Case study: dsm-firmenich and Oz Medicann Group (OMG) Pharma pioneer patient-centric CBD drug dosage form

dsm-firmenich

Background

Early drug development plays a critical role in expanding treatment options and convenience that will ultimately support global patient health. Cannabinoid innovation is an emerging and exciting field of research with promising potential across a wide range of indications. However, existing cannabidiol (CBD)-based therapies exhibit limited bioavailability, and therefore efficacy, due to the poor solubility and absorption of cannabinoid molecules.

Consequently, large doses of CBD are needed for effective therapy and require administration via inconvenient and unpleasant oil-based oral solutions. This has created an unmet need for more patient-friendly oral solid dosage forms, like orally disintegrating tablets (ODTs).

ODTs represent an innovative and patient-centric solid oral drug form for CBD delivery. Designed to dissolve quickly in the mouth without the need for water, they bypass first-pass metabolism – a process that can significantly reduce CBD bioavailability – to allow rapid absorption of the API into the bloodstream. This makes ODTs an appealing drug delivery form for:

- Patients who have difficulty swallowing pills or tablets, like older adults
- Health conditions requiring immediate or fast effects, like insomnia
- Medicines that do not absorb easily in the stomach
- Medicines with limited bioavailability and therefore limited efficacy due to first-pass metabolism

The challenge

Insomnia is a widespread condition that affects between 10–30% of the global population, but remains largely unaddressed by current treatments due to its complexity, individual differences in therapy response and challenges related to accurate diagnosis.[1] Insomnia treatment is one area where CBD-based therapies are showing promise. However, present oil-based CBD formulations mean that the ingredient is still subjected to significant first-pass metabolism in the liver and therefore cannot act fast enough to treat the condition.

The task was to develop a CBD-based ODT that allowed faster CBD absorption for insomnia management. The product had to be patient-friendly and regulatory compliant, while demonstrating optimized bioavailability and therapeutic effectiveness.

The solution

To address patient needs for oral solid dosage forms with higher drug loading, innovative CBD-based delivery systems, like ODT, were needed. However, currently available CBD isolates cannot be absorbed – and is the reason why oil-based formulations with low CBD loading have been developed to date.

With a legacy of pioneering breakthroughs, decades of in-house experience and a pioneering mindset, dsm-firmenich offers a unique proposition aimed at securing first-to-market leadership in the cannabinoid space – and was able to overcome this challenge with its novel CBD drug product intermediate, CBtru®, and technical experience.

CBtru® is an innovative formulation of CBD that allows for the development of solid oral dosage forms with higher drug loading and optimized bioavailability, helping to meet patient convenience and compliance. The premium formulated GMP CBD drug product intermediate is trial-ready and supported by the relevant documentation.

Together elevating cannabinoid-based developments.

Together with Brains Bioceutical, manufacturer of high-quality pharma-grade cannabinoids, dsm-firmenich offers an end-to-end innovation platform designed to support early-stage cannabinoid drug development and inspire patient-centric solutions including:

- Leading-edge **formulation capabilities**, including bioavailability expertise
- A global network of **regulatory specialists**
- **Expertise in preclinical and clinical studies** and scientific teams

Technical capabilities in solid dosage formulation, tailored to address patient needs and align with specific drug development goals

Aiming to inspire more patient-centric solutions than those currently on the market, dsm-firmenich has successfully developed CBtru® with optimized stability, high active loading and improved pharmacokinetic performance – supporting ODT development and more.

Solid dosage form	Higher API loading	Optimized bioavailability
• Improved patient compliance vs liquid • Wider applicability in finished drug products • Good chemical and physical stability (6 months at 25°C & 40°C)	• Lower daily dosage of final drug product vs commercial oil • Lower cost in use (CIU) • 3x to 4x increase in API loading vs commercially available product	• Similar bioavailability compared to CBD oil in a pre-clinical animal model • Reliable delivery with low intra-patient variability • Reduced adverse effects

The outcome

dsm-firmenich formed a strategic collaboration with Oz Medicann Group (OMG) Pharma – an Australian-based biotech innovator in the cannabinoid medicines domain – to enhance the bioavailability of its CBD-based ODT for insomnia. Together, the companies will progress the next phase of OMG Pharma's clinical trial using CBtru®, investigating the therapeutic potential of the Schedule 3 solution.

The collaboration will result in a first-to-market and medically compliant ODT for CBD delivery. The innovative dosage form provides a more convenient and patient-friendly alternative to current oil-based oral dosage forms. Given this, the format also has the potential to transform cannabis medicine delivery to address numerous conditions, beyond insomnia; thereby driving meaningful advancements in patient care.

Together we can elevate patient care.

dsm-firmenich can support you across the entire cannabinoid-based drug development journey.

Connect with one of our experts to learn how you can develop purpose-led cannabinoid pharmaceuticals that enrich patients' lives.

Learn more

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1. Bhaskar S, Hemavathy D, Prasad S. Prevalence of chronic insomnia in adult patients and its correlation with medical comorbidities. J Family Med Prim Care, 2016, vol. 5(4), pg. 780-784.