Project Myos

Human Pk And Inflammatory Study

MICROENCAPSULATION OF CANNABINOIDS

93 Tabernacle Street, London EC2A 4BA Company Reg 12518547 | VAT 349 9264 51 Mr. Lee Sacker | (P) +44 20 4534 3034



Based

Clean

Study Location

St. Vincent's Private Clinical Hospital, Dublin, Ireland

Principal Prof. C. Le Roux Investigator

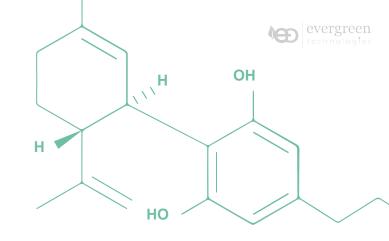
Date September 2021

Executive Summary

mi

22%

14%



STUDY RESULTS INCLUDE

Evergreen microencapsulation demonstrated an approx. 3x (2.83x) increase in CBD absorption vs Liposomal delivery

Evergreen microencapsulation demonstrated peak blood levels for CBD to be 2x (1.98x) those seen with Liposomal delivery

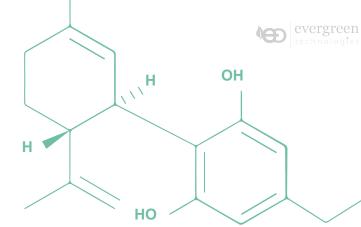
Evergreen microencapsulation demonstrated a slower, more controlled release of CBD into the bloodstream vs Liposomal Delivery (90 minutes vs. 30 minutes)

Evergreen microencapsulation lowered ESR values (inflammation and immune-modulatory response measurement) by 22% after 28 days

Evergreen microencapsulation reduced ESR values >14% better than Liposomal Delivery

Study Design

METHODOLOGIES

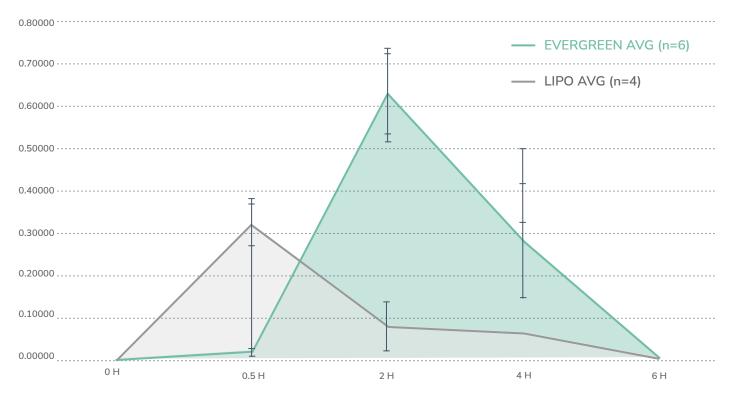


SAMPLE SIZE	Total of 16 people (6+6+4) for PK Study and ESR value testing	16 PEOPLE PK & ESR Value Testing
TYPE OF STUDY	Single-center, double-blinded randomized study	SINGLE-CENTER Double-Blinded
STUDY OBJECTIVE	 Evaluation of Evergreen microencapsulation for enhanced bioavailability of CBD relative to Liposomal delivery CBD formats Evaluation of ESR values (Inflammation and immunomodulatory measurement) after 28 days of supplementation, and as compared to Liposomal delivery 	EVALUATION Evergreen microencapsulation EVALUATION ESR Values after 28 Days

AIM	 To demonstrate efficient delivery of microencapsulated cannabinoids, while also validating the protective properties of microencapsulation during transit through the body and subsequent release in the intestine for potential absorption into the blood stream with slow release effects Influence of microencapsulation of cannabinoids on inflammation and immune response in the body 	DEMONSTRATE Efficient delivery of microencapsulated cannabinoids INFLUENCE microencapsulation of cannabinoids
ENDPOINT	Appearance of CBD in peripheral blood plasma and ESR value testing. Participants were blinded with regard to intervention or control; all samples are provided in the form of non-descript bottles for consumption	of CBD in peripheral blood plasma and ESR value testing
SAMPLES	 Blood samples taken on Day 0 at specific time intervals: Time 0, 0.5h, 2h, 4h, 6h after consumption of the test drink (10 mg CBD in 500 ml water) Day 28 assessment was conducted thereafter with one timepoint. Each participant would represent their own control (time 0) and participants were randomized 	SAMPLE AT DAY 0 Time 0, 0.5h, 2h, 4h, 6h SAMPLE AT DAY 0 Time 0, 0.5h, 2h, 4h, 6h
STUDY POWER & RECRUITMENT	Based on the proposed design, 17 participants were recruited allowing Evergreen microencapsulation and Liposomal to be compared	17 PARTICIPANTS Recruited



MICROENCAPSULATED CBD (EVERGREEN AVG VS. LIPO AVG)



30 minutes

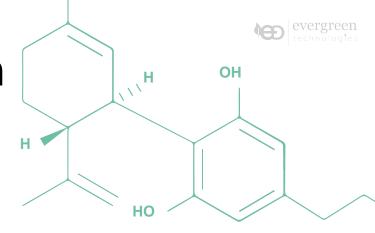
Liposomal CBD - detected in the blood 30 minutes after consumption

120 minutes

Evergreen CBD - detected 120 minutes hours after consumption

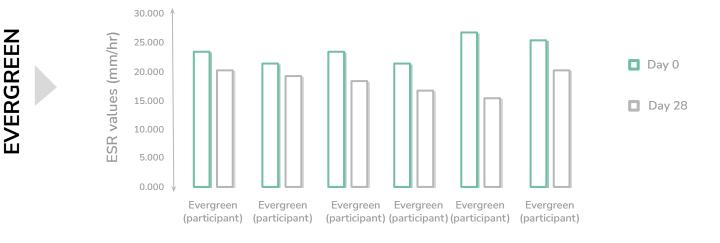


% Reduction in ESR Values

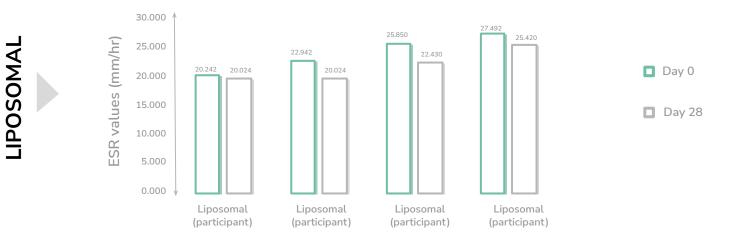


INFLAMMATORY & IMMUNOMODULATORY MEASUREMENT

> INFLAMMATORY MARKERS - EVERGREEN DELIVERY AS A FUNCTION OF TIME



INFLAMMATORY MARKERS - LIPOSOMAL DELIVERY AS A FUNCTION OF TIME



Significant Response -

Statistically Significant response is seen with batch Evergreen microencapsulation

RESULTS



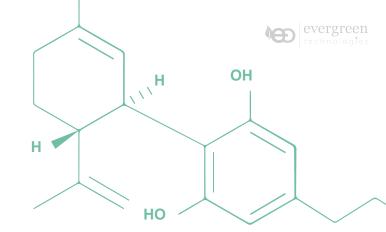
Marginal Effects

Liposomal formats demonstrates marginal effects

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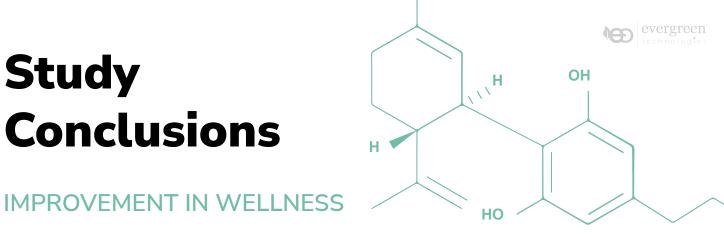
Study Conclusions

KEY DATA & RESULTS



01	Delivery	Evergreen microencapsulation delivers cannabinoids 3x more efficiently than Liposomal delivery
02	Delivery	Evergreen microencapsulation had 2x peak cannabinoid levels than Liposomal delivery
03	Slow Release	Evergreen microencapsulation demonstrates slow release kinetics up to 2 hours after consumption
04	Bioavailability	Evergreen microencapsulation shows > 80% bioavailability
05	Reduced ESR	After 28 days supplementation, the average ESR blood biomarker values were reduced for all subjects. The greatest reduction in ESR values was seen with participants who consumed Evergreen samples (>22%)
06	Inflammatory and Immunomodulatory Response	The inflammatory and immunomodulatory response is least effective with liposomal delivery (>14% less reduction).
07	Regulate Inflammation	The Evergreen microencapsulation has the potential to regulate inflammation through the immunomodulatory properties delivered by CBD.
08	Attenuation	Attenuation of immunomodulatory responses is greatest with Evergreen microencapsulation technology relative to liposomal delivery

Study Conclusions



OVERALL SUMMARY OF FACTORIALS

