IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Serial No.: 18/196,567
Filing or 371(c) Date: May 12, 2023
Entitled: ADMINISTRATION OF A PSYCHEDELIC COMPOUND

Confirmation No.: 1673
Group No.:
Examiner:

THIRD-PARTY PRE-ISSUANCE SUBMISSION

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application

1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022)
2. SHEKUNOV (2006) "Particle Size Analysis in Pharmaceutics: Principles, Methods and Applications" *Pharmaceutical Research.* 24(2): 203-227
3. ANASTOS (2005) "Investigation into the temporal stability of aqueous standard solutions of psilocin and psilocybin using high performance liquid chromatography" *Science & Justice: Journal of the Forensic Science Society.* 46(2): 91-96

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list of the elements of the presently pending claims.

U.S.S.N. 18/196,567 Pending Claims	References
1. A method of treating or preventing a disease or condition in a patient, the method comprising administering a therapeutically effective amount of a psychedelic compound to the patient by subcutaneous injection, wherein the psychedelic compound is psilocybin or psilocin, or a pharmaceutically acceptable salt thereof.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
2. A method according to claim 1, wherein the psychedelic compound is psilocybin or a pharmaceutically acceptable salt thereof.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or**

	more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
3. A method according to claim 1, wherein the psychedelic compound is psilocin or a pharmaceutically acceptable salt thereof.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."

4. The method according to any one of the preceding claims, wherein the therapeutically effective amount of the psychedelic compound is from about 0.5 mg to about 25 mg, from about 1 mg to about 24 mg, from about 1.5 mg to about 23 mg, from about 2 mg to about 22 mg, from about 2.5 mg to about 21 mg, from about 3 mg to about 20 mg, from about 3.5 mg to about 19 mg, from about 4 mg to about 18 mg, from about 4.5 mg to about 17 mg, from about 5 mg to about 16 mg, from about 5.5 mg to about 15 mg, from about 6 mg to about 14 mg, from about 6.5 mg to about 13 mg, or from about 7 mg to about 12 mg.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
5. The method according to any one of the preceding claims, wherein the therapeutically effective amount of the psychedelic compound is from about 3.5 mg to about 4.5 mg, from	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from

about 4.5 mg to about 5.5 mg, from about 5.5 mg to about 6.5 mg, from about 6.5 mg to about 7.5 mg, from about 7.5 mg to about 8.5 mg, from about 8.5 mg to about 9.5 mg, from about 9.5 mg to about 10.5 mg, from about 10.5 mg to about 11.5 mg, from about 11.5 mg to about 12.5 mg, from about 12.5 mg to about 13.5 mg, from about 13.5 mg to about 14.5 mg, from about 14.5 mg to about 15.5 mg, from about 15.5 mg to about 16.5 mg, or from about 16.5 mg to about 17.5 mg.	about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
6. The method according to any one of the preceding claims, wherein administering the therapeutically effective amount of the psychedelic compound to the patient by subcutaneous injection achieves a maximum blood plasma concentration (C.sub.max) of psilocin in the patient which is at least about 3 ng/mL, at least about 4 ng/mL, at least about 5 ng/mL, at least about 6 ng/mL, at least about 7 ng/mL, at	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0023]** "In some embodiments, the therapeutically effective amount of 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug (e.g., psilocybin) thereof is provided to a subject in need thereof in an amount and/or **formulation to provide a maximum plasma concentration (C.sub.max) of (e.g. active form of the) 5HT receptor agonist (e.g., psilocin)** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of about **0.1 ng/mL or more and less than 6 ng/mL** (e.g. **at least 0.5 ng/mL and less than 6 ng/mL, about 1 ng/mL to about 5.5 ng/mL, about 2 ng/mL to about 5 ng/mL, or the like**)." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is**

least about 8 ng/mL, at least about 9 ng/mL, or at least about 10 ng/mL.	**psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
7. The method according to any one of the preceding claims, wherein administering the therapeutically effective amount of the psychedelic compound to the patient by subcutaneous injection achieves a maximum blood plasma concentration (C.sub.max) of psilocin in the patient which is no greater than about 20 ng/mL, no greater than about 18 ng/mL, no greater than about 16 ng/mL, no greater than about 14 ng/mL, no greater than about 12 ng/mL, or no greater than about 10 ng/mL.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0023]** "In some embodiments, the therapeutically effective amount of 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug (e.g., psilocybin) thereof is provided to a subject in need thereof in an amount and/or **formulation to provide a maximum plasma concentration (C.sub.max) of (e.g. active form of the) 5HT receptor agonist (e.g., psilocin)** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of about **0.1 ng/mL or more and less than 6 ng/mL** (e.g. **at least 0.5 ng/mL and less than 6 ng/mL, about 1 ng/mL to about 5.5 ng/mL, about 2 ng/mL to about 5 ng/mL, or the like**)." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological**

	condition in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
8. The method according to any one of the preceding claims, wherein administering the therapeutically effective amount of the psychedelic compound to the patient by subcutaneous injection achieves a maximum blood plasma concentration (C.sub.max) of psilocin in the patient which is from about 3 ng/mL to about 4 ng/mL, from about 4 ng/mL to about 5 ng/mL, from about 5 ng/mL to about 6 ng/mL, from about 6 ng/mL to about 7 ng/mL, from about 7 ng/mL to about 8 ng/mL, from about 8 ng/mL to about 9 ng/mL, from about 9 ng/mL to about 10	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0023]** "In some embodiments, the therapeutically effective amount of 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug (e.g., psilocybin) thereof is provided to a subject in need thereof in an amount and/or **formulation to provide a maximum plasma concentration (C.sub.max) of (e.g. active form of the) 5HT receptor agonist (e.g., psilocin)** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of about **0.1 ng/mL or more and less than 6 ng/mL** (e.g. **at least 0.5 ng/mL and less than 6 ng/mL, about 1 ng/mL to about 5.5 ng/mL, about 2 ng/mL to about 5 ng/mL, or the like**)." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate,

ng/mL, from about 10 ng/mL to about 11 ng/mL, from about 11 ng/mL to about 12 ng/mL, from about 12 ng/mL to about 13 ng/mL, from about 13 ng/mL to about 14 ng/mL, or from about 14 ng/mL to about 15 ng/mL.	metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
9. The method according to any one of the preceding claims, wherein the method comprises administering a pharmaceutical composition comprising a therapeutically effective amount of the psychedelic compound to a patient by subcutaneous injection, which pharmaceutical composition is a formulation selected from a solution, suspension, emulsion, gel, liposome poorly soluble salt formulation, oily depot, viscous depot, protein binding system, lipidic system, polymer system, particulate system, or an in-situ gelling system.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, **gel**, paste, salve, **solution, suspension**, tincture, patch, and atomized vapor." From **[0157]** "…Thus, for example, **the pharmaceutical compositions are optionally formulated with** suitable **polymeric** or hydrophobic materials (for example as **an emulsion in an acceptable oil**) or ion exchange resins, or as sparingly soluble derivatives, for example, as a sparingly soluble salt." From **[0159]** "In some instances, the pharmaceutical formulation includes multiparticulate formulations. In some instances, the pharmaceutical formulation includes nanoparticle formulations. In some instances, nanoparticles comprise cyclodextrins or **lipids**. In some cases, nanoparticles comprise solid **lipid nanoparticles**, polymeric nanoparticles, **self-emulsifying nanoparticles, liposome**s, **microemulsions**, or micellar solutions." From **[0267] "Poor solubility" means a small amount of compound dissolved in a solven**t. Poor solubility is not an absolute term, but depends on the amount of the compound that is needed for effective treatment of a disease or condition. A compound will be poorly soluble if its solubility is lower than is desired in order for an effective treatment of a disease or

	condition. From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
10. The method according to claim 9, wherein the pharmaceutical composition is a formulation which is a solution or a formulation which is a suspension.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate,

	metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
11. The method according to claim 9 or claim 10, wherein the formulation comprises the psychedelic compound at a concentration of at least about 50 mg/g.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, **about 5% w/w**, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, about 7% w/w, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about

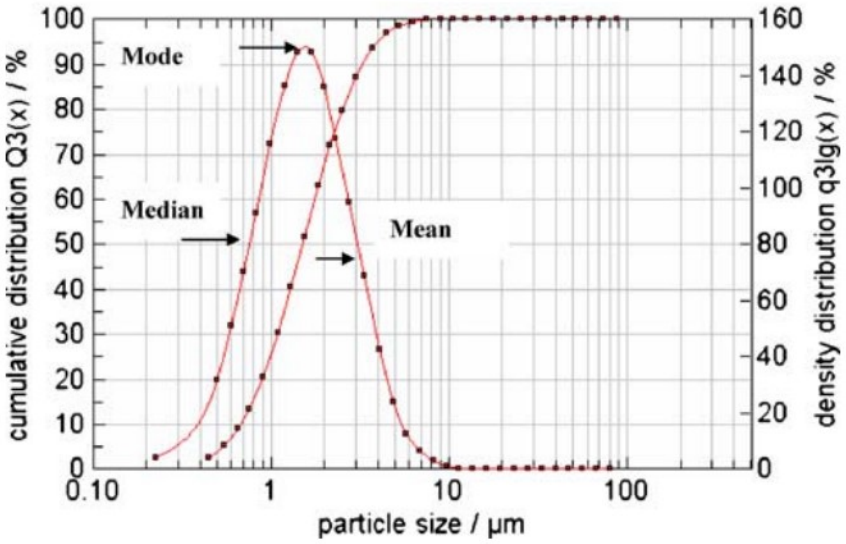
	9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, about 20% w/w, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation.”
12. The method according to claim 11, wherein the formulation comprises the psychedelic compound at a concentration of at least about 70 mg/g.	1. U.S. Pat. App. Pub. No. 2022/0096504 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS” (Published March 31, 2022) From **[0191]** “... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, **about 7% w/w**, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w,

	about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, about 20% w/w, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation."
13. The method according to claim 12, wherein the formulation comprises the psychedelic compound at a concentration of at least about 90 mg/g.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6%

	w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, about 7% w/w, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, **about 9% w/w**, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, about 20% w/w, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation."
14. The method according to claim 13, wherein the formulation comprises the psychedelic compound at a concentration of at least about 200 mg/g.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about

	4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, about 7% w/w, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, **about 20% w/w**, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation."
15. The method according to any one of claims 9 to 14, wherein the formulation is a suspension comprising particles of the psychedelic compound and the particles of the psychedelic compound have a D.sub.50 of less than about 3 μm.	2. SHEKUNOV (2006) "Particle Size Analysis in Pharmaceutics: Principles, Methods and Applications" *Pharmaceutical Research*. 24(2): 203-227 Form **page 219** "**A typical PSD with average particle diameter**s is shown in Fig. 7. **The mode average diameter corresponds to the peak and the median represents 50% (of mass, volume or number, d50)**." From **page 203** "The purpose of particle size analysis is to obtain quantitative data on the mean size, **particle size distribution (PSD)** and shape of the compounds to be used **in pharmaceutical formulation**."

	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**."
16. The method according to claim 15, wherein the particles of the psychedelic compound in the formulation have a D.sub.50 of less than about 1.5 μm.	2. SHEKUNOV (2006) "Particle Size Analysis in Pharmaceutics: Principles, Methods and Applications" *Pharmaceutical Research*. 24(2): 203-227 Form **page 219** "**A typical PSD with average particle diameter**s is shown in Fig. 7. **The mode average diameter corresponds to the peak and the median represents 50% (of mass, volume or number, d50)**." From **page 203** "The purpose of particle size analysis is to obtain quantitative data on the mean size, **particle size distribution (PSD)** and shape of the compounds to be used **in pharmaceutical formulation**." 1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**."
17. The method according to any one of claims 9 to 16, wherein the formulation is a suspension comprising particles of the psychedelic compound and the particles of the psychedelic compound in the formulation have a D.sub.90 of from 2.0 to 4.0 μm.	2. SHEKUNOV (2006) "Particle Size Analysis in Pharmaceutics: Principles, Methods and Applications" *Pharmaceutical Research*. 24(2): 203-227 Form **page 219** "**A typical PSD with average particle diameter**s is shown in Fig. 7. **The mode average diameter corresponds to the peak and the median represents 50% (of mass, volume or number, d50)**." From **page 203** "The purpose of particle size analysis is to obtain quantitative data on the mean size, **particle size distribution (PSD)** and shape of the compounds to be used **in pharmaceutical formulation**." From **page 219** "**Fig. 7. A typical volume-weighted particle size distribution (PSD)** obtained using an LD instrument (RODOS, Sympatec

	GmbH) and corresponding average diameters…  "
18. The method according to any one of claims 9 to 17, wherein the formulation is a suspension comprising particles of the psychedelic compound, polyvinylpyrrolidone, polyoxyethylene (80) sorbitan monooleate, and phosphate-buffered saline, and wherein the psychedelic compound is psilocybin.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0112]** "In some embodiments, **hydrophilic agents are included in a composition, formulation,** core or coating described herein, such as to promote wetting of the coating when in contact with gastrointestinal fluids. Such hydrophilic agents include, by way of non-limiting example, hydrophilic water soluble polymers such as hydroxypropyl methylcellulose (HPMC) (e.g. Pharmacoat® 606 or Hypromellose), hydroxypropyl cellulose (HPC), methyl cellulose, hydroxyethyl cellulose, hydroxyethyl methylcellulose, **polyvinylpyrrolidone**…" From **[0115]** "**In some embodiments, an emulsifying agent** (also called emulsifiers or emulgents) **is included in a composition, formulation**, core or coating described herein, such as to facilitate actual emulsification during manufacture of the coating, and/or to provide emulsion stability during the shelf-life of the product. In some instances, suitable emulsifying agents include, but are not limited to naturally occurring materials and their semi synthetic derivatives, such as the polysaccharides, as well as glycerol esters, cellulose ethers, sorbitan esters and polysorbates. Mixtures are operable. In at least one embodiment the emulsifying agent used is **Polysorbate 80 (polyoxyethylene sorbitan mono-oleate**)…" From **[0167]** "In some instances, **the pharmaceutical formulations**

	further include diluent which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
19. The method according to any one of claims 9 to 17, wherein the formulation is a suspension comprising particles of the psychedelic compound, 2-hydroxypropyl-β-cyclodextrin, and phosphate-buffered saline, and wherein the psychedelic compound is psilocybin.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, N-methylpyrrolidone, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, **hydroxypropyl cyclodextrins**, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol, propylene glycol, and dimethyl isosorbide and any combination thereof. From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor."

	From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
20. The method according to any one of claims 9 to 17, wherein the formulation is a suspension comprising particles of the psychedelic compound, polyethylene-polypropylene glycol, and phosphate-buffered saline, and wherein the psychedelic compound is psilocybin.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0110]** "In certain embodiments, a coating composition comprises a polyglycol, such as with a melting point of at least about 55° C. …Other suitable polyglycol derivatives having a melting point of at least about 55° C. might be, but are not limited to, **Poloxamer 188, Poloxamer 338, Poloxamer 407**, polyethylene oxides, polyoxyethylene alkyl ethers, polyoxyethylene stearates, and mixtures thereof." From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
21. The method according to any one of claims 9 to 14, wherein the formulation is a solution comprising the psychedelic compound,	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022)

2-hydroxypropyl-β-cyclodextrin, and water, and wherein the psychedelic compound is psilocin.	From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, N-methylpyrrolidone, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, **hydroxypropyl cyclodextrins**, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol, propylene glycol, and dimethyl isosorbide and any combination thereof. From **[0253]** "It should be understood that a reference to a pharmaceutically acceptable salt **includes the solvent addition forms**, i.e. solvates. In some embodiments, solvates contain either stoichiometric or non-stoichiometric amounts of a solvent, and are formed during the process of isolating or purifying the compound with **pharmaceutically acceptable solvents such as water**, ethanol, and the like..." From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, **solution**, suspension, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
22. The method according to any one of claims 9 to 14, wherein the formulation is a solution comprising the psychedelic compound and water, and wherein the psychedelic compound is psilocin.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0253]** "It should be understood that a reference to a pharmaceutically acceptable salt **includes the solvent addition forms**, i.e. solvates. In some embodiments, solvates contain either stoichiometric or non-stoichiometric amounts of a solvent, and are formed during the process of isolating or

	purifying the compound with **pharmaceutically acceptable solvents such as water**, ethanol, and the like..." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, **solution**, suspension, tincture, patch, and atomized vapor." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
23. The method according to any one of claims 9 to 17, wherein the formulation is a suspension comprising particles of the psychedelic compound, corn oil, N-methylpyrrolidone, and polyoxyl-35-**castor oil**, wherein the psychedelic compound is psilocin.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, **N-methylpyrrolidone**, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, hydroxypropyl cyclodextrins, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol, propylene glycol, and dimethyl isosorbide and any combination thereof." From **[0175]** "Surfactants include compounds such as sodium lauryl sulfate, sodium docusate, Tween 60 or 80, triacetin, vitamin E TPGS, sorbitan monooleate, polyoxyethylene sorbitan monooleate, polysorbates, polaxomers, bile salts, glyceryl monostearate, copolymers of ethylene oxide and propylene oxide, e.g. Pluronic® (BASF), and any combination thereof. Additional surfactants include polyoxyethylene fatty acid glycerides and **vegetable oils**, e.g. polyoxyethylene (60) hydrogenated **castor oil**; and polyoxyethylene alkylethers and alkylphenyl ethers, e.g. octoxynol 10, octoxynol 40. Sometimes, surfactants are included to enhance physical stability or for other purposes." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate,

	metabolite, derivative, or prodrug thereof..."
24. The method according to any one of the preceding claims, wherein administering the therapeutically effective amount of the psychedelic compound to the patient by subcutaneous injection comprises administering: a first dose of the psychedelic compound with a first absorption half-life of the psychedelic compound of (t.sub.firstdose).sub.1/2; and a second dose of the psychedelic compound with a second absorption half-life of the psychedelic compound of (t.sub.seconddose).sub.1/2; wherein (t.sub.seconddose).sub.1/2>(t.sub.firstdose).sub.1/2.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or more…**" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)." From **[0020]** "In some embodiments, the pharmaceutical composition comprises a **controlled release component**." From **[0240]** "The term **"controlled release matrix" refers to a polymeric matrix that is capable of delivering a bioactive agent** at a controlled rate for a period of time. Although there might be an **initial burst phase**, the overall release kinetics of the bioactive agent from the matrix are generally linear, such that a relatively constant supply of bioactive agent is released over the desired time period. The time period might vary from several hours to several days, depending upon the bioactive agent and its intended use. In general, it is preferable that the percentage of bioactive agent released from the controlled matrix over the treatment period be relatively high (e.g. at least about 50%, at least about 75%, at least about 90%, or at least about 95%) to avoid waste of unreleased bioactive agent."
25. The method according to claim 24,	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR

wherein (t.sub.seconddose).sub.1 /2>n (t.sub.firstdose).sub.1/2; and wherein n=1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20.	THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or more…**" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)." From **[0020]** "In some embodiments, the pharmaceutical composition comprises a **controlled release component**." From **[0240]** "The term **"controlled release matrix" refers to a polymeric matrix that is capable of delivering a bioactive agent** at a controlled rate for a period of time. Although there might be an **initial burst phase**, the overall release kinetics of the bioactive agent from the matrix are generally linear, such that a relatively constant supply of bioactive agent is released over the desired time period. The time period might vary from several hours to several days, depending upon the bioactive agent and its intended use. In general, it is preferable that the percentage of bioactive agent released from the controlled matrix over the treatment period be relatively high (e.g. at least about 50%, at least about 75%, at least about 90%, or at least about 95%) to avoid waste of unreleased bioactive agent."
26. The method according to claim 24 or claim 25, wherein the first dose is from about 0.1 mg to about 10 mg, from about 0.2 mg to about 9 mg, from about	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0157]** "In addition to the disclosed formulations, the pharmaceutical

0.3 mg to about 8 mg, from about 0.4 mg to about 7 mg, from about 0.5 mg to about 6 mg, from about 0.6 mg to about 5 mg, from about 0.7 mg to about 4 mg, from about 0.8 mg to about 3 mg, from about 0.9 mg to about 2 mg, or from about 1 mg to about 1.5 mg.	compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or more…**" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg,** about 10 mg to about 50 mg, or the like)." From **[0020]** "In some embodiments, the pharmaceutical composition comprises a **controlled release component**." From **[0240]** "The term **"controlled release matrix" refers to a polymeric matrix that is capable of delivering a bioactive agent** at a controlled rate for a period of time. Although there might be an **initial burst phase**, the overall release kinetics of the bioactive agent from the matrix are generally linear, such that a relatively constant supply of bioactive agent is released over the desired time period. The time period might vary from several hours to several days, depending upon the bioactive agent and its intended use. In general, it is preferable that the percentage of bioactive agent released from the controlled matrix over the treatment period be relatively high (e.g. at least about 50%, at least about 75%, at least about 90%, or at least about 95%) to avoid waste of unreleased bioactive agent."
27. The method according to any one of claims 24 to 26, wherein the first dose is from about 0.1 mg to about 0.3 mg, from about 0.3 mg to about 0.5 mg, from about 0.5 mg to about 0.7 mg, from about 0.7 mg to about 0.9 mg, from about 0.9 mg to about 1.1 mg,	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."

from about 1.1 mg to about 1.3 mg, from about 1.3 mg to about 1.5 mg, from about 1.5 mg to about 1.7 mg, or from about 1.7 mg to about 1.9 mg.	From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or more…**" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg,** about 10 mg to about 50 mg, or the like)." From **[0020]** "In some embodiments, the pharmaceutical composition comprises a **controlled release component**." From **[0240]** "The term **"controlled release matrix" refers to a polymeric matrix that is capable of delivering a bioactive agent** at a controlled rate for a period of time. Although there might be an **initial burst phase**, the overall release kinetics of the bioactive agent from the matrix are generally linear, such that a relatively constant supply of bioactive agent is released over the desired time period. The time period might vary from several hours to several days, depending upon the bioactive agent and its intended use. In general, it is preferable that the percentage of bioactive agent released from the controlled matrix over the treatment period be relatively high (e.g. at least about 50%, at least about 75%, at least about 90%, or at least about 95%) to avoid waste of unreleased bioactive agent."
28. The method according to any one of claims 24 to 27, wherein the first dose is less than or equal to 50%, less than or equal to 40%, less than or equal to 30%, less than or equal to 20%, or less than or equal to 10% of the second dose.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or**

	more…" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg,** about 10 mg to about 50 mg, or the like)." From **[0020]** "In some embodiments, the pharmaceutical composition comprises a **controlled release component**." From **[0240]** "The term **"controlled release matrix" refers to a polymeric matrix that is capable of delivering a bioactive agent** at a controlled rate for a period of time. Although there might be an **initial burst phase**, the overall release kinetics of the bioactive agent from the matrix are generally linear, such that a relatively constant supply of bioactive agent is released over the desired time period. The time period might vary from several hours to several days, depending upon the bioactive agent and its intended use. In general, it is preferable that the percentage of bioactive agent released from the controlled matrix over the treatment period be relatively high (e.g. at least about 50%, at least about 75%, at least about 90%, or at least about 95%) to avoid waste of unreleased bioactive agent."
29. The method according to any one of claims 24 to 28, wherein (t.sub.firstdose).sub.1/2 is from about 0.5 minutes to about 15 minutes, from about 1 minute to about 8 minutes, from about 2 minutes to about 7 minutes, from about 3 minutes to about 6 minutes, or from about 4 minutes to about 5 minutes.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From Table 7 "Apparent t1/2 = apparent terminal half-life TABLE 7 Plasma PK parameters summary for psilocybin following 1.0 mg/kg s.c. administration. Parameter / Mean / SD t_{max} (h) 0.357 0.283 C_{max} (ng/mL) 78.3 39.8 C_{max}/Dose (kg*ng/mL/mg) 78.3 39.8 Apparent $t_{1/2}$ (h) 0.445 0.236 $AUC_{0-tlast}$ (h*ng/mL) 53.1 23.7 "
30. The method according to any one of claims 24 to 29, wherein (t.sub.seconddose).sub.1	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31,

/2 is from about 10 minutes to about 200 minutes, from about 20 minutes to about 170 minutes, from about 30 minutes to about 140 minutes, from about 40 minutes to about 110 minutes, or from about 50 minutes to about 100 minutes.	2022) From Table 16 "Apparent t1/2 = apparent terminal half-life TABLE 16 Plasma PK parameters summary for psilocin following 10 mg/kg s.c. administration of psilocybin. Parameter / Mean / SD t_{max} (h) 0.714 0.267 C_{max} (ng/mL) 1106 434 Apparent $t_{1/2}$ (h) 1.65 0.325 $AUC_{0-tlast}$ (h*ng/mL) 2280 1524 AUC_{0-inf} (h*ng/mL) 3376 1056 MRT_{0-inf} (h) 2.66 0.395 "
31. The method according to any one of claims 24 to 30, wherein the first and second doses are administered as a single subcutaneous injection.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0240]** "The term **"controlled release matrix" refers to a polymeric matrix that is capable of delivering a bioactive agent** at a controlled rate for a period of time. Although there might be an **initial burst phase**, the overall release kinetics of the bioactive agent from the matrix are generally linear, such that a relatively constant supply of bioactive agent is released over the desired time period. The time period might vary from several hours to several days, depending upon the bioactive agent and its intended use. In general, it is preferable that the percentage of bioactive agent released from the controlled matrix over the treatment period be relatively high (e.g. at least about 50%, at least about 75%, at least about 90%, or at least about 95%) to avoid waste of unreleased bioactive agent." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or**

	more…" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg,** about 10 mg to about 50 mg, or the like)." From **[0020]** "In some embodiments, the pharmaceutical composition comprises a **controlled release component**."
32. The method according to any one of claims 24 to 31, wherein **the first dose** of the psychedelic compound is formulated as a first pharmaceutical composition which is a first formulation selected from a solution, suspension, emulsion, gel, liposome poorly soluble salt formulation, oily depot, viscous depot, protein binding system, lipidic system, polymer system, particulate system, or an in-situ gelling system.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, **gel**, paste, salve, **solution, suspension**, tincture, patch, and atomized vapor." From **[0157]** "…Thus, for example, t**he pharmaceutical compositions are optionally formulated with** suitable **polymeric** or hydrophobic materials (for example as **an emulsion in an acceptable oil**) or ion exchange resins, or as sparingly soluble derivatives, for example, as a sparingly soluble salt." From **[0159]** "In some instances, the pharmaceutical formulation includes multiparticulate formulations. In some instances, the pharmaceutical formulation includes nanoparticle formulations. In some instances, nanoparticles comprise cyclodextrins or **lipids**. In some cases, nanoparticles comprise solid **lipid nanoparticles**, polymeric nanoparticles, **self-emulsifying nanoparticles, liposome**s, **microemulsions**, or micellar solutions." From **[0267] "Poor solubility" means a small amount of compound dissolved in a solven**t. Poor solubility is not an absolute term, but depends on the amount of the compound that is needed for effective treatment of a disease or condition. A compound will be poorly soluble if its solubility is lower than is desired in order for an effective treatment of a disease or condition. From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or

	transcutaneous delivery (for example subcutaneously or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or more…**" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)."
33. The method according to claim 32, wherein the first formulation is a formulation as defined in any one of claims 10 to 23.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0159]** "In some instances, **the pharmaceutical formulation includes multiparticulate formulations**. In some instances, the pharmaceutical formulation includes nanoparticle formulations. In some instances, nanoparticles comprise cyclodextrins or **lipids**. In some cases, nanoparticles comprise solid **lipid nanoparticles**, polymeric nanoparticles, **self-emulsifying nanoparticles, liposome**s, **microemulsions**, or micellar solutions." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or more…**" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate,

	metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)."
34. The method according to any one of claims 24 to 33, wherein the second dose of the psychedelic compound is formulated as a **second pharmaceutical** composition which is a second formulation selected from a solution, suspension, emulsion, gel, liposome poorly soluble salt formulation, oily depot, viscous depot, protein binding system, lipidic system, polymer system, particulate system, or an in-situ gelling system.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, **gel**, paste, salve, **solution, suspension**, tincture, patch, and atomized vapor." From **[0157]** "…Thus, for example, t**he pharmaceutical compositions are optionally formulated with** suitable **polymeric** or hydrophobic materials (for example as **an emulsion in an acceptable oil**) or ion exchange resins, or as sparingly soluble derivatives, for example, as a sparingly soluble salt." From **[0159]** "In some instances, the pharmaceutical formulation includes multiparticulate formulations. In some instances, the pharmaceutical formulation includes nanoparticle formulations. In some instances, nanoparticles comprise cyclodextrins or **lipids**. In some cases, nanoparticles comprise solid **lipid nanoparticles**, polymeric nanoparticles, **self-emulsifying nanoparticles, liposome**s, **microemulsions**, or micellar solutions." From **[0267] "Poor solubility" means a small amount of compound dissolved in a solven**t. Poor solubility is not an absolute term, but depends on the amount of the compound that is needed for effective treatment of a disease or condition. A compound will be poorly soluble if its solubility is lower than is desired in order for an effective treatment of a disease or condition. From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent**

	is administered once per day, **twice per day, three times per day or more…**" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)."
35. The method according to claim 34, wherein the second formulation is a formulation as defined in any one of claims 10 to 23.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0159]** "In some instances, **the pharmaceutical formulation includes multiparticulate formulations**. In some instances, the pharmaceutical formulation includes nanoparticle formulations. In some instances, nanoparticles comprise cyclodextrins or **lipids**. In some cases, nanoparticles comprise solid **lipid nanoparticles**, polymeric nanoparticles, **self-emulsifying nanoparticles, liposome**s, **microemulsions**, or micellar solutions." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or more…**" From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)."
36. The method according to any one of claims 24 to 35, wherein administering the	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31,

therapeutically effective amount of the psychedelic compound to the patient by subcutaneous injection further comprises administering a third dose of the psychedelic compound with a third absorption half-life of the psychedelic compound of (t.sub.thirddose).sub.1/2.	2022) From **[0224]** "In some embodiments, **any pharmaceutical composition or formulation or 5HT receptor agonist agent** disclosed herein is administered for therapeutic application. In some embodiments, the pharmaceutical composition or formation or **5HT receptor agonist agent is administered** once per day, **twice per day, three times per day or more…**" From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **claim 3** "The method of any one of the preceding claims, wherein **the 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about **0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like**)."
37. The method according to any one of the preceding claims, wherein the disease or condition is selected from a psychological, neurological and central nervous system disorder.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression, bipolar disorder, anxiety, social anxiety, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder**." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."

	From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
38. The method according to any one of the preceding claims, wherein the disease or condition is selected from depression, anxiety, death anxiety, demoralization, hopelessness, adjustment disorders, suicidal ideation and desire for hastened death.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) **From claim 43** "The method of any one of claims 1-38, wherein the neurological condition is **depression**, bipolar disorder**, anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
39. The method according to any one of claims 1 to 37, wherein the disease or condition is selected from cocaine-related disorders, opioid-related disorders and stimulant-related disorders.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0217] "Further examples of the disorders, conditions and symptoms which may be managed or treated include** by way of non-limiting example,… **addictive disorders, substance dependence, substance abuse**, alcoholism, **drug addiction**, **opioid addiction**, **cocaine**

	addiction, gambling addiction, tobacco dependence, food addiction, other forms of addiction to substances and behaviors, obesity, cognitive disorders,…" From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
40. A psychedelic compound for use in a method of treating or preventing a disease or condition in a patient, wherein: the psychedelic compound is psilocybin or psilocin, or a pharmaceutically acceptable salt thereof; and the method comprises administering a therapeutically effective amount of a psychedelic compound to the patient by subcutaneous injection.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate,

	metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
41. The psychedelic compound for use according to claim 40, wherein: administering the psychedelic compound by subcutaneous injection is as further defined in any one of claims 2 to 36.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
42. The psychedelic compound for use according to claim 40 or claim 41, wherein the psychedelic compound is for use in the treatment of a disease or condition selected from	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression,** bipolar disorder, **anxiety, social**

a psychological, neurological and central nervous system disorder, and preferably selected from depression, anxiety, death anxiety, demoralization, hopelessness, adjustment disorders, suicidal ideation and desire for hastened death.	**anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
43. The psychedelic compound for use according to claim 40 or claim 41, wherein the psychedelic compound is for use in the treatment of a disease or condition selected from cocaine-related disorders, opioid-related disorders and stimulant-related disorders.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0217] "Further examples of the disorders, conditions and symptoms which may be managed or treated include** by way of non-limiting example,… **addictive disorders, substance dependence, substance abuse**, alcoholism, **drug addiction**, **opioid addiction**, **cocaine addiction**, gambling addiction, tobacco dependence, food addiction, other forms of addiction to substances and behaviors, obesity, cognitive disorders,…" From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…"

	From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
44. Use of a psychedelic compound in the manufacture of a medicament for use in a method of treating or preventing of a disease or condition in a patient, wherein: the psychedelic compound is psilocybin or psilocin, or a pharmaceutically acceptable salt thereof; and the method comprises administering a therapeutically effective amount of a psychedelic compound to the patient by subcutaneous injection.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0217] "Further examples of the disorders, conditions and symptoms which may be managed or treated include** by way of non-limiting example,… **addictive disorders, substance dependence, substance abuse**, alcoholism, **drug addiction**, **opioid addiction**, **cocaine addiction**, gambling addiction, tobacco dependence, food addiction, other forms of addiction to substances and behaviors, obesity, cognitive disorders,…" From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
45. A formulation suitable for administration by	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE,

subcutaneous injection comprising a psychedelic compound which is psilocybin or a pharmaceutically acceptable salt thereof, wherein the formulation is a suspension and the formulation comprises the psychedelic compound at a concentration of at least about 70 mg/g.	BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, **about 7% w/w**, about 7.1% w/w, about 7.2% w/w, about 7.3%

	w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, about 20% w/w, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation."
46. A formulation suitable for administration by subcutaneous injection comprising a psychedelic compound which is psilocin or a pharmaceutically acceptable salt thereof, wherein the formulation is a suspension or a solution and the formulation comprises psilocin at a concentration of at least about 200 mg/g.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is**

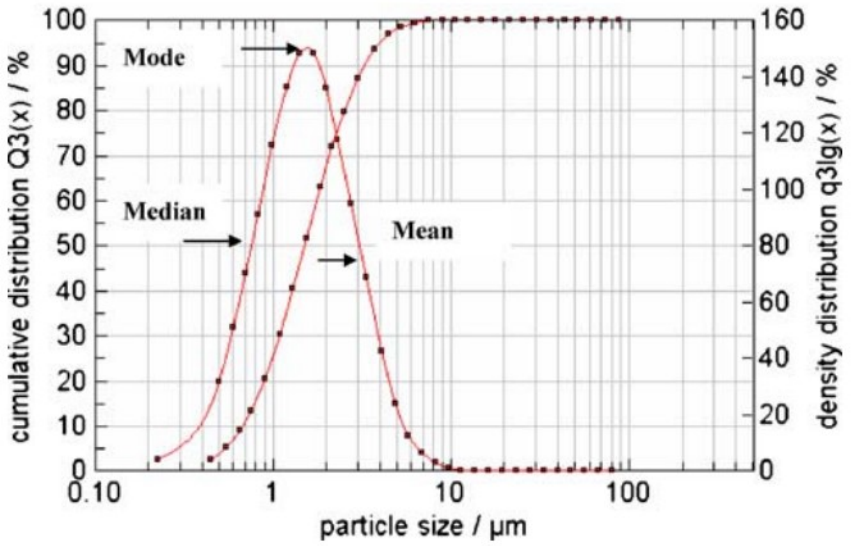
	psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, about 7% w/w, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, **about 20% w/w**, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about

	29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation."
47. The formulation according to claim 45 or 46, wherein the formulation is a suspension comprising particles of the psychedelic compound and the particles of the psychedelic compound have a D.sub.50 of less than about 3 μm.	2. SHEKUNOV (2006) "Particle Size Analysis in Pharmaceutics: Principles, Methods and Applications" *Pharmaceutical Research*. 24(2): 203-227 Form **page 219** "**A typical PSD with average particle diameter**s is shown in Fig. 7. **The mode average diameter corresponds to the peak and the median represents 50% (of mass, volume or number, d50)**." From **page 203** "The purpose of particle size analysis is to obtain quantitative data on the mean size, **particle size distribution (PSD)** and shape of the compounds to be used **in pharmaceutical formulation**." 1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate,

	metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, about 7% w/w, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, **about 20% w/w**, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33%

	w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation."
48. The formulation according to claim 47, wherein the formulation is a suspension comprising particles of the psychedelic compound and the particles of the psychedelic compound have a D.sub.50 of less than about 1.5 μm.	2. SHEKUNOV (2006) "Particle Size Analysis in Pharmaceutics: Principles, Methods and Applications" *Pharmaceutical Research*. 24(2): 203-227 Form **page 219** "**A typical PSD with average particle diameter**s is shown in Fig. 7. **The mode average diameter corresponds to the peak and the median represents 50% (of mass, volume or number, d50)**." From **page 203** "The purpose of particle size analysis is to obtain quantitative data on the mean size, **particle size distribution (PSD)** and shape of the compounds to be used **in pharmaceutical formulation**." 1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."

	From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, about 7% w/w, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, **about 20% w/w**, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w,

	about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation."
49. The formulation according to any one of claims 45 to 47, wherein the formulation is a suspension comprising particles of the psychedelic compound and the particles of the psychedelic compound have a D.sub.90 of from 2.0 to 4.0 μm.	2. SHEKUNOV (2006) "Particle Size Analysis in Pharmaceutics: Principles, Methods and Applications" *Pharmaceutical Research*. 24(2): 203-227 Form **page 219** "**A typical PSD with average particle diameter**s is shown in Fig. 7. **The mode average diameter corresponds to the peak and the median represents 50% (of mass, volume or number, d50)**." From **page 203** "The purpose of particle size analysis is to obtain quantitative data on the mean size, **particle size distribution (PSD)** and shape of the compounds to be used **in pharmaceutical formulation**." From **page 219** "**Fig. 7. A typical volume-weighted particle size distribution (PSD)** obtained using an LD instrument (RODOS, Sympatec GmbH) and corresponding average diameters…  " From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or**

	more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, about 7% w/w, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9% w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8%

	w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, **about 20% w/w**, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation."
50. The formulation according to any one of claims 45 to 49, wherein the formulation further comprises at least one pharmaceutically acceptable diluent, and optionally further comprises at least one pharmaceutically acceptable buffer, solubiliser, polymer, and/or surfactant.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…"
51. The formulation according to claim 50, wherein the formulation is a suspension comprising polyvinylpyrrolidone, polyoxyethylene (80) sorbitan monooleate, and phosphate-buffered saline, and wherein the psychedelic compound is psilocybin.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0112]** "In some embodiments, **hydrophilic agents are included in a composition, formulation,** core or coating described herein, such as to promote wetting of the coating when in contact with gastrointestinal fluids. Such hydrophilic agents include, by way of non-limiting example, hydrophilic water soluble polymers such as hydroxypropyl methylcellulose (HPMC) (e.g. Pharmacoat® 606 or Hypromellose), hydroxypropyl cellulose (HPC), methyl cellulose, hydroxyethyl cellulose, hydroxyethyl methylcellulose, **polyvinylpyrrolidone**…" From **[0115]** "**In some embodiments, an emulsifying agent** (also called emulsifiers or emulgents) **is included in a composition, formulation**, core or coating described herein, such as to facilitate actual emulsification

	during manufacture of the coating, and/or to provide emulsion stability during the shelf-life of the product. In some instances, suitable emulsifying agents include, but are not limited to naturally occurring materials and their semi synthetic derivatives, such as the polysaccharides, as well as glycerol esters, cellulose ethers, sorbitan esters and polysorbates. Mixtures are operable. In at least one embodiment the emulsifying agent used is **Polysorbate 80 (polyoxyethylene sorbitan mono-oleate**)…" From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
52. The formulation according to claim 51, wherein the formulation comprises polyvinylpyrrolidone at a concentration of from 0.1 to 1.0% w/v, polyoxyethylene (80) sorbitan monooleate at a concentration of from 0.01 to 0.50% w/v, and phosphate-buffered saline at a concentration of at least 98.5% w/v.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0112]** "In some embodiments, **hydrophilic agents are included in a composition, formulation,** core or coating described herein, such as to promote wetting of the coating when in contact with gastrointestinal fluids. Such hydrophilic agents include, by way of non-limiting example, hydrophilic water soluble polymers such as hydroxypropyl methylcellulose (HPMC) (e.g. Pharmacoat® 606 or Hypromellose), hydroxypropyl cellulose (HPC), methyl cellulose, hydroxyethyl cellulose, hydroxyethyl methylcellulose, **polyvinylpyrrolidone**… **In certain embodiments the hydrophilic agent is present in an amount of from greater than about 0% to about 35% by dry weight** of the coat…"

	From **[0115]** "**In some embodiments, an emulsifying agent** (also called emulsifiers or emulgents) **is included in a composition, formulation**, core or coating described herein, such as to facilitate actual emulsification during manufacture of the coating, and/or to provide emulsion stability during the shelf-life of the product. In some instances, suitable emulsifying agents include, but are not limited to naturally occurring materials and their semi synthetic derivatives, such as the polysaccharides, as well as glycerol esters, cellulose ethers, sorbitan esters and polysorbates. Mixtures are operable. In at least one embodiment the emulsifying agent used is **Polysorbate 80 (polyoxyethylene sorbitan mono-oleate**)… **The emulsifying agent or agents, if present, might be present in certain embodiments in an amount of from greater than 0% to about 0.5% by weight** of the coat composition…"
53. The formulation according to claim 50, wherein the formulation is a suspension comprising 2-hydroxypropyl-β-cyclodextrin and phosphate-buffered saline, and wherein the psychedelic compound is psilocybin.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, N-methylpyrrolidone, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, **hydroxypropyl cyclodextrins**, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol, propylene glycol, and dimethyl isosorbide and any combination thereof. From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is**

	psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
54. The formulation according to claim 53, wherein the formulation comprises 2-hydroxypropyl-β-cyclodextrin at a concentration of from 5 to 15% w/v, and phosphate-buffered saline at a concentration of from 85 to 95% w/v.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, N-methylpyrrolidone, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, **hydroxypropyl cyclodextrins**, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol, propylene glycol, and dimethyl isosorbide and any combination thereof. From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From [**0182]** "…Such formulations might comprise pharmaceutically acceptable carriers … **diluents** or fillers, sterile aqueous media and various non-toxic organic solvents. Generally, the compositions disclosed herein will be included at concentration levels ranging from about 0.5%, about 5%, about 10%, about 20%, or about 30% to about 50%, about 60%, about 70%, **about 80% or about 90% by weight** of the total ..." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
55. The formulation according to claim 50,	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR

wherein the formulation is a suspension comprising polyethylene-polypropylene glycol and phosphate-buffered saline, and wherein the psychedelic compound is psilocybin.	THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0110]** "In certain embodiments, a coating composition comprises a polyglycol, such as with a melting point of at least about 55° C. …Other suitable polyglycol derivatives having a melting point of at least about 55° C. might be, but are not limited to, **Poloxamer 188, Poloxamer 338, Poloxamer 407**, polyethylene oxides, polyoxyethylene alkyl ethers, polyoxyethylene stearates, and mixtures thereof." From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
56. The formulation according to claim 55, wherein the formulation comprises polyethylene-polypropylene glycol at a concentration of from 1 to 5% w/v, and phosphate-buffered saline at a concentration of from 95 to 99% w/v.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0110]** "In certain embodiments, a coating composition comprises a polyglycol, such as with a melting point of at least about 55° C. … In still other embodiments the **polyglycol is present in the coating composition in an amount of from about** 0.2% to about 2.8% by dry weight of the tablet, for example, about 0.3%, about 0.4%, about 0.5%, about 0.6%, about 0.7%, about 0.8%, about 0.9%, **about 1%, about 1.1%, about 1.2%, about 1.3%, about 1.4%, about 1.5%, about 1.6%, about 1.7%, about 1.8%, about 1.9%, about 2%, about 2.1%, about 2.2%, about 2.3%, about 2.4%, about 2.5%, about 2.6%, and about 2.7% by dry weight** of

	the tablet. Other suitable polyglycol derivatives having a melting point of at least about 55° C. might be, but are not limited to, **Poloxamer 188, Poloxamer 338, Poloxamer 407**, polyethylene oxides, polyoxyethylene alkyl ethers, polyoxyethylene stearates, and mixtures thereof." From **[0167]** "In some instances, **the pharmaceutical formulations further include diluent** which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment. Salts dissolved in buffered solutions (which also provide pH control or maintenance) are utilized as diluents in the art, including, but not limited to a **phosphate buffered saline** solution…" From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is** psilocin or **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
57. The formulation according to claim 50, wherein the formulation is a solution comprising 2-hydroxypropyl-β-cyclodextrin and water, and wherein the psychedelic compound is psilocin.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, N-methylpyrrolidone, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, **hydroxypropyl cyclodextrins**, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol, propylene glycol, and dimethyl isosorbide and any combination thereof. From **[0253]** "It should be understood that a reference to a pharmaceutically acceptable salt **includes the solvent addition forms**, i.e. solvates. In some embodiments, solvates contain either stoichiometric or non-stoichiometric amounts of a solvent, and are formed during the process of isolating or purifying the compound with **pharmaceutically acceptable solvents such as water**, ethanol, and the like..."

	From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
58. The formulation according to claim 57, wherein the formulation comprises 2-hydroxypropyl-β-cyclodextrin at a concentration of from 5 to 15% w/v, and water at a concentration of from 85 to 95% w/v.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, N-methylpyrrolidone, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, **hydroxypropyl cyclodextrins**, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol, propylene glycol, and dimethyl isosorbide and any combination thereof. From **[0253]** "It should be understood that a reference to a pharmaceutically acceptable salt **includes the solvent addition forms**, i.e. solvates. In some embodiments, solvates contain either stoichiometric or non-stoichiometric amounts of a solvent, and are formed during the process of isolating or purifying the compound with **pharmaceutically acceptable solvents such as water**, ethanol, and the like..." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
59. The formulation	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND

according to claim 50, wherein the formulation is a solution comprising water, and wherein the psychedelic compound is psilocin.	COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0253]** "It should be understood that a reference to a pharmaceutically acceptable salt **includes the solvent addition forms**, i.e. solvates. In some embodiments, solvates contain either stoichiometric or non-stoichiometric amounts of a solvent, and are formed during the process of isolating or purifying the compound with **pharmaceutically acceptable solvents such as water**, ethanol, and the like..." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, **solution**, suspension, tincture, patch, and atomized vapor." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
60. The formulation according to claim 59, wherein the formulation comprises 100% w/v water.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0253]** "It should be understood that a reference to a pharmaceutically acceptable salt **includes the solvent addition forms**, i.e. solvates. In some embodiments, solvates contain either stoichiometric or non-stoichiometric amounts of a solvent, and are formed during the process of isolating or purifying the compound with **pharmaceutically acceptable solvents such as water**, ethanol, and the like..." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, **solution**, suspension, tincture, patch, and atomized vapor." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
61. The formulation according to claim 50, wherein the formulation is a suspension	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31,

comprising corn oil, N-methylpyrrolidone and polyoxyl-35-castor oil, and wherein the psychedelic compound is psilocin.	2022) From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, **N-methylpyrrolidone**, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, hydroxypropyl cyclodextrins, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol, propylene glycol, and dimethyl isosorbide and any combination thereof." From **[0175]** "Surfactants include compounds such as sodium lauryl sulfate, sodium docusate, Tween 60 or 80, triacetin, vitamin E TPGS, sorbitan monooleate, polyoxyethylene sorbitan monooleate, polysorbates, polaxomers, bile salts, glyceryl monostearate, copolymers of ethylene oxide and propylene oxide, e.g. Pluronic® (BASF), and any combination thereof. Additional surfactants include polyoxyethylene fatty acid glycerides and **vegetable oils**, e.g. polyoxyethylene (60) hydrogenated **castor oil**; and polyoxyethylene alkylethers and alkylphenyl ethers, e.g. octoxynol 10, octoxynol 40. Sometimes, surfactants are included to enhance physical stability or for other purposes." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
62. The formulation according to claim 61, wherein the formulation comprises corn oil at a concentration of from 70 to 90% w/w, N-methylpyrrolidone at a concentration of from 5 to 15% w/w, and polyoxyl-35-castor oil at a concentration of from 5 to 15% w/w.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) From **[0172]** "Solubilizers include compounds such as triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, sodium lauryl sulfate, sodium doccusate, vitamin E TPGS, dimethylacetamide, **N-methylpyrrolidone**, N-hydroxyethylpyrrolidone, PVP, hydroxypropylmethyl cellulose, hydroxypropyl cyclodextrins, ethanol, n-butanol, isopropyl alcohol, cholesterol, bile salts, polyethylene glycol 200-600, glycofurol, transcutol,

	propylene glycol, and dimethyl isosorbide and any combination thereof." From **[0175]** "Surfactants include compounds such as sodium lauryl sulfate, sodium docusate, Tween 60 or 80, triacetin, vitamin E TPGS, sorbitan monooleate, polyoxyethylene sorbitan monooleate, polysorbates, polaxomers, bile salts, glyceryl monostearate, copolymers of ethylene oxide and propylene oxide, e.g. Pluronic® (BASF), and any combination thereof. Additional surfactants include polyoxyethylene fatty acid glycerides and **vegetable oils**, e.g. polyoxyethylene (60) hydrogenated **castor oil**; and polyoxyethylene alkylethers and alkylphenyl ethers, e.g. octoxynol 10, octoxynol 40. Sometimes, surfactants are included to enhance physical stability or for other purposes." From **[0091]** "…In some embodiments, **the pharmaceutical composition is in a form selected from** a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, **suspension**, tincture, patch, and atomized vapor." From **[0162]** "In some cases, **a nanoparticle has at least one dimension of less than about 500 nm, 400 nm, 300 nm, 200 nm, or 100 nm**." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin** or psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..."
63. A formulation according to any one of claims 45 to 62, wherein the formulation comprises psilocybin and is stable for 7 days at 25° C.	*From the **application of interest 18/196,567** paragraph [0178] "TABLE 12 Stability results for Formulations 1-3…In conclusion, Formulations 1-3 were physically and chemically stable for at least 7 days at 25° C. **The percentage peak area for all formulations after 7 days is comparable to t=0 (i.e. no degradation detected by HPLC).** The pH and osmolality values were also comparable. XRPD analysis of all 3 suspensions showed conversion of psilocybin to the trihydrate form from t=0 and no changes for at least 7 days.*

TABLE 12

Stability results for Formulations 1-3

Formulation	Time-point/ storage condition	pH	Osmolality (mOsm/kg)	Dissolved fraction (mg/g)	Top section assay (%)/ concentration (mg/g)	Bottom section assay (%)/ concentration (mg/g)	Purity (%)
1	t = 0	5.3	314	8.4 ± 0.09	94.1 ± 1.8/ 84.7 ± 1.6	97.1 ± 10.1/ 87.4 ± 9.1	99.4
	t = 24 h/ 25° C.	5.5	355	8.3 ± 0.04	93.8 ± 0.7/ 84.4 ± 0.7	95.4 ± 0.7/ 85.8 ± 0.6	99.4
	t = 4 d/ 25° C.	5.5	336	8.6 ± 0.04	91.1 ± 0.9/ 82.0 ± 0.8	91.6 ± 1.0/ 82.4 ± 0.9	99.4
	t = 7 d/ 25° C.	5.3	455	9.3 ± 0.07	102.5 ± 2.8/ 92.3 ± 2.5	101.1 ± 2.3/ 91.0 ± 2.0	99.4
2	t = 0	5.2	408	9.2 ± 0.1	98.0 ± 1.0/ 87.9 ± 0.9	97.1 ± 4.2/ 87.0 ± 3.7	99.4
	t = 24 h/ 25° C.	5.4	428	9.3 ± 0.3	94.8 ± 0.6/ 85.0 ± 0.5	93.6 ± 0.8/ 83.9 ± 0.7	99.4
	t = 4 d/ 25° C.	5.4	474	9.5 ± 0.3	93.3 ± 4.4/ 83.6 ± 3.9	90.1 ± 0.1/ 80.8 ± 0.1	99.4
	t = 7 d/ 25° C.	5.2	511	10.6 ± 0.4	95.1 ± 0.1/ 85.2 ± 0.1	105.3 ± 0.2/ 94.4 ± 0.1	99.4
3	t = 0	5.2	325	8.5 ± 0.08	96.1 ± 1.0/ 86.8 ± 0.9	86.4 ± 3.0/ 78.0 ± 2.7	99.4
	t = 24 h/ 25 ° C.	5.4	388	8.6 ± 0.04	86.9 ± 0.2/ 78.5 ± 0.2	90.3 ± 0.1/ 81.6 ± 0.1	99.4
	t = 4 d/ 25° C.	5.4	351	8.6 ± 0.03	99.7 ± 7.0/ 90.1 ± 6.3	85.6 ± 0.05/ 86.3 ± 0.05	99.4
	t = 7 d/ 25° C.	5.4	370	9.5 ± 0.1	86.6 ± 3.7/ 78.2 ± 3.3	82.6 ± 1.7/ 74.6 ± 1.6	99.3

”

3. ANASTOS (2005) “Investigation into the temporal stability of aqueous standard solutions of psilocin and psilocybin using high performance liquid chromatography” *Science & Justice: Journal of the Forensic Science Society.* 46(2): 91-96

From **page 95** “**Psilocybin standards were found to be very stable under these conditions for seven days** compared with those without protection from ambient light.”

From **page 92** “**The stability of** a 10 ug mL-I aqueous solution of psilocin and **psilocybin was investigated over a fourteen day period.** Two different conditions at ambient temperature were investigated; (i) protection from light and (ii) no protection from light.”

From page 96 “These results are in line with earlier studies by Jakubovic et al. [27] for related biogenic indole amines and illustrates that **aqueous**

	standard solutions of psilocybin and psilocin are stable for one week of analysis using lightproof conditions."
64. A formulation according to any one of claims 45 to 62, wherein the formulation comprises psilocin and is stable for 7 days at 2-8° C.	*From the* ***application of interest 18/196,567 paragraph [0186]*** *"TABLE 13 Stability results for Formulations 4 and 5…* TABLE 13 Stability results for formulations 4 and 5 Formulation / Time-point/ storage condition / pH / Osmolality (mOsm/kg) / Assay (%) / Measured concentration (mg/g) / Purity (%) 4 / t = 0 / 4.2 / 1521 / 110.9 ± 2.3 / 278.2 ± 5.9 / 99.2 t = 24 h/ 2-8° C. / 3.9 / 1525 / 116.4 ± 0.5 / 292.0 ± 1.2 / 99.2 t = 5 d/ 2-8° C. / 3.7 / 1526 / 125.4 ± 12.5 / 314.5 ± 31.4 / 99.1 t = 7 d/ 2-8° C. / 3.7 / 1532 / 112.5 ± 7.7 / 282.2 ± 19.4 / 99.2 5 / t = 0 / 4.2 / 1211 / 114.4 ± 3.4 / 287.3 ± 8.6 / 99.2 t = 24 h/ 2-8° C. / 4.3 / 1212 / 103.3 ± 4.7 / 259.3 ± 11.9 / 99.2 t = 5 d/ 2-8° C. / 4.1 / 1205 / 108.9 ± 2.2 / 273.5 ± 5.5 / 99.2 t = 7 d/ 2-8° C. / 4.2 / 1207 / 105.9 / 265.9 / 99.2 " 3. ANASTOS (2005) "Investigation into the temporal stability of aqueous standard solutions of psilocin and psilocybin using high performance liquid chromatography" *Science & Justice: Journal of the Forensic Science Society.* 46(2): 91-96 From **page 95** "**Psilocin was also found to be stable under these conditions for seven days.**" From **page 92** "**The stability of** a 10 ug mL-I aqueous solution of **psilocin** and psilocybin **was investigated over a fourteen day period.** Two different conditions at ambient temperature were investigated; (i) protection from light and (ii) no protection from light."
65. A kit comprising: one or more formulations suitable for	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE,

administration by subcutaneous injection, which one or more formulations comprise a psychedelic compound which is psilocybin or psilocin, or a pharmaceutically acceptable salt thereof; and instructions for use of the one or more formulations in a method as defined in any one of claims 1 to 39.	BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) **From [0232]** "A **kit typically includes** labels listing contents and/or **instructions for use**, and package inserts with instructions for use. **A set of instructions will also typically be included**." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or more 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch."
66. The kit of claim 65, wherein each of the one or more formulations are as defined in any one of claims 45 to 64.	1. U.S. Pat. App. Pub. No. 2022/0096504 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVORIAL, AND/OR MOOD DISORDERS" (Published March 31, 2022) **From [0232]** "A **kit typically includes** labels listing contents and/or **instructions for use**, and package inserts with instructions for use. **A set of instructions will also typically be included**." From **claim 2** "A method of **treating the symptoms of a neurological condition** in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of **one or**

	more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or **a pharmaceutically acceptable salt**, solvate, metabolite…" **From claim 43** "The method of any one of claims 1-38, wherein the **neurological condition is depression**, bipolar disorder, **anxiety, social anxiety**, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder." From **[0218]** "…In some embodiments, **the 5HT receptor agonist is psilocin or psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof..." From **[0157]** "In addition to the disclosed formulations, the pharmaceutical compositions are optionally formulated as a depot preparation. Such long acting **formulations might be administered by** implantation or **transcutaneous delivery (for example subcutaneously** or intramuscularly), intramuscular injection or use of a transdermal patch." From **[0191]** "... In other embodiments, **the amount of** the pharmaceutically acceptable salt of **a 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof correspond to about 1% w/w, **about** 1.1% w/w, about 1.2% w/w, about 1.3% w/w, about 1.4% w/w, about 1.5% w/w, about 1.6% w/w, about 1.7% w/w, about 1.8% w/w, about 1.9% w/w, about 2% w/w, about 2.1% w/w, about 2.2% w/w, about 2.3% w/w, about 2.4% w/w, about 2.5% w/w, about 2.6% w/w, about 2.7% w/w, about 2.8% w/w, about 2.9% w/w, about 3% w/w, about 3.1% w/w, about 3.2% w/w, about 3.3% w/w, about 3.4% w/w, about 3.5% w/w, about 3.6% w/w, about 3.7% w/w, about 3.8% w/w, about 3.9% w/w, about 4% w/w, about 4.1% w/w, about 4.2% w/w, about 4.3% w/w, about 4.4% w/w, about 4.5% w/w, about 4.6% w/w, about 4.7% w/w, about 4.8% w/w, about 4.9% w/w, about 5% w/w, about 5.1% w/w, about 5.2% w/w, about 5.3% w/w, about 5.4% w/w, about 5.5% w/w, about 5.6% w/w, about 5.7% w/w, about 5.8% w/w, about 5.9% w/w, about 6% w/w, about 6.1% w/w, about 6.2% w/w, about 6.3% w/w, about 6.4% w/w, about 6.5% w/w, about 6.6% w/w, about 6.7% w/w, about 6.8% w/w, about 6.9% w/w, **about 7% w/w**, about 7.1% w/w, about 7.2% w/w, about 7.3% w/w, about 7.4% w/w, about 7.5% w/w, about 7.6% w/w, about 7.7% w/w, about 7.8% w/w, about 7.9% w/w, about 8% w/w, about 8.1% w/w, about 8.2% w/w, about 8.3% w/w, about 8.4% w/w, about 8.5% w/w, about 8.6% w/w, about 8.7% w/w, about 8.8% w/w, about 8.9% w/w, about 9% w/w, about 9.1% w/w, about 9.2% w/w, about 9.3% w/w, about 9.4% w/w, about 9.5% w/w, about 9.6% w/w, about 9.7% w/w, about 9.8% w/w, about 9.9%

	w/w, about 10% w/w, about 10.2% w/w, about 10.4% w/w, about 10.6% w/w, about 10.8% w/w, about 11% w/w, about 11.2% w/w, about 11.4% w/w, about 11.6% w/w, about 11.8% w/w, about 12% w/w, about 12.2% w/w, about 12.4% w/w, about 12.6% w/w, about 12.8% w/w, about 13% w/w, about 13.2% w/w, about 13.4% w/w, about 13.6% w/w, about 13.8% w/w, about 14% w/w, about 14.2% w/w, about 14.4% w/w, about 14.6% w/w, about 14.8% w/w, about 15% w/w, about 15.5% w/w, about 16% w/w, about 16.5% w/w, about 17% w/w, about 17.5% w/w, about 18% w/w, about 18.5% w/w, about 19% w/w, about 19.5% w/w, about 20% w/w, about 21% w/w, about 22% w/w, about 23% w/w, about 24% w/w, about 25% w/w, about 26% w/w, about 27% w/w, about 28% w/w, about 29% w/w, about 30% w/w, about 31% w/w, about 32% w/w, about 33% w/w, about 34% w/w, about 35% w/w, about 36% w/w, about 37% w/w, about 38% w/w, about 39% w/w, about 40% w/w, about 41% w/w, about 42% w/w, about 43% w/w, about 44% w/w, about 45% w/w, about 46% w/w, about 47% w/w, about 48% w/w, about 49% w/w, or about 50% w/w of the solids in the oral liquid formulation.”

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/196,567	**05/02/2024 04:24:21 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	Sisi Li
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CUSTOMER #	–	FIRST NAMED INVENTOR	
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 8

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	51 KB
Concise-description-generated.pdf		2	Concise Description of Relevance	28 KB
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	14 KB
Claims_Chart.pdf		60	-	1017 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-60)	60	Concise Description of Relevance	859 KB
Claims_Chart-	(1-60)	60	Concise Description of	859 KB

3P.RELEVANCE.pdf			Relevance	
Claims_Chart-3P.RELEVANCE.pdf	(1-60)	60	Concise Description of Relevance	859 KB
2_SHEKUNOV.pdf		25	-	877 KB
2_SHEKUNOV-NPL.pdf	(1-25)	25	Non Patent Literature	845 KB
3_ANASTOS.pdf		6	-	1015 KB
3_ANASTOS-NPL.pdf	(1-6)	6	Non Patent Literature	1006 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
third-party-preissuance-submission.pdf	882EF09CA5A78340309D8623AFF7375C763229090F3540531C008FF9642C83D4523EE70C7C22A71AE07F8113114D1395AD72EA67095FC999602AB7707DF3446D
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Third-party-notification-request.pdf	42477D572FCF5CFA5BBBCC63EA7261E3C8BC191D2240407C190DE4A152055FEF44AB0BB2711D0C7DF31FE80262D31876BC25FDEE84F667B68C50D894C75AB262
Claims_Chart.pdf	257BADAD17CB5D1E60C668D6431948277095C1D319C2A997DF461EE43315CBBEABBAD4C2A3FA4663C3C928C32BD9832B75D3E071B119C38815256506C9546375
Claims_Chart-3P.RELEVANCE.pdf	A14C086F62A786CA51FCB99CC80EA084713B88693BBA1EDD576716ADDB09C71EEBB9DDE6E49A6F52E0E483FA47FC26764B7FE12EDA3F3A0AACF056CCA2D26647
Claims_Chart-	25D35DDC57F7EC97F470973E8C933A69AE0F8638F05763D42

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Claims_Chart-3P.RELEVANCE.pdf	6DE506C0A5986591060DA3477BD68846004EED30C71A862E62819878A713FF0177432BA0852F647D4B032DFD273E2493E618C54EC7EC1E87868E1C382C8D1433
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3_ANASTOS-NPL.pdf	96D9B15921F8795D5AC728C8E005102311CAA66DE7450C7A703CE6379884C460346AA71CA2773967B00B63A20E115F5ADE91F212C8932145923A0C30F3731B45

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