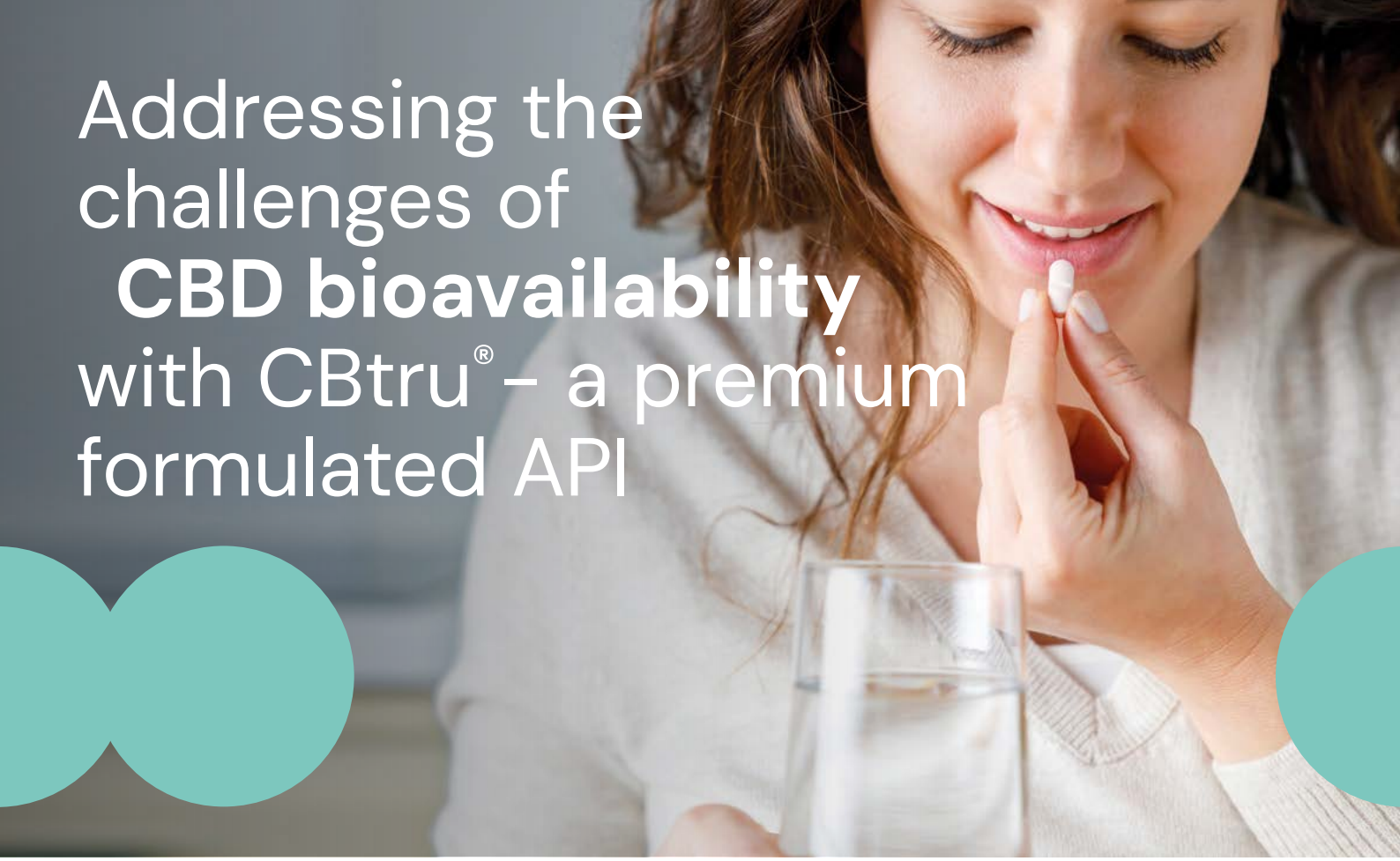

Addressing the challenges of **CBD bioavailability** with CBtru® – a premium formulated API

Why CBD?

Cannabinoid molecules – like cannabidiol (CBD) – demonstrate **significant potential** in pharmaceutical research and development and have proven themselves to be a promising avenue for improving patients' quality of life, especially in cases of drug resistant central nervous system (CNS) disorders like epilepsy.

Following the recent discovery of the human endocannabinoid system in the late eighties, the science behind CBD has grown rapidly. The molecule is showing promising therapeutic potential in several health areas, including CNS diseases, pain conditions, cancer, sleep, mood disorders and more.

Understanding the opportunity at hand

While there is remarkable opportunity for the development of CBD-based pharmaceutical products, formulating a highly lipophilic and poorly soluble crystalline active pharmaceutical ingredient (API) can be a complex task.
In addition to physical and chemical stability challenges, the **oral bioavailability** of CBD has been shown to be **very low** in humans (6%), as a result of incomplete absorption in the gut and significant pre-systemic elimination in the liver.[1]
Innovation and formulation capabilities of the dsm-firmenich labs can help address concerns around bioavailability and open new opportunities for drug manufacturers.

Developing solutions: CBtru® – a premium formulated CBD API

dsm-firmenich has developed CBtru®, a premium formulated CBD API that presents several opportunities for patients, healthcare professionals, and manufacturers of pharmaceutical products, including:

- The possibility to offer patients solid dosage forms, that have wider applicability and easier patient acceptance vs existing liquid dosing (e.g., using syringes).
- The possibility for higher CBD API loading, meaning that patients can meet their needs with lower daily dosages than what is currently available with oil formats.
- The possibility for optimized CBD bioavailability leading to potentially more effective medicine formats, decreased probability of drug-drug interactions, and minimized adverse effects.[2]

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

1. Perucca and Bialer. Critical aspects affecting cannabidiol oral bioavailability and metabolic elimination, and related clinical implications. Cannabinoids in Neurology and Psychiatry, 2020.
2. Millar et al. Towards better delivery of cannabidiol (CBD). Pharmaceuticals (Basel), vol. 13, pg. 219, 2020.

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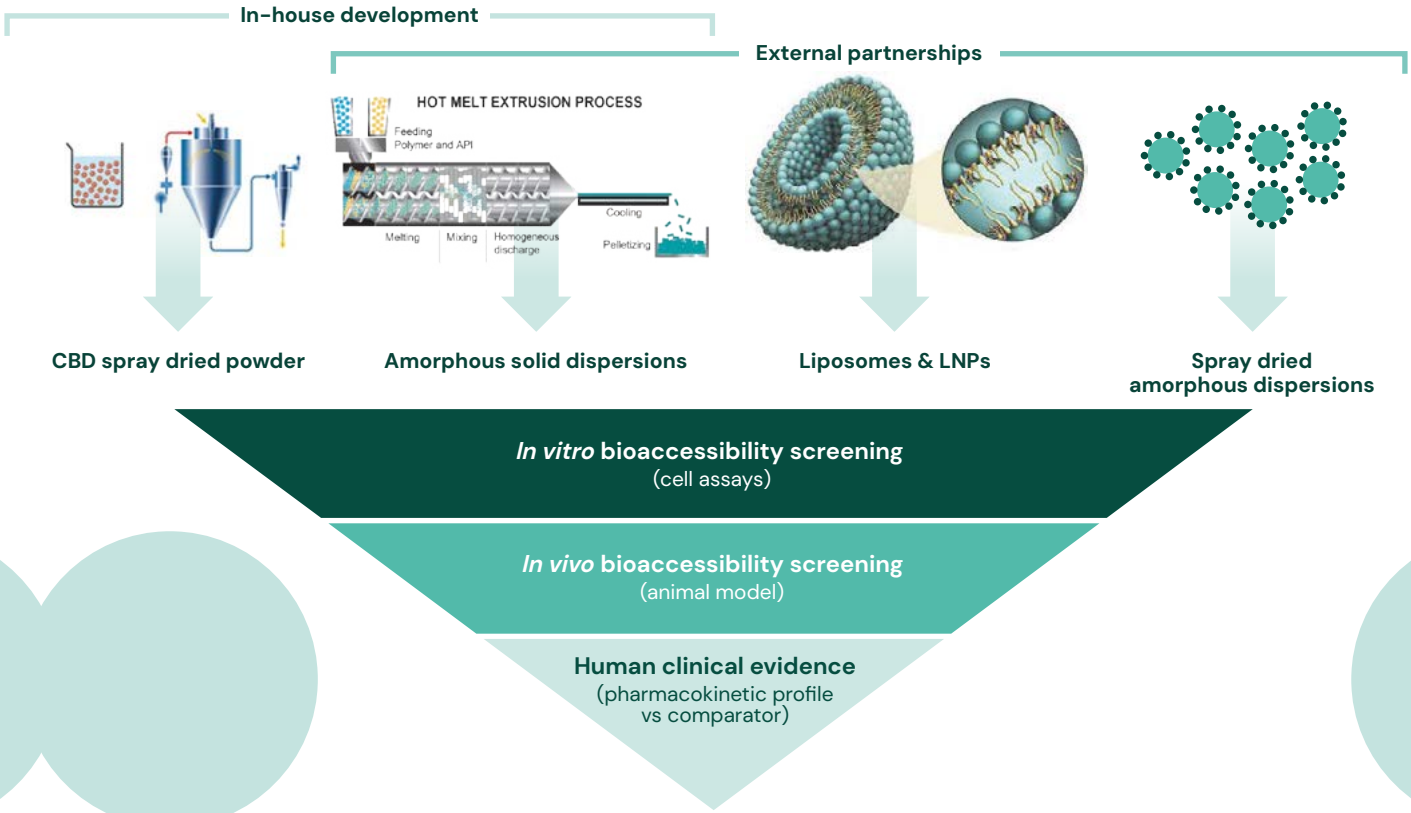
With CBtru®, for the first time in the case of cannabinoids, the development of stable solid dosage formulations enables the creation of finished drug products like tablets, orally dispersible films, orally dispersible tablets, capsules, gums, chewables etc. or stick-packs, expanding treatment options and convenience for patients worldwide.

Taking advantage of a solid innovation platform to develop your CBD-based products

dsm-firmenich is investing significantly in an advanced R&D process to offer you the right solutions that help meet patient needs. We have completed a full technology screening and validation process of over 200 candidates in the lab.

In our research we benchmarked nano-emulsification, liposomal and lipid nanoparticle (LNP) encapsulation with formation of amorphous dispersions to identify optimal solutions and build a formulation toolbox for CBD-based therapies.



dsm-firmenich has now completed its pre-clinical evaluation in animal models and is moving to validate findings with human clinical trials. Promising results from the pre-clinical evaluation indicate that our selected candidates for clinical testing have:

- A good physical and chemical stability (6 months stability in accelerated conditions).
- 3x to 4x increase in API loading vs commercial products.
- Similar bioavailability vs CBD oil in an animal model.

Aiming to inspire more patient-centric solutions than those currently on the market, we successfully developed CBtru®, a premium formulated CBD drug product intermediate, serving solid oral dosage forms with a high API loading, good physical and chemical stability, and optimized bioavailability.

Ready to discover the full therapeutic potential of cannabinoids, like CBD, and deliver patient driven pharmaceuticals with purpose?

Partner with dsm-firmenich and get started!

Connect with us today

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