

Claims:

1. A solid dose formulation having a compressive strength of at least about 80 MPa for
5 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
10 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
15 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
20 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
25 agent is an immunogen.
7. A solid dose formulation according to any proceeding claim, wherein the at least one
30 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.
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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.
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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).
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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.
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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%.
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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.
- 5 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.
- 10 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°.
- 15 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 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).
- 25 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.
- 30 23. A solid dose formulation according to any preceding claim, for use in the treatment or prevention of one or more diseases or disorders.

24. A solid dose formulation according to claim 23 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 solid dose formulation according to any previous claim, wherein the solid dose formulation is for use as a vaccine, preferably a single dose vaccine.
26. A solid dose formulation according to claim 23, 24 or 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, in a method of needle-free vaccination.
28. Use of the solid dose formulation according to any previous claim in a method of needle-free vaccination against infection by 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. A vaccine comprising a solid dose formulation according to any previous claim 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. 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. A method according to claim 30, 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.

32. 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:

- 5 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.

10 33. A method according to claim 30, 31 or 32 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.

15 34. A method according to any of claims 30 to 33, wherein the drying step comprises drying at approximately 25°C to 40°C, for 5 to 11 days under vacuum, preferably at 10 mbar.

35. A method according to claim 33, wherein the drying is at approximately 25°C, 10 mbar, for at least 5 days.

20 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.