CLAIMS

1. A ~~self-supporting, dissolvable, film,~~composition comprising:

   (i) dexmedetomidine or a pharmaceutically acceptable salt thereof;

   (ii) ~~one or more~~ a first water-soluble hydroxypropyl cellulose polymers having a molecular weight of about 40,000 daltons in an amount of about 3% to about 15% w/w of the total composition weight; ~~and, optionally,~~

   (iii) ~~one or more pharmaceutically acceptable carriers~~a second water-soluble hydroxypropyl cellulose polymer having a molecular weight of about 140,000 daltons in an amount of about 3% to about 8% w/w of the total composition weight;

   (iv) a third water-soluble hydroxypropyl cellulose polymer having a molecular weight of about 370,000 daltons in an amount of about 10% to about 50% w/w of the total composition weight; and

   (v) a water-soluble polyethylene oxide polymer having a molecular weight of about 600,000 daltons in an amount of about 40% to about 70% w/w of the total composition weight..

2. ~~A film~~ The composition according to claim 1~~,~~ in form of a self-supporting, dissolvable mucoadhesive firm~~wherein (ii) comprises a low molecular weight, water-soluble polymer~~.

3. ~~A film~~ The composition according to claim ~~1~~2, wherein ~~(ii) comprises a low molecular weight, water-soluble polymer and one or more high molecular weight, water-soluble polymers~~the self-supporting, dissolvable mucoadhesive film is suitable for sublingual or buccal administration.

~~4. A film according to claim 1, wherein (ii) comprises a low molecular weight, water-soluble polymer and two high molecular weight, water-soluble polymers.~~

~~5. A film according to claim 3 or claim 4, wherein each high molecular weight, water-soluble polymer has a molecular weight of greater than about 60,000 daltons.~~

~~6. A film according to any one of claims 2 to 4, wherein the low molecular weight, water-soluble polymer has a molecular weight of less than about 60,000 daltons.~~

~~7. A film according to claim 3 or claim 4, wherein the low molecular weight, water-soluble polymer has a molecular weight of less than about 60,000 daltons, and each high molecular weight, water-soluble polymer has a molecular weight of greater than about 60,000 daltons.~~

~~8. A film according to claim 3 or claim 4, wherein the low molecular weight, water-soluble polymer has a molecular weight from about 5,000 daltons to about 49,000 daltons, and each high molecular weight, water-soluble polymer has a molecular weight of greater than about 60,000 daltons.~~

~~9. A film according to claim 3, wherein the low molecular weight, water-soluble polymer has a molecular weight of less than about 60,000 daltons, and each of the two high molecular weight, water-soluble polymers has a molecular weight from about 90,000 daltons to about 200,000 daltons.~~

~~10. A film according to claim 3, wherein the low molecular weight, water-soluble polymer has a molecular weight of less than about 60,000 daltons, one of the two high molecular weight, water-soluble polymers has a molecular weight from about 90,000 daltons to about 200,000 daltons, and the other high molecular weight, water-soluble polymer has a molecular weight from about 200,000 daltons to about 500,000 daltons.~~

~~11. A film according to claim 3, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 5,000 daltons to about 49,000 daltons, one of the two high molecular weight, water-soluble polymers has a molecular weight from about 90,000 daltons to about 200,000 daltons, and the other high molecular weight, water-soluble polymer has a molecular weight from about 200,000 daltons to about 500,000 daltons.~~

~~12. A film according to claim 3, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 40,000 daltons, one of the two high molecular weight, water-soluble polymers has a molecular weight of about 140,000 daltons, and the other high molecular weight, water-soluble polymer has a molecular weight of about 370,000 daltons.~~

~~13. A film according to claim 3, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 30,000 daltons, one of the two high molecular~~

~~weight, water-soluble polymers has a molecular weight of about 90,000 daltons, and the other high molecular weight, water-soluble polymer has a molecular weight of about 140,000 daltons.~~

~~14. A film according to any preceding claim, wherein each water-soluble polymer is independently selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl cellulose, carboxymethyl cellulose, and methyl cellulose.~~

~~15. A film according to any preceding claim, wherein each water-soluble polymer is hydroxypropyl cellulose or hydroxypropyl methylcellulose.~~

~~16. A film according to claim 9 or claim 13, wherein the low molecular weight, water-soluble polymer and one of the two high molecular weight, water-soluble polymers is hydroxypropyl methylcellulose.~~

~~17. A film according to claim 9 or claim 13, wherein the low molecular weight, water-soluble polymer and one of the two high molecular weight, water-soluble polymers is hydroxypropyl methylcellulose, and the other high molecular weight, water-soluble polymer is hydroxypropyl cellulose.~~

~~18. A film according to any one of claims 1 to 8, 10, 11 or12, wherein each water-soluble polymer is hydroxypropyl cellulose.~~

~~19. A film according to any preceding claim also comprising one or more pharmaceutically acceptable carriers.~~

~~20. A film according to claim 19, wherein the pharmaceutically acceptable carriers are selected from the group consisting of: liquid carriers, flavors, sweeteners, refreshing agents, pH adjusting agents, permeation enhancers, mucoadhesive agents, plasticizers, bulking agents, surfactants, anti-foaming agents, and colorants.~~

~~21. A film according to claim 20, wherein the plasticizer is a polyalcohol.~~

~~22. A film according to claim 21, wherein the polyalcohol is a polyethylene glycol.~~

~~23. A film according to claim 20, wherein the mucoadhesive agent is a polyethylene oxide.~~

~~24. A film according to claim 23, wherein the polyethylene oxide is a water-soluble, high molecular weight polymer.~~

~~25. A film according to claim 24, wherein the polyethylene oxide has a molecular weight from about 100,000 daltons to about 1,500,000 daltons.~~

~~26. A film according to claim 25, wherein the polyethylene oxide has a molecular weight of about 100,000, 200,000, 300,000, 600,000, 900,000 or 1,000,000 daltons.~~

~~27. A film according to claim 25, wherein the polyethylene oxide has a molecular weight of about 600,000 daltons.~~

~~28. A self-supporting, dissolvable, film, comprising:~~

~~(i) dexmedetomidine or a pharmaceutically acceptable salt thereof;~~

~~(ii) a low molecular weight, water-soluble polymer having a molecular weight of less than about 60,000 daltons;~~

~~(iii) a high molecular weight, water-soluble polymer having a molecular weight from about 90,000 daltons to about 200,000 daltons;~~

~~(iv) a high molecular weight, water-soluble polymer having a molecular weight from about 200,000 daltons to about 500,000 daltons; and~~

~~(v) a mucoadhesive agent which is a polyethylene oxide.~~

~~29. A film according to claim 28, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 5,000 daltons to about 49,000 daltons.~~

~~30. A film according to claim 28, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 40,000 daltons, the high molecular weight, water-soluble polymer (iii) has a molecular weight of about 140,000 daltons, and the high molecular weight, water-soluble polymer (iv) has a molecular weight of about 370,000 daltons.~~

~~31. A film according to any one of claims 28 to 30, wherein the polyethylene oxide is a water-soluble, high molecular weight polymer.~~

~~32. A film according to claim 31, wherein the polyethylene oxide has a molecular weight from about 100,000 daltons to about 1,500,000 daltons.~~

~~33. A film according to claim 31, wherein the polyethylene oxide has a molecular weight of about 100,000, 200,000, 300,000, 600,000, 900,000 or 1,000,000 daltons.~~

~~34. A film according to claim 31, wherein the polyethylene oxide has a molecular weight of about 600,000 daltons.~~

~~35. A film according to any preceding claim, wherein the film components form a single layer in which dexmedetomidine or a pharmaceutically acceptable salt thereof is substantially uniformally distributed throughout the film.~~

~~36. A film according to any one of claims 1 to 34, wherein the film components excluding dexmedetomidine or a pharmaceutically acceptable salt thereof form a single layer film substrate, and dexmedetomidine or a pharmaceutically acceptable salt thereof is present on the surface of the film substrate.~~

~~37. A film according to claim 36, wherein dexmedetomidine or a pharmaceutically acceptable salt thereof is present on the surface of the film substrate within a composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof and one or more water-soluble polymers.~~

~~38. A film according to claim 37, wherein the composition comprises dexmedetomidine or a pharmaceutically acceptable salt thereof and a low molecular weight, water-soluble polymer.~~

~~39. A film according to claim 38, wherein the low molecular weight, water-soluble polymer has a molecular weight of less than about 60,000 daltons.~~

~~40. A film according to claim 38, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 5,000 daltons to about 49,000 daltons.~~

~~41. A film according to claims 37, wherein the composition comprises one or more high molecular weight, water-soluble polymers.~~

~~42. A film according to any one of claims 38 to 40, wherein composition also comprises one or more high molecular weight, water-soluble polymers.~~

~~43. A film according to claim 41 or claim 42, wherein each high molecular weight, water-soluble polymer has a molecular weight of greater than about 60,000 daltons.~~

~~44. A film according to claim 41 or claim 42, wherein the composition comprises one high molecular weight, water-soluble polymer having a molecular weight from about 90,000 daltons to about 200,000 daltons.~~

~~45. A film according to claim 41 or claim 42, wherein the composition comprises two high molecular weight, water-soluble polymers, one having a molecular weight from about 90,000 daltons to about 200,000 daltons, and the other having a molecular weight from about 200,000 daltons to about 500,000 daltons.~~

~~46. A film according to claim 45, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 40,000 daltons, one of the two high molecular weight, water-soluble polymers has a molecular weight of about 140,000 daltons, and the other high molecular weight, water-soluble polymer has a molecular weight of about 370,000 daltons.~~

~~47. A film according to claim 37, wherein the composition comprises dexmedetomidine or a pharmaceutically acceptable salt thereof, a low molecular weight, water-soluble polymer having a molecular weight of about 40,000 daltons, and one high molecular weight, water-soluble polymer having a molecular weight of about 140,000 daltons.~~

~~48. A film according to any one of claims 37 to 47, wherein each water-soluble polymer is independently selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl cellulose, carboxymethyl cellulose, and methyl cellulose.~~

~~49. A film according to claim 48, wherein each water-soluble polymer is hydroxypropyl cellulose.~~

~~50. A film according to any one of claims 37 to 49, also comprising a mucoadhesive polyalcohol.~~

~~51. A film according to claim 50, wherein the polyalcohol is a polyethylene oxide.~~

~~52. A film according to claim 51, wherein the polyethylene oxide is a water-soluble, high molecular weight polymer.~~

53. A film according to claim 52, wherein the polyethylene oxide has a molecular weight from about 100,000 daltons to about 1,500,000 daltons.

54. A film according to claim 52, wherein the polyethylene oxide has a molecular weight of about 100,000, 200,000, 300,000, 600,000, 900,000 or 1,000,000 daltons.

55. A film according to claim 52, wherein the polyethylene oxide has a molecular weight of about 600,000 daltons.

56. A film according to any one of claims 1 to 55, where the film is dissolvable by oral mucosal fluid.

57. A film according to any one of claims 1 to 55, where the film is administered sublingually.

58. A film according to claim 57 for the treatment of agitation.

59. A pharmaceutical film composition suitable for sublingual administration, comprising:
    (i) a therapeutically effective amount of dexmedetomidine or a pharmaceutically acceptable salt thereof;
    (ii) a polymer component consisting of one or more water-soluble polymers; and, optionally,
    (iii) one or more pharmaceutically acceptable carriers.

60. A pharmaceutical film composition suitable for sublingual administration, consisting essentially of
    (i) a therapeutically effective amount of dexmedetomidine or a pharmaceutically acceptable salt thereof;
    (ii) a polymer component consisting of one or more water-soluble polymers, and, optionally,
    (iii) one or more pharmaceutically acceptable carriers.

61. A pharmaceutical film composition according to claim 59 or claim 60, wherein the polymer component consists of:
    (a) a first water-soluble polymer having a molecular weight from about 5,000 daltons to about 49,000 daltons, and/or

(b) one or more second water-soluble polymers having a molecular weight greater than about 60,000 daltons.

62. A pharmaceutical film composition according to claim 61, wherein the first water-soluble polymer is hydroxypropyl cellulose and the one or more second water-soluble polymers is selected from the group consisting of polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl cellulose, carboxy methylcellulose, and methylcellulose.

63. A pharmaceutical film composition according to claim 62, wherein the one or more second water-soluble polymers is selected from the group consisting of hydroxypropyl cellulose, and polyethylene oxide.

64. A pharmaceutical film composition according to any one of claims 59 to 63, wherein the pharmaceutically acceptable carrier is selected from the group consisting of: liquid carriers, flavors, sweeteners, refreshing agents, pH adjusting agents, permeation enhancers, mucoadhesive agents, plasticizers, bulking agents, surfactants, anti-foaming agents, and colorants, and mixtures thereof.

65. A film according to any one of claims 1 to 64, wherein the dexmedetomidine or a pharmaceutically acceptable salt thereof is dexmedetomidine hydrochloride.

66. A film according to Claim 65, wherein dexmedetomidine hydrochloride is present in an amount of from about 0.01% to about 5% w/w based on the total dry film weight.

67. A film according to any one of claims 1 to 66, wherein the film has a thickness of about 20 micrometers to about 1200 micrometers.

68. A film according to any one of claims 1 to 67, wherein the film has a dissolution time of about 15 seconds to 180 seconds

69. A film according to any one of claims 1 to 68, wherein the film has a mucoadhesion force at or above 1000g.

70. A film according to any one of claims 1 to 69, wherein the film has a mucoadhesion force of about 1000g to about 2000g.

71. A process for preparing a film product, wherein dexmedetomidine or a pharmaceutically acceptable salt thereof is present on the film surface, comprising the steps of (1) preparing a dried polymer film substrate which does not include dexmedetomidine or a pharmaceutically acceptable salt thereof (2) depositing a solution or suspension composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof onto the substrate surface and (3) drying the resulting film product.

72. A process according to claim 71, wherein step (1) comprises:

(i) preparing a mixture comprising one or more water-soluble polymers in a liquid carrier, optionally together with one or more pharmaceutically acceptable carriers;

(ii) dispersing or casting the mixture formed in step (i) onto a substrate to form a film substrate; and

(iii) drying the film substrate produced in step (ii) to remove at least a portion of the liquid carrier.

73. A process according to claim 72, wherein in step (i) the mixture comprises a colorant.

74. A process according to claim 71, wherein step (2) comprises:

(i) preparing a composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof in a liquid carrier, optionally together with one or more water-soluble polymers and/or one or more pharmaceutically acceptable carriers; and

(ii) depositing, as one or more droplets, the solution or suspension composition formed in step (i) onto the dried film substrate.

75. A process according to claim 74, wherein in step (i) the composition comprises a colorant which is different from the colorant used in the film substrate.

76. A dexmedetomidine composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof, a low molecular weight, water-soluble polymer and a liquid carrier.

77. A dexmedetomidine composition according to claim 76, wherein the low molecular weight, water-soluble polymer has a molecular weight of less than about 60,000 daltons.

78. A dexmedetomidine composition according to claim 76, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 5,000 daltons to about 49,000 daltons.

79. A dexmedetomidine composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof, one or more high molecular weight, water-soluble polymers and a liquid carrier.

80. A dexmedetomidine composition according to any one of claims 76 to 78, wherein the composition also comprises one or more high molecular weight, water-soluble polymers.

81. A dexmedetomidine composition according to claim 79 or claim 80, wherein each high molecular weight, water-soluble polymer has a molecular weight of greater than about 60,000 daltons.

82. A dexmedetomidine composition according to claim 79 or claim 80, wherein the composition comprises one high molecular weight, water-soluble polymer having a molecular weight from about 90,000 daltons to about 200,000 daltons.

83, A dexmedetomidine composition according to claim 79 or claim 80, wherein the composition comprises two high molecular weight, water-soluble polymers, one having a molecular weight from about 90,000 daltons to about 200,000 daltons and the other having a molecular weight from about 200,000 daltons to about 500,000 daltons.

84. A dexmedetomidine composition according to claim 83, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 40,000 daltons, one of the two high molecular weight, water-soluble polymers has a molecular weight of about 140,000 daltons, and the other high molecular weight, water-soluble polymer has a molecular weight of about 370,000 daltons.

85. A dexmedetomidine composition according to claim 82, wherein the low molecular weight, water-soluble polymer has a molecular weight of about 40,000 daltons, and the

high molecular weight, water-soluble polymer has a molecular weight of about 140,000 daltons.

86. A dexmedetomidine composition according to any one of claims 76 to 85, wherein each water-soluble polymer is independently selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl cellulose, carboxymethyl cellulose, and methyl cellulose.

87. A dexmedetomidine composition according to claim 86, wherein each water-soluble polymer is hydroxypropyl cellulose.

88. A dexmedetomidine composition according to any one of claims 76 to 87, also comprising a polyalcohol.

89. A dexmedetomidine composition according to claim 88, wherein the polyalcohol is a polyethylene oxide.

90. A dexmedetomidine composition according to claim 89, wherein the polyethylene oxide is a water-soluble, high molecular weight polymer.

91. A dexmedetomidine composition according to claim 90, wherein the polyethylene oxide has a molecular weight from about 100,000 daltons to about 1,500,000 daltons.

92. A dexmedetomidine composition according to claim 90, wherein the polyethylene oxide has a molecular weight of about 100,000, 200,000, 300,000, 600,000, 900,000 or 1,000,000 daltons.

93. A dexmedetomidine composition according to claim 90, wherein the polyethylene oxide has a molecular weight of about 600,000 daltons.

94. A dexmedetomidine composition according to any one of claims 76 to 93, wherein the composition has a viscosity in the range of about 6 cps to about 20 cps at 25°C and a shear rate of about 7 (1/s).

95. A dexmedetomidine composition according to any one of claims 76 to 94, wherein the liquid carrier is ethanol.

~~96. A dexmedetomidine composition according to any one of claims 76 to 95, wherein dexmedetomidine or a pharmaceutically acceptable salt thereof is present at about 15% to about 25% w/w of the dexmedetomidine composition.~~

~~97. A dexmedetomidine composition according to any one of claims 76 to 96, also comprising a colorant.~~

~~98. A film according to any one of claims 36 to 55, wherein a composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof covers the whole surface of the film substrate.~~

~~99. A film according to any one of claims 36 to 55, wherein a composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof covers a portion of the surface of the film substrate.~~

~~1004~~. A ~~film comprising~~

~~(a) a~~ composition comprising:

(~~i~~a) dexmedetomidine hydrochloride; and further comprising

~~(ii) hydroxypropyl cellulose (40,000MW); and~~

~~(iii) hydroxypropyl cellulose (140,000MW); and~~

(b) a film substrate comprising:

(i) hydroxypropyl cellulose having a molecular weight of about ~~(~~40,000~~MW)~~ daltons in an amount of about 3% to about 15% w/w of the total composition weight;

(ii) hydroxypropyl cellulose having a molecular weight of about ~~(~~140,000~~MW)~~ daltons in an amount of about 3% to about 8% w/w of the total composition weight;

(iii) hydroxypropyl cellulose having a molecular weight of about ~~(~~370,000~~MW)~~ daltons in an amount of about 10% to about 50% w/w of the total composition weight; and

(iv) polyethylene oxide having a molecular weight of about ~~(~~600,000~~MW)~~ daltons in an amount of about 40% to about 70% w/w of the total composition weight~~;~~

~~wherein the composition of part (a) is present on the surface of the film substrate (b)~~.

~~101. A film according to any one of claims 36 to 55, or claims 98 to 100, wherein the composition on the surface of the film substrate constitutes about 0.1% to about 10% w/w of the total film weight.~~

~~1025~~. ~~A film~~ The composition according to ~~any one of claims 1 to 70, or claims 98 to 101~~claim 4, wherein dexmedetomidine ~~is present as the~~ hydrochloride ~~salt, and~~ is present at about 0.05% to about 3% w/w of the total ~~film~~ composition weight.

~~103. A film according to any one of claims 1 to 70, or claims 98 to 102, wherein hydroxypropyl cellulose is present as a low molecular weight, water-soluble polymer, and is present at about 5% to about 8% w/w of the total film weight.~~

~~104. A film according to any one of claims 1 to 70, or claims 98 to 103, wherein hydroxypropyl cellulose is present as one or more high molecular weight, water-soluble polymers, and is present at about 25% to about 40% w/w of the total film weight.~~

~~105. A film according to any one of claims 1 to 70, or claims 98 to 104, wherein a polyethylene oxide is present, and is present at about 50% to about 60% w/w of the total film weight.~~

~~106. A film suitable for sublingual administration, comprising~~

~~(a) a composition comprising:~~

~~(i) dexmedetomidine hydrochloride present at about 9% to about 50% w/w of the deposit composition;~~

~~(ii) hydroxypropyl cellulose (40,000MW) present at about 5% to about 85% w/w of the deposit composition;~~

~~(iii) hydroxypropyl cellulose (140,000MW) present at about 5% to 85% w/w of the deposit composition; and~~

~~(iv) hydroxypropyl cellulose (370,000MW) present at about 0% to about 65% w/w of the deposit composition; and~~

~~(b) a film substrate comprising:~~

~~(i) hydroxypropyl cellulose (40,000MW) present at about 3% to about 40% w/w of the polymer matrix;~~

~~(ii) hydroxypropyl cellulose (140,000MW) present at about 3% to about 40% w/w of the polymer matrix;~~

~~(iii) hydroxypropyl cellulose (370,000MW) present at about 0% to about 30% w/w of the polymer matrix, and~~

~~(iv) polyethylene oxide (600,000MW) present at about 55% to about 75% w/w of polymer matrix;~~

~~wherein the composition of part (a) is present on the surface of the film substrate (b).~~

~~107. A film comprising~~

~~(a) a composition consisting essentially of:~~

~~(i) dexmedetomidine hydrochloride;~~

~~(ii) hydroxypropyl cellulose (40,000MW); and~~

~~(iii) hydroxypropyl cellulose (140,000MW); and~~

~~(b) a film substrate consisting essentially of:~~

~~(i) hydroxypropyl cellulose (40,000MW);~~

~~(ii) hydroxypropyl cellulose (140,000MW);~~

~~(iii) hydroxypropyl cellulose (370,000MW); and~~

~~(iv) polyethylene oxide (600,000MW);~~

~~wherein the composition of part (a) is present on the surface of the film substrate (b).~~

~~108. A film according to claim 107, wherein the composition of part (a) also comprises a colorant and the film substrate of part (b) also comprises a colorant, wherein the colorant in part (a) is a different color from the colorant in part (b).~~

~~109. A film according to claim 108, wherein the colorant in part (a) is blue and the colorant in part (b) is green~~

~~110. A film according to any one of claims 107 to 109, also comprising, within part (b), a flavouring agent and a sweetener~~

~~1116~~. ~~A film~~ The composition according to claim ~~100~~ 4~~or any one of claims 107 to 110~~, wherein dexmedetomidine hydrochloride is present at about 0.1% to about 0.2% w/w of the total ~~film~~ composition weight, hydroxypropyl cellulose ~~(~~having a molecular weight of about 40,000~~MW)~~ daltons is present at about 45% ~~to about 6%~~ w/w of the total ~~film~~ composition weight~~,~~ and hydroxypropyl cellulose ~~(~~having a molecular weight of about 140,000~~MW)~~ daltons is present at about 45% ~~to about 6%~~ w/w of the total ~~film~~ composition weight~~, hydroxypropyl cellulose (370,000MW) is present at about 27% to~~

~~about 30% w/w of the total film weight, and polyethylene oxide (600,000MW) is present at about 55% to about 60% w/w of the total film weight~~.

7. The composition according to claim 4, wherein the composition comprises one or more colorants.

8. The composition according to claim 2, wherein the film has a thickness of about 20 micrometers to about 200 micrometers.

9. The composition according to claim 2, wherein the film has a thickness of about 20 micrometers to about 200 micrometers and covers an area (widthxlength) of about 100mm^2 to about 300mm^2.

10. The composition according to claim 2, wherein the film has a disintegration time of about 60 seconds to about 180 seconds.

11. The composition according to claim 2, wherein the film has a mucoadhesion force of about 1000g to about 200g.

~~1112~~12. ~~A film~~ The composition according to claim ~~1114~~, ~~containing about 10 micrograms of~~ wherein said dexmedetomidine hydrochloride is present in an amount of about 10 micrograms.

~~1113~~13. ~~A film~~ The composition according to claim ~~1114~~, wherein said ~~containing about 20 micrograms of~~ dexmedetomidine hydrochloride is present in an amount of about 20 micrograms.

~~1114~~14. ~~A film~~ The composition according to claim ~~1114~~, ~~containing about 40 micrograms of~~ wherein said dexmedetomidine hydrochloride is present in an amount of about 30 micrograms.

~~1115~~15. ~~A film~~ The composition according to claim ~~1114~~, ~~containing about 60 micrograms of~~ wherein said dexmedetomidine hydrochloride is present in an amount of about 40 micrograms.

~~1116~~16. ~~A film~~ The composition according to claim ~~1114~~, ~~containing about 80 micrograms of~~ wherein said dexmedetomidine hydrochloride is present in an amount of about 60 micrograms.

17. The composition according to claim 2, wherein the film is completely dissolvable in oral mucosal fluid in about 1 minute to about 5 minutes.

~~1171~~18. ~~A film~~ The composition according to claim ~~1114~~, ~~containing about 100 micrograms of~~ wherein said dexmedetomidine hydrochloride is present in an amount of about 90 micrograms.

19. The composition according to claim 4, wherein said dexmedetomidine hydrochloride is present in an amount of about 120 micrograms.

20. The composition according to claim 4, wherein said composition is administered in one or more units to provide a total daily dose of dexmedetomidine hydrochloride of about 120 micrograms.

21. The composition according to claim 4, wherein said composition is administered in one or more units to provide a total daily dose of dexmedetomidine hydrochloride of about 180 micrograms.

22. The composition according to claim 3, wherein said film is administered in one or more units to provide a total daily dose of dexmedetomidine or a pharmaceutically acceptable salt thereof of about 120 micrograms.

23. The composition according to claim 3, wherein said film is administered in one or more units to provide a total daily dose of dexmedetomidine or a pharmaceutically acceptable salt thereof of about 180 micrograms.

~~118. A self-supporting, dissolvable, film containing about 10 micrograms of dexmedetomidine hydrochloride, wherein application of the film on the human sublingual mucosa results in absorption levels from about 80% to about 125% of the following values: C_{max} from about 18 ng/L to about 38 ng/L and AUC from about 49 hr*pg/L to about 179 hr*pg/L.~~

~~119. A self-supporting, dissolvable, film containing about 20 micrograms of dexmedetomidine hydrochloride, wherein application of the film on the human sublingual mucosa results in absorption levels from about 80% to about 125% of the~~

~~following values: C_{max} from about 42 ng/L to about 86 ng/L and AUC from about 198 hr*pg/L to about 401 hr*pg/L.~~

~~120. A self-supporting, dissolvable, film containing about 40 micrograms of dexmedetomidine hydrochloride, wherein application of the film on the human sublingual mucosa results in absorption levels from about 80% to about 125% of the following values: C_{max} from about 78 ng/L to about 204 ng/L and AUC from about 292 hr*pg/L to about 778 hr*pg/L.~~