Claims

1. A pharmaceutically-acceptable composition in the form of a solid, amorphous, mono-particulate powder comprising a mixture of:

(a) a pharmacologically-effective dosage amount of epinephrine (adrenaline), or a pharmaceutically-acceptable salt thereof; and

(b) a pharmaceutically-acceptable carrier material, which carrier material comprises a maltodextrin with a dextrose equivalent (DE) that is above 15.

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

3. A composition as claimed in Claim 2, wherein the disaccharide comprises lactose and/or trehalose.

4. A composition as claimed in Claim 2 or Claim 3, wherein the carrier material comprises a combination of trehalose and maltodextrin 19DE.

5. A composition as claimed in any one of Claims 2 to 4, wherein the ratio of disaccharide:maltodextrin by weight is in the range of 10:1 (±10%) to 1:20 (±10%).

6. A composition as claimed in Claim 5, wherein the ratio of disaccharide:maltodextrin by weight is in the range of 3:1 (±10%) to 1:8 (±10%).

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

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

9. A composition as claimed in Claim 8, wherein the sucrose ester comprises sucrose monolaurate.

10. The composition as claimed in Claim 9, wherein the composition comprises 0.75% (±10%) to 3% (±10%) by weight of sucrose monolaurate.

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

12. A composition as claimed in Claim 11, wherein the powder has a particle size distribution that includes:

(a) a D10 that is above 3 μm (±10%);

(b) a volume-based mean diameter within the range of 10 μm (±10%) and 100 μm (±10%); and/or

(c) a D90 below 100 μm (±10%).

13. A composition as claimed in any one of the preceding claims, wherein the pharmacologically-effective dosage amount of epinephrine or a pharmaceutically-acceptable salt thereof is between 0.1 mg (±10%) and 10 mg (±10%) (calculated as the free base).

14. A composition as claimed in Claim 13, wherein the pharmacologically-effective dosage amount is between 0.5 mg (±10%) and 3 mg (±10%) (calculated as the free base).

15. A composition as claimed in Claim 14, wherein the composition consists essentially of the pharmacologically-effective dosage amount of epinephrine or pharmaceutically-acceptable salt thereof.

16. A composition as claimed in any one of the preceding claims, wherein the composition is essentially free of water.

17. A composition as claimed in Claim 16, wherein the composition comprises less than 5% (±10%) of water.

18. A pharmaceutically-acceptable composition in the form of an amorphous spray-dried powder, comprising a mixture of:

(a) 0.5 mg (±10%) to 3 mg (±10%) (calculated as the free base) of epinephrine (adrenaline) or a pharmaceutically-acceptable salt thereof;

(b) a pharmaceutically-acceptable carrier material, which carrier material comprises a combination of trehalose and maltodextrin 19DE, in a ratio of between 3:1 (±10%) and 1:3 (±10%) by weight;

(c) 0.75% (±10%) to 3% (±10%) by weight of sucrose monolaurate; and

(d) less than 5% (±10%) of water; and

wherein the particle size distribution of the powder comprises a D10 above 10 μm (±10%) and a D90 below 100 μm (±10%).

19. A nasal applicator device suitable and/or adapted for delivery of a composition as defined in any one of the preceding claims to the nose, which comprises, or is adjunct and/or attached to, a reservoir, within which reservoir said composition is contained, and which applicator device is configured such that said device, upon actuation, is capable of depositing said pharmaceutically-effective dosage amount of epinephrine (adrenaline), or salt thereof, to the nasal mucosa.

20. A nasal applicator device suitable and/or adapted for delivery of a pharmaceutically-acceptable composition to the nose, which composition is in the form of a spray-dried powder with a particle size distribution that comprises a D10 above 10 μm (±10%) and a D90 below 100 μm (±10%), which composition comprises a mixture of:

(a) 0.5 mg (±10%) to 3 mg (±10%) (calculated as the free base) of epinephrine (adrenaline), or a pharmaceutically-acceptable salt thereof;

(b) a pharmaceutically-acceptable carrier material, which carrier material comprises a combination of trehalose and maltodextrin 19DE, in a ratio of between 3:1 (±10%) and 1:3 (±10%) by weight;

(c) 0.75% (±10%) to 3% (±10%) by weight of sucrose monolaurate; and

(d) less than 5% (±10%) of water; and

which nasal applicator device:

(i) comprises, or is adjunct and/or attached to, a reservoir, within which reservoir said composition is contained; and

(ii) is configured such that said device, upon actuation, is capable of depositing an effective dose of epinephrine, or salt thereof, to the nasal mucosa.

21. The nasal applicator device as claimed in Claim 19 or 20, which is packaged within a container that substantially prevents the ingress of atmospheric water.

22. A nasal applicator device as claimed in Claim 21, wherein the container 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.

23. 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 claimed in Claim 19 or 20.

24. A composition as defined in any one of Claims 1 to 18 for use in the treatment of an allergic reaction.

25. The use of a composition as defined in any one of Claims 1 to 18 for the manufacture of a medicament for the treatment of an allergic reaction.

26. The composition for use as claimed in Claim 24, or the use as claimed in Claim 25, wherein the reaction comprises anaphylaxis.

27. The composition for use, or the use as claimed in Claim 26, wherein the reaction is to an insect sting or bite, a foodstuff or a drug and/or another chemical substance.

28. A composition for use, or a use as claimed in Claim 26, wherein the anaphylaxis is idiopathic anaphylaxis or exercise-induced anaphylaxis.