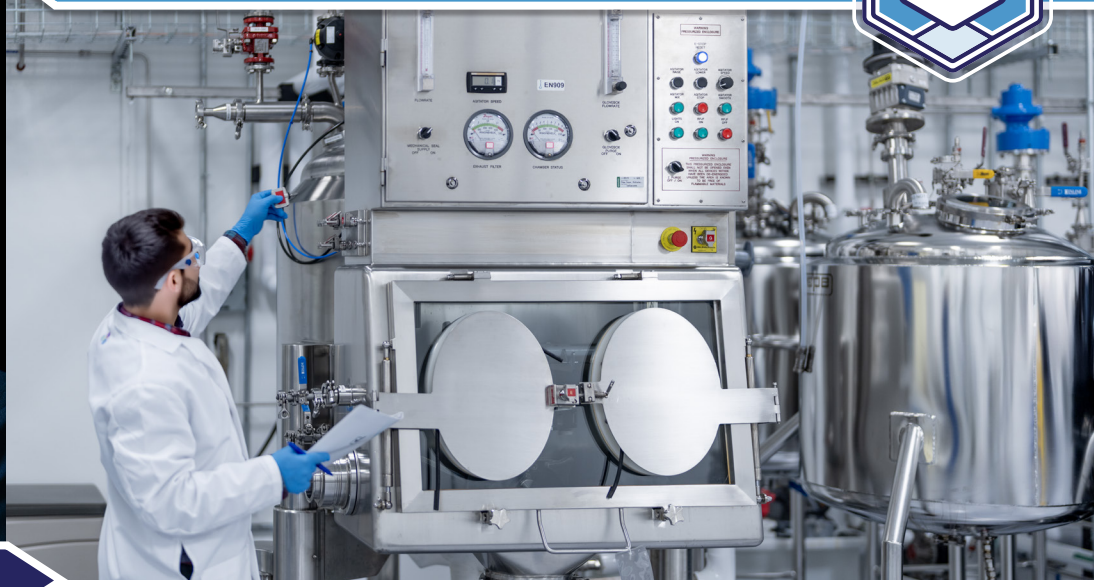
Benuvia
CONTROLLED SUBSTANCE SOLUTIONS





By Aruna Earla, Ph.D.

Aruna Earla, Ph.D., has approximately 20 years of experience in pharmaceutical research, development, and manufacturing within the CRO and CDMO sectors. As Director of AP R&D, She oversees API process development, specializing in cannabinoids and psychedelics.

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## SUMMARY

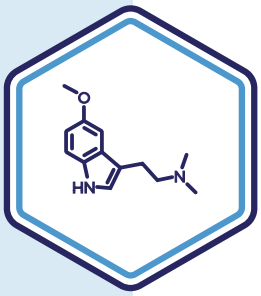
Production processes for psychedelics, including 5-MeO-DMT, DMT, MDMA, Psilocin, and Psilocybin, have been innovated to ensure compliance within a GMP-regulated environment, making them ideal for FDA-regulated clinical trials. These substances are also available as GLP material for preclinical toxicology studies or as non-GMP research-grade material, supporting a wide range of research and development needs.

# Unlocking the Future of Mental Health: GMP-Grade Psychedelics

## Empowering Research with Pharmaceutical-Grade Solutions

The momentum around psychedelic research is transforming the landscape of mental health treatment, driven by their potential to address conditions like depression, PTSD, and substance use disorders. Compounds such as psilocybin and MDMA are showing promise by disrupting entrenched thought patterns and enhancing the effectiveness of psychotherapy. However, as Schedule I controlled substances, their accessibility remains tightly restricted, presenting significant challenges for researchers and developers.

Benuvia is meeting this critical industry need by delivering pharmaceutical-grade psychedelics manufactured in a GMP-compliant environment, adhering to stringent ICH guidelines. Our innovative, elegant syntheses ensure the highest standards of purity, consistency, and safety. By enabling reliable access to these controlled substances, Benuvia is empowering researchers to unlock the therapeutic potential of psychedelics and accelerate progress in addressing some of today's most pressing mental health challenges.




**IUPAC Chemical Name**
2-(5-methoxy-1H-indol-3-yl)-N, N-dimethylethan-1-aminium succinate

**Common Synonyms**
5-MeODMT, O-Methyl bufotenine, Mebufotenine

**DEA Schedule**
Schedule I

**Controlled Substances Code Number (CSCN)**
7431

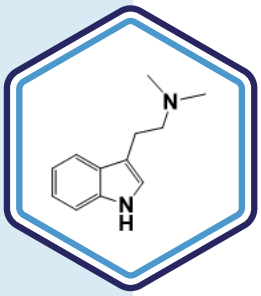
## 5-Methoxy-N,N-dimethyl tryptamine Succinate (5-MeODMT)

5-MeODMT (5-methoxy-N, N-dimethyltryptamine) is a potent psychedelic compound from the tryptamine family. It is found in various plants and secreted by the Colorado River toad (Bufo alvarius), and it can also be synthetically produced. Known for its intense and rapid onset, the effects of 5-MeO-DMT typically last between 15 to 30 minutes.

The therapeutic potential of 5-MeODMT is gaining interest in psychedelic research. Potential benefits include treatment for treatment-resistant depression, PTSD and trauma, addiction, and existential distress. Unlike other psychedelics that primarily target the 5-HT2A receptors, 5-MeODMT acts as a potent agonist at the 5-HT1A receptors, which are involved in mood regulation and anxiety.

Current research is focused on the safety, efficacy, and optimal dosing of 5-MeODMT in therapeutic contexts. High-quality GMP-grade 5-MeODMT is essential for clinical trials aimed at helping patients with various conditions. To support these trials, the active pharmaceutical ingredient (API) must be prepared with adequate controls to ensure its identity, potency, purity, and strength. Since 5-MeODMT is a Schedule I controlled substance, companies need DEA licenses to manufacture it.

**Benuvia, a DEA-licensed manufacturing facility, can support these efforts by providing ICH-compliant 5-MeODMT produced in an FDA-regulated GMP-certified facility.**




**IUPAC Chemical Name**
2-(1H-indol-3-yl)-N, N-dimethylethan-1-amine

**Common Synonyms**
DMT, N, N-DMT, Dimethyltryptamine, Ayahuasca

**CAS Number**
61-50-7

**DEA Schedule**
Schedule I

**Controlled Substances Code Number (CSCN)**
7435

## N, N-dimethyl tryptamine Fumarate (DMT)

N, N-Dimethyltryptamine (DMT) is a potent hallucinogenic compound found naturally in many plants and can also be synthetically produced. Known for its intense and brief psychedelic effects, DMT often induces a rapid and profound journey into altered states of consciousness. It is the main active ingredient in Ayahuasca, a traditional South American brew used in spiritual and healing ceremonies. When used on its own, DMT is typically smoked, vaporized, or injected, with effects lasting about 15 to 30 minutes.

There is growing interest in the potential therapeutic applications of DMT, including its use in treating depression, anxiety, and PTSD. Current research focuses on the safety, efficacy, and optimal dosing of DMT in therapeutic contexts. High-quality GMP-grade DMT is essential for clinical trials aimed at helping patients with various conditions. To support these trials, the active pharmaceutical ingredient (API) must be prepared with strict controls to ensure its identity, potency, purity, and strength. Since DMT is a Schedule I controlled substance, companies need DEA licenses to manufacture it.

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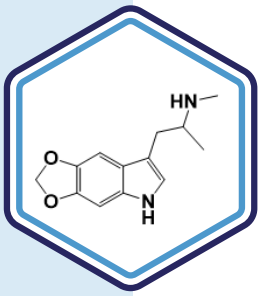



**IUPAC Chemical Name**
3-(2-(dimethylamino)ethyl)-1H-indol-4-ol

**Common Synonyms**
Psilocyn,
4-hydroxy-N, N-dimethyltryptamine,
4-OH-DMT, Magic Mushroom

**CAS Number**
520-53-6

**DEA Schedule**
Schedule I

**Controlled Substances Code Number (CSCN)**
7438

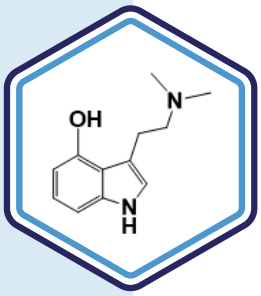
## 3,4-Methylenedioxymethamphetamine Hydrochloride (MDMA)

MDMA, or 3,4-methylenedioxymethamphetamine, is a synthetic psychoactive drug known for its stimulant and mild psychedelic effects. It is popular for enhancing sensory perception, boosting energy, and promoting feelings of empathy and emotional closeness. The effects of MDMA typically last between 3 to 6 hours, characterized by heightened sensations, emotional warmth, and a sense of well-being. Recently, there has been growing interest in the therapeutic uses of MDMA, particularly for treating PTSD. MDMA-assisted psychotherapy has proven highly effective for individuals with PTSD, as clinical trials have shown that MDMA helps patients process traumatic memories more effectively by reducing fear and increasing feelings of trust and empathy.

Beyond PTSD, there is increasing interest in MDMA's potential for treating other conditions such as anxiety, depression, and social anxiety in autism spectrum disorder. Clinical trials have shown promising results, leading to ongoing research into its safety and efficacy in these contexts. MDMA works by increasing the release of serotonin, dopamine, and norepinephrine in the brain, enhancing mood and emotional processing. This makes it easier for patients to engage in therapy and confront traumatic experiences.

While MDMA shows promise, further research is needed to fully understand its safety and efficacy. High-quality, GMP-grade MDMA is essential for clinical trials, and due to its status as a Schedule I controlled substance, manufacturing requires DEA licenses.

**Benuvia, a DEA-licensed manufacturing facility, can support these efforts by providing ICH-compliant MDMA produced in an FDA-regulated GMP-certified facility.**

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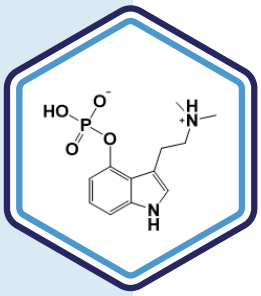
## Psilocin Fumarate

Psilocin is a naturally occurring psychedelic compound found in various species of psychedelic mushrooms, such as Psilocybe mexicana and Psilocybe cubensis. It is the pharmacologically active form of psilocybin, which is rapidly converted to psilocin in the body. Psilocin primarily acts on serotonin receptors, particularly the 5-HT2A receptor, leading to its hallucinogenic effects. These effects can include altered perception of time and space, visual and auditory hallucinations, and profound changes in thought and mood.

Historically, psilocin and psilocybin have been used in religious and spiritual ceremonies by indigenous cultures in Mexico and Central America. Psilocin, the active metabolite of psilocybin, has shown promising therapeutic potential in several areas, including depression, anxiety, PTSD, alcohol and nicotine addiction, and obsessive-compulsive disorder (OCD). Ongoing research aims to further understand the safety, efficacy, and optimal dosing of psilocin in these therapeutic contexts.

High-quality GMP-grade psilocin is essential for clinical trials aimed at helping patients with various conditions. To support these trials, the active pharmaceutical ingredient (API) must be prepared with strict controls to ensure its identity, potency, purity, and strength. Since psilocin is a Schedule I controlled substance, companies need DEA licenses to manufacture it.

**Benuvia, a DEA-licensed manufacturing facility, can support these efforts by providing ICH-compliant psilocin produced in an FDA-regulated GMP-certified facility.**

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**CAS Number**
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**DEA Schedule**
Schedule I

**Controlled Substances Code Number (CSCN)**
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## Psilocybin Trihydrate

Psilocybin is a naturally occurring psychedelic compound found in over 200 species of mushrooms, commonly known as “magic mushrooms.” It is a prodrug, meaning it is biologically inactive until the body converts it into psilocin, which then produces its psychoactive effects. Psilocybin primarily acts on serotonin receptors in the brain, particularly the 5-HT2A receptor, leading to effects such as altered perception of time and space, visual and auditory hallucinations, and profound changes in thought and mood. These experiences can range from euphoria to intense emotional and spiritual insights.

Historically, psilocybin has been used in religious and spiritual ceremonies by indigenous cultures in Mexico and Central America. Today, there is growing interest in its potential therapeutic applications, particularly for conditions like depression, anxiety, PTSD, and addiction.

High-quality GMP-grade psilocybin is essential for clinical trials aimed at helping patients with various conditions. To support these trials, the active pharmaceutical ingredient (API) must be prepared with strict controls to ensure its identity, potency, purity, and strength. Since psilocybin is a Schedule I controlled substance, companies need DEA licenses to manufacture it.

**Benuvia, a DEA-licensed manufacturing facility, can support these efforts by providing ICH-compliant psilocybin produced in an FDA-regulated GMP-certified facility.**

## ABOUT BENUVIA

Benuvia Operations, LLC is a global Contract Development and Manufacturing Organization (CDMO) that helps pharmaceutical, and biotech companies deliver life-changing therapies to patients in need. The company provides end-to-end development and manufacturing services for Active Pharmaceutical Ingredients (APIs) and finished dosage products and has extensive experience with cannabinoids, psychedelics, and other controlled substances. Benuvia operates an 83,000 square foot, best-in-class manufacturing facility in Round Rock, Texas that can produce Schedule I-V compounds, offering comprehensive solutions for companies throughout the entire drug development lifecycle—from API Process Development, clinical trial supply to commercial production.

Visit us at **www.benuvia.com**