Claims

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

(a) a pharmacologically-effective dosage amount of at least one biopharmaceutical drug compound, wherein the at least one biopharmaceutical drug compound comprises one or more vaccines; and

(b) a pharmaceutically-acceptable carrier material, which carrier material comprises a combination of a disaccharide and a polymeric material, wherein the polymeric material comprises a polysaccharide, and the ratio of disaccharide: polymeric material by weight is in the range of about 5:1 to about 1:5.

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

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 lowest measurable glass transition temperature of the composition is at least about 10ºC when measured at a relative humidity of up to about 35%.

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

8. A composition as claimed in Claim 7, wherein the sucrose ester comprises sucrose monolaurate.

9. A composition as claimed in any one of the preceding claims, wherein the composition further comprises an adjuvant.

10. A composition as claimed in any one of the preceding claims, wherein the one or more vaccine is selected from the group consisting of whole-pathogen vaccine, subunit vaccine, nucleic acid vaccine, live-attenuated vaccine, inactivated vaccine, recombinant vaccine, polysaccharide vaccine, conjugate vaccine, toxoid vaccine, viral vector vaccine, messenger RNA (mRNA) vaccine, and combinations thereof.

11. A composition as claimed in Claim 10, wherein the one or more vaccine is:
(a) a live-attenuated vaccine; or
(b) a nucleic acid vaccine, optionally wherein the nucleic acid vaccine is
(i) a DNA vaccine; or
(ii) an RNA vaccine.

12. A composition as claimed in Claim 10, wherein the subunit vaccine is:
(a) a protein subunit vaccine, a recombinant vaccine, a virus like particle (VLP) vaccine, a polysaccharide vaccine or a conjugate vaccine,
optionally wherein:
(i) the VLP is a capsid virus-like particle, or a viral capsid-derived virus-like particle;
(ii) the polysaccharide vaccine is a pneumococcal polysaccharide vaccine, or a meningococcal vaccine; or
(iii) the conjugate vaccine is a pneumococcal conjugate vaccine, a haemophilus influenza type b conjugate, a meningococcal conjugate vaccine or MenACWY;
(b) against hepatitis B, acellular pertussis vaccines influenza, HIV, HPV, malaria, gonorrhoea, polio, Zika, smallpox, monkey pox, a cancer or an acute respiratory disease caused by a virus,
optionally wherein:
(i) the cancer expresses and/or overexpresses HER2 (human epidermal growth factor receptor 2), EGFR (epidermal growth factor receptor), CD-20, VEGF (Vascular endothelial growth factor), VEGFR (Vascular endothelial growth factor receptor), CEA (carcinoembryonic antigen), CA-125 (cancer antigen 125), MUC-1 (mucin 1) or MAGE (melanoma-associated antigen);
(ii) the acute respiratory disease is caused by respiratory syncytial virus (RSV) or a coronavirus; or
(iii) the acute respiratory disease is acute respiratory distress syndrome (ARDS), severe acute respiratory syndrome (SARS) or COVID-19;
(c) a spike protein or part thereof; and/or
(d) produced in an E. coli system, yeast cell system, insect cell system, plant system, or mammalian cell system.

13. A composition as claimed in Claim 1, wherein the one or more vaccine is a nanoparticle-based vaccine, optionally wherein:
(a) the nanoparticle-based vaccine is:
(i) a mesoporous silica nanoparticle (MSN)-based vaccine; or
(ii) a solid lipid nanoparticle (sLNP)-based vaccine,
(b) the nanoparticle-based vaccine also carries and/or delivers proteins or parts thereof, DNA, lipids, polysaccharides, toxins, mRNA, RNA, or virus vaccines.

14. A composition as claimed in Claim 1, wherein the one or more vaccine is a bacterial vector vaccine.

15. A composition as claimed in any one of the preceding claims, wherein the composition is made by a process of spray drying.

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

17. A composition as claimed in Claim 16, wherein the particle size distribution includes a D10 that is above about 3 μm.

18. A composition as claimed in Claim 16 or Claim 17, 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.

19. A composition as claimed in any one of Claims 1 to 15 which is dissolved in a pharmaceutically-acceptable solvent for delivery by injection or by infusion.

20. 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 vaccines and pharmaceutically-acceptable carrier materials, in an appropriate volatile solvent,
(ii) spray-drying the mixture from step (i).

21. A nasal applicator device suitable and/or adapted for delivery of a composition as defined in any one of Claims 1 to 18 to the nose, which comprises, or is adjunct and/or attached to, a reservoir, within which reservoir said composition is contained.

22. A process for the manufacturing of an applicator device as claimed in Claim 21, which comprises a process as claimed in Claim 20 followed by loading the composition so formed into a reservoir within, or adjunct or attached to, said applicator device.

23. A composition as defined in any one of Claims 1 to 19for use in vaccinating against, reducing the risk of, preventing, or combatting a disease, disorder and/or condition.

24. The use of a composition as defined in any one of Claims 1 to 19 for the manufacture of a medicament for vaccinating against, reducing the risk of, preventing, or combatting a disease, disorder and/or condition.

25. The composition as claimed in Claim 23 or use as claimed in Claim 24, wherein the disease, disorder and/or condition is caused by viral, bacterial and/or parasitic infections.