

Claims

1. A solid pharmaceutical composition that is suitable for nasal delivery of an opioid antagonist, comprising a pharmacologically-effective amount of an opioid antagonist, an alkyl saccharide and a pharmaceutically-acceptable carrier material.
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2. A composition as claimed in Claim 1 which is in the form of a dry powder.
3. A composition as claimed in Claim 2, wherein the particle size distribution includes a d₁₀ that is above about 3 µm.
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4. A composition as claimed in Claim 2 or Claim 3, 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.
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5. A composition as claimed in any one of the preceding claims, wherein the opioid antagonist is naloxone, nalmeferene or naltrexone.
6. A composition as claimed in Claim 5, wherein the opioid antagonist is naloxone.
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7. A composition as claimed in Claim 5, wherein the opioid antagonist is nalmeferene.
8. A composition as claimed in any one of the preceding claims, wherein the carrier material comprises a low molecular weight saccharide.
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9. A composition as claimed in Claim 8, wherein the saccharide is a disaccharide.
10. A composition as claimed in any one of the preceding claims, wherein the carrier material comprises a dextrin.
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11. A composition as claimed in any one of the preceding claims, wherein the carrier material comprises a combination of a disaccharide and a dextrin.
12. A solid pharmaceutical composition in the form of a spray-dried powder that is suitable for nasal delivery of an opioid antagonist, comprising a pharmacologically-effective amount of an opioid antagonist and a pharmaceutically-acceptable carrier material as defined in Claim 11.
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13. A composition as claimed in Claim 12, wherein the powder has a particle size distribution as defined in Claim 3 or Claim 4.
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14. A composition as claimed in Claim 12 or Claim 13, wherein the opioid antagonist is as defined in any one of Claims 5 to 7.
15. A composition as claimed in Claim 1 to 11, or a composition as claimed in any one of Claims 12 to 14 but which further includes an alkyl saccharide, wherein the alkyl saccharide comprises a sucrose ester.
16. A composition as claimed in Claim 15 wherein the sucrose ester comprises sucrose monolaurate.
17. A composition as claimed in any one of Claims 9 to 16 wherein the disaccharide is selected from the group consisting of maltitol, trehalose, sucralose, sucrose, isomalt, maltose and lactose.
18. A composition as claimed in Claim 17 wherein the disaccharide comprises lactose and/or trehalose.
19. A composition as claimed in any one of Claims 10 to 18, wherein the dextrin comprises a cyclodextrin or a maltodextrin.
20. A composition as claimed in any one of Claims 9 to 19, which comprises one or more of α -D-lactose monohydrate, 2-hydroxypropyl- β -cyclodextrin and/or maltodextrin 12DE.
21. A composition as claimed in any one of Claims 11 to 20, wherein the disaccharide is present in an amount of between about 15% and about 25% by weight based on the total weight of the composition.
22. A composition as claimed in any one of Claims 11 to 21, wherein the dextrin is present in an amount of between 40% and about 70% by weight based on the total weight of the composition.
23. 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%.
24. A process for the manufacturing of a composition as defined in any one of Claims 2 to 23, wherein said process comprises the steps of:
- mixing together the opioid antagonist and the pharmaceutically-acceptable carrier material and, if present, the alkyl saccharide in an appropriate volatile solvent; and

- ii) spray-drying the mixture from step i) to form a spray-dried plurality of particles.

25. A composition obtainable by a process as defined in Claim 24.

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26. A nasal applicator device suitable and/or adapted for delivery of a composition as defined in any one of Claims 2 to 23 or 25 to the nose, which comprises, or is adjunct and/or attached to, a reservoir, within which reservoir said composition is contained.

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27. A process for the manufacturing of an applicator device as claimed in Claim 26, which comprises a process as claimed in Claim 24 followed by loading the composition so formed into a reservoir within or adjunct or attached to said applicator device.

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28. A composition as defined in any one of Claims 1 to 23 or 25 for use in a method of treating opioid overdose.

29. A composition for use as claimed in Claim 28, wherein the composition is administered to the nose by way of an applicator as defined in Claim 26.

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30. The use of a composition as defined in any one of Claims 1 to 23 or 25 for the manufacture of a medicament for a method of treating opioid overdose.

31. The use as claimed in Claim 30, wherein the composition is administered to the nose by way of an applicator as defined in Claim 26.

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32. A method of treating opioid overdose, which method comprises administering a composition as defined in any one of Claims 1 to 23 or 25 to a subject in need of such treatment.

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33. A method as claimed in Claim 32, wherein the composition is administered to said subject by way of an applicator as defined in Claim 26.