Claims

1. A pharmaceutically-acceptable composition, which composition is in the form of an amorphous powder comprising a 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 combination of a disaccharide and a polymeric material,
   wherein the particles of the powder comprise an amorphous composite of epinephrine or salt thereof and the carrier material.

2. A composition as claimed in Claim 1, wherein:
   (a) the polymeric material comprises a dextrin and/or hydroxypropylmethyl cellulose; and/or
   (b) the disaccharide is selected from the group consisting of maltitol, trehalose, sucralose, sucrose, isomalt, maltose and lactose.

3. A composition as claimed in Claim 2, wherein:
   (a) the disaccharide comprises lactose and/or trehalose; and/or
   (b) the dextrin comprises a cyclodextrin or a maltodextrin.

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

5. A composition as claimed in any one of the preceding claims, wherein the ratio of disaccharide:polymer by weight is in the range of 10:1 (±10%) and 1:20 (±10%).

6. A composition as claimed in Claim 5, wherein the ratio of disaccharide:polymer by weight is in the range of 2:1 (±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 40ºC (±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. A composition as claimed in any one of the preceding claims, wherein the pharmacologically-effective dosage amount of epinephrine is between 0.1 mg (±10%) and 5 mg (±10%) (calculated as the free base compound).

11. A composition as claimed in any one of the preceding claims, wherein the epinephrine or pharmaceutically-acceptable salt thereof is the only active ingredient in the composition.

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

13. A composition as claimed in any one of the preceding claims, wherein the particle size distribution includes:
    (a) a D10 that is above 3 μm (±10%); and/or
    (b) a volume-based mean diameter within the range of 10 μm (±10%) and 100 μm (±10%).

14. A composition as claimed in any one of the preceding claims, wherein the particles of said powder have:
    (a) a D10 above 10 μm (±10%); and/or
    (b) a D90 below 500 μm (±10%).

15. A composition as claimed in Claim 14, wherein the particles of said powder have a D90 below 100 μm (±10%).

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

17. 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) mixing together the epinephrine or salt thereof and pharmaceutically-acceptable carrier materials, in an appropriate volatile solvent,
    (ii) spray-drying the mixture from step i).

18. A nasal applicator device suitable and/or adapted for delivery of a composition as defined in any one of Claims 1 to 16 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 an effective dose of epinephrine, or salt thereof, to the nasal mucosa.

19. The nasal applicator device as claimed in Claim 18, which is packaged within a container that substantially prevents the ingress of atmospheric water.

20. The nasal applicator device as claimed in Claim 19, wherein the container comprises a material selected from the group: heat-sealed aluminium pouches and thermoformed plastics.

21. A process for the manufacturing of an applicator device as claimed in Claim 18, which comprises a process as claimed in Claim 17 followed by loading the composition so formed into a reservoir within, or adjunct or attached to, said applicator device.

22. The use of a composition as defined in any one of Claims 1 to 16 for the manufacture of a medicament for the treatment of an allergic reaction.

23. The use as claimed in Claim 22, wherein the allergic reaction is an extreme allergic reaction or comprises anaphylactic shock.

24. The use as claimed in Claim 23, wherein the reaction is to an insect sting, an insect bite, a foodstuff, a drug, or another substance.

25. The use as claimed in Claim 22, wherein the composition is suitable for nasal administration by way of an applicator as defined in Claim 18.