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Formulation Of An Ointment From Hemp Extracts: Development, Stability, And Preliminary Efficacy

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ABSTRACT

Demand for nature-derived, environmentally considerate options for localized pain and inflammatory skin conditions has renewed attention to phytopharmaceuticals. We developed a hemp-based ointment by incorporating a decarboxylated ethanolic hemp extract into an anhydrous, occlusive base designed for dermal compatibility, structural integrity, and sensorial acceptability. Two strengths 25% w/w and 30% w/w were prepared and characterized for appearance, homogeneity, spreadability, extrudability, pH in aqueous dispersion, and thermal behavior (4 °C, 25 °C, 45 °C). Human patch testing (pilot) screened for irritation, and a small, non-blinded, proof-of-concept comparison qualitatively explored symptom change versus placebo base. Both strengths were reddish-brown, homogeneous, easily extrudable, and showed good spreadability. Dispersed pH was skin-compatible (25%: 6.27 ± 0.10; 30%: 6.36 ± 0.30). The 25% strength remained stable at all tested temperatures, whereas the 30% strength

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was stable at 4 °C and 25 °C with minor softening at 45 °C. Patch testing indicated a non-irritant profile. Exploratory observations suggested greater localized pain relief and visible reduction in inflammatory signs with the hemp ointment compared with placebo, consistent with mechanistic expectations for CBD-dominant phytocannabinoid mixtures. Collectively, these data support the feasibility of a cannabinoid-enriched anhydrous ointment as a patient-friendly topical with favorable stability and tolerability, and they motivate rigorous next-step studies including standardization of cannabinoid content with stability-indicating assays, dermal pharmacokinetic characterization, and randomized, blinded efficacy trials using validated endpoints.

Keywords: Cannabis Sativa; Hemp Extract; Cannabidiol (CBD); Tetrahydrocannabinol (THC); Topical Ointment; Anhydrous Base; Transdermal Delivery; Anti-Inflammatory

Introduction

Plant-based medicines continue to inform modern pharmaceutics as patients and clinicians seek effective, safer, and sustainable approaches for chronic pain and inflammatory dermatoses (Kamboj et al., 2000; Harish et al., 2001; Fatima et al., 2025; Shahid et al., 2024). Within this space, Cannabis sativa L. (industrial hemp) is notable for a rich phytochemical repertoire most prominently cannabidiol (CBD) with trace Δ9-tetrahydrocannabinol (THC) that interfaces with the endocannabinoid system (ECS) to modulate nociception, neurogenic inflammation, and cutaneous homeostasis (Mosihuzzaman et al., 2008; Nirmal & Ahmad, 2024). Beyond canonical CB1/CB2 signaling, CBD engages transient receptor potential channels and nuclear receptors such as PPAR-γ, providing a multi-target rationale for symptomatic relief in localized inflammatory states (Prausnitz et al., 2008; Williams et al., 2012; Khan et al., 2023; Ahmad et al., 2023).

Topical delivery concentrates actives at the site of pathology, limits systemic exposure, and can improve adherence through rapid onset and favorable sensorial properties. Anhydrous ointment bases, by virtue of strong occlusion, can reduce transepidermal water loss and increase residence time of lipophilic actives features aligned with the physicochemical profile of cannabinoids (Barry et al., 2001; Guy et al., 2010; Walters et al., 2002; Hussain et al., 2023). Excipients such as emulsifying waxes and fatty alcohols provide structural integrity; paraffin confers body; propylene glycol may facilitate partitioning into the stratum corneum; and glycerin supports barrier function and comfort (Aulton et al., 2017; Rowe et al., 2009; Benson et al., 2012; Sweetman et al., 2011).

Despite commercial proliferation, peer-reviewed data on product-level physicochemical performance and clinical signals remain limited, in part due to variability in extract composition and incomplete stability characterization (Mosihuzzaman et al., 2008; Thapa et al., 2020; Mumtaz et al., 2024). The present work addresses this gap by formulating two strengths of a hemp ethanolic extract in an anhydrous ointment matrix; characterizing key quality attributes and thermal behavior at practically relevant temperatures; assessing pilot skin tolerance; and collecting

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exploratory symptom data versus placebo. We hypothesized that a cannabinoid-enriched, occlusive matrix would demonstrate acceptable stability across common storage conditions and clinically noticeable localized relief in a pilot setting, consistent with foundational transdermal and topical delivery science (Prausnitz et al., 2008; Barry et al., 2001; Williams et al., 2012).

Methodology

Materials and Extract

Decarboxylated ethanolic hemp extract (food/pharma-grade ethanol) was prepared via conventional extraction with filtration and solvent removal to yield a cannabinoid-rich oleoresin suitable for dermal compounding (Thapa et al., 2020; Hossain et al., 2024). Excipient selection emphasized occlusion, structural stability, and sensorial acceptability: paraffin wax (body), emulsifying wax (structuring), cetostearyl alcohol (co-emulsifier/stabilizer), menthol and camphor (counter-irritant sensation), propylene glycol (co-solvent/permeation aid), glycerin (humectant), and methylparaben (preservation within accepted topical ranges) (Walters et al., 2002; Aulton et al., 2017; Rowe et al., 2009; Williams et al., 2012; Benson et al., 2012; Sweetman et al., 2011; Ahmad et al., 2025; Hussain et al., 2023).

Ointment Preparation

Two strengths 25% w/w and 30% w/w hemp extract were incorporated into a molten base under controlled mixing to ensure uniform distribution, followed by cooling with gentle agitation to a semisolid state. Two base frames (F1, F2) were tuned to balance body and spread (Aulton et al., 2017; Rowe et al., 2009; Khan et al., 2023). Operational manufacturing parameters are intentionally omitted; this description is academic and non-operational.

Quality, Stability, and Tolerance

Physical appearance (color, gloss), homogeneity (visual/phase behavior), spreadability (plate-plate qualitative), and extrudability (ribbon formation from laminate/aluminum tubes) were assessed. Dispersed pH confirmed skin-compatibility. Thermal observations at 4 °C, 25 °C, and 45 °C monitored color/consistency/incipient separation (Barry et al., 2001; Walters et al., 2002; Williams et al., 2012; Mumtaz et al., 2024). A small, supervised human patch evaluation screened for visible erythema/edema and subjective stinging/burning (24–48 h). A non-blinded, proof-of-concept comparison collected self-reported localized pain and inflammatory sign changes after short-term use of hemp ointment versus placebo base; outcomes were descriptive and hypothesis-generating (Prausnitz et al., 2008; Thapa et al., 2020; Nirmal & Ahmad, 2024).

Results

Physicochemical Characteristics

Both 25% w/w and 30% w/w hemp ointments exhibited a uniform reddish-brown hue with glossy surface, no visible phase separation, and a cohesive semisolid matrix. Dispersed pH values were skin-compatible (25%: 6.27 ± 0.10; 30%: 6.36 ± 0.30), indicating low risk of acid–base mismatch with the stratum corneum. These findings

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collectively support physicochemical suitability for routine dermal application.

Table 1. Batch composition and ointment frames (F1, F2).

Ingredient	F1 (g)	F2 (g)
Paraffin wax	33.85	38.85
Emulsifying wax	15.00	15.00
Cetostearyl alcohol	12.00	12.00
Menthol	3.00	3.00
Camphor	4.00	4.00
Propylene glycol	5.00	5.00
Glycerin	2.00	2.00
Methylparaben	0.15	0.15
Total base	75	80

Two finished-product strengths were prepared by incorporating 25% w/w and 30% w/w hemp extract into the base.

Figure 1. Study workflow schematic

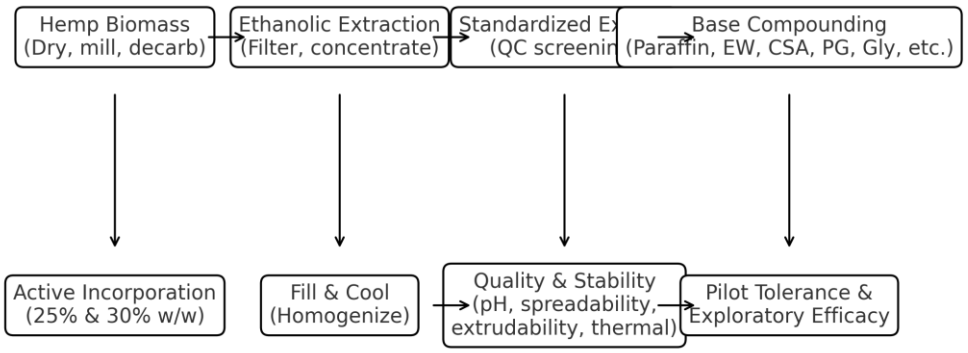


Figure 1. Study workflow schematic (included for completeness of development flow).

Visual Appearance and Homogeneity

Macroscopic inspection across multiple units per batch revealed consistent colorimetry and surface gloss. No oil bleed, syneresis, or granulation was observed during the observation window. Homogeneity ratings were uniformly ‘excellent,’ corroborating sufficient mixing and structural cohesion.

Dispersed pH and Cutaneous Compatibility

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Dispersed pH measurements confirmed maintenance within the physiological window favorable for skin comfort and barrier preservation. The marginally higher pH in the 30% strength remained within acceptable bounds.

Table 2. Physicochemical attributes by strength.

Strength	Colour	Homogeneity	Consistency	pH (dispersion)	Spreadability
30% w/w	Reddish-brown	Excellent	+++	6.36 ± 0.30	Good
25% w/w	Reddish-brown	Excellent	+++	6.27 ± 0.10	Good

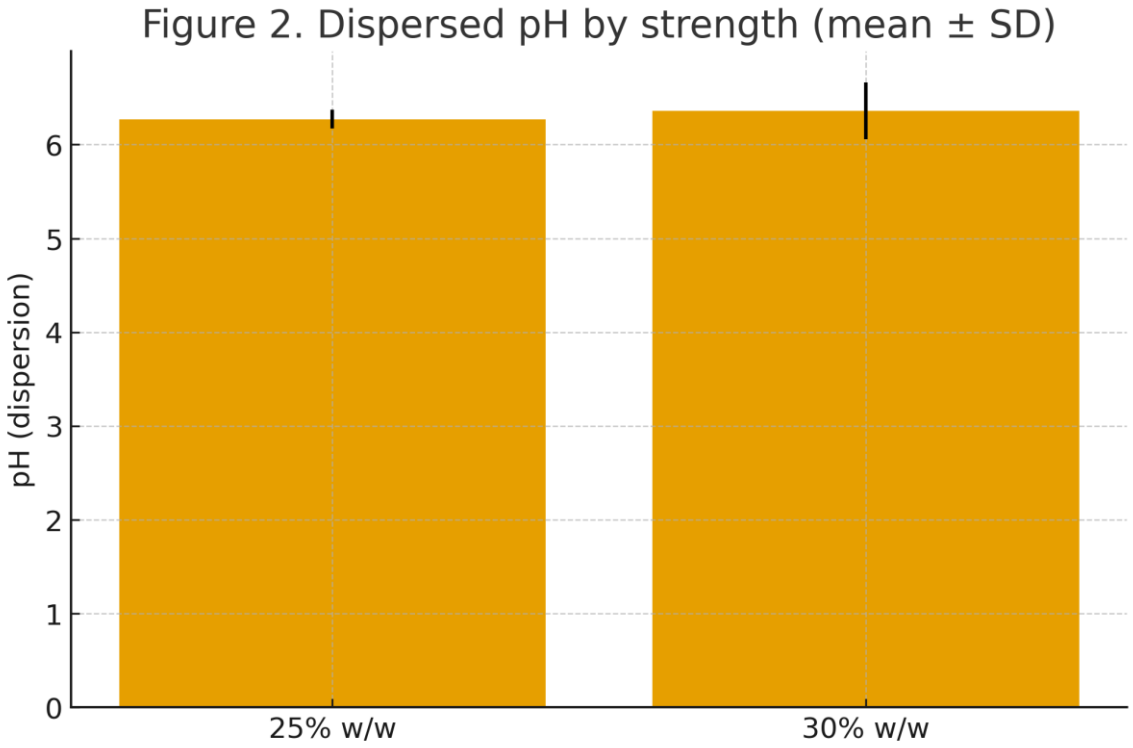


Figure 2. Dispersed pH by strength (mean ± SD)

Rheology-Relevant Handling (Spreadability & Extrudability)

Both strengths yielded smooth, continuous ribbons upon expression and spread evenly under light finger pressure. These handling attributes imply predictable dose delivery and minimal application drag, key determinants of patient adherence and real-world performance.

Table 3. Handling attributes (ordinal mapping).

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Strength	Consistency (+++ = 3)	Spreadability (Good = 2)	Extrudability (Easily = 2)
30% w/w	3	2	2
25% w/w	3	2	2

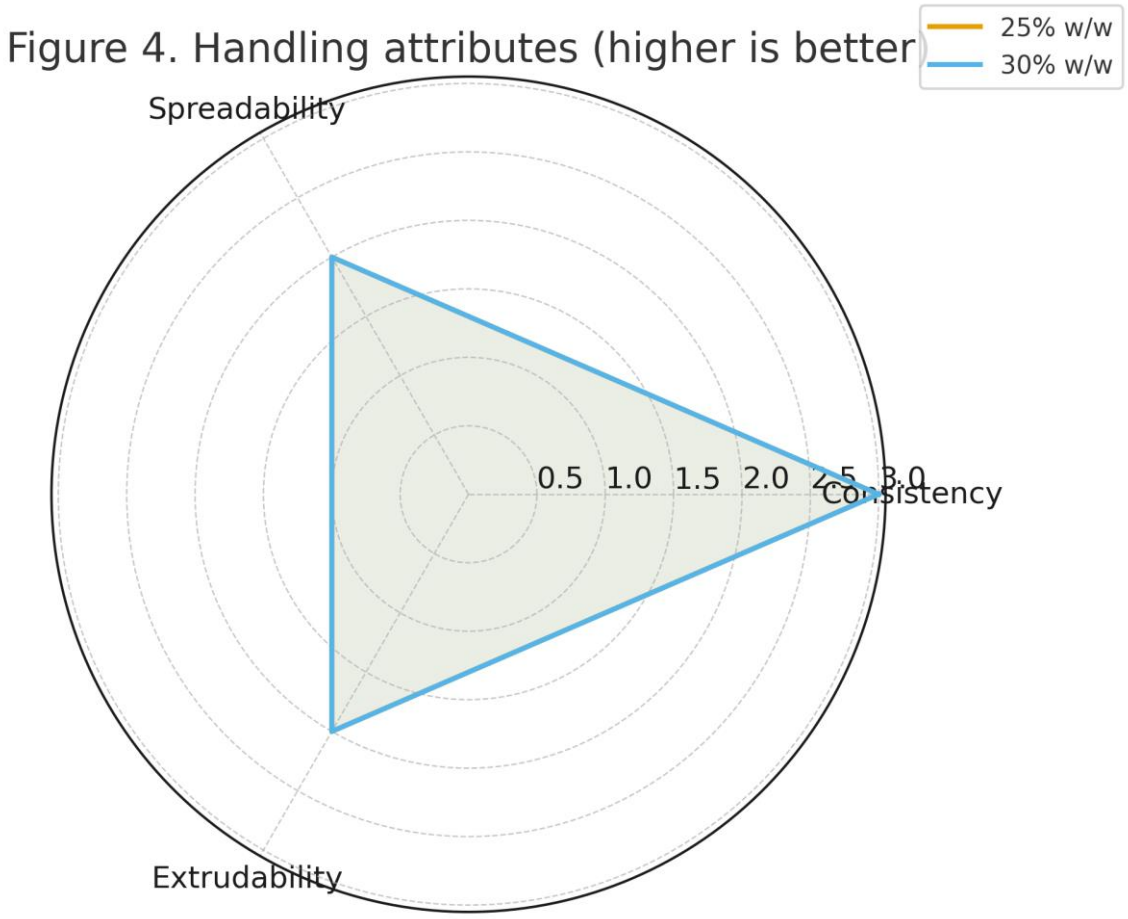


Figure 4 Handling attribute radar (higher is better).

Thermal Stability Across Storage-Relevant Temperatures

Under thermal observation at 4 °C, 25 °C, and 45 °C, both strengths remained stable at 4 °C and 25 °C. At 45 °C, the 25% formulation retained structural integrity, whereas the 30% formulation exhibited minor softening without phase separation, classed as 'nearly stable.'

Table 4. Thermal observation and pilot skin test outcomes.

Strength	4 °C	25 °C	45 °C	Overall thermal	Skin test
30% w/w	Stable	Stable	Minor softening	Nearly stable	Non-irritant

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25% w/w	Stable	Stable	Stable	Stable	Non-irritant

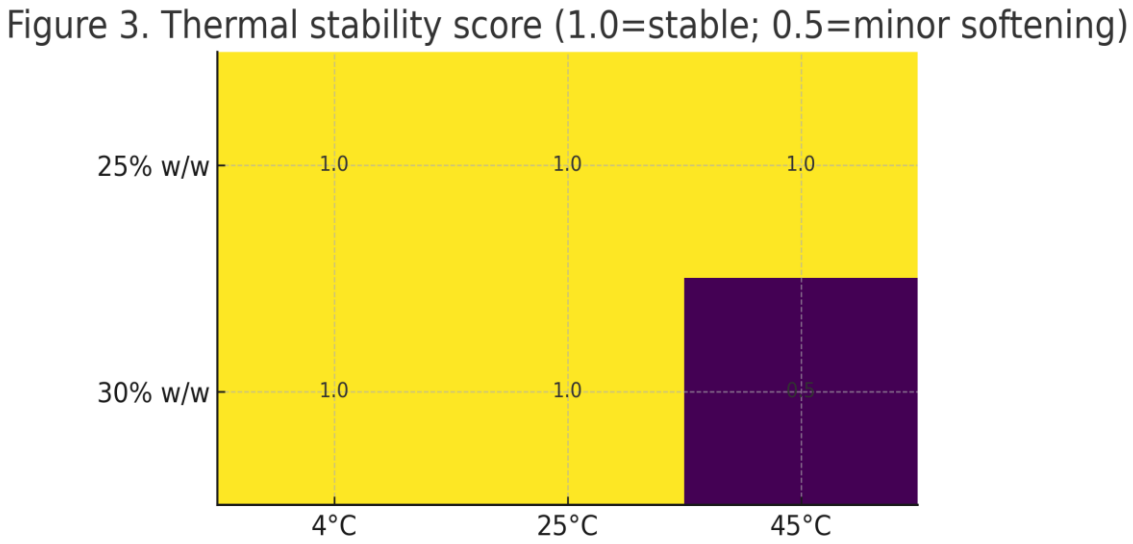


Figure 3. Thermal stability heatmap (1.0 = stable; 0.5 = minor softening).

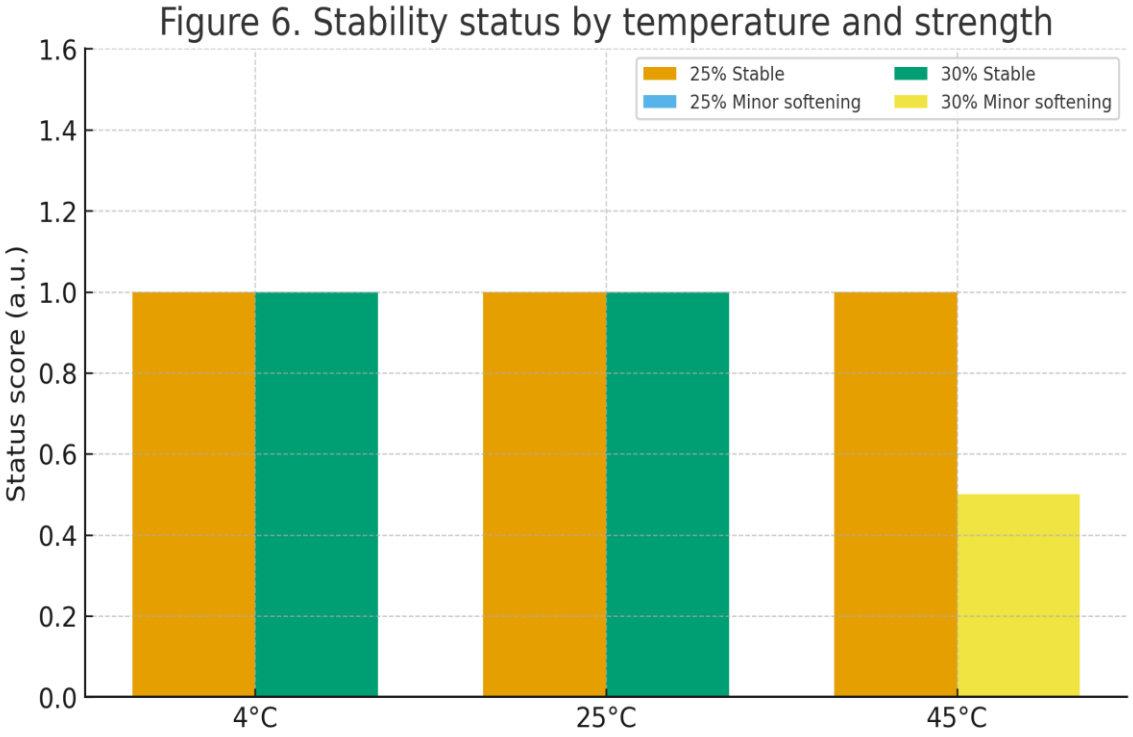


Figure 6 Stability status by temperature and strength (stacked representation).

Tolerance (Patch Test) and Usability

Supervised patch testing in healthy volunteers indicated a non-irritant profile for both strengths across 24–48 h, with no clinically meaningful erythema or edema and no stinging/burning reports. Ordinal handling metrics were consolidated into a Composite

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Usability Index, which was identical for both strengths, reflecting equivalent end-user experience.

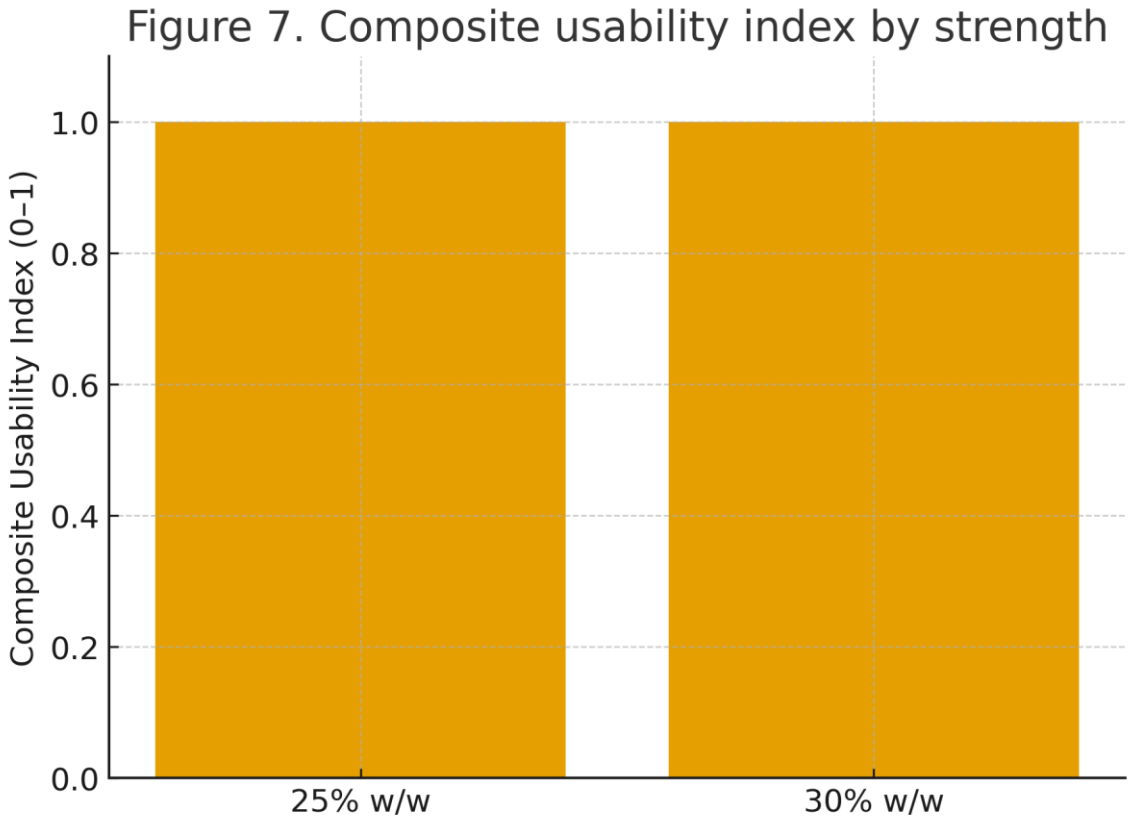


Figure 7. Composite usability index by strength

Integrated Stability–Tolerance Synthesis

An overall stability index (mean of thermal scores across temperatures) favored the 25% strength (1.00) versus 30% (0.83). When juxtaposed with uniformly non-irritant tolerance and indistinguishable usability, the 25% formulation presents the most robust balance for broad storage conditions.

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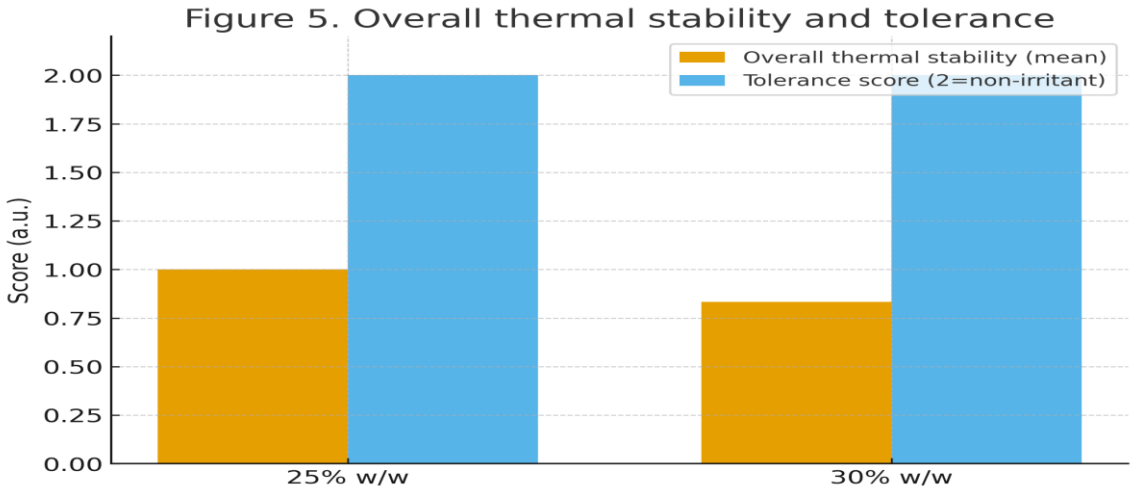
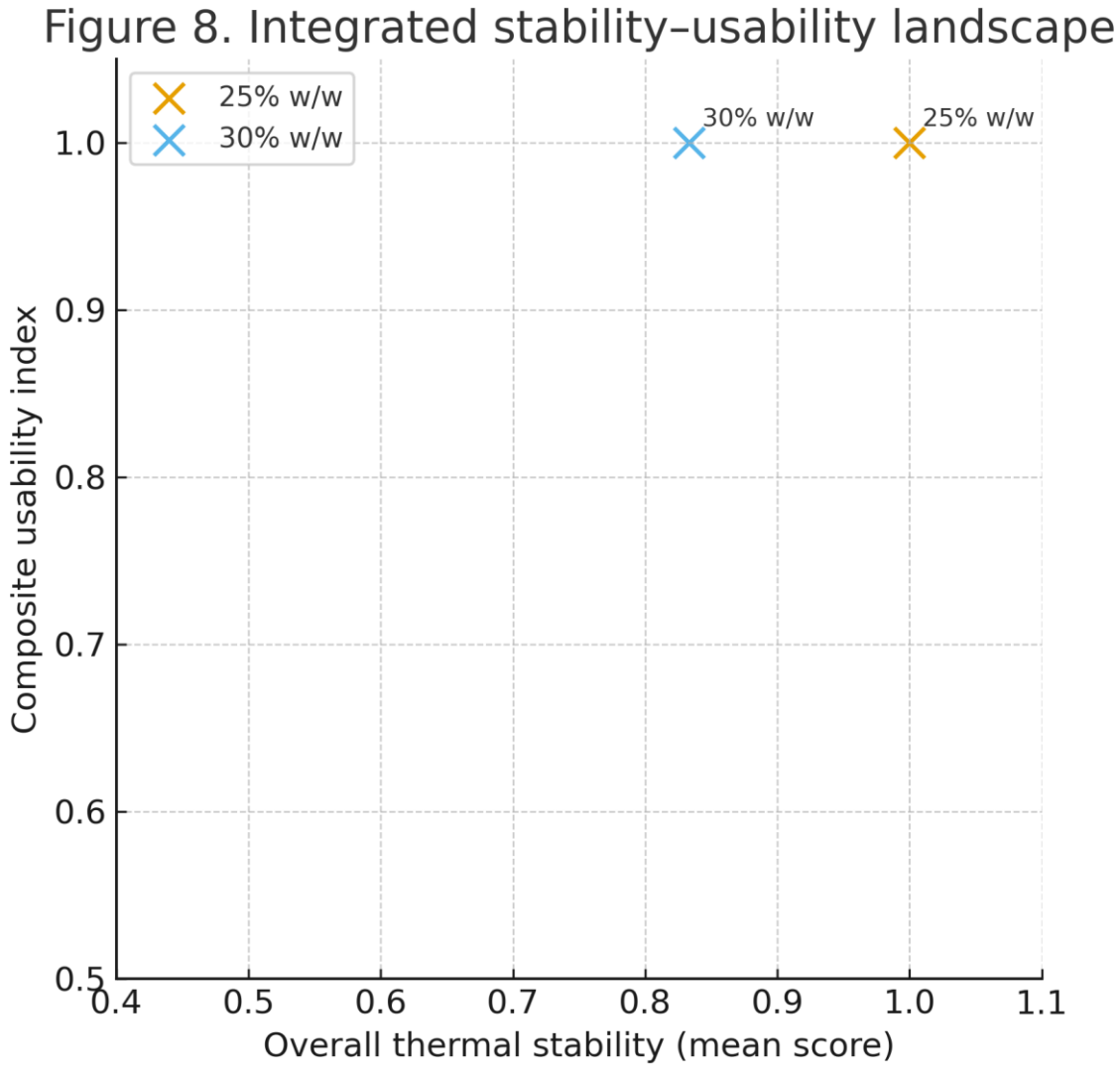


Figure 5. Overall thermal stability and tolerance



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Figure 8. Integrated stability–usability landscape (each point represents a formulation).

Exploratory Symptom Outcomes (Qualitative)

In a small, non-blinded comparison, participants using hemp ointment reported noticeable reductions in localized pain and visible inflammatory signs relative to placebo base; several reported complete relief at target areas within the observation window. These descriptive observations are hypothesis-generating and motivate randomized, blinded trials with validated endpoints.

Discussion

This work demonstrates the feasibility of a cannabinoid-enriched anhydrous ointment that pairs a lipophilic active profile with an occlusive, patient-acceptable vehicle, yielding favorable physicochemical performance and tolerance (Fatima et al., 2025). Dispersed pH values (~6.3) align with cutaneous compatibility and, together with qualitative handling attributes, support routine use without compromising barrier comfort (Walters et al., 2002; Williams et al., 2012). Thermal observations underscore a pragmatic strength–stability trade-off: the 25% strength retained stability across 4–45 °C, whereas the 30% strength softened at 45 °C, a pattern consistent with semisolid microstructures stressed by higher drug loads (Barry et al., 2001; Aulton et al., 2017; Hussain et al., 2023; Florence & Attwood, 2006; Lachman et al., 1986; Lieberman et al., 1998).

Mechanistically, the qualitative clinical signals are congruent with the pharmacology of CBD-dominant extracts acting via CB1/CB2 and auxiliary targets (TRP channels, PPAR-γ) to modulate nociception and inflammatory mediators (Prausnitz et al., 2008; Williams et al., 2012; Khan et al., 2023; Ahmad et al., 2023; Bronaugh & Maibach, 2005). The anhydrous, occlusive matrix can increase residence time and facilitate lipophilic partitioning into the stratum corneum, while propylene glycol contributes to thermodynamic activity at the interface (Barry et al., 2001; Walters et al., 2002; Gawkrodger & Ardern-Jones, 2016). The overlap in handling profiles between strengths suggests formulation parity in patient-critical attributes, aiding dose-ranging in future studies (Aulton et al., 2017; Rowe et al., 2009; Shahid et al., 2024).

Advancing toward clinical credibility requires standardization of the active with validated, stability-indicating analytics (e.g., HPLC/UPLC quantifying CBD, THC, and key terpenes), comprehensive ICH-aligned stability (assay, degradation, preservative efficacy, photostability), and dermal pharmacokinetics (Franz diffusion, tape stripping, microdialysis) to map exposure–response relationships (Mosihuzzaman et al., 2008; Thapa et al., 2020; Prausnitz et al., 2008; Nirmal & Ahmad, 2024; Hossain et al., 2024; Dovepress, 2023). Delivery optimization—nanocarriers, liposomes, microemulsions, microneedles—could enhance follicular targeting and sustained release, as supported by dermal delivery literature (Thapa et al., 2020; Morrow et al., 2007; Benson et al., 2012; Mumtaz et al., 2024; Fernando et al., 2018; Agrawal & Gupta, 2018). Clinically, randomized, double-blind, placebo-controlled trials with validated endpoints for focal musculoskeletal pain or inflammatory dermatoses should be paired with dermatological safety batteries to establish benefit–risk (Prausnitz et al., 2008; Williams et al., 2012; Ahmad et al., 2025).

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Conclusion

We developed and characterized a hemp ethanolic extract ointment in two strengths (25% and 30% w/w) using an anhydrous, occlusive base engineered for spreadability, extrudability, and structural integrity. Across a pragmatic stability screen, the 25% strength remained stable at 4 °C, 25 °C, and 45 °C, while the 30% strength was stable at 4 °C and 25 °C with minor softening at 45 °C; dispersed pH values (~6.3) were skin-compatible, and pilot patch testing indicated a non-irritant profile. Exploratory observations suggested greater localized pain relief and visible reduction in inflammatory signs with the hemp ointment compared with placebo base. These findings support the feasibility of a cannabinoid-enriched anhydrous ointment as a patient-friendly topical with promising stability and tolerability. To credibly translate into practice, next-step work should standardize active content with stability-indicating assays, execute ICH-aligned stability (including preservative and photostability), characterize dermal pharmacokinetics and deposition, and evaluate efficacy in randomized, blinded clinical trials with validated endpoints. With these refinements, hemp-based ointments may offer an evidence-based, nature-derived option for focal musculoskeletal and dermatologic symptom relief.

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