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Terpenolol-L: An Anhydrous Lipophilic Micellar Cannabidiol Platform for Medical Devices, Cosmeceutical, and Nutraceutical Applications

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Abstract

Cannabidiol is a highly lipophilic compound whose formulation and biological performance are limited by poor aqueous solubility and variable bioavailability. Terpenolol was previously developed as a hydrophilic nanomicellar cannabidiol system intended to improve aqueous dispersion and early systemic exposure. The present work extends this rationale to anhydrous lipid-based formulations using Terpenolol-L. The platform was incorporated into three experimental prototypes: an oral elixir containing 25 mL of Terpenolol-L in 250 mL of Cannabis sativa seed oil, a skin and hand cream containing 20% Terpenolol-L, and a body and hair balm containing 10% Terpenolol-L. Macroscopic appearance, homogeneity, phase separation, precipitation, and organoleptic or application characteristics were observed during routine storage. All three prototypes retained physical integrity without visible phase separation or precipitation for six months.

These findings demonstrated formulation feasibility across nutraceutical, medical-device-oriented, and cosmeceutical matrices. However, they did not establish enhanced bioavailability, micellar persistence, dermal penetration, or clinical efficacy. Terpenolol-L is therefore presented as a formulation platform whose central hypothesis, that pre-organized cannabidiol may retain advantages when transferred from a lipid vehicle to aqueous biological interfaces, requires direct physicochemical and pharmacokinetic testing.

Keywords: Cannabidiol, Micellar System, Nanomedicine, Drug Delivery, Supramolecular Organization, Lipid Formulation, Nutraceutical, Medical Device, Cosmeceutical

Abbreviations:

- CBD: Cannabidiol
- MCT: Medium-Chain Triglycerides
- NLC: Nanostructured Lipid Carrier
- SEDDS: Self-Emulsifying Drug Delivery System
- SNEDDS: Self-Nanoemulsifying Drug Delivery System

Introduction

Cannabidiol (CBD) is a highly lipophilic phytocannabinoid with poor aqueous solubility, extensive presystemic metabolism, and highly variable pharmacokinetics. These characteristics complicate its incorporation into reproducible pharmaceutical, nutraceutical, and topical delivery systems [1-3].

Formulation strongly influences CBD exposure. Food, particularly lipid-rich meals, can substantially increase systemic exposure, whereas different commercial and experimental formulations generate markedly different pharmacokinetic

profiles. Lipid vehicles offer clear advantages; however, simple dissolution in oil does not necessarily resolve interfacial transfer, dispersion during digestion, or delivery across biological barriers [4-6].

Nanotechnological strategies developed for CBD include polymeric micelles, nanoemulsions, self-emulsifying systems, solid self-nanoemulsifying systems, protein nanoparticles, solid lipid nanoparticles, and nanostructured lipid carriers. Several studies have reported improved dissolution, more rapid absorption, and greater systemic exposure compared to conventional oil-based comparators [7-14].

The original Terpenolol platform was developed as a hydrophilic nanomicellar CBD-derived system. It showed aqueous dispersion, 30-day physicochemical stability, and greater early plasma CBD concentrations than an oil-based reference in a small crossover investigation (Scrimali, 2026). This study introduced the proposition that CBD performance may depend not only on dose and vehicle composition but also on the organizational state in which CBD is presented to biological environments.

Terpenolol-L was subsequently conceived as an anhydrous lipophilic extension of this platform. The rationale was that micellization was not required to dissolve CBD in the lipid phase. Rather, Terpenolol-L was designed to preserve a pre-organized supramolecular state within lipid formulations, thereby creating a platform potentially suited to the subsequent transition from a lipid vehicle to aqueous biological interfaces.

The present study describes the conceptual basis, formulation feasibility, and six-month macroscopic stability of Terpenolol-L in three experimental lipid-based prototypes. It also distinguishes the demonstrated formulation findings from the hypotheses concerning bioavailability, dermal transport, and biological activity.

Conceptual Basis of the Terpenolol-L Platform

CBD is readily soluble in many lipid vehicles, and conventional oils, creams, and balms can therefore be prepared without prior nanostructuring. However, the formulation vehicle is only the first environment encountered during delivery. After oral administration, CBD must disperse during gastrointestinal processing and transfer into absorbable phases. After topical administration, it must partition through structurally heterogeneous skin layers. In both settings, performance is governed by the interfaces rather than lipid solubility alone.

The distinction between simple lipid dissolution and organized delivery is supported by comparative formulation studies. In healthy volunteers, a CBD self-emulsifying system produced higher peak concentrations and exposure than an MCT-based comparator. In vitro digestion, animal, and human data have also shown that the lipid profile and self-emulsifying behavior of formulations influence the fraction of CBD recovered in the aqueous phase and its systemic exposure. Recent investigations on nanoemulsions, SNEDDS, and NLChave reported enhanced absorption and bioavailability compared to conventional controls.

For topical delivery, nanostructured lipid systems and micellar carriers have been investigated to protect CBD, promote retention or penetration within the skin, and sustain release. These studies do not prove that Terpenolol-L behaves in the same manner, but they establish a scientifically plausible context for testing whether controlled supramolecular organization offers advantages over molecular CBD dissolved in the same lipid vehicle [15-17].

Therefore, the central working hypothesis is that Terpenolol-L may preserve a useful preorganized state of CBD within an anhydrous lipid matrix and may facilitate later dispersion at aqueous biological interfaces. This hypothesis requires direct verification through particle-size analysis, structural characterization, dispersion studies in biorelevant media, release testing, permeability studies, and comparative pharmacokinetics.

Materials and Methods – Study Design

This formulation-development study evaluated the feasibility of incorporating Terpenolol-L into three experimental lipid-based prototypes intended for nutraceutical, medical-device-oriented, and cosmeceutical applications. No clinical efficacy studies, pharmacokinetic comparisons, dermal penetration experiments, or nanoscale structural analyses were performed in the present investigation.

Experimental Prototypes

Terpenolol-L oral elixir was prepared by adding 25 mL of Terpenolol-L to 250 mL of Cannabis sativa seed oil. The prototype was designed as an oral lipid-based nutraceutical formulation.

Terpenolol-L Skin and Hand Cream contained mango seed butter (70%), Terpenolol-L (20%), jojoba oil (9%), and orange blossom essence (1%). The prototype was developed as a topical formulation intended for future evaluation as a Class I medical device for mild redness, irritation, and environmental skin stress.

Terpenolol-L Body and Hair Balm contained jojoba oil (89%), Terpenolol-L (10%), and orange blossom essence (1%). The prototype was developed as a lipid-rich cosmeceutical preparation for massage, wellness, and spa applications.

Stability Observations

Each prototype was observed for six months under routine storage conditions. The evaluation was macroscopic and included visible homogeneity, phase separation, precipitation, gross changes in appearance, and preservation of the expected sensory or application characteristics. Because storage temperature, humidity, packaging configuration, sampling schedule, and instrumental measurements were not standardized in the present developmental observation, the findings should be interpreted as preliminary physical-compatibility data rather than formal stability studies conducted under International Council for Harmonization conditions.

Descriptive Evaluation

The oral prototypes were additionally assessed for overall taste acceptability. The topical prototypes were assessed descriptively for spreadability, skin feel, and suitability for their intended application contexts. These observations were not collected using validated scales or blinded comparative procedures and are therefore reported only as formulation-development observations.

Results – Terpenolol-L Oral Elixir

The oral elixir remained macroscopically homogeneous for six months without visible phase separation or precipitation. Its taste was judged favorably during developmental evaluation. These observations supported the compatibility of Terpenolol-L with Cannabis sativa seed oil but did not establish biological efficacy or enhanced oral bioavailability.

Terpenolol-L Skin and Hand Cream

The skin and hand cream maintained physical integrity and visible homogeneity throughout the six-month observation period. No gross phase separation was observed. The formulation retained acceptable spreadability and skin feel. Developmental use suggested suitability for application after shaving or depilation and during exposure to cold and windy conditions; however, these observations were not derived from a controlled clinical investigation.

Results – Terpenolol-L Body and Hair Balm

The body and hair balm remained physically stable for six months and retained their expected spreadability and sensory characteristics. The prototype was considered suitable for massage and spa-oriented use. No claims regarding penetration to muscles or joints, systemic absorption, central nervous system exposure, analgesia, or muscle relaxation can be made from the present data.

Prototype	Intended domain	Composition	Six-month observation
Oral Elixir	Nutraceutical	25 mL Terpenolol-L in 250 mL Cannabis sativa seed oil	No visible phase separation or precipitation; favourable taste
Skin and Hand Cream	Medical-device-oriented topical prototype	70% mango seed butter; 20% Terpenolol-L; 9% jojoba oil; 1% orange blossom essence	Physical integrity and visible homogeneity maintained
Body and Hair Balm	Cosmeceutical	89% jojoba oil; 10% Terpenolol-L; 1% orange blossom essence	Physical stability, spreadability, and sensory characteristics maintained

Table 1: Composition and Six-Month Observations for the Three Terpenolol-L Prototypes

Discussion

This study demonstrated that Terpenolol-L could be incorporated into three substantially different lipid matrices while retaining macroscopic physical integrity for six months. This finding supports formulation versatility across oral oil, semi-solid cream, and massage-balm systems. However, it does not, by itself, demonstrate preserved micellar architecture, nanoscale dimensions, improved bioavailability, or biological superiority over non-micellized CBD.

Nevertheless, the scientific basis for further investigation is strong. CBD pharmacokinetics are highly formulation-dependent, and self-emulsifying or nanostructured systems have repeatedly outperformed simple lipid controls in experimental and clinical comparisons. These findings support the broader proposition that lipid solubility alone does not determine CBD delivery performance [18].

For the oral prototype, the relevant next question is whether Terpenolol-L forms or preserves nanoscale assemblies during dilution and gastrointestinal digestion, and whether these assemblies increase the fraction of CBD transferred to aqueous or mixed-micellar phases. Comparative testing should use identical CBD doses in Terpenolol-L and molecular-CBD oil controls and should measure particle size, polydispersity, release, simulated digestion behavior, and pharmacokinetic exposure.

For topical prototypes, the principal questions concern CBD release from the vehicle, retention within skin layers, and permeation beyond the stratum corneum. Published work on CBD-loaded polymeric micelles and lipid nanoparticles provides relevant methods and comparators. Therefore, the present prototypes should be evaluated using in vitro release testing and ex vivo skin permeation models before advancing any systemic or deep-tissue claims.

The results also define the necessary terminological caution. Until nanoscale organisation has been directly demonstrated in the final Terpenolol-L preparations, the terms micellar and supramolecular should describe the design concept and starting platform rather than an experimentally verified structural state within each finished prototype. Direct characterization using dynamic light scattering, electron microscopy, spectroscopy, or complementary methods would materially strengthen the platform claim.

This study has several limitations. The terpenolol-L composition and manufacturing parameters were not disclosed in sufficient detail for independent replication. Stability observations were macroscopic and were not conducted under standardized accelerated or long-term conditions. No assay of CBD content, degradation products, droplet or particle size, microbial quality, release kinetics, permeability, pharmacokinetics, safety, or efficacy was performed. No comparator containing the same concentration of non-micellized CBD was evaluated. These limitations mean that the current evidence supports feasibility and hypothesis generation, not claims of enhanced efficacy or bioavailability.

Notwithstanding these limitations, the prototypes establish a coherent experimental program. Terpenolol-L can now be tested as a platform rather than as a single product, with the same central comparison applied across oral and topical matrices: pre-organized Terpenolol-L versus molecular CBD in otherwise matched vehicles.

Conclusions

Terpenolol-L was successfully incorporated into an oral elixir, a skin and hand cream, and a body and hair balm, and all three experimental prototypes maintained macroscopic physical integrity for six months. Therefore, this work supports the technological feasibility and formulation versatility of an anhydrous lipophilic Terpenolol-L platform.

The broader hypothesis is that a pre-organized cannabidiol system may retain delivery advantages even when introduced into a lipid vehicle because biological performance depends on subsequent transfer across aqueous and interfacial environments rather than lipid solubility alone. The present study did not directly test this hypothesis. Controlled physicochemical, biopharmaceutical, pharmacokinetic, and topical-permeation studies are required before claims of improved bioavailability, tissue penetration, or efficacy can be made.

Terpenolol-L should therefore be regarded as a promising formulation platform and a defined experimental program for investigating supramolecular organization as a technological variable in cannabinoid delivery.

Declarations

Author Contributions: Tullio Scrimali conceived the Terpenolol-L platform, developed the prototypes, collected developmental observations, and prepared the manuscript.

Funding: The authors received no external funding for this study.

Institutional Review Board Statement: Not applicable.

The present study reports the formulation development and non-clinical macroscopic observations. No identifiable human-participant data were included.

Informed Consent Statement: Not applicable.

Data Availability Statement: The observations supporting this study are reported within the manuscript. Additional technical data may be made available by the authors upon reasonable request.

Conflicts of Interest: The author developed Terpenolol and Terpenolol-L, and is associated with their prospective commercial development. This relationship constitutes a potential conflict of interest and is disclosed transparently.

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