CLAIMS

We claim:

1. An intracutaneous delivery system, comprising a plurality of microprojections that are adapted to penetrate or pierce the stratum corneum of a human patient, the microprojections having a solid formulation coating thereon covering about 10% to 80% of the length of each microprojection measured from the tip to the base, wherein the coating comprises a therapeutically effective amount of a vaccine, and wherein at least 95% of the vaccine is released from the system within about 20 minutes after the application of the system to the stratum corneum of the human patient.

2. The system of claim 1 wherein at least 95% of the vaccine is released within about 10 minutes.

3. The system of claim 1 wherein at least 95% of the vaccine is released within about 5 minutes.

4. The system of claim 1 wherein the vaccine is a coronavirus vaccine.

5. The system of claim 1 wherein the therapeutically effective amount is about 5 mcg to about 500 mcg.

6. The system of claim 1 wherein the therapeutically effective amount is about 25 mcg to about 300 mcg.

7. The system of claim 1 further comprising a disaccharide.

8. The system of claim 7 wherein the disaccharide is sucrose.

9. The system of claim 7 wherein the disaccharide is trehalose.

10. The system of claim 1 wherein it is stable at room temperature for at least 6 months.

11. The system of claim 1 wherein it is stable at room temperature for at least 12 months.

12. A method for vaccinating a human patient against a coronavirus or an influenza disease, comprising the steps of:

a. Providing an intracutaneous delivery system, comprising:

i. a disposable patch assembly having a plurality of microprojections disposed in an array of about 3 cm^2 to about 6 cm^2, the array having a density of about 200 to about 2000 microprojections/cm^2, the microprojections adapted to penetrate or pierce the stratum corneum of a human patient,

ii. the microprojections having a solid formulation coating disposed thereon, wherein the coating comprises a therapeutically effective amount of a vaccine,

iii. the microprojections having a width of about 10 μm to about 500 μm and a tip angle of about 30 to about 70 degrees, and

b. applying the microprojections to a selected area of skin of the patient,

wherein at least 95% of the vaccine is released from the system within about 20 minutes after application to the stratum corneum.

13. The method of claim 12 wherein the disease is COVID-19.

14. The method of claim 12 wherein at least 95% of the vaccine is released within about 10 minutes.

15. The method of claim 12 wherein at least 95% of the vaccine is released within about 5 minutes.

16. The method of claim 12 wherein the vaccine is a coronavirus vaccine.

17. The method of claim 12 wherein the therapeutically effective amount is about 5 mcg to about 500 mcg.

18. The method of claim 12 wherein the therapeutically effective amount is about 25 mcg to about 300 mcg.

19. The method of claim 12 further comprising a disaccharide.

20. The method of claim 19 wherein the disaccharide is sucrose.

21. The method of claim 19 wherein the disaccharide is trehalose.

22. The method of claim 12 wherein the system is stable at room temperature for at least 6 months.

23. The method of claim 12 wherein the system is stable at room temperature for at least 12 months.

24. The method of claim 12 wherein the system is self-administered.

25. The method of claim 12 wherein when the system is administered to a population of patients, a statistically significant number of patients are successfully vaccinated.

26. The method of claim 25 wherein at least 25% of the patients are seroprotected.

27. The method of claim 25 wherein at least 50% of the patients are seroprotected.

28. The method of claim 25 wherein at least 75% of the patients are seroprotected.

30. The method of claim 12 wherein the wear time is about 5 to 30 minutes.

CLAIMS

1. An intracutaneous delivery system, comprising a plurality of microprojections that are adapted to penetrate or pierce the stratum corneum of a human patient, the microprojections having a coating thereon comprising a therapeutically effective amount of a vaccine.

2. A system according to Claim 1, in which at least 95% of the vaccine is released within about 20 minutes after application of the system to the stratum corneum of the human patient, preferably in which at least 95% of the vaccine is released within about 10 minutes or about 5 minutes after application of the system to the stratum corneum of the human patient.

3. A system according to Claim 1 or 2, in which the vaccine is a coronavirus vaccine.

4. A system according to Claim 3, in which the vaccine is against SARS-CoV-2.

5. A system according to Claim 1 or 2, in which the vaccine is an influenza vaccine.

6. A system according to any preceding claim, in which the vaccine is a peptide vaccine.

7. A system according to any of Claims 1 to 5, in which the vaccine, when administered to a subject, stimulates production of antibodies.

8. A system according to any preceding claim, in which the coating is a solid coating.

9. A system according to any preceding claim , in which the coating further comprises a disaccharide and/or a surfactant.

10. A system according to Claim 9, in which:

(i) the disaccharide is sucrose or trehalose; and/or

(ii) the surfactant is polysorbate 20.

11. A system according to any preceding claim, in which the system comprises a disposable patch assembly having a plurality of microprojections disposed in an array of about 3 cm^2 to about 6 cm^2, the array having a density of about 200 to about 2000 microprojections/cm^2.

12. A system according to any preceding claim, in which the microprojections are rectangular, with a triangular tip to facilitate penetration of the stratum corneum of a human.

13. A system according to any preceding claim, in which the microprojections have:

(i) a length of about 25 to about 600 μm;

(ii) a width of about 10 μm to about 500 μm;

(iii) a thickness of about 1 μm to about 500 μm; and

(iv) a tip angle of about 30 to about 70 degrees.

14. A system according to any preceding claim, in which the coating covers about 10% to 80% of the length of each microprojection measured from the tip to the base.

15. A system according to any preceding claim , in which the system is stable at room temperature for at least 6 months, preferably in which it is stable at room temperature for at least 12 months.

16. Use of a therapeutically effective amount of a vaccine in the manufacture of a medicament for vaccinating a human patient against a coronavirus or an influenza disease, in which:

(a) the medicament takes the form of an intracutaneous delivery system as defined in any preceding claim; and

(b) the vaccine is to be administered by applying the microprojections of the intracutaneous delivery system to a selected area of skin of the patient.

17. Use according to Claim 16, in which the vaccine is a coronavirus vaccine.

18. Use according to Claim 17, in which the disease is COVID-19.

19. Use according to Claim 16, in which the vaccine is an influenza vaccine.

20. Use according to any of Claims 16 to 19, in which the vaccine is to be self-administered.

21. Use according to any of Claims 16 to 20, in which the system has a wear time of about 5 to 30 minutes.