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 psilocybin, LSD or MDMA, and wherein at least 95% of the psilocybin, LSD or MDMA 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 psilocybin, LSD or MDMA is released within about 10 minutes.

3. The system of claim 1 wherein at least 95% of the psilocybin, LSD or MDMA is released within about 5 minutes.

4. The system of claim 1 wherein the formulation further comprises an excipient.

5. The system of claim 1 wherein the therapeutically effective amount is about 1 mg to about 10 mg.

6. The system of claim 1 wherein the therapeutically effective amount is about 2 mg to about 5 mg.

7. The system of claim 1 wherein the formulation coating further comprises an acid.

8. The system of claim 7 wherein the acid it tartaric acid.

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

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

11. A method for treating depression in a human patient in need thereof, 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 psilocybin, LSD or MDMA,

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 psilocybin, LSD or MDMA is released from the system within about 20 minutes after application to the stratum corneum.

12. The method of claim 11 wherein at least 95% of the psilocybin, LSD or MDMA is released within about 10 minutes.

13. The method of claim 11 wherein at least 95% of the psilocybin, LSD or MDMA is released within about 5 minutes.

14. The method of claim 11 wherein the therapeutically effective amount is about 1 mg to about 10 mg.

15. The method of claim 11 wherein the therapeutically effective amount is about 2 mg to about 5 mg.

16. The method of claim 11 wherein the system is self-administered.

17. The method of claim 11 wherein when the system is administered to a population of patients, a statistically significant number of patients are successfully treated for depression as measured by a method or scale selected from the group consisting of the Beck Depression Inventory (BDI), the Center for Epidemiologic Studies Depression Scale (CES-D), the EQ-5D, the HRSD, the MADRS, and combinations thereof.

18. 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 psilocybin, LSD or MDMA.

2. A system according to Claim 1, in which at least 95% of the psilocybin, LSD or MDMA 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 psilocybin, LSD or MDMA 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 coating further comprises an excipient.

4. A system according to Claim 1, 2 or 3, in which the therapeutically effective amount of psilocybin, LSD or MDMA is about 1 mg to about 10 mg.

5. A system according to Claim 4, in which the therapeutically effective amount of psilocybin, LSD or MDMA is about 2 mg to about 5 mg.

6. A system according to any preceding claim, in which the coating further comprises an acid.

7. A system according to Claim 6, in which the acid is tartaric acid.

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 system comprises a disposable patch assembly having a plurality of microprojections disposed in an array of about 3 cm2 to about 6 cm2, the array having a density of about 200 to about 2000 microprojections/cm2.

10. A system according to any preceding claim, in which the microprojections are rectangular with a triangular tip.

11. 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.

12. 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.

13. 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.

14. Use of a therapeutically effective amount of psilocybin, LSD or MDMA in the manufacture of a medicament for treating depression in a human patient, in which:

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

(b) the psilocybin, LSD or MDMA is to be administered by applying the microprojections of the intracutaneous delivery system to a selected area of skin of the patient.

15. Use according to Claim 14, in which the psilocybin, LSD or MDMA is to be self-administered.

16. Use according to Claim 14 or 15, in which when the psilocybin, LSD or MDMA is to be administered to a population of patients, a statistically significant number of patients are successfully treated for depression as measured by a method or scale selected from the group consisting of the Beck Depression Inventory (BDI), the Center for Epidemiologic Studies Depression Scale (CES-D), the EQ-5D, the HRSD, the MADRS, and combinations thereof.

17. Use according to Claim 14, 15 or 16, in which the system has a wear time of about 5 to 30 minutes.