Claims:

1. A solid dosage form adapted for the release of a biologically active material in the oral cavity wherein the dosage form comprises:

    a) at least one biologically active material, and

    b) at least one matrix forming agent,

    wherein the dosage form substantially dissolves in the oral cavity and wherein the biologically active material is chosen from the list comprising: at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor, an active material that binds to one or more adrenergic receptors, and an N-methyl-D-aspartate receptor antagonist.

2. The solid dosage form of claim 1 wherein the solid dosage form is a fast dissolving solid dosage form.

3. The solid dosage form of claim 1 wherein the N-methyl-D-aspartate receptor antagonist is chosen from the list comprising: dextromethorphan, dextrorphan or ketamine.

4. The solid dosage form of claim 1 wherein the active material that binds to one or more adrenergic receptors is adrenaline (epinephrine), or an adrenaline salt.

5. The solid dosage form of claim 1 the cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

6. A method to produce a solid dosage form adapted for the release of a biologically active material in the oral cavity wherein the dosage form substantially dissolves in the oral cavity, comprising the steps of:

    a) combining at least one matrix forming agent with a biologically active material to form a homogeneous mixture; and

    b) freeze drying the mixture to prepare the solid dosage form of the present invention

    wherein the biologically active material is chosen from the list comprising: at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor, an active material that binds to one or more adrenergic receptors, and an N-methyl-D-aspartate receptor antagonist.

7. The method of claim 6 wherein the solid dosage form is a fast dissolving solid dosage form.

8. The method of claim 6 wherein the N-methyl-D-aspartate receptor antagonist is chosen from the list comprising: dextromethorphan, dextrorphan or ketamine.

9. The method of claim 6 wherein the active material that binds to one or more adrenergic receptors is adrenaline, or an adrenaline salt.

10. The method of claim 6 wherein the cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

11. A kit comprising:

a) a solid dosage form adapted for the release of a biologically active material in the oral cavity wherein the dosage form substantially dissolves in the oral cavity, wherein the dosage form comprises:

(i) at least one biologically active material, and

(ii) at least one matrix forming agent; and

b) instructions for use

wherein the biologically active material is chosen from the list comprising: at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor, an active material that binds to one or more adrenergic receptors, and an N-methyl-D-aspartate receptor antagonist.

12. The kit of claim 11 wherein the solid dosage form is a fast dissolving solid dosage form.

13. The kit of claim 11 wherein the N-methyl-D-aspartate receptor antagonist is chosen from the list comprising: dextromethorphan, dextrorphan or ketamine.

14. The kit of claim 11 wherein the active material that binds to one or more adrenergic receptors is adrenaline, or an adrenaline salt.

15. The kit of claim 11 wherein the cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

16. A solid dosage form wafer adapted for the release of a biologically active material in the oral cavity wherein the dosage form comprises:

a) at least one biologically active material, and

b) at least one matrix forming agent,

wherein the wafer substantially dissolves in the oral cavity and wherein the biologically active material is chosen from the list comprising: at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor, an active material that binds to one or more adrenergic receptors, and an N-methyl-D-aspartate receptor antagonist.

17. The wafer of claim 16 wherein the solid dosage form is a fast dissolving solid dosage form.

18. The wafer of claim 16 wherein the N-methyl-D-aspartate receptor antagonist is chosen from the list comprising: dextromethorphan, dextrorphan or ketamine.

19. The wafer of claim 16 wherein the active material that binds to one or more adrenergic receptors is adrenaline, or an adrenaline salt.

20. The wafer of claim 16 wherein the cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

21. A pharmaceutical composition comprising: the solid dosage form of claim 1 or claim 16.

22. The solid dosage form of claim 1, method of claim 6, kit of claim 11 or wafer of claims 16 wherein the dosage form is adapted to not leave a residue of said dosage form in the oral cavity that is detectable by the patient.

23. The solid dosage form of claim 1, method of claim 6, kit of claim 11 or wafer of claim 16 wherein the dosage form substantially dissolves once placed in the oral cavity in a time period selected from the group consisting of: less than 2 minutes; less than 1 minute; less than 50 seconds; less than 40 seconds; less than 30 seconds; less than 20 seconds; less than 15 seconds; less than 10 seconds; less than 7.5 seconds; less than 5 seconds; less than 4 seconds; less than 3 seconds; and less than 2 seconds after administration of the dosage form.

24. The solid dosage form of claim 1, method of claim 6, kit of claim 11 or wafer of claim 16 wherein the dosage form completely dissolves once placed in the oral cavity in a

time period selected from the group consisting of: less than 2 minutes; less than 1 minute; less than 50 seconds; less than 40 seconds; less than 30 seconds; less than 20 seconds; less than 15 seconds; less than 10 seconds; less than 7.5 seconds; less than 5 seconds; less than 4 seconds; less than 3 seconds; and less than 2 seconds after administration of the dosage form.

25. The solid dosage form of claim 1, method of claim 6, kit of claim 11 or wafer of claim 16 wherein the dosage form provides an effective plasma concentration of the biologically active material within a period of no more than two hours, 30 minutes, 20 minutes, or 15 minutes.

26. The provision of an effective plasma concentration of claim 25, wherein the period is within 10 minutes.

Claims:

1. Use of a solid dosage form in the manufacture of a medicament for treating a disease or disorder,

wherein the dosage form comprises:

a) at least one biologically active material from 0.01 to 95% by dry weight of the dosage form, comprising an active material that binds to one or more adrenergic receptors at a concentration, or is a cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor, or is an N-methyl-D-aspartate receptor antagonist, or is fentanyl or a pharmaceutically active salt thereof; and

b) a matrix forming agent comprising amylopectin at a concentration from 2% to 17% by dry weight of the dosage form,

wherein the dosage form is adapted for the release of a biologically active material in an oral cavity of a subject for sublingual administration;

wherein the dosage form is a fast disintegrating and dissolving solid freeze-dried wafer dosage form;

wherein the dosage form is capable of substantially dissolving in the oral cavity without leaving a residue of said dosage form in the oral cavity that is detectable by a subject, thereby avoiding the urge for the subject to swallow the dosage form;

wherein the dosage form is capable of disintegrating in the oral cavity in a time of less than 15 seconds and dissolving in the oral cavity in a time of less than 60 seconds;

wherein the dosage form is capable of delivering an effective plasma concentration of the active material by providing a C_{max} concentration that is lower than that reached by the equivalent intravenous administration of the same active and a t_{max} comparable to intravenous administration; and

wherein the disease or disorder is selected from the group consisting of pain, depression, addiction, inflammation, migraine, asthma, epilepsy, cardiac arrest or cardiac dysrhythmia, angina pectoris, hair loss, sexual dysfunction, psoriasis, pulmonary hypertension, allergy and anaphylaxis.

2. The use of claim 1 wherein an effective plasma concentration is achieved within 120 minutes, within 30 minutes, or within 20 minutes or within 5 minutes.

3. Use of a solid dosage form in the manufacture of a medicament for providing allergy relief and anaphylaxis treatment,

wherein the dosage form comprises:

a) at least one biologically active material comprising an active material that binds to one or more adrenergic receptors at a concentration from 0.01 to 95%, 0.1 to 75%, or 1 to 45% by dry weight of the dosage form, and

b) a matrix forming agent comprising amylopectin at a concentration from 2% to 17% by dry weight of the dosage form,

wherein the dosage form is adapted for the release of a biologically active material in an oral cavity of a subject for sublingual administration;

wherein the dosage form is a fast disintegrating and dissolving solid freeze-dried wafer dosage form;

wherein the dosage form is capable of substantially dissolving in the oral cavity without leaving a residue of said dosage form in the oral cavity that is detectable by the subject, thereby avoiding the urge for the subject to swallow the dosage form;

wherein the dosage form is capable of disintegrating in the oral cavity in a time of less than 15 seconds and dissolving in the oral cavity in a time of less than 60 seconds; and

wherein the dosage form is capable of delivering an effective plasma concentration of the active material by providing a C_{max} concentration that is lower than that reached by the equivalent intravenous administration of the same active and a t_{max} comparable to intravenous administration of an active material that binds to one or more adrenergic receptors.

4. The use of claim 3 wherein an effective plasma concentration is achieved within 120 minutes, within 30 minutes, or within 20 minutes or within 5 minutes.

5. Use of a solid dosage form in the manufacture of a medicament for treating or preventing hair loss, sexual dysfunction, pulmonary hypertension or psoriasis,

wherein the dosage form comprises:

a) at least one biologically active material comprising at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor at a concentration from 0.01 to 95%, 0.1 to 75%, or 1 to 45% by dry weight of the dosage form, and

b) a matrix forming agent comprising amylopectin at a concentration from 2% to 17% by dry weight of the dosage form,

wherein the dosage form is adapted for the release of a biologically active material in an oral cavity of a subject for sublingual administration;

wherein the dosage form is a fast disintegrating and dissolving solid freeze-dried wafer dosage form;

wherein the dosage form is capable of substantially dissolving in the oral cavity without leaving a residue of said dosage form in the oral cavity that is detectable by the subject, thereby avoiding the urge for the subject to swallow the dosage form;

wherein the dosage form is capable of disintegrating in the oral cavity in a time of less than 15 seconds and dissolving in the oral cavity in a time of less than 60 seconds; and

wherein the dosage form is capable of delivering an effective plasma concentration of the active material by providing a C_{max} concentration that is lower than that reached by the equivalent intravenous administration of the same active and a t_{max} comparable to intravenous administration of at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor.

6. The use of claim 5 wherein an effective plasma concentration is achieved within 120 minutes, within 30 minutes, or within 20 minutes.

7. Use of a solid dosage form in the manufacture of a medicament for providing pain relief and/or anaesthesia, treating or preventing depression and/or addiction, or treating an epileptic seizure,

wherein the dosage form comprises:

a) at least one biologically active material comprising an N-methyl-D-aspartate receptor antagonist at a concentration from 0.01 to 95%, 0.1 to 75%, or 1 to 45% by dry weight of the dosage form, and

b) a matrix forming agent comprising amylopectin at a concentration from 2% to 17% by dry weight of the dosage form,

wherein the dosage form is adapted for the release of a biologically active material in an oral cavity of a subject for sublingual administration;

wherein the dosage form is a fast disintegrating and dissolving solid freeze-dried wafer dosage form;

wherein the dosage form is capable of substantially dissolving in the oral cavity without leaving a residue of said dosage form in the oral cavity that is detectable by a subject, thereby avoiding the urge for the subject to swallow the dosage form;

wherein the dosage form is capable of disintegrating in the oral cavity in a time of less than 15 seconds and dissolving in the oral cavity in a time of less than 60 seconds; and

wherein the dosage form is capable of delivering an effective plasma concentration of an active material by providing a C_{max} concentration that is lower than that reached by the equivalent intravenous administration of the same active and a t_{max} comparable to intravenous administration of an N-methyl-D-aspartate receptor antagonist.

8. The use of claim 7 wherein an effective plasma concentration is achieved within 120 minutes, within 30 minutes, or within 20 minutes.

9. The use of claim 7 wherein the C_{max} is between 50 ng/mL and 130 ng/mL for a 25 mg dose.

10. Use of a solid dosage form in the manufacture of a medicament for providing pain relief and/or anaesthesia,

wherein the dosage form comprises:

a) at least an active material that binds to one or more adrenergic receptors at a concentration from 0.01 to 95%, or 0.1 to 75% by dry weight of the dosage form, and

b) a matrix forming agent comprising amylopectin at a concentration from 2% to 17% by dry weight of the dosage form,

wherein the dosage form is adapted for the release of a biologically active material in an oral cavity of a subject for sublingual administration;

wherein the dosage form is a fast disintegrating and dissolving solid freeze-dried wafer dosage form;

wherein the dosage form is capable of substantially dissolving in the oral cavity without leaving a residue of said dosage form in the oral cavity that is detectable by a subject, thereby avoiding the urge for the subject to swallow the dosage form;

wherein the dosage form is capable of disintegrating in the oral cavity in a time of less than 15 seconds and dissolving in the oral cavity in a time of less than 60 seconds; and

wherein the dosage form is capable of delivering an effective plasma concentration of an active material by providing a C_{max} concentration that is lower than that reached by the equivalent intravenous administration of the same active and a t_{max} comparable to intravenous administration of fentanyl or a pharmaceutically acceptable salt thereof.

11. The use of claim 10 wherein an effective plasma concentration is achieved within 120 minutes, within 30 minutes, within 20 minutes or within 5 minutes.

12. The use of claim 10 wherein the C_{max} is between 80 pg/mL and 360 pg/mL for a 100 ug dose.

13. The use of any one of claims 1 or 7 to 9 wherein the N-methyl-D-aspartate receptor antagonist is chosen from the list comprising: dextromethorphan, dextrorphan or ketamine or a pharmaceutically acceptable salt thereof.

14. The use of any one of claims 1, 3 or 4 wherein the active material that binds to one or more adrenergic receptors is adrenaline (epinephrine), or an adrenaline salt.

15. The use of any one of claims 1, 5 or 6 the cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

16. The use of any one of claims 1, or 10 to 12 wherein the active material is fentanyl.

17. A method of producing a fast disintegrating and dissolving solid freeze dried wafer dosage form for the release of a biologically active material in the oral cavity for sublingual administration wherein the dosage form substantially dissolves in the oral cavity without leaving a residue of said dosage form in the oral cavity that is detectable by a subject, thereby avoiding the urge for the subject to swallow the dosage form and wherein said dosage form disintegrates in the oral cavity in a time of less than 15 seconds and dissolves in the oral cavity in a time of less than 60 seconds, comprising the steps of:

a) combining a matrix forming agent comprising amylopectin at a concentration from 2% to 17% by dry weight of the dosage form with a biologically active material at a concentration from 0.01 to 95%, 0.1 to 75%, or 1 to 45% by dry weight of the dosage form to form a homogeneous mixture; and
b) freeze drying the mixture to prepare the solid dosage form

wherein the biologically active material is chosen from the list comprising:
an active material that binds to one or more adrenergic receptors; at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor; an N-methyl-D-aspartate receptor antagonist; or fentanyl or a pharmaceutically acceptable salt thereof; and
wherein the biologically active material delivers an effective plasma concentration of an active material and a C_{max} concentration that is lower than that reached by the equivalent intravenous administration of the same active and a t_{max} comparable to intravenous administration.

18. The method of claim 17 wherein an effective plasma concentration is achieved within 120 minutes, within 30 minutes, or within 20 minutes.

19. The method of claim 17 wherein the biologically active material is chosen from the list comprising:

an active material that binds to one or more adrenergic receptors and delivers an effective plasma concentration within 120 minutes, within 30 minutes, within 20 minutes or within 5 minutes;
at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor and delivers an effective plasma concentration within 120 minutes, within 30 minutes, or within 20 minutes;
an N-methyl-D-aspartate receptor antagonist that delivers a C_{max} of between 50 ng/mL and 130 ng/mL for a 25 mg dose; or
fentanyl or a pharmaceutically acceptable salt thereof and delivers a C_{max} of between 148.8 pg/mL and 289.8 pg/mL for a 100 ug dose.

20. The method of any one of claims 17 to 19 wherein the N-methyl-D-aspartate receptor antagonist is chosen from the list comprising: dextromethorphan, dextrorphan or ketamine or a pharmaceutically acceptable salt thereof.

21. The method of any one of claims 17 to 19 wherein the active material that binds to one or more adrenergic receptors is adrenaline, or an adrenaline salt.

22. The method of any one of claims 17 to 19 wherein the cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

23. The method of any one of claims 17 to 19 wherein the active material is fentanyl.

24. A kit comprising:

a) a fast disintegrating and dissolving solid freeze dried wafer dosage form for the release of a biologically active material in the oral cavity wherein the dosage form substantially dissolves in the oral cavity for sublingual administration wherein the dosage form substantially dissolves in the oral cavity without leaving a residue of said dosage form in the oral cavity that is detectable by a subject, thereby avoiding the urge for the subject to swallow the dosage form and wherein said dosage form disintegrates in the oral cavity in a time of less than 15 seconds and dissolves in the oral cavity in a time of less than 60 seconds, wherein the dosage form comprises:
   (i) at least one biologically active material at a concentration from 0.01 to 95%, 0.1 to 75%, or 1 to 45% by dry weight of the dosage form, and
   (ii) a matrix forming agent comprising amylopectin at a concentration from 2% to 17% by dry weight of the dosage form; and

b) instructions for use

wherein the biologically active material is chosen from the list comprising: an active material that binds to one or more adrenergic receptors; at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor; an N-methyl-D-aspartate receptor antagonist; or fentanyl or a pharmaceutically acceptable salt thereof; and

wherein the biologically active material delivers an effective plasma concentration of an active material and a C_{max} concentration that is lower than that reached by the equivalent intravenous administration of the same active and a t_{max} comparable to intravenous administration.

25. The kit of claim 24 wherein an effective plasma concentration is achieved within 120 minutes, within 30 minutes, or within 20 minutes.

26. The kit of claim 24 wherein the biologically active material is chosen from the list comprising:

an active material that binds to one or more adrenergic receptors and delivers an effective plasma concentration within 120 minutes, within 30 minutes, within 20 minutes or within 5 min;

at least one cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor and delivers an effective plasma concentration within 120 minutes, within 30 minutes, or within 20 minutes;

an N-methyl-D-aspartate receptor antagonist that delivers a C_{max} of between 50 ng/mL and 130 ng/mL for a 25 mg dose; or

fentanyl or a pharmaceutically acceptable salt thereof and delivers a C_{max} of between 148.8 pg/mL and 289.8 pg/mL for a 100 ug dose.

27. The kit of any one of claims 24 to 26 wherein the N-methyl-D-aspartate receptor antagonist is chosen from the list comprising: dextromethorphan, dextrorphan or ketamine or a pharmaceutically acceptable salt thereof.

28. The kit of any one of claims 24 to 26 wherein the active material that binds to one or more adrenergic receptors is adrenaline, or an adrenaline salt.

29. The kit of any one of claims 24 to 26 wherein the cyclic guanosine monophosphate (cGMP) phosphodiesterase type 5 (PDE5) inhibitor is sildenafil or a pharmaceutically acceptable salt thereof.

30. The kit of any one of claims 24 to 26 wherein the active material is fentanyl or a pharmaceutically acceptable salt thereof.

31. The dosage form of any one of claims 1 to 16, or method of any one of claims 17 to 23, or kit of any one of claims 24 to 30 wherein the dosage form completely dissolves once placed in the oral cavity in a time period selected from the group consisting of: less than 50 seconds; less than 40 seconds; less than 30 seconds; less than 20 seconds; less than 15 seconds; less than 10 seconds; less than 7.5 seconds; less than 5 seconds; less than 4 seconds; less than 3 seconds; and less than 2 seconds after administration of the dosage form.