CLAIMS

1. A composition wherein said composition comprises a biologically active material wherein the composition is adapted to release the biologically active material to a mucosal surface of a patient in need thereof.

2. The composition of claim 1, wherein the composition is adapted to induce a biological or immunological response at the epithelial layer of the mucosal system.

3. The composition of claims 1 of 2, wherein the composition is a solid dosage form.

4. The composition of any one of the above claims, wherein the composition comprises one or more agents selected from the group consisting of: an amorphous non-ionic matrix forming agent; an ionic water soluble post-disintegration viscosity agent; a low MW ionic matrix agent; a second non-ionic matrix agent; and a non-ionic crystalline matrix forming agent.

5. The composition of any one of the above claims, wherein the composition comprises the following agents: an ionic water soluble post-disintegration viscosity agent; a low MW ionic matrix agent; a second non-ionic matrix agent; and a non-ionic crystalline matrix forming agent.

6. The composition of any one of the above claims, wherein the composition comprises one or more agents selected from the group consisting of: an amorphous non-ionic matrix forming agent; an ionic water soluble post-disintegration viscosity agent; a second water soluble post-disintegration viscosity agent; a low MW ionic matrix agent; a second non-ionic matrix agent; and a non-ionic crystalline matrix forming agent.

7. The composition of any one of the above claims, wherein the composition comprises the following agents: an amorphous non-ionic matrix forming agent; an ionic water soluble post-disintegration viscosity agent; a second water soluble post-disintegration viscosity agent; a low MW ionic matrix agent; a second non-ionic matrix agent; and a non-ionic crystalline matrix forming agent.

8. The composition of any one of the above claims, wherein the composition comprises one or more agents selected from the group consisting of: an amorphous non-ionic matrix forming agent; an ionic water soluble post-disintegration viscosity agent; a second water soluble post-disintegration viscosity agent; an adjuvant; a low MW ionic matrix agent; a second non-ionic matrix agent; a non-ionic crystalline matrix forming agent; a second non-ionic crystalline matrix forming agent; and a further non-ionic matrix agent.

9. The composition of any one of the above claims, wherein the composition comprises the following agents: an amorphous non-ionic matrix forming agent; an ionic water soluble post-disintegration viscosity agent; a second water soluble post-disintegration viscosity agent; an adjuvant; a low MW ionic matrix agent; a second non-ionic matrix agent; a non-ionic crystalline matrix forming agent; a second non-ionic crystalline matrix forming agent; and a further non-ionic matrix agent.

10. The composition of any one of the above claims, wherein the composition is a rapidly disintegrating solid dosage form.

11. The composition of any one of the above claims, wherein the biologically active material is present in the composition at a concentration selected from the group consisting of: between 1 nanogram and 100 milligrams; and between 0.01 nanogram and 1000 milligrams.

12. The composition of any one of the above claims, wherein the biologically active material is present in the composition at a concentration selected from the group consisting of: 1% (w/w); 2% (w/w); 3% (w/w); 4% (w/w); 5% (w/w); 6% (w/w); 7% (w/w); 8% (w/w); 9% (w/w); 10% (w/w); 11% (w/w); 12% (w/w); 13% (w/w); 14% (w/w); 15% (w/w); 16% (w/w); 17% (w/w); 18% (w/w); 19% (w/w); 20% (w/w); 21% (w/w); 22% (w/w); 23% (w/w); 24% (w/w); 25% (w/w); 26% (w/w); 27% (w/w); 28% (w/w); 29% (w/w); 30% (w/w); 31% (w/w); 32% (w/w); 33% (w/w); 34% (w/w); 35% (w/w); 36% (w/w); 37% (w/w); 38% (w/w); 39% (w/w); 40% (w/w); 41% (w/w); 42% (w/w); 43% (w/w); 44% (w/w); 45% (w/w); 46% (w/w); 47% (w/w); 48% (w/w); 49% (w/w); 50% (w/w); and 2-95% (w/w); 3-65% (w/w); 4-55% (w/w); 5-45% (w/w); 6-35% (w/w); 7-25% (w/w); 8-15% (w/w); and within 2 decimal points of each figure.

13. The composition of any one of the above claims, wherein the biologically active material is selected from the group consisting of: haemagglutinins; vaccines; immunoglobulins; allergens; interferons; monoclonal immunoglobulins; and monoclonal antibodies.

14. The composition of any one of the above claims, wherein the biologically active molecules are components in vaccines for respiratory viruses which initially contact a mucosal surface prior to replication and spread of infection, including those selected from the group consisting of: influenza; COVID-19 (coronavirus disease 2019); and RSV (respiratory syncytial virus).

15. The composition of any one of the above claims, wherein the biologically active material is one of the family of biological molecules designed to elicit an immunogenic response at a

mucosal surface, selected from the group consisting of: hemagglutinins; monoclonal antibodies; and viral fragments.

16. The composition of any one of the above claims, wherein the biologically active material is preferably selected from the group consisting of: hemagglutinins (HA).

17. The composition of any one of the above claims, wherein the HA is present at a level selected from the group consisting of: 0.1 to 1000µg; 1-100µg; 1-50µg; and 5-20µg.

18. The composition of any one of the above claims, wherein the biologically active material is selected from the group consisting of: from vitamins; pharmaceutical actives; small chemical entities; biologics; amino acids; proteins; peptides; polypeptides; nucleotides; nucleic acids; oligonucleotides; vaccines; monoclonal antibodies; nucleic acids; and a pharmaceutically acceptable salt; analog; homolog; derivative; solvate; hydrate; and polymorph thereof.

19. The composition of any one of the above claims, wherein the biologically active material is selected from the group consisting of: anti-obesity drugs; central nervous system stimulants; carotenoids; corticosteroids; elastase inhibitors; anti-fungals; oncology therapies; anti-emetics; analgesics; cardiovascular agents; anti-inflammatory agents; such as NSAIDs and COX-2 inhibitors; anthelmintics; anti-arrhythmic agents; antibiotics (including penicillins); anticoagulants; antidepressants; antidiabetic agents; antiepileptics; antihistamines; antihypertensive agents; antimuscarinic agents; antimycobacterial agents; antineoplastic agents; immunosuppressants; antithyroid agents; antiviral agents; anxiolytics; sedatives (hypnotics and neuroleptics); astringents; alpha-adrenergic receptor blocking agents; beta-adrenoceptor blocking agents; blood products and substitutes; cardiac inotropic agents; contrast media; cough suppressants (expectorants and mucolytics); cytokines; diagnostic agents; diagnostic imaging agents; diuretics; dopaminergics (anti-parkinsonian agents); haemostatics; immunological agents; lipid regulating agents; muscle relaxants; parasympathomimetics; parathyroid calcitonin and biphosphonates; prostaglandins; radio-pharmaceuticals; sex hormones (including steroids); anti-allergic agents; stimulants and anoretics; sympathomimetics; thyroid agents; vaccines; vasodilators; xanthines; and a pharmaceutically acceptable salt, analog, homolog, derivative, solvate, hydrate, and polymorph thereof.

20. A pharmaceutical composition comprising the composition of any one of claims 1 to 19 together with a pharmaceutical excipient or carrier.

21. A dosage form comprising the composition of any one of claims 1 to 19.

22. A vaccine comprising the composition of any one of claims 1 to 19.

23. A method of treating or preventing or delaying a disease or disorder, said method comprising administering to a patient in need thereof a therapeutically effective amount of the dosage form of claim 21.

24. A method of vaccination against a disease or disorder, said method comprising administering to a patient in need thereof a therapeutically effective amount of the dosage form of claim 21.

25. A method of initiating a mucosal immune response against an antigen, said method comprising administering to a patient in need thereof a therapeutically effective amount of the dosage form of claim 21 to a mucosal surface, wherein the biologically active material contains an amino acid sequence which is at least partially homologous to a sequence on the antigen.

26. A method of generating IgA immunity against an antigen, said method comprising administering to a patient in need thereof a therapeutically effective amount of the dosage form of claim 21 to a mucosal surface, wherein the biologically active material contains an amino acid sequence which is at least partially homologous to a sequence on the antigen.

27. Use of the composition of claims 1 to 19 in the manufacture of a medicament for the treatment or prevention of a disease or disorder.

28. A process of preparing the composition of claims 1 to 19, said process comprising the steps of: (1) combining at least one matrix forming agent with a biological active material to form a mixture; and (2) freeze drying the mixture to form the solid dosage form.