical composition comprises additionally at least one filler, at least one lubricant and at least one binder.

29. Pharmaceutical composition according to claim 28, wherein said filler is lactose monohydrate.

30. Pharmaceutical composition according to claim 28, wherein magnesium stearate and/or talc are used as lubricants.

31. Pharmaceutical composition according to claim 28, wherein co-povidone, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone vinyl alcohol (PVPVA), microcrystalline cellulose, polyethylene glycols (PEGs), gelatine, starch or glycerol esters of fatty acids is used as binder.

32. Pharmaceutical composition according to claim 28, wherein the prolonged release pharmaceutical composition does not comprise povidone as a binder.

33. Pharmaceutical composition according to any of claims 19 to 32, wherein the composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 900 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min: 10 to 30 % by weight of the pharmaceutically active agents,
at 2 h: 40 to 65% by weight of the pharmaceutically active agents,
at 10 h: more than 80% by weight of the pharmaceutically active agents.

34. An oral prolonged release pharmaceutical composition, comprising at least:

a) at least one prolonged release material;
b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof; and wherein the

c) pharmaceutical composition after storage under stressed conditions releases the pharmaceutically active agents with substantially the same release rate as before subjecting the pharmaceutical composition to stressed conditions.

35. Pharmaceutical composition according to claim 34, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 to 15 mg, preferably 1 to 9 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 to 7.5 mg, preferably 0.5 to 4.5 mg of naloxone HCl.

36. Pharmaceutical composition according to 34 or 35, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a ratio of 2:1 by weight.

37. Pharmaceutical composition according to claim 34, 35 or 36, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1.25 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 7.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 3.75 mg of naloxone HCl, oxycodone or a

pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 12.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 6.25 mg of naloxone HCl or oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 7.5 mg of naloxone HCl.

38. Pharmaceutical composition according to any of claims 34 to 37, wherein the at least one prolonged release material and oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof are combined to form a prolonged release matrix.

39. Pharmaceutical composition according to claim 38, wherein the prolonged release material is selected from the group comprising hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, natural and synthetic oils and waxes.

40. Pharmaceutical composition according to claim 39, wherein the prolonged release material is a cellulose ether, a (meth)acrylic based (co)polymer and/or a fatty alcohol.

41. Pharmaceutical composition according to any of claims 38, 39 or 40, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose as prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

42. Pharmaceutical composition according to any of claims 38, 39 or 40, comprising at least:

a) at least one fatty alcohol as prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

43. Pharmaceutical composition according to any of claims 38, 39 or 40, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose and at least one fatty alcohol as prolonged release materials;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative

thereof are combined with said prolonged release materials to form a prolonged release matrix.

44. Pharmaceutical composition according to any of claims 38, 39, 40, 41, 42 or 43 wherein the pharmaceutical composition comprises additionally at least one filler, at least one lubricant and at least one binder.

45. Pharmaceutical composition according to claim 44, wherein said filler is lactose monohydrate.

46. Pharmaceutical composition according to claim 44, wherein magnesium stearate and/or talc are used as lubricants.

47. Pharmaceutical composition according to claim 44, wherein hydroxypropyl cellulose, povidone, co-povidone, hydroxypropylmethyl cellulose polyvinyl pyrrolidone vinyl alcohol (PVPVA), microcrystalline cellulose, polyethylene glycols (PEGs), gelatine, starch or glycerol esters of fatty acids is used as binder.

48. Pharmaceutical composition according to claim 44, wherein the prolonged release pharmaceutical composition does not comprise hydroxypropyl cellulose as a binder.

49. Pharmaceutical composition according to claim 44, wherein the prolonged release pharmaceutical composition comprises hydroxypropyl cellulose as a binder.

50. Pharmaceutical composition according to any of claims 34 to 49, wherein the composition releases the pharmaceutically active agents with the

following in vitro release rate when measured using the Ph. Eur. paddle method in 500 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees° C:

at 15 min: 10 to 30 % by weight of the pharmaceutically active agents,

at 2 h: 40 to 60% by weight of the pharmaceutically active agents,

at 10 h: more than 80% by weight of the pharmaceutically active agents.

51. Pharmaceutical composition according to claim 34, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 to 160 mg, preferably 16 to 160 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 to 80 mg, preferably 8 to 80 mg of naloxone HCl.

52. Pharmaceutical composition according to claim 34 or 51, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a ratio of 2:1 by weight.

53. Pharmaceutical composition according to any of claims 34, 51 or 52, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to

40 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 60 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 40 mg of naloxone HCl and oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 160 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of naloxone HCl.

54. Pharmaceutical composition according to any of claims 34, 51, 52 or 53, wherein the at least one prolonged release material and oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof are combined to form a prolonged release matrix.

55. Pharmaceutical composition according to claim 54, wherein the prolonged release material is selected from the group comprising hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, natural and synthetic oils and waxes.

56. Pharmaceutical composition according to claim 55, wherein the prolonged release material is a cellulose ether, a (meth)acrylic based (co)polymer and/or a fatty alcohol.

57. Pharmaceutical composition according to any of claims 54, 55 or 56, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose as prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

58. Pharmaceutical composition according to any of claims 54, 55 or 56, comprising at least:

a) at least one fatty alcohol as prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

59. Pharmaceutical composition according to any of claims 54, 55 or 56, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose and at least one fatty alcohol as prolonged release materials;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative

thereof are combined with said prolonged release materials to form a prolonged release matrix.

60. Pharmaceutical composition according to any of claims 54, 55, 56, 57, 58 or59 wherein the pharmaceutical composition comprises additionally at least one filler, at least one lubricant and at least one binder.

61. Pharmaceutical composition according to claim 60, wherein said filler is lactose monohydrate.

62. Pharmaceutical composition according to claim 60, wherein magnesium stearate and/or talc are used as lubricants.

63. Pharmaceutical composition according to claim 60, wherein co-povidone, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone vinyl alcohol (PVPVA), microcrystalline cellulose, polyethylene glycols (PEGs), gelatine, starch or glycerol esters of fatty acids is used as binder.

64. Pharmaceutical composition according to claim 60, wherein the prolonged release pharmaceutical composition does not comprise povidone as a binder.

65. Pharmaceutical composition according to any of claims 34 and 51 to 64, wherein the composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 900 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min:	10 to 30 % by weight of the pharmaceutically active agents,
at 2 h:	40 to 65% by weight of the pharmaceutically active agents,
at 10 h:	more than 80% by weight of the pharmaceutically active agents.

66. Pharmaceutical dosage form according to any of claims 1to 65, wherein oxycodone hydrochloride and naloxone hydrochloride are used.

67. Use of a binder for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof wherein the pharmaceutical composition after storage under stressed conditions has less than 4 % of total substances related to oxycodone or a pharmaceutically acceptable salt or derivative thereof and/or related to naloxone or a pharmaceutically acceptable salt or derivative thereof.

68. Use of a binder for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof wherein the pharmaceutical composition after storage under stressed conditionspharmaceutical composition has less than 0.5 % of known oxycodone or a pharmaceutically acceptable salt or derivative thereof related substances or known naloxone or a pharmaceutically acceptable salt or derivative thereof related substances.

69. Use of a binder for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition after storage under stressed conditions releases the pharmaceutically active agents with substantially the same release rate as before subjecting the pharmaceutical composition to stressed conditions.

70. Use according to claim 67, 68 or 69, wherein the pharmaceutical composition comprises at least part of oxycodone or a pharmaceutically acceptable

salt thereof and at least part of naloxone or a pharmaceutically acceptable salt in a prolonged release matrix.

71. Use according to claim 70, wherein the prolonged release matrix comprises a prolonged release matrix material being selected from the group comprising hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, oils and waxes.

72. Use according to claim 71, wherein the pharmaceutical composition does not comprise ethyl cellulose and/or stearyl alcohol as prolonged release matrix material.

73. Use according to any of claims 67 to 72, wherein the pharmaceutical composition comprises additionally at least one filler and at least one lubricant.

74. Use according to claim 73, wherein said filler is lactose monohydrate.

75. Use according to claim 73, wherein magnesium stearate and/or talc are used as lubricants.

76. Use according to any of claims 67 to 75, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 to 15 mg, preferably 1 to 9 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 to 7.5 mg, preferably 0.5 to 4.5 mg of naloxone HCl.

77. Use according to claim 76, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in 2:1 ratio by weight.

78. Use according to claim 76 or 77, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1.25 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 7.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 3.75 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 12.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 6.25 mg of naloxone HCl, or oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 7.5 mg of naloxone HCl.

79. Use according to any of claims 76, 77 or 78, wherein the pharmaceutical composition does not comprise povidone as a binder.

80. Use according to any of claims 76, 77 or 78, wherein the pharmaceutical composition comprises hydroxypropyl cellulose as a binder.

81. Use according to any of claims 76, 77 or 78, wherein the pharmaceutical composition does not comprise hydroxypropyl cellulose as a binder.

82. Use according to any of claims 76 to 81, wherein the pharmaceutical composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 500 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min: 10 to 30 % by weight of the pharmaceutically active agents,
at 2 h: 40 to 60% by weight of the pharmaceutically active agents,
at 10 h: more than 80% by weight of the pharmaceutically active agents.

83. Use according to any of claims 67 to 75, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 to 160 mg, preferably 16 to 160 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 to 80 mg, preferably 8 to 80 mg of naloxone HCl.

84. Use according to claim 83, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in 2:1 ratio by weight.

85. Use according to claim 83 or 84, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of naloxone HCl, oxycodone or a pharmaceutically

acceptable salt thereof in an amount equivalent to 40 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 60 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 40 mg of naloxone HCl and oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 160 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of naloxone HCl.

86. Use according to any of claims 83, 84 or 85, wherein the pharmaceutical composition does not comprise povidone as a binder.

87. Use according to any of claims 83, 84 or 85, wherein the pharmaceutical composition comprises povidone as a binder.

88. Use according to any of claims 83 to 87 wherein the composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 900 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min:	10 to 30 % by weight of the pharmaceutically active agents,
at 2 h:	40 to 65% by weight of the pharmaceutically active agents,
at 10 h:	more than 80% by weight of the pharmaceutically active agents.

89. Use of a hydroxypropyl cellulose for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof

wherein the pharmaceutical composition after storage under stressed conditions has less than 4 % of total substances related to oxycodone or a pharmaceutically acceptable salt or derivative thereof and/or related to naloxone or a pharmaceutically acceptable salt or derivative thereof.

90. Use of a hydroxypropyl cellulose for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof wherein the pharmaceutical composition after storage under stressed conditions has less than 0.5 % of known oxycodone or a pharmaceutically acceptable salt or derivative thereof related substances or known naloxone or a pharmaceutically acceptable salt or derivative thereof related substances.

91. Use of hydroxypropyl cellulose for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition after storage under stressed conditions releases the pharmaceutically active agents with substantially the same release rate as before subjecting the pharmaceutical composition to stressed conditions.

92. Use according to claim 89, 90 or 91, wherein the pharmaceutical composition comprises at least part of oxycodone or a pharmaceutically acceptable salt thereof and at least part of naloxone or a pharmaceutically acceptable salt in a prolonged release matrix.

93. Use according to claim 92, wherein the prolonged release matrix comprises a prolonged release matrix material being selected from the group comprising hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, oils and waxes.

94. Use according to claim 93, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose as prolonged release matrix material.

95. Use according to claim 93, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one fatty alcohol as prolonged release material as prolonged release matrix material.

96. Use according to any of claims 93, 94, or 95, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose and at least one fatty alcohol as prolonged release matrix materials.

97. Use according to any of claims 89 to 96, wherein the pharmaceutical composition comprises additionally at least one filler and at least one lubricant.

98. Use according to claim 97, wherein said filler is lactose monohydrate.

99. Use according to claim 97, wherein magnesium stearate and/or talc are used as lubricants.

100. Use according to any of claims 89 to 99, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in 2:1 ratio by weight.

101. Use according to any of claims 89 to 100, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 to 15 mg, preferably, 1 to 9 mg of oxycodone HCl and

naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 to 7.5 mg, preferably 0.5 to 4.5 mg of naloxone HCl.

102. Use according to claim 100 or 101, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1.25 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 7.5 mg of oxycodone HCl and naloxone in an amount equivalent to 3.75 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 12.5 mg of oxycodone HCl and naloxone in an amount equivalent to 6.25 mg of naloxone HCl, or oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of oxycodone HCl and naloxone in an amount equivalent to 7.5 mg of naloxone HCl.

103. Use according to any of claims 100, 101 or 102, wherein the pharmaceutical composition does not comprise povidone as a binder.

104. Use according to any of claims 89 to 103, wherein the pharmaceutical composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 500 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min: 10 to 30 % by weight of the pharmaceutically active agents,
at 2 h: 40 to 60% by weight of the pharmaceutically active agents,
at 10 h: more than 80% by weight of the pharmaceutically active agents.

105. Use of povidone for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof wherein the pharmaceutical composition after storage under stressed conditions has less than 4 % of total substances related to oxycodone or a pharmaceutically acceptable salt or derivative thereof and/or related to naloxone or a pharmaceutically acceptable salt or derivative thereof.

106. Use of povidone for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof wherein the pharmaceutical composition after storage under stressed conditions has less than 0.5 % of known oxycodone or a pharmaceutically acceptable salt or derivative thereof related substances or known naloxone or a pharmaceutically acceptable salt or derivative thereof related substances.

107. Use of povidone for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition after storage under stressed conditions releases the pharmaceutically active agents with substantially the same release rate as before subjecting the pharmaceutical composition to stressed conditions.

108. Use according to claim 105, 106, or 107, wherein the pharmaceutical composition comprises at least part of oxycodone or a pharmaceutically acceptable salt thereof and at least part of naloxone or a pharmaceutically acceptable salt in a prolonged release matrix.

109. Use according to claim 108, wherein the prolonged release matrix comprises a prolonged release matrix material being selected from the group comprising hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, oils and waxes.

110. Use according to claim 109, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose as prolonged release matrix material.

111. Use according to claim 109, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one fatty alcohol as prolonged release material as prolonged release matrix material.

112. Use according to any of claims 109 to 111, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose and at least one fatty alcohol as prolonged release matrix materials.

113. Use according to any of claims 105 to 112, wherein the pharmaceutical composition comprises additionally at least one filler and at least one lubricant.

114. Use according to claim 113, wherein said filler is lactose monohydrate.

115. Use according to claim 113, wherein magnesium stearate and/or talc are used as lubricants.

116. Use according to any of claims 105 to 115, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in 2:1 ratio by weight.

117. Use according to any of claims 105 to116, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 to 160 mg, preferably 16 to 160 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 to 80 mg, preferably 8 to 80 mg of naloxone HCl.

118. Use according to claim 116 or 117, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 40 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an

amount equivalent to 60 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 40 mg of naloxone HCl, and oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 160 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of naloxone HCl.

119. Use according to any of claims 105 to 118, wherein the pharmaceutical composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 900 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min: 10 to 30 % by weight of the pharmaceutically active agents,
at 2 h: 40 to 65% by weight of the pharmaceutically active agents,
at 10 h: more than 80% by weight of the pharmaceutically active agents.

120. Use of HPC for stabilizing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof.

121. Use according to claim 120, wherein the pharmaceutical composition comprises at least part of oxycodone or a pharmaceutically acceptable salt thereof and of naloxone or a pharmaceutically acceptable salt thereof in a prolonged release matrix.

122. Use according to any of claims 120 or 121, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 to 15 mg, preferably 1 to 9 mg of

oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 to 7.5 mg, preferably 0.5 to 4.5 mg of naloxone HCl.

123. Use according to any of claims 120, 121 or 122, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in 2:1 ratio by weight.

124. An oral prolonged release pharmaceutical composition comprising at least:

a) at least one prolonged release material;
b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof; and
c) HPC as a binder.

125. Pharmaceutical composition according to claim 124, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 to 80 mg, of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 to 40 mg of naloxone HCl.

126. Pharmaceutical composition according to claim 124 or 125, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a ratio of 2:1 by weight.

127. Pharmaceutical composition according to claim 124, 125, or 126, wherein the prolonged release pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 mg of

oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1.25 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 7.5 mg of oxycodone HCl and naloxone in an amount equivalent to 3.75 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 12.5 mg of oxycodone HCl and naloxone in an amount equivalent to 6.25 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of oxycodone HCl and naloxone in an amount equivalent to 7.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 20 mg of oxycodone HCl and naloxone in an amount equivalent to 10 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 30 mg of oxycodone HCl and naloxone in an amount equivalent to 15 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 40 mg of oxycodone HCl and naloxone in an amount equivalent to 20 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 60 mg of oxycodone HCl and naloxone in an amount equivalent to 30 mg of naloxone HCl, or oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 80 mg of oxycodone HCl and naloxone in an amount equivalent to 40 mg of naloxone HCl.

128. Pharmaceutical composition according to any of claims 124 to 127, wherein the at least one prolonged release material and oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof are combined to form a prolonged release matrix.

129. Pharmaceutical composition according to claim 128, wherein the prolonged release material is selected from the group comprising hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, natural and synthetic oils and waxes.

130. Pharmaceutical composition according to claim 129, wherein the prolonged release material is a cellulose ether, a (meth)acrylic based (co)polymer and/or a fatty alcohol.

131. Pharmaceutical composition according to any of claims 128, 129 or 130, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose as prolonged release material;
b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein
c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

132. Pharmaceutical composition according to any of claims 128, 129 or 130, comprising at least:

a) at least one fatty alcohol as prolonged release material;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release material to form a prolonged release matrix.

133. Pharmaceutical composition according to any of claims 128, 129 or 130, comprising at least:

a) at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose and at least one fatty alcohol as prolonged release materials;

b) at least oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof, wherein

c) oxycodone or a pharmaceutically acceptable salt or derivative thereof and naloxone or a pharmaceutically acceptable salt or derivative thereof are combined with said prolonged release materials to form a prolonged release matrix.

134. Pharmaceutical composition according to any of claims 128, 129, 130, 131, 132, or 133, wherein the pharmaceutical composition comprises additionally at least one filler and at least one lubricant.

135. Pharmaceutical composition according to claim 134, wherein said filler is lactose monohydrate.

136. Pharmaceutical composition according to claim 134, wherein magnesium stearate and/or talc are used as lubricants.

137. Pharmaceutical composition according to any of claims 124 to 136, wherein the composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 500 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min: 10 to 30 % by weight of the pharmaceutically active agents,

at 2 h: 40 to 65% by weight of the pharmaceutically active agents,

at 10 h: more than 80% by weight of the pharmaceutically active agents.

138. Use of HPC as a binder to produce a prolonged release formulation in accordance with any of claims 124 to 138.

The claims defining the invention are as follows:

1. Use of hydroxypropyl cellulose for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof wherein the pharmaceutical composition after storage under stressed conditions has less than 4 % of total substances related to oxycodone or a pharmaceutically acceptable salt or derivative thereof and/or related to naloxone or a pharmaceutically acceptable salt or derivative thereof.

2. Use of hydroxypropyl cellulose for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof wherein the pharmaceutical composition after storage under stressed conditions has less than 0.5 % of known oxycodone or a pharmaceutically acceptable salt or derivative thereof related substances or known naloxone or a pharmaceutically acceptable salt or derivative thereof related substances.

3. Use of hydroxypropyl cellulose for manufacturing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition after storage under stressed conditions releases the pharmaceutically active agents with substantially the same release rate as before subjecting the pharmaceutical composition to stressed conditions.

4. Use according to any one of claims 1 to 3, wherein the pharmaceutical composition comprises at least part of oxycodone or a pharmaceutically acceptable salt thereof and at least part of naloxone or a pharmaceutically acceptable salt in a prolonged release matrix.

5. Use according to claim 4, wherein the prolonged release matrix comprises a prolonged release matrix material being selected from the group comprising

hydrophobic or hydrophilic polymers, gums, substituted or unsubstituted hydrocarbons, carbohydrates, fatty acids, fatty alcohols, glyceryl esters of fatty acids, oils and waxes.

6. Use according to claim 5, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose as prolonged release matrix material.

7. Use according to claim 5, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one fatty alcohol as prolonged release material as prolonged release matrix material.

8. Use according to any one of claims 5 to 7, wherein the pharmaceutical composition comprises a prolonged release matrix which comprises at least one cellulose ether, preferably at least one hydrophobic cellulose ether such as ethyl cellulose and at least one fatty alcohol as prolonged release matrix materials.

9. Use according to any one of claims 1 to 8, wherein the pharmaceutical composition comprises additionally at least one filler and at least one lubricant.

10. Use according to claim 9, wherein said filler is lactose monohydrate.

11. Use according to claim 9, wherein magnesium stearate and/or talc are used as lubricants.

12. Use according to any one of claims 1 to 11, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in 2:1 ratio by weight.

13. Use according to any one of claims 1 to 12, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 to 15 mg, preferably, 1 to 9 mg of oxycodone HCl and naloxone or a

pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 to 7.5 mg, preferably 0.5 to 4.5 mg of naloxone HCl.

14. Use according to claim 12 or 13, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1.25 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 5 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 2.5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 7.5 mg of oxycodone HCl and naloxone in an amount equivalent to 3.75 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 10 mg of oxycodone HCl and naloxone in an amount equivalent to 5 mg of naloxone HCl, oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 12.5 mg of oxycodone HCl and naloxone in an amount equivalent to 6.25 mg of naloxone HCl, or oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 15 mg of oxycodone HCl and naloxone in an amount equivalent to 7.5 mg of naloxone HCl.

15. Use according to any one of claims 12 to 14, wherein the pharmaceutical composition does not comprise povidone as a binder.

16. Use according to any one of claims 1 to 15, wherein the pharmaceutical composition releases the pharmaceutically active agents with the following in vitro release rate when measured using the Ph. Eur. paddle method in 500 ml of Simulated Gastric Fluid at 50 rpm at 37 degrees C°:

at 15 min: 10 to 30 % by weight of the pharmaceutically active agents,

at 2 h: 40 to 60% by weight of the pharmaceutically active agents,

at 10 h: more than 80% by weight of the pharmaceutically active agents.

17. Use of hydroxypropyl cellulose for stabilizing a prolonged release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof.

18. Use according to claim 17, wherein the pharmaceutical composition comprises at least part of oxycodone or a pharmaceutically acceptable salt thereof and of naloxone or a pharmaceutically acceptable salt thereof in a prolonged release matrix.

19. Use according to claim 17 or 18, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof in an amount equivalent to 1 to 15 mg, preferably 1 to 9 mg of oxycodone HCl and naloxone or a pharmaceutically acceptable salt thereof in an amount equivalent to 0.5 to 7.5 mg, preferably 0.5 to 4.5 mg of naloxone HCl.

20. Use according to any one of claims 17 to 19, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in 2:1 ratio by weight.