Claims

1. A pharmaceutically-acceptable composition, which composition is in the form of a solid, amorphous mono-particulate powder composition comprising a mixture of:
   (a) a pharmacologically-effective dosage amount of at least one biopharmaceutical drug compound; and
   (b) a pharmaceutically-acceptable carrier material, which carrier material comprises a combination of a disaccharide and a polymeric material.

2. A composition as claimed in Claim 1, wherein the polymeric material comprises a maltodextrin.

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, maltose and lactose.

4. A composition as claimed in Claim 3, wherein the disaccharide comprises a lactose or trehalose.

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

6. 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 10:1 and about 1:10.

7. A composition as claimed in Claim 6, wherein the ratio of disaccharide:polymer is in the range of about 2:1 to about 1:8.

8. 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 10ºC when measured at a relative humidity of up to about 35%.

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

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

11. A composition as claimed in any one of the preceding claims wherein the pharmacologically-effective dosage amount of the at least one biopharmaceutical drug compound is no more than about 100 mg.

12. A composition as claimed in any one of the preceding claims wherein at least one biopharmaceutical drug compound is selected from the group: a protein, as oligopeptide, a polypeptide, an enzyme, an antibody, a vaccine and a nucleotide.

13. A 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 particle size distribution of the powder includes a D10 that is above about 3 μm.

15. A 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. A composition as claimed in any one of Claims 13 to 15, wherein the biopharmaceutical drug compound is a vaccine.

17. A composition as claimed in any one of Claims 1 to 12 which is suitable and/or adapted for peroral delivery.

18. A composition as claimed in Claim 17, wherein the biopharmaceutical drug compound is an enzyme.

19. A composition as claimed in any one of Claims 1 to 12 which is dissolved in a pharmaceutically-acceptable solvent for delivery by injection or by infusion.

20. A composition as claimed in Claim 19, wherein the biopharmaceutical drug compound is an antibody.

21. 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 one or more biopharmaceutical drug compounds and pharmaceutically-acceptable carrier materials, in an appropriate volatile solvent,
    (ii) spray-drying the mixture from step i).

22. A composition obtainable by a process as defined in Claim 21.

23. A nasal applicator device suitable and/or adapted for delivery of a composition as defined in any one of Claims 1 to 16 or 22 to the nose, which comprises, or is adjunct and/or attached to, a reservoir, within which reservoir said composition is contained.

24. A process for the manufacturing of an applicator device as claimed in Claim 23, which comprises a process as claimed in Claim 21 followed by loading the composition so formed into a reservoir within, or adjunct or attached to, said applicator device.

25. A composition as defined in any one of Claims 1 to 20 or 22 for use in the treatment of a condition for which the at least one biopharmaceutical drug compound that is/are included therein is/are useful for.

26. The use of a composition as defined in any one of Claims 1 to 20 or 22 for the manufacture of a medicament for the treatment of a condition for which the at least one biopharmaceutical drug compound that is/are included therein is/are useful for.