Bioavailability of Q FUSE™ Full Spectrum Hemp Oil in Human Subjects (2018)

Introduction

Cannabis sativa is a species of herb which has been grown and cultivated over thousands of years for uses in clothing, textiles, and paper from its fibers; It has been used medicinally and recreationally from its oils and resins. There are well over 100 chemical compounds found in the Cannabis sativa or hemp plant. These chemical compounds are known as cannabinoids. The most notable and well-studied cannabinoids are THC (tetrahydrocannabinol) and Cannabidiol (CBD). THC, specifically THCΔ9, is responsible for the euphoric, mind-altering effects of cannabis and is the primary composition of marijuana due to its high THCΔ9. CBD, on the other hand, is a non-psychoactive component of the cannabis plant. Cannabidiol is a pleiotropic drug in that it produces many effects through multiple molecular pathways. The cannabis plant is also composed of a chemical mixture that includes phytocannabinoids, terpenoids, flavonoids, steroids and enzymes. While the exact mechanism of action is not fully known, all of these other components have a synergistic effect combined with cannabinoids. This has become known as the entourage effect. The cannabis plant has been consumed by humans for thousands of years in medicine for its sedative, antidepressant, analgesic, anticonvulsant, antiemetic, and anti-inflammatory properties.

CBD is an antagonists at the cannabinoid receptors and modulators of the endogenous cannabinoid system are also promising candidates for clinical research and therapeutic uses. Cannabinoid receptors including C1 and C2 are distributed in the central nervous system and many peripheral tissues (spleen, leukocytes, reproductive, urinary and gastrointestinal tracts, endocrine glands, arteries and heart, etc.). (Pertwee, 2008) Additionally, there is now evidence for non-receptor dependent mechanisms of cannabinoids.

Five endogenous cannabinoids, anandamide, 2-Arachidonyl glycerol, noladin ether, virodhamine, and NADA, have been detected and studied. There is also evidence that besides the two cannabinoid receptor subtypes cloned so far, additional cannabinoid receptor subtypes and vanilloid receptors are involved in the complex physiological functions of endocannabinoids that include, for example, motor coordination, memory procession, pain modulation and neuroprotection. (Grotenhermen, 2004)

Pharmacokinetics
Pharmacokinetics refers to what happens to a substance from entering into the body until the exit of all traces. The absorption of a drug or a supplement into the blood stream and utilization by body systems is also called its bioavailability.

The purpose of this study is to identify and define full spectrum hemp oil and specifically the cannabidiol (CBD) bioavailability when a special absorption product is added. Understanding the pharmacokinetics of a drug is essential to understanding the onset, magnitude, and duration of its pharmacodynamic effects, maximizing therapeutic and minimizing negative side effects.

Both THC and CBD are highly lipophilic and have poor oral bioavailability (estimated to be as low as 6%). Oral THC formulations have shown variable absorption and undergo extensive hepatic first-pass metabolism resulting in lower peak plasma THC concentration relative to inhalation and a longer delay (~ 120 minutes) to reach peak concentration. While the metabolic pathways differ slightly, CBD exhibits similar pharmacokinetics. Following oral administration of CBD, a similar plasma concentration-time profile to oral THC has been observed and documented. (Lucas, 2017; Huestis, 2007)

Increasing bioavailability of poorly absorbed compounds is an ongoing challenge in the both pharmaceutical and nutritional science. Q Fuse Full Spectrum Hemp Oil utilizes BioAbsorb™ a licensed proprietary micellization process, which micellizes a decarboxylated full spectrum hemp oil (including CBD and trace amounts of THC) mixture suitable for oral ingestion. According to the manufacturer, each particle size is approximately 22 nm making it highly permeable in water. Animal models with Q Fuse Hemp Oil with BioAbsorb have demonstrated a rapid and almost complete absorption (85%) in the intestinal lining using Franz diffusion apparatus. (PHRX, 2016)

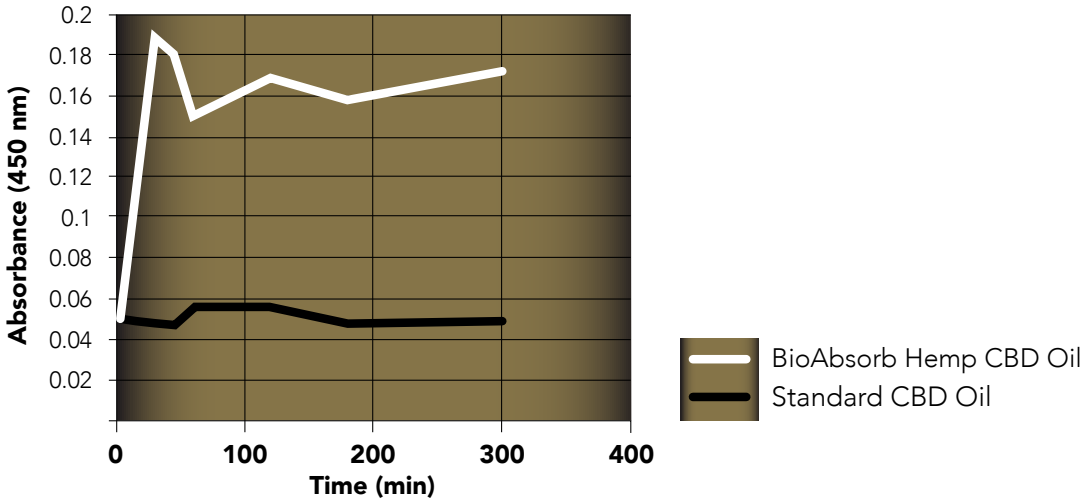

Figure 1. Q Fuse CBD Oil and standard CBD oil (formulated in MCT) absorption in animal intestinal model.

Background

HPLC Testing

High-performance liquid chromatography (HPLC; formerly referred to as high-pressure liquid chromatography), is a technique in analytical chemistry used to separate, identify, and quantify each component in a mixture. Each component in the sample interacts slightly differently with the adsorbent material, causing different flow rates for the different components and leading to the separation of the components.

Human Studies

These human studies will evaluate the blood levels of Q Fuse Hemp Oil orally administered to human subjects over a 12-hour period. Each time set had 3 vials of arterial blood drawn. Each sample was tested using HPLC. The report indicates the average of the three blood vials drawn and tested from each subject at each time point. Samples were drawn at: Baseline and Post ingestion of product 15-minutes, 30-minutes, 45-minutes, 1 hour 45 minutes, 2 hours 45 minutes, 3 hours 45 minutes, 4 hours 45 minutes, 5 hours 45 minutes, 6 hours 45 minutes, 7 hours 45 minutes, 8 hours 45 minutes, 9 hours 45 minutes, 10 hours 45 minutes, and 11 hours 45 minutes.

Two consecutive studies were carried out with fourteen subjects participating for a period of twelve hours. At the onset of these studies each subject had arterial blood drawn to set the Baseline of CBD in their bodies, each had a Baseline of 0.0 mg of CBD at Baseline. Each subject was given an oral dose of one vial with 8.95 mg of CBD. Vials were prepared by a third party on behalf of Q Sciences and delivered to the researcher for use in this study. Each subject was given a vial and instructed to spray the liquid under their tongue and hold it there for 30 seconds before swallowing. The nurse in attendance let each subject know when their 30 seconds was up so they could swallow the remaining liquid.

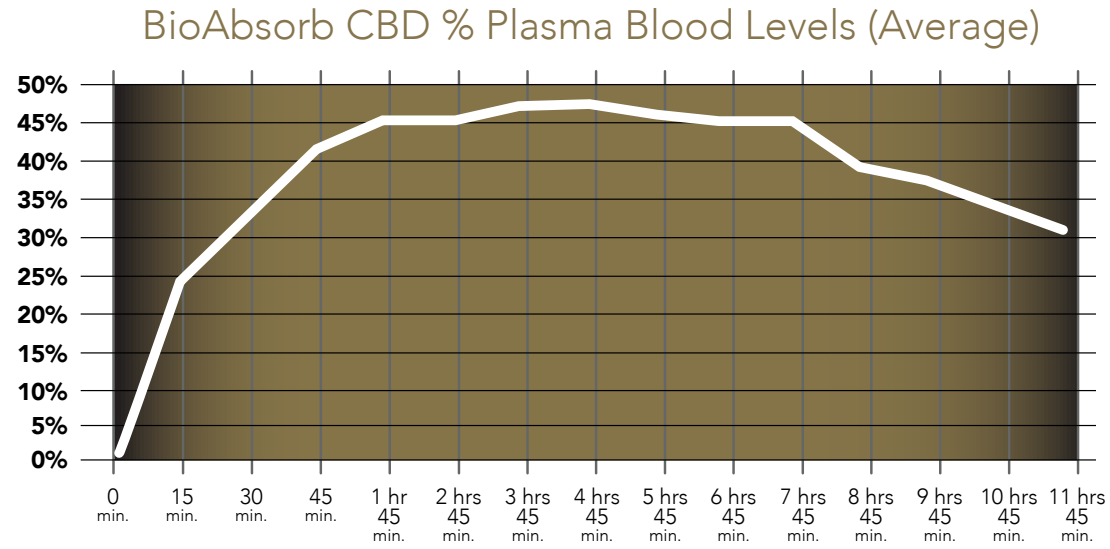

Figure 2. Plasma blood levels prior to adjustment for blood volume.

Conclusion

The onset of Q Fuse Hemp Oil is rapid and it has a lasting duration of CBD availability in the blood stream. All the patients were measured to have over 50% of the available CBD in their blood stream by the first measurement of 15 minutes. This exceeds what has been shown with CBD or THC that has been inhaled or vaped. The blood levels then measured significantly higher than what has been seen with standard CBD oil and other solubilizing methods. From these studies it is concluded that the uptake of Q Fuse Hemp Oil CBD with BioAborb far exceeds the average uptake of CBD products available on the market today.

References

Pertwee, R G. The diverse CB1 and CB2 receptor pharmacology of three plant cannabinoids: Δ9-tetrahydrocannabinol, cannabidiol and Δ9-tetrahydrocannabivarin. Br J Pharmacology (2008) 153 (2): 199-215.

Grotenhermen F1. Pharmacokinetics and pharmacodynamics of cannabinoids. Clin Pharmacokinet. (2003) 42(4):327-60

Lucas, CJ; et al. The Pharmacokinetics and the Pharmacodynamics of Cannabinoids, Br J Clin Pharmacol (2018) 84 2477–2482.

Huestis, MA. Human Cannabinoid Pharmacokinetics, National Institute of Health Manuscript (2007) 4(8); 1770-1804.

Q Sciences., The Bioavailability of BioAbsorb CBD in Animal Intestinal Model. (2016) Unpublished abstract.