



CBD pharma- grade APIs

A new scientific frontier
for benefiting patients'
health globally



Enter the CBD APIs market with confidence

Early-stage drug development plays a critical role in expanding treatment options that will ultimately support global patient health. That's why DSM has created a platform, where it can partner to explore the potential of CBD-based therapies – a new and exciting field of science with promising research across a wide variety of indications.

Partner with us to realize the full potential of CBD-based pharmaceutical innovation.

Visit www.dsm.com/cbd-apis

Make a difference with cannabinoid pharmaceuticals: the new frontier of medical science

The CBD-based drug market is growing rapidly, powered by increasing scientific research indicating the positive therapeutic potential of CBD actives, mostly cannabidiol (CBD), in a wide variety of health areas, including CNS (central nervous system) diseases, pain disorders, cancer, and more.

This renewed scientific interest in the medical use of hemp plant derivatives follows the recent discovery of the endocannabinoid system in humans. The endocannabinoid system is a widespread and complex cell-signaling system that regulates multiple functions, including cognition, sleep, mood, inflammation and pain, and is activated via the CB1 and CB2 receptors in the brain and body respectively.

Tap into CBD-based innovation opportunities

\$798
million

Global sales of cannabinoid-based pharmaceuticals in 2020¹

20%

CAGR Global sales 2020-2024²



Positive science

CNS disorders, pain management, cancer, mood disorders



Natural vs synthetic CBD

To date, most approved CBD-based drug products have been developed using natural CBD, which is supported by significant safety data and preferred by patients.



What are minor cannabinoids (CBx)?

Minor cannabinoids – also referred to as CBx – are cannabinoids that make up less than 1% of the hemp biomass. There are over 100 types in the hemp plant. Although there is limited research currently focused on CBx, it is an area of growing scientific interest and will be an innovation focus for DSM in the future. DSM is developing capabilities to support its customers explore the possibilities of CBD.

What are CBD APIs?

The cannabis (or hemp) plant contains hundreds of compounds, some of which are cannabinoids. THC (tetrahydrocannabinol) is a well-known cannabinoid, known for its psychoactive properties. CBD is the second most prevalent cannabinoid and is non-psychoactive. CBD interacts with the CB1 and CB2 receptors in the endocannabinoid system, which is how it is thought to exert its effects in the body. CBD is well-tolerated in humans and safe at established tolerable upper limits.

The cannabis plant has two primary varieties: hemp and marijuana. Hemp has been used for many industrial applications and has recently become popular for CBD extraction due to its high CBD, low THC content.

Some mild side effects of CBD include dry mouth, diarrhea, reduced appetite, drowsiness and fatigue.



Hemp



< 0.3% THC
CBD



Marijuana



> 0.3% THC
CBD



The possibilities are endless

The science behind cannabinoids is rapidly evolving (see Table 1) and the medical potential of CBD is significant. This is creating a myriad of opportunities to expand treatment possibilities and better support patients through the development of bespoke cannabinoid-based drug products.

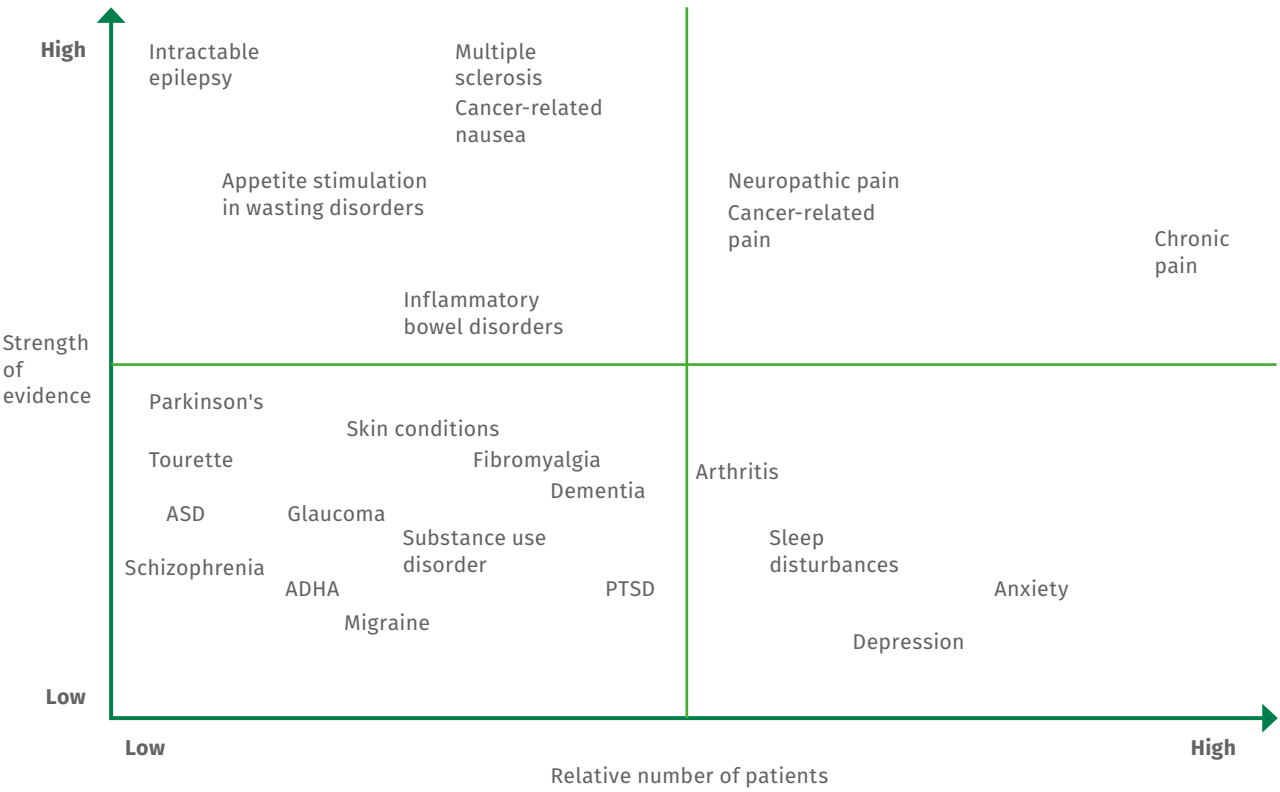


Table 1. Evidence supporting cannabinoid efficacy in a number of therapeutic areas. (Schlag 2021.)



Science in this new and exciting field is still emerging. Leverage DSM’s science, toxicology and clinical research expertise to:



Remain at the forefront of cutting-edge CBD API research, and partner to discover the therapeutic potential of CBD



Create next generation CBD-based drugs by bringing our cannabinoids and expert services to early-stage drug development

Central Nervous System and CBD

CBD API science is strongest and most established in the field of CNS disorders – a broad category of neurological conditions including epilepsy, Alzheimer’s disease, Parkinson’s disease and stroke. As the global population grows and ages, the prevalence of major disabling CNS disorders is expected to rise. Often these are fatal or cause major disabilities, whereas other neurological disorders, like headaches, can be chronic and have a significant impact on quality of life.

There has already been significant research into the potential of CBD as an epilepsy treatment, especially in patients that do not respond to conventional anti-epileptic drugs. This is significant since up to 70% of people diagnosed with epilepsy could live seizure-free if properly diagnosed and treated.³

\$100 billion CNS market by 2025⁴

160+ active CBD clinical trials⁵

~50% existing research focused on CNS

Your guide to the evolving regulatory market

Active monitoring of regulatory developments in key geographical markets shows a changing trend towards a favorable regulatory landscape. The CBD API regulatory landscape is already reasonably well-established as the majority of countries apply standard API regulations, with some sub-regional specificities.

With a global network of regulatory specialists, DSM has the expertise and local knowledge needed to support our customers with the market entry process. Our strong track record of successful registrations and close collaborations with a wide range of authorities, including the US Food and Drug Administration (FDA), European Directorate for the Quality of Medicines (EDQM), and Health Canada (HC), ensure we are on top of changing regulatory frameworks and can facilitate cross-regional registrations.



Global network of specialists



Expertise and knowledge



Strong track record

Creating CBD-based pharmaceuticals with purpose

It takes more than ingredients to enter the cannabinoid market with confidence. It takes a partner.

DSM has created a platform to help our customers realize the full therapeutic potential of CBD-based pharmaceuticals. Together with pioneer in the CBD API market, Brains Bioceutical, we can partner with you to develop therapies that will safely and efficiently improve people's lives. Through this purpose-led strategy involving a rapidly evolving field, we are aligned with the UN Sustainable Development Goal 3, which aims to achieve good health and wellbeing in all individuals worldwide.

We have more than 70 years of experience in producing and securing the supply of APIs.

This, combined with our unique innovation expertise and unparalleled ability to manage the market entry registration process, makes us an trusted partner for the development of over-the-counter products and prescription medications.

Our CBD API offering

- 1. High quality ingredient**

Natural (plant-based), THC-free CBD pharma-grade API.
- 2. Customized solutions**

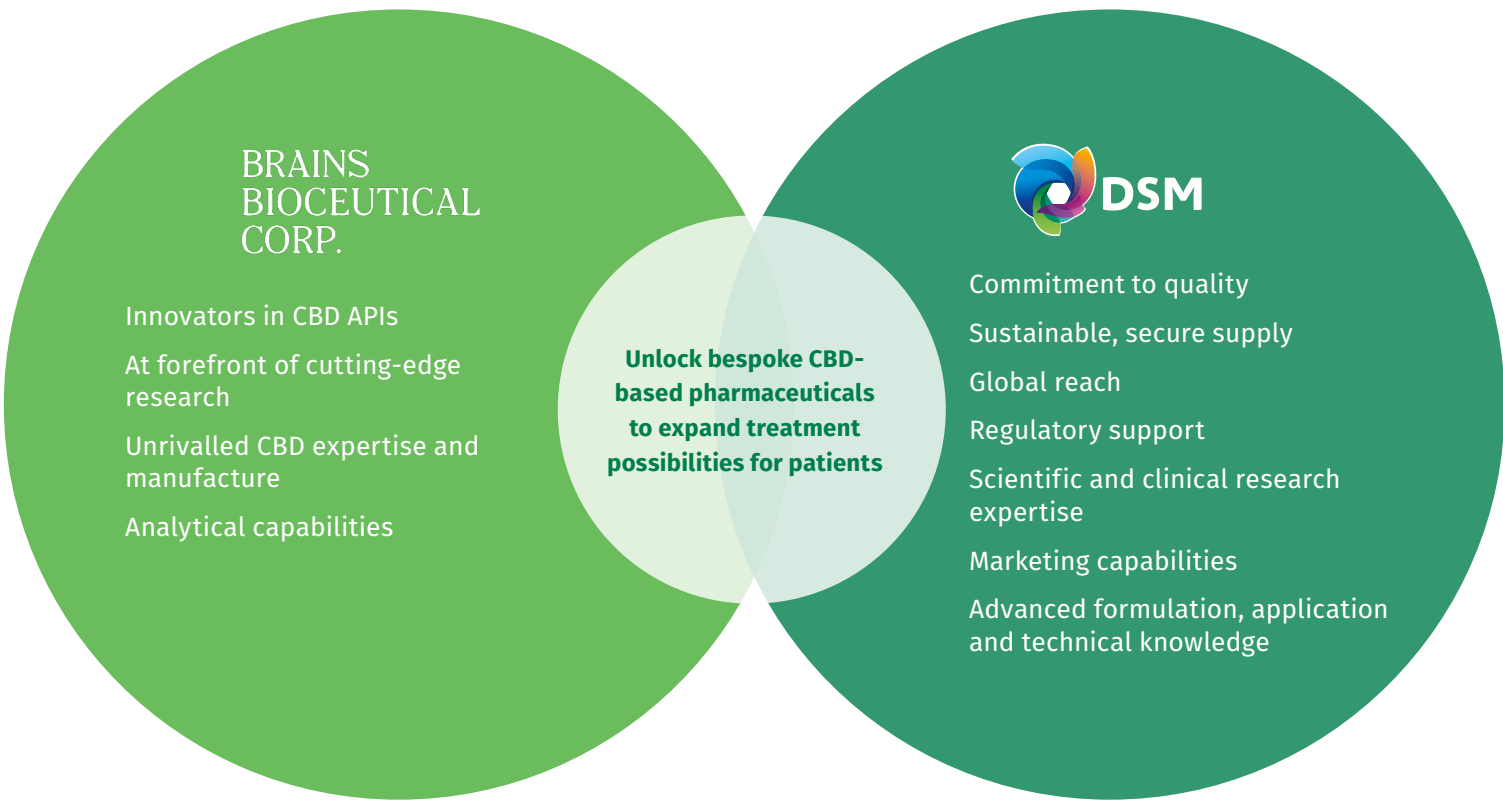
Capability to manufacture custom CBD upon request, plus formulation, technical and application capabilities in high commercial quantities.
- 3. Expert services**

Quality, regulatory and scientific expertise in early-stage drug development and beyond.

Request a sample of our CBD API

- ✓ Highest quality
- ✓ 3-year stability data
- ✓ 100% natural, hemp-derived
- ✓ Science-backed
- ✓ THC-free, <0.01%
- ✓ GMP-compliant
- ✓ Batch-to-batch quality consistency

Request a sample



About Brains Bioceutical

Brains Bioceutical is a pioneer in the CBD space. As one of the only companies worldwide to provide a secure supply of standardized THC-free, CBD APIs of natural origin, Brains Bioceutical is setting the global standard for CBD active innovation.

BSPG Laboratories is a wholly-owned subsidiary of Brains Bioceutical and is where its pure THC-free CBD is manufactured. BSPG Laboratories is a GMP-compliant facility assessed by the UK Medicines & Healthcare products Regulatory Agency (MHRA) for the manufacturing and distribution of CBD API for use in pharmaceutical applications of human and veterinary medicinal products. Its capabilities include:



Together, let's deliver patient driven CBD-based pharmaceuticals with purpose. Visit www.dsm.com/cbd-apis to start the conversation.

References

- 1) The Pharmaceutical Cannabis Report V07, Prohibition Partners; internal research.
- 2) The Pharmaceutical Cannabis Report V07, Prohibition Partners; internal research.
- 3) Epilepsy, a public health imperative; World Health Organization, 2019.
- 4) IQVIA A New Dawn: At the cusp of the CNS decade, Jan 2021.
- 5) Clinicaltrials.gov as of April 2021.



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