

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Mack, Peter Confirmation No.: 9957  
Serial No.: 17/809,198 Group No.:  
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Entitled: Immediate Release Formulations of D-Lysergic Acid Diethylamide for Therapeutic Applications

**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. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)

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. 17/809.198 Pending Claims	References
1. A composition of a solid oral immediate release formulation of LSD, comprising LSD contained within an immediate release dosage form chosen from the group consisting of a capsule, tablet, and orally disintegrating tablet.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0007] “In particular embodiments, the pharmaceutical composition is a unit dosage form including from 2 to 30 µg of <b>lysergic acid diethylamide</b> or a pharmaceutically acceptable salt thereof (e.g., 25±5, 15±5 µg, 12.5±5 µg, 10±2 µg, 8±2 µg, 7.5±2.5 µg, 6±2 µg, or 4±2 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof) ... In particular embodiments, the pharmaceutical composition is formulated for sustained release. In still other embodiments, the pharmaceutical composition is formulated for <b>immediate release.</b> ”
2. The composition of claim 1, wherein said LSD is in a form chosen from free base and salt.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0007] “In particular embodiments, the pharmaceutical composition is a unit dosage form including from 2 to 30 µg of <b>lysergic acid diethylamide</b> or a pharmaceutically acceptable salt thereof (e.g., 25±5, 15±5 µg, 12.5±5 µg, 10±2 µg, 8±2 µg, 7.5±2.5 µg, 6±2 µg, or 4±2 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof) ... In particular embodiments, the pharmaceutical composition is formulated for sustained release. In still other embodiments, the pharmaceutical composition is formulated for <b>immediate release.</b> ”

<p>3. The composition of claim 2, wherein said LSD is in a salt form and the salt is chosen from the group consisting of hydrochloride, hydrobromide, maleate, tartrate, citrate, phosphate, fumarate, sulfate, mesylate, acetate, and oxalate.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0065] “Capsules containing 5 µg, 10 µg, 15 µg, and 20 µg <b>D-lysergic acid diethylamide tartrate</b> can be useful in the methods of the invention.”</p>
<p>4. The composition of claim 1, wherein said LSD is present in an amount of 0.01-1 mg.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “In particular embodiments, the pharmaceutical composition is a unit dosage form including from <b>2 to 30 µg of lysergic acid diethylamide</b> or a pharmaceutically acceptable salt thereof (e.g., 25±5, 15±5 µg, 12.5±5 µg, 10±2 µg, 8±2 µg, 7.5±2.5 µg, 6±2 µg, or 4±2 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof) ... In particular embodiments, the pharmaceutical composition is formulated for sustained release. In still other embodiments, the pharmaceutical composition is formulated for immediate release.”</p>
<p>5. The composition of claim 1, wherein said LSD is in a form chosen from crystalline and non-crystalline.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “In particular embodiments, the pharmaceutical composition is a unit dosage form including from 2 to 30 µg <b>of lysergic acid diethylamide</b> or a pharmaceutically acceptable salt thereof (e.g., 25±5, 15±5 µg, 12.5±5 µg, 10±2 µg, 8±2 µg, 7.5±2.5 µg, 6±2 µg, or 4±2 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof) ... In particular embodiments, the pharmaceutical composition is formulated for sustained release. In still other embodiments, the pharmaceutical composition is formulated for <b>immediate release</b>.”</p>
<p>6. The composition of claim 1, wherein said composition is produced by granulation.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0047]-[0048] “Controlled release compositions for oral use may, e.g., be constructed to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, by controlling the dissolution and/or the diffusion of the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof. Dissolution or diffusion controlled release can be achieved by appropriate coating of a tablet, capsule, pellet, or <b>granulate formulation</b> of compounds, or by incorporating the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, into an appropriate matrix.”</p>
<p>7. The composition of claim 6, further including</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p>

<p>a filler chosen from the group consisting of lactose, mannitol, dicalcium phosphate, calcium sulfate, starch, cellulose, kaolin, sodium chloride, sorbitol, trehalose, and sucrose.</p>	<p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, <b>inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate)</b>; granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginate); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p>8. The composition of claim 6, further including a binder chosen from the group consisting of acacia gum, hydroxypropyl methylcellulose, hydroxypropyl cellulose, tragacanth, polyvinyl pyrrolidone (PVP), and starch.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginate); <b>binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol)</b>; and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p>9. The composition of claim 6, further including an absorbent chosen from the group consisting of croscarmellose sodium, starch, mesoporous silicon dioxide, and microcrystalline cellulose.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, <b>microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate)</b>; granulating and disintegrating agents (e.g., cellulose derivatives including <b>microcrystalline cellulose</b>, starches including</p>

	<p>potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, <b>pregelatinized starch, microcrystalline cellulose</b>, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>10.</b> The composition of claim 6, further including a disintegrant chosen from the group consisting of croscarmellose sodium, starch, microcrystalline cellulose, crospovidone, and sodium starch glycolate.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, <b>microcrystalline cellulose, starches including potato starch</b>, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, <b>starch, pregelatinized starch, microcrystalline cellulose</b>, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>11.</b> The composition of claim 6, further including a glidant chosen from the group consisting of magnesium stearate and colloidal silicon dioxide.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, <b>glidants</b>, and antiadhesives (e.g., <b>magnesium stearate</b>, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>

<p><b>12.</b> The composition of claim 6, further including a lubricant chosen from the group consisting of magnesium stearate, sodium stearyl fumarate, polyethylene glycol (PEG), polyoxyethylene stearates, lauryl sulphate salts, talc, glyceryl behenate, stearic acid, glyceryl palm itostearate, calcium stearate, and hydrogenated vegetable oils.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); <b>and lubricating agents</b>, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, <b>hydrogenated vegetable oils</b>, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>13.</b> The composition of claim 6, further including an agent for adjusting pH chosen from the group consisting of citrate, phosphate, acetate, sodium hydroxide, and hydrochloric acid.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0053] “Among acceptable vehicles and solvents that may be employed are water, water adjusted to a <b>suitable pH</b> by addition of an appropriate amount of hydrochloric acid, <b>sodium hydroxide or a suitable buffer</b>, 1,3-butanediol, Ringer's solution, and isotonic sodium chloride solution.”</p>
<p><b>14.</b> The composition of claim 6, further including an antioxidant chosen from the group consisting of ascorbic acid, butylated hydroxyanisole (BHA), and butylated hydroxytoluene (BHT).</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0057] “Examples of <b>antioxidants</b> are <b>butylated hydroxy anisole (BHA)</b>, ascorbic acid and derivatives thereof, tocopherol and derivatives thereof, <b>butylated hydroxy anisole</b>, and cysteine”</p>
<p><b>15.</b> The composition of claim 6, further including a photostabilization agent.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0057] “Examples of <b>antioxidants</b> are butylated hydroxy anisole (BHA), ascorbic acid and derivatives thereof, tocopherol and derivatives thereof, butylated hydroxy anisole, and cysteine”</p>

<p><b>16.</b> The composition of claim 6, further including a permeation enhancer chosen from the group consisting of sulphoxides, azones, pyrrolidones, alcohols, alkanols, glycols, surfactants, and terpenes.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0057] “Examples of <b>penetration enhancers</b> are propylene glycol, DMSO, triethanolamine, N,N-dimethylacetamide, N,N-dimethylformamide, 2-pyrrolidone and derivatives thereof, <b>tetrahydrofurfuryl alcohol</b>, and AZONE™.”</p>
<p><b>17.</b> The composition of claim 6, further including coloring agents, sweeteners, and flavoring agents.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043] “Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>18.</b> The composition of claim 1, wherein said composition is produced by dry blending.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043] “<b>Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients.</b> These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>19.</b> The composition of claim 18, further including a filler chosen from the group consisting of lactose, mannitol, dicalcium phosphate, calcium sulfate, starch, cellulose, kaolin, sodium</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043] “Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, <b>inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate);</b> granulating and disintegrating agents (e.g.,</p>

chloride, sorbitol, and sucrose.	cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”
20. The composition of claim 18, further including a glidant chosen from the group consisting of magnesium stearate and colloidal silicon dioxide.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, <b>glidants</b> , and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”
21. The composition of claim 18, further including a dry binder of microcrystalline cellulose.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, <b>microcrystalline cellulose</b> , starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including <b>microcrystalline cellulose</b> , starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, <b>microcrystalline cellulose</b> , magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”

<p><b>22.</b> The composition of claim 18, further including a disintegrant chosen from the group consisting of croscarmellose sodium, starch, microcrystalline cellulose, crospovidone, and sodium starch glycolate.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, <b>microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate</b>); granulating and disintegrating agents (e.g., cellulose derivatives including <b>microcrystalline cellulose</b>, starches including potato starch, croscarmellose sodium, alginates, or alginate); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginate, sodium alginate, gelatin, starch, pregelatinized starch, <b>microcrystalline cellulose</b>, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>23.</b> A method of making a solid oral immediate release formulation of LSD, including the steps of: granulating LSD with excipients of fillers, absorbents, binders, disintegrants, lubricants, and/or glidants; and encapsulating or compressing to form a tablet of a solid oral immediate release formulation of LSD.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0049] “A <b>buoyant tablet formulation of the lysergic acid diethylamide</b>, or a pharmaceutically acceptable salt thereof, can be prepared by <b>granulating a mixture of the drug(s) with excipients</b> and 20-75% w/w of hydrocolloids, such as hydroxyethylcellulose, hydroxypropylcellulose, or hydroxypropylmethylcellulose. The obtained <b>granules can then be compressed into tablets.</b>”</p>
<p><b>24.</b> The method of claim 23, wherein said granulating step is further defined as moisture activated dry granulation.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0046] “Powders and <b>granulates</b> may be prepared using the ingredients mentioned above under tablets and capsules in a conventional manner using, e.g., a mixer, a fluid bed apparatus or a <b>spray drying equipment.</b>”</p>
<p><b>25.</b> The method of claim 24, wherein said granulating step includes charging powders of LSD, binders, and fillers</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“<b>Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof,</b></p>



<p>to a closed container which contains mixing/blending components, wetting the powders with a binder solution/suspension while mixing allowing for particle cohesion and granule growth, and adding fillers, glidants, disintegrants, and lubricants.</p>	<p><b>in a mixture with non-toxic pharmaceutically acceptable excipients.</b> These excipients may be, for example, <b>inert diluents or fillers</b> (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and <b>lubricating agents, glidants,</b> and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p> <p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0046] “Powders and <b>granulates</b> may be prepared using the ingredients mentioned above under tablets and capsules in a conventional manner using, e.g., a mixer, a fluid bed apparatus or a <b>spray drying equipment.</b>”</p>
<p>26. The method of claim 23, wherein the LSD is in a form chosen from free base and salt.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0065] “Capsules containing 5 µg, 10 µg, 15 µg, and 20 µg <b>D-lysergic acid diethylamide tartrate</b> can be useful in the methods of the invention.”</p>
<p>27. The method of claim 23, wherein the filler is chosen from the group consisting of lactose, mannitol, dicalcium phosphate, calcium sulfate, starch, cellulose, kaolin, sodium chloride, sorbitol, trehalose, and sucrose.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043] “Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, <b>inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate);</b> granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable</p>

	oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”
28. The method of claim 23, wherein the binder is chosen from the group consisting of acacia gum, hydroxypropyl methylcellulose, hydroxypropyl cellulose, tragacanth, polyvinyl pyrrolidone (PVP), and starch.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginate); <b>binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginate, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol)</b> ; and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”
29. The method of claim 23, wherein the absorbent is chosen from the group consisting of croscarmellose sodium, starch, mesoporous silicon dioxide, and microcrystalline cellulose.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, <b>starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate</b> ); granulating and disintegrating agents (e.g., cellulose derivatives including <b>microcrystalline cellulose</b> , starches including potato starch, <b>croscarmellose sodium</b> , alginates, or alginate); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginate, sodium alginate, gelatin, <b>starch, pregelatinized starch, microcrystalline cellulose</b> , magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”
30. The method of claim 23, wherein the disintegrant is chosen from the group consisting of croscarmellose sodium, starch, microcrystalline	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may

<p>cellulose, crospovidone, and sodium starch glycolate.</p>	<p>be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and <b>disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid)</b>; binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>31.</b> The method of claim 23, wherein the glidant is chosen from the group consisting of magnesium stearate and colloidal silicon dioxide.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, <b>glidants</b>, and antiadhesives (e.g., <b>magnesium stearate</b>, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>32.</b> The method of claim 25, wherein the lubricant is chosen from the group consisting of magnesium stearate, sodium stearyl fumarate, polyethylene glycol (PEG), polyoxyethylene stearates, lauryl sulphate salts, talc, glyceryl behenate, stearic acid, glyceryl palm itostearate, calcium stearate, and hydrogenated vegetable oils.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol);</p>

	and <b>lubricating agents</b> , glidants, and antiadhesives (e.g., <b>magnesium stearate</b> , zinc stearate, stearic acid, silicas, <b>hydrogenated vegetable oils</b> , or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”
33. The method of claim 23, wherein the LSD is in a salt form and the salt is chosen from the group consisting of hydrochloride, hydrobromide, maleate, tartrate, citrate, phosphate, fumarate, sulfate, mesylate, acetate, and oxalate.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0065] “Capsules containing 5 µg, 10 µg, 15 µg, and 20 µg <b>D-lysergic acid diethylamide tartrate</b> can be useful in the methods of the invention.”
34. A method of making a solid oral immediate release formulation of LSD by dry blending, including the steps of: blending LSD minimally with filler excipients and additionally a disintegrant, dry binder, glidant and lubricant; and a forming step chosen from the group consisting of directly compressing to form a tablet or orally disintegrating tablet (ODT) of a solid oral immediate release formulation of LSD and encapsulating to form a solid oral immediate release formulation of LSD.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0043] “ <b>Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients.</b> These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”  From [0044] “The tablets may be uncoated or they may be coated by known techniques, optionally to delay disintegration and absorption in the gastrointestinal tract and thereby providing a sustained action over a longer period. The coating may be adapted to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a <b>predetermined pattern</b> (e.g., in order to achieve a controlled release formulation) or it may be adapted not to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, until after passage of the stomach (enteric coating).”
35. The method of claim 34, wherein the filler is chosen from the group consisting of lactose,	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)

mannitol, dicalcium phosphate, calcium sulfate, starch, cellulose, kaolin, sodium chloride, sorbitol, trehalose, and sucrose.	From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or <b>fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate)</b> ; granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, <b>flavoring agents, plasticizers, humectants, buffering agents, and the like.</b> ”
<b>36.</b> The method of claim 34, wherein the dry binder is microcrystalline cellulose	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, <b>microcrystalline cellulose</b> , magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, <b>flavoring agents, plasticizers, humectants, buffering agents, and the like.</b> ”
<b>37.</b> The method of claim 34, wherein the disintegrant is chosen from the group consisting of croscarmellose sodium, starch, microcrystalline cellulose, crospovidone, and sodium starch glycolate.	1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)  From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including <b>microcrystalline cellulose, starches including potato starch, croscarmellose sodium</b> , alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin,

	<p>starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>38.</b> The method of claim 34, wherein the glidant is chosen from the group consisting of magnesium stearate and colloidal silicon dioxide.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., <b>magnesium stearate</b>, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>39.</b> The method of claim 34, wherein the lubricant is chosen from the group consisting of magnesium stearate, sodium stearyl fumarate, polyethylene glycol (PEG), polyoxyethylene stearates, lauryl sulphate salts, talc, glyceryl behenate, stearic acid, glyceryl palm itostearate, calcium stearate, and hydrogenated vegetable oils.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0043]“Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., <b>magnesium stearate</b>, zinc stearate, stearic acid, silicas, <b>hydrogenated vegetable oils</b>, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like.”</p>
<p><b>40.</b> The method of claim 34, wherein the LSD is in</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p>

<p>a form chosen from free base and salt.</p>	<p>From [0007] “In particular embodiments, the pharmaceutical composition is a unit dosage form including from 2 to 30 <math>\mu\text{g}</math> of <b>lysergic acid diethylamide</b> or a pharmaceutically acceptable salt thereof (e.g., <math>25\pm 5</math>, <math>15\pm 5</math> <math>\mu\text{g}</math>, <math>12.5\pm 5</math> <math>\mu\text{g}</math>, <math>10\pm 2</math> <math>\mu\text{g}</math>, <math>8\pm 2</math> <math>\mu\text{g}</math>, <math>7.5\pm 2.5</math> <math>\mu\text{g}</math>, <math>6\pm 2</math> <math>\mu\text{g}</math>, or <math>4\pm 2</math> <math>\mu\text{g}</math> of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof) ... In particular embodiments, the pharmaceutical composition is formulated for sustained release. In still other embodiments, the pharmaceutical composition is formulated for immediate release.”</p>
<p><b>41.</b> The method of claim 34, wherein the LSD is in a salt form and the salt is chosen from the group consisting of hydrochloride, hydrobromide, maleate, tartrate, citrate, phosphate, fumarate, sulfate, mesylate, acetate, and oxalate.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “In particular embodiments, the pharmaceutical composition is a unit dosage form including from 2 to 30 <math>\mu\text{g}</math> of <b>lysergic acid diethylamide or a pharmaceutically acceptable salt thereof</b> (e.g., <math>25\pm 5</math>, <math>15\pm 5</math> <math>\mu\text{g}</math>, <math>12.5\pm 5</math> <math>\mu\text{g}</math>, <math>10\pm 2</math> <math>\mu\text{g}</math>, <math>8\pm 2</math> <math>\mu\text{g}</math>, <math>7.5\pm 2.5</math> <math>\mu\text{g}</math>, <math>6\pm 2</math> <math>\mu\text{g}</math>, or <math>4\pm 2</math> <math>\mu\text{g}</math> of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof) ... In particular embodiments, the pharmaceutical composition is formulated for sustained release. In still other embodiments, the pharmaceutical composition is formulated for immediate release.”</p>
<p><b>42.</b> A method of treating an individual, including the steps of: administering a solid oral immediate release formulation of LSD chosen from the group consisting of a capsule, tablet, and orally disintegrating tablet; and treating the individual.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “The invention features a method of <b>treating Alzheimer's disease in a subject, the method including administering to the subject a pharmaceutical composition comprising lysergic acid diethylamide, or a salt thereof, (LSD)</b> in an amount sufficient to treat the Alzheimer's disease”</p>
<p><b>43.</b> The method of claim 42, wherein the individual has trouble swallowing, is elderly, or has dementia.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “The methods of the invention can include reducing agitation, reducing apathy, reducing irritability, or reducing aggression in a subject having Alzheimer's disease with <b>comorbid dementia</b>”</p>
<p><b>44.</b> The method of claim 42, wherein said treating step is further defined as treating a condition or disease chosen from the group consisting of anxiety disorders, depression, headache</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “The methods of the invention can include improving memory in the subject, improving learning capacity in the subject, delaying the loss of memory in the subject, delaying the loss of learning capacity in the subject, reducing the severity of dementia in the subject, delaying the onset of</p>

<p>disorder, obsessive compulsive disorder (OCD), personality disorders, stress disorders, drug disorders, gambling disorder, eating disorder, body dysmorphic disorder, pain, neurodegenerative disorders, autism spectrum disorder, eating disorders, and neurological disorders.</p>	<p>dementia in the subject, reducing the severity of <b>depression</b> in the subject, delaying the onset of <b>depression</b> in the subject, reducing the severity of <b>anxiety</b> in the subject, and/or delaying the onset of <b>anxiety</b> in the subject.”</p>
<p>45. The method of claim 42, wherein the LSD is in a form chosen from free base and salt.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “The invention features a method of <b>treating Alzheimer's disease in a subject, the method including administering to the subject a pharmaceutical composition comprising lysergic acid diethylamide, or a salt thereof, (LSD)</b> in an amount sufficient to treat the Alzheimer's disease”</p>
<p>46. The method of claim 45, wherein the LSD is in a salt form and the salt is chosen from the group consisting of hydrochloride, hydrobromide, maleate, tartrate, citrate, phosphate, fumarate, sulfate, mesylate, acetate, and oxalate.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “In particular embodiments, the pharmaceutical composition is a unit dosage form including from 2 to 30 <math>\mu\text{g}</math> of <b>lysergic acid diethylamide or a pharmaceutically acceptable salt thereof</b> (e.g., <math>25\pm 5</math>, <math>15\pm 5</math> <math>\mu\text{g}</math>, <math>12.5\pm 5</math> <math>\mu\text{g}</math>, <math>10\pm 2</math> <math>\mu\text{g}</math>, <math>8\pm 2</math> <math>\mu\text{g}</math>, <math>7.5\pm 2.5</math> <math>\mu\text{g}</math>, <math>6\pm 2</math> <math>\mu\text{g}</math>, or <math>4\pm 2</math> <math>\mu\text{g}</math> of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof) ... In particular embodiments, the pharmaceutical composition is formulated for sustained release. In still other embodiments, the pharmaceutical composition is formulated for immediate release.”</p>
<p>47. The method of claim 42, wherein said administering step is further defined as administering 0.01-1 mg of LSD.</p>	<p>1. U.S. Pat. App. Pub. No. US/2020/0085816 “LSD for the Treatment of Alzheimer’s Disease” (Published March 19, 2021)</p> <p>From [0007] “In particular embodiments, the pharmaceutical composition is a unit dosage form including from <b>2 to 30 <math>\mu\text{g}</math> of lysergic acid diethylamide</b> or a pharmaceutically acceptable salt thereof (e.g., <math>25\pm 5</math>, <math>15\pm 5</math> <math>\mu\text{g}</math>, <math>12.5\pm 5</math> <math>\mu\text{g}</math>, <math>10\pm 2</math> <math>\mu\text{g}</math>, <math>8\pm 2</math> <math>\mu\text{g}</math>, <math>7.5\pm 2.5</math> <math>\mu\text{g}</math>, <math>6\pm 2</math> <math>\mu\text{g}</math>, or <math>4\pm 2</math> <math>\mu\text{g}</math> of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof) ... In particular embodiments, the pharmaceutical composition is formulated for sustained release. In still other embodiments, the pharmaceutical composition is formulated for immediate release.”</p>



## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	48117548
<b>Application Number:</b>	17890198
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	9957
<b>Title of Invention:</b>	IMMEDIATE RELEASE FORMULATIONS OF d-LYSERGIC ACID DIETHYLAMIDE FOR THERAPEUTIC APPLICATIONS
<b>First Named Inventor/Applicant Name:</b>	Peter MACK
<b>Customer Number:</b>	48924
<b>Filer:</b>	Kurtzweil Taylor
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	31708 d3ecfebec80b95ff65f557b815f421bd1e4c96c4	no	2

### Warnings:

Information:					
2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	52689 165384d573f6025d95402fa1aaae3428b5aa1bd1	no	2
Warnings:					
Information:					
3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23740 44cbc0d6db4c9a1ea9aa0ab0e27ba33ae694d423	no	1
Warnings:					
Information:					
4	Concise Description of Relevance	20230064429_Claims_Chart.pdf	243820 3d9bb6729e75d17e1f6ac5da398e8d9006545593c	no	16
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