Claims

1. A pharmaceutically-acceptable composition in the form of a solid, amorphous, mono-particulate powder, the particles of which powder comprise a composite mixture of:
   (a) a pharmacologically-effective dosage amount of epinephrine or a pharmaceutically-acceptable salt thereof; and
   (b) a pharmaceutically-acceptable carrier material, which carrier material comprises a maltodextrin,
   wherein, when about 100 mg of said solid composition is dissolved in about 5 mL of deionized water at 25°C, it exhibits a pH of between about 4.5 and about 8.0.

2. The composition as claimed in Claim 1, wherein the pH range is between about 4.5 and about 6.0, or about 4.5 and about 5.5.

3. The composition as claimed in Claim 1 or Claim 2, wherein the carrier material further comprises a disaccharide, selected from the group consisting of maltitol, trehalose, sucralose, sucrose, isomalt, maltose and lactose.

4. The composition as claimed in Claim 3, wherein the disaccharide comprises lactose and/or trehalose.

5. The composition as claimed in any one of the preceding claims, wherein the carrier material comprises a maltodextrin with a dextrose equivalent (DE) that is above 15.

6. The composition as claimed in any one of the preceding claims, wherein the carrier material comprises a maltodextrin with a DE of 19.

7. The composition as claimed in any one of the preceding claims, wherein the carrier material comprises a combination of trehalose and a maltodextrin with a DE of 19.

8. The composition as claimed in any one of Claims 3 to 7, wherein the ratio of disaccharide:maltodextrin by weight is in the range of about 10:1 to about 1:20.

9. The composition as claimed in Claim 8, wherein the ratio is in the range of about 2:1 to about 1:8.

10. The composition as claimed in any one of the preceding claims, wherein the lowest measurable glass transition temperature of the composition is at least about 35ºC when measured at a relative humidity of up to about 35%.

11. The composition as claimed in any one of the preceding claims, wherein the composition further comprises a sucrose ester.

12. The composition as claimed in Claim 11, wherein the sucrose ester comprises sucrose monolaurate.

13. The composition as claimed in any one of the preceding claims which is suitable and/or adapted for nasal delivery.

14. A composition as claimed in Claim 13, wherein the powder has a particle size distribution by volume that includes a D10 that is above about 5 μm.

15. The composition as claimed in Claim 13 or Claim 14, 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.

16. The composition as claimed in any one of Claims 13 to 15, wherein the particle size distribution of said powder by volume includes a D10 above about 10 μm.

17. The composition as claimed in any one of Claims 13 to 16, wherein the particle size distribution of said powder by volume includes a D90 below about 200 μm.

18. The composition as claimed in Claim 17, wherein the particles of said powder by volume have a D90 below about 100 μm.

19. The composition as claimed in any of the preceding claims, wherein the pharmacologically-effective dosage amount of epinephrine is between about 0.1 mg and about 10 mg (calculated as the free base).

20. The composition as claimed in Claim 19, wherein the dosage amount is between about 0.5 mg and about 3 mg (calculated as the free base).

21. The composition as claimed in any one of the preceding claims, wherein the composition consists essentially of epinephrine or pharmaceutically-acceptable salt thereof as the active ingredient.

22. The composition as claimed in any one of the preceding claims, wherein the composition is essentially free of antioxidants, preservatives and chelating agents.

23. A process for the manufacturing of a composition as defined in any one of the preceding claims, wherein said process comprises the steps of:
    i) dissolving and/or mixing the epinephrine or pharmaceutically-acceptable salt thereof in an appropriate volatile aqueous solvent,
    ii) adjusting the pH of the resultant solution such that it is between about 4 and about 8, and/or is within the range as defined in Claim 1 or Claim 2,
    iii) adding the pharmaceutically-acceptable carrier material, and
    iv) spray-drying the mixture from step iii).

24. A composition obtainable by a process as defined in Claim 23.

25. A nasal applicator device suitable and/or adapted for delivery of a composition as defined in any one of Claims 1 to 22 or 24 to the nose, which comprises, or is adjunct and/or attached to, a reservoir, within which reservoir said composition is contained.

26. The nasal applicator as claimed in Claim 25, which is configured such that said device, upon actuation, is capable of depositing said pharmacologically-effective dosage amount of epinephrine, or salt thereof, to the nasal mucosa.

27. A process for the manufacturing of an applicator device as claimed in Claims 25 or Claim 26, which comprises a process as claimed in Claim 23, followed by loading the composition so formed into a reservoir within, or adjunct or attached to, said applicator device.

28. A container that substantially prevents ingress of atmospheric water by comprising thermoformed plastics and/or molecular sieves with a pore size of 3Å or 4Å, which container contains a nasal applicator device as defined in Claim 25 or Claim 26.

29. The container as claimed in Claim 28, which comprises a material selected from the group: heat-sealed aluminium pouches and thermoformed plastics and/or a desiccant selected from the group: silica gel and molecular sieves with a pore size of 3Å or 4Å.

30. A composition as defined in any one of Claims 1 to 22 or 24 for use in the treatment of an allergic reaction.

31. A use of a composition as defined in any one of Claims 1 to 22 or 24 for the manufacture of a medicament for the treatment of an allergic reaction.

32. A composition for use as claimed in Claim 30 or a use as claimed in Claim 31, wherein the allergic reaction is to an insect sting or bite, a foodstuff or a drug and/or another chemical substance.

33. A composition for use, or a use, as claimed in Claim 32, wherein the reaction comprises anaphylaxis.

34. A composition for use or a use, as claimed in Claim 32 or Claim 33, wherein the composition is administered to the nose by way of an applicator as defined in Claim 25 or Claim 26.