IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Xpira Pharmaceuticals	Confirmation No.: 6405
Serial No.:	18/447,553	Group No.:
Filing or 371(c) Date:	August 10, 2023	Examiner:

Entitled: Pharmaceutical Compositions Containing Psilocybin for Improved Dissolution and Rapid Onset by Targeted Stomach and Mucosal Release

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. Priority Doc. No. 63/163,322 of U.S. Pat. App. Pub. No US/2022/0296720A1 "COMPOSITE CHITOSAN-TANNIN-ACTIVE AGENT COMPOSITIONS AND METHODS OF MAKING AND USING SAME" (Filed March 19, 2021)
2. Int'l Pat. App. Pub. No. WO/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020)
3. LISBETH ILLUM (1998) "Chitosan and Its Use as a Pharmaceutical Excipient" Pharmaceutical Research. 15(9): pages 1326-1331
4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114

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

U.S.S.N. 18/447,553 Pending Claims	References

1. A pharmaceutical composition comprising, (a) psilocybin in an amount of about 5% w/w to about 15% w/w of the pharmaceutical composition; and (b) chitosan in an amount of about 85% w/w to about 95% w/w of the pharmaceutical composition; wherein the pharmaceutical composition has a dissolution performance such that about 80% or greater of the psilocybin in the pharmaceutical composition is released in a subject's stomach within the first 5 minutes of oral administration.	1. U.S. Priority Doc. No. 63/163,322 of U.S. Pat. App. Pub. No US/2022/0296720A1 "COMPOSITE CHITOSAN-TANNIN-ACTIVE AGENT COMPOSITIONS AND METHODS OF MAKING AND USING SAME" (Filed March 19, 2021) From **[0002]**: **The invention provides tannin-chitosan composite thin-films and other composite forms incorporating active pharmaceutical ingredients**, **including psilocybin** (a psychedelic), biosimilars (melatonin and serotonin), and other active agents. From **[0086]**: **The chitosan, tannin, and active agent employed in the methods can include any type of chitosan, tannin, or active agent described herein in any amount and/or relative weight ratio.** From **[0068]**: **In some versions, the active agent comprises an indole alkaloid**... From **[0069]**: **Exemplary indole alkaloids include tryptamine alkaloids...** From **[0070]**: **Exemplary tryptamine alkaloids include tryptamine** (3-(2-aminoethyl)indole or 2-(1H-indol-3-yl)ethanamine) **and substituted tryptamines...** From **[0071]**: **Exemplary substituted tryptamines include... psilocybin (4-phosphoryloxy-N,N-dimethyltryptamine)** From **[0003]**: **The films of the invention can be dissolved in a small volume of water, simulating the dissolution that would occur in the oral cavity. The active agents can be released in dissolution tests in less than 5 minutes with up to 100% recovery**...
2. The pharmaceutical composition according to claim 1, comprising, (a) psilocybin in an amount of about 9.4% w/w to about 10.9% w/w of the pharmaceutical composition; and (b) chitosan in an amount of about 89.1% w/w to about 90.6% w/w of the pharmaceutical composition.	1. U.S. Priority Doc. No. 63/163,322 of U.S. Pat. App. Pub. No US/2022/0296720A1 "COMPOSITE CHITOSAN-TANNIN-ACTIVE AGENT COMPOSITIONS AND METHODS OF MAKING AND USING SAME" (Filed March 19, 2021) From **[0002]**: **The invention provides tannin-chitosan composite thin-films and other composite forms incorporating active pharmaceutical ingredients**, **including psilocybin** (a psychedelic), biosimilars (melatonin and serotonin), and other active agents. From **[0086]**: **The chitosan, tannin, and active agent employed in the methods can include any type of chitosan, tannin, or active agent described herein in any amount and/or relative weight ratio.** From **[0003]**: **The films of the invention can be dissolved in a small volume of water, simulating the dissolution that would occur in the oral**

	cavity. The active agents can be released in dissolution tests in less than 5 minutes with up to 100% recovery...
3. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition has a dissolution performance such that about 85% or greater of the psilocybin in said pharmaceutical composition is released in a subject's stomach within the first 5 minutes of oral administration.	1. U.S. Priority Doc. No. 63/163,322 of U.S. Pat. App. Pub. No US/2022/0296720A1 "COMPOSITE CHITOSAN-TANNIN-ACTIVE AGENT COMPOSITIONS AND METHODS OF MAKING AND USING SAME" (Filed March 19, 2021) From **[0002]**: **The invention provides tannin-chitosan composite thin-films and other composite forms incorporating active pharmaceutical ingredients**, **including psilocybin** (a psychedelic), biosimilars (melatonin and serotonin), and other active agents. From **[0086]**: **The chitosan, tannin, and active agent employed in the methods can include any type of chitosan, tannin, or active agent described herein in any amount and/or relative weight ratio.** From **[0003]**: **The films of the invention can be dissolved in a small volume of water, simulating the dissolution that would occur in the oral cavity. The active agents can be released in dissolution tests in less than 5 minutes with up to 100% recovery**...
4. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is in particulate form, and wherein at least 90% (D90) of the pharmaceutical composition has a particle size of less than 3.37 μm.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** From **[141]: 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, liposomes, microemulsions, or micellar solutions. From **[144]: 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.** 3. LISBETH ILLUM (1998) "Chitosan and Its Use as a Pharmaceutical Excipient" Pharmaceutical Research. 15(9): pages 1326-1331 From **Abstract**: **Chitosan has been investigated as an excipient in the pharmaceutical industry**, to be used in direct tablet compression, as a tablet disintegrant, for the production of controlled release solid dosage forms or for the improvement of drug dissolution.
5. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is in particulate form, and wherein at least 90% (D90) of the pharmaceutical composition has a particle size of less than 1.54 μm.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and**

	b) a pharmaceutically acceptable excipient." From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** From **[141]: 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, liposomes, microemulsions, or micellar solutions. From **[144]: 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.** 3. LISBETH ILLUM (1998) "Chitosan and Its Use as a Pharmaceutical Excipient" Pharmaceutical Research. 15(9): pages 1326-1331 From **Abstract**: **Chitosan has been investigated as an excipient in the pharmaceutical industry**, to be used in direct tablet compression, as a tablet disintegrant, for the production of controlled release solid dosage forms or for the improvement of drug dissolution.

6. The pharmaceutical composition according to claim 1, wherein pharmaceutical composition further comprises one or more pharmaceutically acceptable excipients.	1. U.S. Priority Doc. No. 63/163,322 of U.S. Pat. App. Pub. No US/2022/0296720A1 "COMPOSITE CHITOSAN-TANNIN-ACTIVE AGENT COMPOSITIONS AND METHODS OF MAKING AND USING SAME" (Filed March 19, 2021) From **[0002]**: **The invention provides tannin-chitosan composite thin-films and other composite forms incorporating active pharmaceutical ingredients**, **including psilocybin** (a psychedelic), biosimilars (melatonin and serotonin), and other active agents. From **[0086]**: **The chitosan, tannin, and active agent employed in the methods can include any type of chitosan, tannin, or active agent described herein in any amount and/or relative weight ratio.** From **[0003]**: **The films of the invention can be dissolved in a small volume of water, simulating the dissolution that would occur in the oral cavity. The active agents can be released in dissolution tests in less than 5 minutes with up to 100% recovery**... From **[0079]: In addition to the chitosan, tannin, and active agent, the compositions of the invention can include any of a number of other components. Such components can include** sweeteners (e.g., sucralose, sucrose), flavoring agents (e.g., essential oil), carboxymethylcellulose, sodium lauryl sulfate, citric acid, ascorbic acid, glycerol, and **excipients.**
7. The pharmaceutical composition according to claim 6, wherein the one or more pharmaceutically acceptable excipients are selected from the group consisting of: binders, disintegrants, lubricants, flowing agents, glidants, anti-adherents, surfactants, stabilizers, binders, bulking agents, colouring agents, and coating agents.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[79]: I**n some embodiments, **the pharmaceutically acceptable excipient is selected from the group consisting of** fillers, **binders,** suspending agents, **disintegrants, lubricants**, and combinations thereof. From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions

	disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."**
8. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is in a unit dosage form that is an oral dosage form.	1. U.S. Priority Doc. No. 63/163,322 of U.S. Pat. App. Pub. No US/2022/0296720A1 "COMPOSITE CHITOSAN-TANNIN-ACTIVE AGENT COMPOSITIONS AND METHODS OF MAKING AND USING SAME" (Filed March 19, 2021) From **[0002]**: **The invention provides tannin-chitosan composite thin-films and other composite forms incorporating active pharmaceutical ingredients**, **including psilocybin** (a psychedelic), biosimilars (melatonin and serotonin), and other active agents. From **[0086]**: **The chitosan, tannin, and active agent employed in the methods can include any type of chitosan, tannin, or active agent described herein in any amount and/or relative weight ratio.** From **[0003]**: **The films of the invention can be dissolved in a small volume of water, simulating the dissolution that would occur in the oral cavity. The active agents can be released in dissolution tests in less than 5 minutes with up to 100% recovery**... From **[0080]**: **The compositions of the invention can take any of a number of forms. Exemplary forms include** films (e.g., thin films or **oral thin films**), foams, wafers (e.g., **oral wafers**; dissolvable products that are not thin films), gels (e.g., hydrogels), and nanoparticles
9. The pharmaceutical composition of claim 8,	1. U.S. Priority Doc. No. 63/163,322 of U.S. Pat. App. Pub. No US/2022/0296720A1 "COMPOSITE CHITOSAN-TANNIN-ACTIVE

wherein the oral dosage form contains about of about 25 to about 30 mg psilocybin.	AGENT COMPOSITIONS AND METHODS OF MAKING AND USING SAME" (Filed March 19, 2021) From **[0002]**: **The invention provides tannin-chitosan composite thin-films and other composite forms incorporating active pharmaceutical ingredients**, **including psilocybin** (a psychedelic), biosimilars (melatonin and serotonin), and other active agents. From **[0086]**: **The chitosan, tannin, and active agent employed in the methods can include any type of chitosan, tannin, or active agent described herein in any amount and/or relative weight ratio.** From **[0003]**: **The films of the invention can be dissolved in a small volume of water, simulating the dissolution that would occur in the oral cavity. The active agents can be released in dissolution tests in less than 5 minutes with up to 100% recovery**... From **[0080]**: **The compositions of the invention can take any of a number of forms. Exemplary forms include** films (e.g., thin films or **oral thin films**), foams, wafers (e.g., **oral wafers**; dissolvable products that are not thin films), gels (e.g., hydrogels), and nanoparticles
10. The pharmaceutical composition of claim 8, wherein the oral dosage form is a tablet or a capsule.	1. U.S. Priority Doc. No. 63/163,322 of U.S. Pat. App. Pub. No US/2022/0296720A1 "COMPOSITE CHITOSAN-TANNIN-ACTIVE AGENT COMPOSITIONS AND METHODS OF MAKING AND USING SAME" (Filed March 19, 2021) From **[0002]**: **The invention provides tannin-chitosan composite thin-films and other composite forms incorporating active pharmaceutical ingredients**, **including psilocybin** (a psychedelic), biosimilars (melatonin and serotonin), and other active agents. From **[0086]**: **The chitosan, tannin, and active agent employed in the methods can include any type of chitosan, tannin, or active agent described herein in any amount and/or relative weight ratio.** From **[0068]**: **In some versions, the active agent comprises an indole alkaloid**... From **[0069]**: **Exemplary indole alkaloids include tryptamine alkaloids...** From **[0070]**: **Exemplary tryptamine alkaloids include tryptamine** (3-(2-aminoethyl)indole or 2-(1H-indol-3-yl)ethanamine) **and substituted tryptamines...** From **[0071]**: **Exemplary substituted tryptamines include... psilocybin (4-phosphoryloxy-N,N-dimethyltryptamine)**

	From **[0003]**: **The films of the invention can be dissolved in a small volume of water, simulating the dissolution that would occur in the oral cavity. The active agents can be released in dissolution tests in less than 5 minutes with up to 100% recovery**... From **[0080]**: **The compositions of the invention can take any of a number of forms. Exemplary forms include** films (e.g., thin films or oral thin films), foams, wafers (e.g., oral wafers; **dissolvable products that are not thin films**), gels (e.g., hydrogels), and nanoparticles
11. A pharmaceutical composition comprising, (a) psilocybin in an amount of about 5 to about 15% w/w of the pharmaceutical composition; and (b) polyvinylpyrrolidone in an amount of about 85 to about 95% w/w of the pharmaceutical composition; wherein the pharmaceutical composition has a dissolution performance such that about 100% of the psilocybin in the pharmaceutical composition is released in a subject's oral mucosal wall within the first 1 minute of oral administration.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** ... **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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1,** 1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114

	From **Abstract**: "**Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields.**"
12. The pharmaceutical composition according to claim 11, comprising, (a) psilocybin in an amount of 9.1% w/w of the pharmaceutical composition; and (b) polyvinylpyrrolidone in an amount of 90.9% w/w of the pharmaceutical composition.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** ... **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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1,** 1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: "**Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields.**"
13. The pharmaceutical composition of claim 11, wherein the	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR

pharmaceutical composition has a dissolution performance such that about 85% or greater of the psilocybin in the pharmaceutical composition is released in a subject's oral mucosal wall within the first 30 seconds of oral administration.	THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** ... **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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1,** 1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: "**Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields**."
14. The pharmaceutical composition of claim 11, wherein the pharmaceutical composition is in particulate form, and wherein at least 90% (D90) of the	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a

pharmaceutical composition has a particle size of less than 1.54 μm.	subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[62]:** In some embodiments, any **suitable dosage of 5HT receptor agonist may be administered to an individual in need thereof, such as about** 0.1 mg to about 10 mg or about **10 mg to about 50 mg is administered.** From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** From **[141]: 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, liposomes, microemulsions, or micellar solutions.

	From **[144]: 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.** 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: **"Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields."**
15. The pharmaceutical composition of claim 11, wherein the pharmaceutical composition is in particulate form, and wherein at least 90% (D90) of the pharmaceutical composition has a particle size between 0.7-1.5 μm.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at

	least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** From **[141]: 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, liposomes, microemulsions, or micellar solutions. From **[144]: 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.** 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: "**Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields.**"
16. The pharmaceutical composition according to claim 11, wherein pharmaceutical composition further comprises one or more pharmaceutically acceptable excipients.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: "**Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields**."
17. The pharmaceutical composition according to claim 16, wherein the one or more pharmaceutically acceptable excipients are selected from the group consisting of: binders, disintegrants, lubricants, flowing agents, glidants, anti-adherents, surfactants, stabilizers, binders, bulking agents, colouring agents, and coating agents.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[79]: I**n some embodiments, **the pharmaceutically acceptable excipient is selected from the group consisting of** fillers, **binders,** suspending agents, **disintegrants**, **lubricants, and combinations thereof.** From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a

	patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: "**Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields.**"
18. The pharmaceutical composition according to claim 11, wherein the pharmaceutical composition is in a unit dosage form that is a sublingual dosage form.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a

	patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** From **[228]: "The term "transmucosal administration" refers to the route of administration in which the drug is diffused through the mucous membrane.** This might refer to inhalation, nasal, **sublingual,** vaginal, rectal, or ocular routes." 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: "**Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields.**"
19. The pharmaceutical composition according to claim 18, wherein the sublingual dosage form contains about 25 to about 30 mg of the psilocybin.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[62]:** In some embodiments, any **suitable dosage of 5HT receptor agonist may be administered to an individual in need thereof, such as**

	about 0.1 mg to about 10 mg or about **10 mg to about 50 mg is administered.** From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** From **[228]: "The term "transmucosal administration" refers to the route of administration in which the drug is diffused through the mucous membrane.** This might refer to inhalation, nasal, **sublingual,** vaginal, rectal, or ocular routes." 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: "**Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields.**"
20. The pharmaceutical composition according to claim 18, wherein sublingual dosage form is a tablet, a wafer, or a film.	2. Int'l Pat. App. Pub. No. Wo/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published June 8, 2020) From **[8]:** "Also provided herein in some embodiments is a method of managing a neurological condition or one or more symptoms thereof in a

	subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: **a) a therapeutically effective amount of one or more 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof (e.g., psilocybin); and** **b) a pharmaceutically acceptable excipient.**" From **[164]: "For oral administration, the pharmaceutical compositions disclosed herein are, in some instances, formulated readily by combining the active compound(s) with pharmaceutically acceptable carriers** well known in the art. Such carriers enable the compositions disclosed herein to be formulated as tablets, including chewable tablets, pills, dragees, capsules, lozenges, hard candy, liquids, gels, syrups, slurries, powders, suspensions, elixirs, wafers, and the like, for oral ingestion by a patient to be treated. Such formulations might comprise pharmaceutically acceptable carriers including solid 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 composition of oral dosage forms, in an amount sufficient to provide a desired unit of dosage."** From **[133]: "**In some embodiments, **the amount of 5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof containing composition **that adheres to a surface of the mucous membrane for 5 seconds, 10 seconds, or 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5**, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 minutes **is** at least 1%, at least 2%, at least 3%, at least 4%, at least 5%, at least 6%, at least 7%, at least 8%, at least 9%, at least 10%, at least 15%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, **at least 90% or at least 95% by weight after administration to the surface of the mucous membrane."** From **[140]: "In some embodiments, the pharmaceutical formulations include,** but are not limited to, aqueous liquid dispersions, self-emulsifying dispersions, solid solutions, liposomal dispersions, aerosols, solid dosage forms, powders, **immediate-release formulations,** controlled release formulations, fast melt formulations, **tablets**, capsules, pills, delayed release formulations, extended release formulations, pulsatile release formulations, multiparticulate formulations (e.g. nanoparticle formulations), and mixed immediate and controlled release formulations." From **[228]: "The term "transmucosal administration" refers to the route of administration in which the drug is diffused through the**

	mucous membrane. This might refer to inhalation, nasal, **sublingual,** vaginal, rectal, or ocular routes." 4. PAOLO FRANCO (2020) "The Use of Poly(N-vinyl pyrrolidone) in the Delivery of Drugs: A Review" Polymers (Basel). Vol 12(5): page 1114 From **Abstract**: "Polyvinylpyrrolidone (PVP) is a hydrophilic polymer widely employed as a carrier in the pharmaceutical, biomedical, and nutraceutical fields."

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/447,553	**07/09/2024 01:02:10 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	Jeremy Rolquin
PATENT CENTER #	66287236	FILING DATE	08/10/2023
CUSTOMER #	–	FIRST NAMED INVENTOR	
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 10

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	54 KB
Concise-description-generated.pdf		2	Concise Description of Relevance	29 KB
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	14 KB
US20240066043 3PS.pdf		20	-	280 KB
US20240066043 3PS-3P.RELEVANCE.pdf	(1-20)	20	Concise Description of Relevance	279 KB
US20240066043 3PS-	(1-20)	20	Concise Description of	279 KB

3P.RELEVANCE.pdf			Relevance	
US20240066043 3PS-3P.RELEVANCE.pdf	(1-20)	20	Concise Description of Relevance	279 KB
US20240066043 3PS-3P.RELEVANCE.pdf	(1-20)	20	Concise Description of Relevance	279 KB
2_WO2020157569A1_Embedded.pdf		139	-	10965 KB
2_WO2020157569A1_Embedded-FOR.pdf	(1-139)	139	Foreign Reference	10968 KB
3_Chitosan and Its Use as a Pharmaceutical Excipient - Springer_Embedded.pdf		3	-	78 KB
3_Chitosan and Its Use as a Pharmaceutical Excipient - Springer_Embedded-NPL.pdf	(1-3)	3	Non Patent Literature	76 KB
4_PVP in the Delivery of Drugs_Embedded .pdf		29	-	715 KB
4_PVP in the Delivery of Drugs_Embedded -NPL.pdf	(1-29)	29	Non Patent Literature	723 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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US20240066043 3PS-3P.RELEVANCE.pdf	2115EF13A9A074978FBD3355434E1AA6DF79AC295C98E02406488081C38EF575E5E07016DE0E1E222CAA9412362005D8701062F42EF8BB6AB8310D6DBEE9851E
US20240066043 3PS-3P.RELEVANCE.pdf	270565B5ACB9881CFD2043910A5F36EC3C14DDF3C4B598E167BF381E8CF8EC2AC780DFD0A6BFA3F9864CED58B2B4FFCD7A3B46D22E8399AF1FA546D81BD58B34
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US20240066043 3PS-3P.RELEVANCE.pdf	1E72483D8E75C078EA842E94CDEC5A54E7764945F1E5C34933768FD20B9BA82696890713FB4922CF32CDC8E1978F110136E2973757B39C010BE1A214DA9AF224
2_WO2020157569A1_Embedded.pdf	381F89AD146902C46CB8A02353C2370B55D722C67D8A5326F7B72277E80FAB1ECF3A90CFFEDDF2AB7ABADAD0E8A45BBDD90DDCC6D751DA1B39C28ECEC2D4E041
2_WO2020157569A1_Embedded-FOR.pdf	F276F04BC0A6FFB901CFDCF8D88A284ED6F768055C0F3EFDB93FCA0D3E0ECF51FB61FDB05BB11A4437AACFE020946201C7E2E5E3C9538FBA9DA392EC90F261B9
3_Chitosan and Its Use as a Pharmaceutical Excipient - Springer_Embedded.pdf	DE85576030348231104064439 61E6595FC9FFD94F3DD23EB9F7537E0A4816906DC2523867E44AFDF80A7C6585680B41E110E254AAD9B88233EA4746B349D7194
3_Chitosan and Its Use as a	8869049F5123B78DE37611200BFA376CF010E2031472E542458

Pharmaceutical Excipient - Springer_Embedded-NPL.pdf	C8D1F5F61D700393F83487010D05FC495BAE639AFAD302F8470E226967DC89F961E3D74354A5F
4_PVP in the Delivery of Drugs_Embedded .pdf	3F081F924AD30B1CA52972C7F26F2BA342860E07DAC43041644298B5377FAB5D7B443D8ABE19A7171C14740312D9409F3CB45AC218A55D47B61DDBD626126EEF
4_PVP in the Delivery of Drugs_Embedded -NPL.pdf	18BF93D380684D121FA6394B2DE8AF436472EB733DD96048ADF3DD6D0EA9C006B66365A528FA91003AB34666C0B1FD6257A58075BA29ADA5C192E8F88891C5B7

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.