

Claims

1. A pharmaceutically-acceptable composition, which composition is in the form of a spray-dried powder comprising a mixture of:
 - 5 (a) a pharmacologically-effective dosage amount of at least one pharmaceutically-active compound; and
 - (b) a pharmaceutically-acceptable carrier material, which carrier material comprises a combination of a disaccharide and a polymeric material.
- 10 2. A composition as claimed in Claim 1, wherein the polymeric material comprises a dextrin and/or hydroxypropylmethyl cellulose.
3. A composition as claimed in Claim 1 or Claim 2, wherein the disaccharide is selected from the group consisting of maltitol, trehalose, sucralose, sucrose, isomalt,
15 maltose and lactose.
4. A composition as claimed in Claim 3, wherein the disaccharide comprises lactose and/or trehalose.
- 20 5. A composition as claimed in any one of Claims 2 to 4, wherein the dextrin comprises a cyclodextrin or a maltodextrin.
6. A composition as claimed in any one of the preceding claims, wherein the carrier materials comprises a combination of α -D-lactose monohydrate and hydroxypropyl- β -cyclodextrin or α -D-lactose monohydrate and maltodextrin 12DE.
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7. A composition as claimed in any one of the preceding claims, wherein the ratio of disaccharide:polymer by weight, based on the total weight of the composition, is in the range of about 2:1 and about 1:10.
- 30 8. A composition as claimed in any one of Claims 2 to 7, wherein the ratio of disaccharide:polymer by weight, based on the total weight of the composition, is in the range of about 1:1 to about 1:8.
- 35 9. A composition as claimed in any one of the preceding claims, wherein the lowest measurable glass transition temperature of the composition is at least about 40°C when measured at a relative humidity of up to about 35%.

10. A composition as claimed in any one of the preceding claims, wherein the composition further comprises a sucrose ester.
11. A composition as claimed in Claim 10, wherein the sucrose ester comprises sucrose monolaurate.
12. A composition as claimed in any one of the preceding claims which is suitable and/or adapted for nasal or sublingual delivery.
13. A composition as claimed in Claim 12, wherein the composition is in the form of a sublingual tablet.
14. A composition as claimed in Claim 12 or Claim 13 wherein the pharmacologically-effective dosage amount of the at least one pharmaceutically-active compound is no more than about 100 mg.
15. A composition as claimed in any one of Claims 12 to 14, wherein the particle size distribution includes a D10 that is above about 3 μm .
16. A composition as claimed in any one of Claims 12 to 15, wherein the powder has a particle size distribution that includes a volume-based mean diameter within the range of about 10 μm and about 100 μm .
17. A composition as claimed in any one of the preceding claims, wherein the active ingredient is an antipsychotic drug.
18. A composition as claimed in Claim 17, wherein the antipsychotic drug is loxapine, olanzapine, aripiprazole, haloperidol, ziprasidone or asenapine.
19. A composition as claimed in any one of Claims 1 to 16, wherein the active ingredient is a peptide.
20. A composition as claimed in Claim 19, wherein the peptide is desmopressin.
21. A composition as claimed in any one of Claims 1 to 16, wherein the active ingredient is an antidepressant, a general anaesthetic and/or a sedative.
22. A composition as claimed in Claim 21, wherein the antidepressant, general anaesthetic or sedative is brexanolone, ketamine or eskatamine.

23. A composition as claimed in any one of Claims 1 to 16, wherein the active ingredient is a modulator of a neurotransmitter receptor.
- 5 24. A composition as claimed in Claim 23, wherein the neurotransmitter receptor is an adrenergic receptor.
25. A composition as claimed in Claim 24, wherein the active ingredient is epinephrine.
- 10 26. A composition as claimed in Claim 23, wherein the neurotransmitter receptor is a dopaminergic receptor.
27. A composition as claimed in Claim 26, wherein the active ingredient is apomorphine.
- 15 28. A composition as claimed in Claim 23, wherein the neurotransmitter receptor is a serotonergic receptor.
29. A composition as claimed in Claim 28, wherein the active ingredient is a triptan.
- 20 30. A composition as claimed in any one of Claims 1 to 16, wherein the active ingredient is a non-steroidal antiinflammatory drug.
31. A composition as claimed in any one of Claims 1 to 16, wherein the active ingredient is a platelet inhibitor.
- 25 32. A composition as claimed in any one of the preceding claims having a molecular structure that includes at least one amine moiety.
- 30 33. A composition as claimed in Claim 30 or Claim 31 (as appropriate), wherein the active ingredient is ketorolac or aspirin.
34. A process for the manufacturing of a composition as defined in any one of the preceding claims, wherein said process comprises the steps of:
- 35 (i) mixing together the one or more active ingredients and pharmaceutically-acceptable carrier materials, in an appropriate volatile solvent,
- (ii) spray-drying the mixture from step i).
35. A composition obtainable by a process as defined in Claim 34.

36. A nasal applicator device suitable and/or adapted for delivery of a composition as defined in any one of Claims 12 to 33 or 35 to the nose, which comprises, or is adjunct and/or attached to, a reservoir, within which reservoir said composition is contained.
37. A process for the manufacturing of an applicator device as claimed in Claim 36, which comprises a process as claimed in Claim 34 followed by loading the composition so formed into a reservoir within, or adjunct or attached to, said applicator device.
38. A composition as defined in any one of Claims 1 to 33 or 35 for use in the treatment of a condition for which the at least one pharmaceutically-active compound that is/are included therein is/are useful for.
39. The use of a composition as defined in any one of Claims 1 to 33 or 35 for the manufacture of a medicament for the treatment of a condition for which the at least one pharmaceutically-active compound that is/are included therein is/are useful for.
40. A method of treatment of a condition for which the at least one pharmaceutically-active compound that is/are included within composition as defined in any one of Claims 1 to 33 or 35 is/are useful for, which method comprises the administration of a composition of the invention to patient suffering from, or susceptible to, said condition.
41. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a method as claimed in Claim 40, wherein the active ingredient is as defined in Claim 17 or Claim 32 (as dependent on Claim 17), and the condition is a psychotic disorder.
42. A composition for use, a use, or a method as claimed in Claim 41, wherein the active ingredient is loxapine and the condition is schizophrenia and/or schizoaffective disorder.
43. A composition for use, a use, or a method as claimed in Claim 41, wherein the active ingredient is olanzapine and the condition is attention deficit hyperactivity disorder.

44. A composition for use, a use, or a method as claimed in Claim 41, wherein the active ingredient is as defined in Claim 18 and the condition is agitation associated with schizophrenia and/or bipolar disorder.
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45. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a method as claimed in Claim 40, wherein the active ingredient is as defined in Claim 20 and the condition is a urinary disorder.
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46. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a method as claimed in Claim 40, wherein the active ingredient is as defined in Claim 21, Claim 22 or Claim 32 (as dependent on Claim 21 or Claim 22), and the condition requires anaesthesia and/or sedation.
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47. A composition for use, a use, or a method as claimed in Claim 46, wherein the condition is an anxiety-related disorder.
48. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a method as claimed in Claim 40, wherein the active ingredient is as defined in Claim 22 and the condition is depression.
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49. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a method as claimed in Claim 40, wherein the active ingredient is as defined in any one of Claims 23 to 25 or Claim 32 (as dependent on any one of Claims 23 to 25) and the condition is an allergic reaction.
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50. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a method as claimed in Claim 40, wherein the active ingredient is as defined in any one of Claims 23, 26, 27 or 32 (as dependent on any one of Claims 23, 26 or 27) and the condition is control of motor fluctuations in a Parkinson's patient.
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51. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a method as claimed in Claim 40, wherein the active ingredient is as defined in any one of Claims 23, 28, 29 or 32 (as dependent on any one of Claims 23, 28 or 29) and the condition is migraine.
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52. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a method as claimed in Claim 40, wherein the active ingredient is as defined in any

one of Claims 21, 22, 30, 32 (as dependent on any one of Claims 21, 22 or 30), or Claim 33, and the condition is pain.

53. A composition for use as claimed in Claim 38, a use as claimed in Claim 39, or a
5 method as claimed in Claim 40, wherein the active ingredient is as defined in Claim 31 or Claim 32 (as dependent on Claim 31), or Claim 33, and the condition is characterised by a blood clot.

54. A composition for use, as use, or a method, as claimed in Claim 53, wherein the
10 active ingredient is aspirin and the condition is a stroke, a transient ischemic attack, a cardiac arrest, a deep vein thrombosis or a pulmonary embolism.

55. A composition for use, as use, or a method, as claimed in any one of Claims 38 to
15 54 (as appropriate), wherein the composition is administered to the nose by way of an applicator as defined in Claim 36.