

Claims:

1. A solid dose formulation having a compressive strength of at least about 80 MPa for needle-free delivery comprising:
0.01% - 60% (w/w) of at least one therapeutic and/or prophylactic agent; and
40.0% - 99.99% (w/w) of dextran.
2. A solid dose formulation having a compressive strength of at least about 80 MPa for needle-free delivery comprising:
0.01% - 25.0% (w/w) of at least one therapeutic and/or prophylactic agent;
at least 25.0% (w/w) of dextran; and
at least 50% (w/w) of at least one, or combination of two or more, different excipients, excluding dextran.
3. A solid dose formulation according to claim 2, comprising at least 50-74% (w/w) of the one, or the combination of two or more, excipients excluding dextran.
4. The solid dose formulation according to claim 2 or 3, wherein the excipient or excipients are selected from trehalose, mannitol and CMC.
5. A solid dose formulation according to any preceding claim, further comprising at least 0.5% (w/w) of a lubricant.
6. A solid dose formulation according to any proceeding claim, wherein the at least one agent is an immunogen.
7. A solid dose formulation according to any proceeding claim, wherein the at least one agent is a biological or chemical preparation for immunization.
8. A solid dose formulation according to any previous claim, wherein the at least one agent is a biological or chemical preparation selected from a vector, a protein, a protein

subunit, DNA, RNA, a toxoid or a polysaccharide-antigen conjugate and a checkpoint inhibitor.

9. A solid dose formulation according to any preceding claim, further comprising a binder, bulking agent, stabiliser or a combination thereof.
10. A solid dose formulation according to any preceding claim, further comprising one or more adjuvants.
11. A solid dose formulation according to any previous claim, wherein the solid dose formulation comprises dextran in the range of -40-99%, 49.5-99%, 50-99%, 51-99%, 63-99%, 66-99% 74-99% or 82-99% (w/w).
12. A solid dose formulation according to any previous claim, wherein the dextran is selected from a grade with a mean molecular weight at or greater than 10 kDa, or between 10 kDa and 110 kDa, preferably 70 kDa.
13. A solid dose formulation according to any previous claim, wherein the dextran selected includes 0.5% to 6% (w/w) water, preferably 1% to 5%, more preferably 1% to 4%.
14. A solid dose formulation according to any preceding claim, wherein the solid dose formulation is a tablet or micro tablet, and/or is preferably elongated.
15. A solid dose formulation according to any preceding claim, wherein the solid dose formulation has a length to width ratio from 2:1 to 6:1, preferably about 4:1.
16. A solid dose formulation according to any preceding claim, wherein the solid dose formulation has a width from 0.5mm to 2 mm, preferably 0.75mm to 1.2mm, most preferably about 0.85mm.

17. A solid dose formulation according to any preceding claim, wherein the solid dose formulation has a length from 1.7 to 12mm, preferably 2 to 6 mm and more preferably about 4 mm.
18. A solid dose formulation according to claim 14, wherein the tablet or micro tablet has a pointed tip with an internal angle of between 22.5° and 90°.
19. A solid dose formulation according to any preceding claim, further comprising one or more of methionine, cysteine, histidine, citric acid, sodium chloride, sodium hydroxide, hydrochloric acid, potassium chloride, tween-20, tween-40, tween-60, tween-80, albumin, mannitol, trehalose, sucrose, sodium carboxymethylcellulose salt or a combination thereof.
20. A solid dose formulation according to any preceding claim, wherein the lubricant is magnesium stearate.
21. A solid dose formulation according to any preceding claim, wherein the formulation comprises the lubricant at a maximum of 5% (w/w).
22. A solid dose formulation according to any preceding claim, wherein the formulation further comprises CMC, preferably in the range of 10-50% (w/w), more preferably wherein the formulation comprises 36% to 50% (w/w) CMC, optionally with 9-39% (w/w) mannitol.
23. AThe solid dose formulation according to any preceding claim, for use in the treatment or prevention of one or more diseases or disorders.
24. AUse of the solid dose formulation according to ~~claim 23~~any one of claims 1-22 in the manufacture of a medicament for the treatment or prevention of one or more diseases or disorders, wherein the disease or disorder is selected from, or associated with, one or more of: cancer, yellow fever, rabies, diphtheria, tetanus, haemophilus influenza type B (Hib), pertussis, pneumococcal diseases, meningococcal diseases, human

papilloma viruses (HPV), HTV, HSV2/HSV1, influenza (types A, B and C), para influenza, polio, RSV, rhinoviruses, rotaviruses, hepatitis A, acquired immunodeficiency syndrome (AIDS), anthrax, gastroenteritis, enterovirus diseases, measles, mumps, varicella-zoster, glandular fever, respiratory diseases, rubella, human T-cell lymphoma type I (HTLV-I), hepatitis B, hepatitis C, hepatitis D, poxvirus diseases, cholera, Japanese encephalitis, zika, chikungunya, bat lyssavirus, Q fever, rift valley fever, hendra virus, tularaemia, nipah virus, lassa fever, typhoid fever, Crimean-Congo haemorrhagic fever, ebola, plague and shigella, or against veterinary diseases, such as foot and mouth disease (including serotypes O, A, C, SAT-1, SAT-2, SAT-3 and Asia-1), coronavirus, bluetongue, feline leukaemia, avian influenza, hendra and nipah virus, pestivirus, canine parvovirus and bovine viral diarrhoea virus.

25. ~~A~~The solid dose formulation according to any ~~previous claim~~one of claims 1-22, wherein the solid dose formulation is for use as a vaccine, preferably a single dose vaccine.

26. ~~A~~The solid dose formulation for use according to claim 23, the use of claim 24 or the solid dose formulation according to claim 25, wherein the treatment or prevention includes the use of a needle-free delivery device.

27. Use of the solid dose formulation according ~~to any previous claim~~of claims 1 to 22, in ~~a method of~~ needle free vaccination.

~~28. Use~~the manufacture of ~~the solid dose formulation according to any previous claim in a method of needle free~~a medicament for vaccination against one or more diseases or disorders, wherein the one or more diseases or disorders includes infection by any one of yellow fever, rabies, diphtheria, tetanus, haemophilus influenza type B (Hib), pertussis, pneumococcal diseases, meningococcal diseases, human papilloma viruses (HPV), HTV, HSV2/HSV1, influenza viruses (types A, B and C), para influenza virus, polio virus, RSV virus, rhinoviruses, rotaviruses, hepatitis A virus, lentiviruses including human immunodeficiency virus (HIV), norwalk virus, enterovirus, astroviruses, measles virus, mumps

virus, varicella-zoster virus, cytomegalovirus, epstein-barr virus, adenoviruses, respiratory diseases, rubella, human T-cell lymphoma type I virus (HTLV-I), hepatitis B virus, hepatitis C virus, hepatitis D virus, poxvirus and vaccinia virus, cholera, Japanese encephalitis virus, zika virus, chikungunya virus, bat lyssavirus, Q fever, rift valley fever virus, hendra virus, tularaemia, nipah virus, lassa fever, typhoid fever, Crimean-Congo haemorrhagic fever virus, ebola virus, plague and shigella, or against veterinary diseases, such as foot and mouth disease (including serotypes O, A, C, SAT-1, SAT-2, SAT-3 and Asia-1), coronavirus, bluetongue, feline leukaemia virus, avian influenza, hendra and nipah virus, pestivirus, canine parvovirus and bovine viral diarrhoea virus.

~~29~~28. A vaccine comprising ~~athe~~ solid dose formulation according to any previous claim numbered 1 to 22, wherein the type of vaccine is selected from an attenuated (live) vaccine, an inactivated vaccine, a toxoid vaccine, a subunit or purified antigen vaccine, a conjugate vaccine, a neoantigen vaccine, an RNA vaccine, a DNA vaccine, heterologous "Jennerian" vaccine, a homologous vaccine, a recombinant vector vaccine.

~~30~~29. A method of producing a tablet comprising the solid dose formulation or vaccine according to any previous claim by:

- combining the components of the solid dose formulation in a dry powder form;
- compressing the powder in a die; and
- drying the solid dose formulation at approximately 25-40°C, for at least 24 hours.

~~31.~~A30. The method according to claim ~~30~~29, wherein the step of combining the components of the solid dose formulation in a dry powder form comprises spray drying or freeze drying the dextran with one or more of the other components of the solid dose formulation.

~~3231.~~ A method of producing a tablet comprising a solid dose formulation including at least one therapeutic and/or prophylactic agent, dextran and at least one excipient, the method comprising:

combining the components of the solid dose formulation into a dry powder form, wherein the dextran is combined with the at least one excipient by spray drying; compressing the powder in a die; and drying the solid dose formulation at approximately 25-40°C, for at least 24 hours.

~~32. The 33.~~ A method according to claim ~~29, 30, 31~~ or ~~3231~~ wherein the die is configured to produce a microtablet, preferably with a diameter from 0.5mm to 2 mm, preferably 0.75mm to 1.2mm, most preferably 0.85mm.

~~33. The 34.~~ A method according to any of claims ~~3029~~ to ~~3332~~, wherein the drying step comprises drying at approximately 25°C to 40°C, for 5 to 11 days under vacuum, preferably at 10 mbar.

~~34. 35. A~~ The method according to claim ~~3332~~, wherein the drying is at approximately 25°C, 10 mbar, for at least 5 days.

~~36. A method of treating or preventing a disease or disorder, said method comprising administering to a subject in need, a therapeutically effective amount of the solid dose formulation as defined in any previous claim numbered from 1 to 26.~~