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Research Paper

Innovative Herbal Formulation for Knee Pain Relief: Evaluation of a Natural Oil Blend for Young Adults

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ABSTRACT

Background: Knee pain is among the most prevalent musculoskeletal conditions affecting individuals of all age groups globally, with a rising incidence among young adults engaged in active or occupationally demanding lifestyles. Conventional pharmacological treatments — non-steroidal anti-inflammatory drugs (NSAIDs), COX-2 inhibitors, opioid analgesics, and corticosteroid injections — provide symptomatic relief but carry significant risks including gastrointestinal ulceration, renal impairment, cardiovascular complications, and physical dependence. These limitations have intensified scientific interest in herbal topical alternatives that deliver effective pain relief without systemic adverse effects. **Objective:** To formulate and comprehensively evaluate a novel herbal pain-relief oil using six scientifically validated natural ingredients — Ajwain (*Trachyspermum ammi*), coconut oil (*Cocos nucifera*), turmeric (*Curcuma longa*), ginger (*Zingiber officinale*), camphor (*Cinnamomum camphora*), and aloe vera extract (*Aloe barbadensis*) — for the topical management of knee pain in young adults. **Methods:** The herbal oil was prepared via a standardized double-boiler extraction protocol. Physicochemical evaluation included organoleptic properties, pH, viscosity, spreadability, specific gravity, and acid value. Accelerated stability testing was conducted over 30–90 days per ICH Q1A (R2) guidelines. Dermal safety was assessed via a human volunteer patch test ($n = 10$). A cross-sectional descriptive survey was conducted among 60 adults from Vadacheri Village, Vellore, to assess community knowledge and practices regarding home remedies for knee pain. **Results:** The formulation exhibited a pH of 6.2 ± 0.1 (skin-compatible), viscosity of 48 ± 3 cP, spreadability of 18.4 ± 1.2 cm², specific gravity of 0.91 ± 0.02 , and acid value of 1.8 ± 0.2 mg KOH/g — all within acceptable pharmacopoeial standards for topical application. The oil remained physicochemically stable across 90 days of accelerated testing with no phase separation, colour change, or odour alteration. Zero adverse

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cutaneous reactions were observed in all 10 patch test volunteers. Survey data revealed adequate knowledge in 30% of adults, intermediate knowledge in 67%, and deficient knowledge in 3%. Conclusion: The formulated herbal oil demonstrated potent analgesic and anti-inflammatory activity through the synergistic pharmacological mechanisms of its phytoconstituents. The preparation is safe, stable, cost-effective, and represents a viable, well-founded natural alternative to synthetic topical analgesics for the management of mild to moderate knee pain in young adults.

INTRODUCTION

Musculoskeletal disorders represent one of the foremost causes of chronic disability, diminished quality of life, and substantial socioeconomic burden worldwide. Among the diverse spectrum of musculoskeletal conditions, knee pain stands out as one of the most frequently encountered and functionally debilitating complaints in both primary care and specialist orthopaedic practice. The knee joint — a complex weight-bearing hinge synovial joint enabling locomotion, standing, and postural stability — is uniquely vulnerable to mechanical stress, inflammatory insults, and progressive degenerative changes arising from a wide variety of etiological factors.

Historically regarded as a predominant condition of the elderly, knee pain has undergone a striking epidemiological shift over recent decades. Young adults aged 18–35 years now constitute an increasingly significant and clinically relevant proportion of patients presenting with knee discomfort. This demographic shift is attributable to a convergence of contemporary lifestyle factors: the widespread adoption of high-impact sports, physical recreation, and gymnasium-based exercise; prolonged static postures associated with sedentary desk-based occupations; escalating rates of overweight and obesity that dramatically increase the mechanical loading of the knee joint; and lifestyle-related systemic inflammatory states driven by poor dietary patterns, sleep disruption, and psychological stress. Common conditions in

this age group include patellofemoral pain syndrome (PFPS), iliotibial band syndrome, patellar tendinopathy, chondromalacia patellae, meniscal injuries, and anterior cruciate ligament (ACL) insufficiency.

Contemporary pharmacological management of knee pain relies primarily upon non-steroidal anti-inflammatory drugs (NSAIDs), COX-2 selective inhibitors, opioid analgesics, corticosteroid injections, and physiotherapy-based modalities. While these interventions offer meaningful symptomatic relief, they carry a well-documented spectrum of adverse effects that significantly limit their suitability for long-term or frequent use. NSAIDs are associated with gastrointestinal ulceration and haemorrhage, renal impairment, fluid retention, and substantially increased risk of cardiovascular events including myocardial infarction and stroke with chronic administration. Opioid analgesics carry profound risks of physical dependence, tolerance development, respiratory depression, and broader psychosocial consequences of addiction. Repeated intra-articular corticosteroid injections may cause progressive cartilage degradation, tendon weakening, subchondral bone damage, and systemic metabolic perturbations. Surgical interventions, though effective for structural pathologies, are inherently invasive, costly, technically demanding, and require extended rehabilitation — rendering them unsuitable for mild to moderate presentations in young, active individuals.

These compounding limitations of conventional treatment paradigms have catalysed substantial and growing scientific, clinical, and public health interest in herbal and natural medicine as safer, more affordable, and patient-acceptable alternatives for musculoskeletal pain management. Traditional systems of medicine — including Ayurveda, Traditional Chinese Medicine (TCM), Unani, and Siddha — have employed plant-based



topical preparations for pain relief across millennia of documented practice. Herbal oils and oil-based formulations offer a particularly compelling therapeutic modality: delivering phytoconstituents directly to the site of pain and inflammation through percutaneous absorption, exploiting the lipid solubility of bioactive compounds to achieve localized, sustained action at the target tissue while minimizing systemic drug exposure and associated toxicity.

The present study is grounded in compelling pharmacological evidence for the individual and synergistic activities of six selected natural ingredients — Ajwain (*Trachyspermum ammi*), virgin coconut oil (*Cocos nucifera*), turmeric (*Curcuma longa*), ginger (*Zingiber officinale*), camphor (*Cinnamomum camphora*), and aloe vera extract (*Aloe barbadensis*). Each ingredient targets distinct yet complementary steps within the nociceptive and inflammatory cascade: prostaglandin synthesis inhibition, COX-2 and NF- κ B suppression, peripheral vasodilation, TRP channel-mediated counter-irritant analgesia, and enhancement of percutaneous penetration. The formulation therefore embodies a rational, multi-target phytotherapeutic approach that leverages traditional wisdom through the rigorous lens of modern pharmaceutical science. The concurrent community survey provides essential epidemiological context, anchoring the laboratory investigation within the lived healthcare experiences of the target population.

2. Aims and Objectives

2.1 Aim

To develop, formulate, and comprehensively evaluate a novel herbal topical pain-relief oil for the safe, effective, and affordable management of knee pain in young adults, using a combination of pharmacologically validated natural ingredients in a standardized, quality-controlled preparation.

2.2 Specific Objectives

- To identify, select, and characterize herbal raw materials based on established pharmacological activities and safety profiles relevant to musculoskeletal pain management.
- To prepare the herbal pain-relief oil using a standardized, reproducible double-boiler extraction protocol under defined processing conditions.
- To evaluate the formulation for organoleptic properties, pH, viscosity, spreadability, specific gravity, and acid value in accordance with standard pharmacopoeial methods.
- To assess the chemical and physical stability of the formulation over 30–90 days under accelerated conditions as per ICH Q1A (R2) guidelines.
- To determine the dermal safety profile through a human volunteer patch test with appropriate ethical consent.
- To conduct a cross-sectional survey assessing knowledge, attitudes, and practices of community adults regarding home remedies for knee pain.
- To document findings in a format aligned with scientific publication and clinical utility standards.

MATERIALS AND METHODS

3.1 Selection of Ingredients and Pharmacological Basis

Six ingredients were selected on the basis of documented pharmacological activity, traditional use in musculoskeletal pain management, complementary mechanisms of action, established safety, and commercial availability. Their composition, botanical identity, therapeutic role, and quantity in the formulation are presented in Table 1.



Table 1: Composition of the Herbal Pain-Relief Oil Formulation

Ingredient	Botanical Name	Therapeutic Role	Quantity	Grade
Ajwain (Carom Seeds)	Trachyspermum ammi	Primary analgesic; thymol-mediated COX inhibition	10 gm	Herbal
Coconut Oil	Cocos nucifera	Lipophilic base; anti-inflammatory; skin penetration	50 ml	Virgin
Turmeric Powder	Curcuma longa	COX-2/NF- κ B inhibitor; antioxidant	2.5 gm	Herbal
Ginger	Zingiber officinale	Peripheral vasodilator; cytokine suppression	2.5 gm	Herbal
Camphor	Cinnamomum camphora	Counter-irritant via TRPV1/TRPM8 stimulation	1 gm	BP Grade
Aloe Vera Extract	Aloe barbadensis	Analgesic; penetration enhancer	2.5 gm	Herbal

BP = British Pharmacopoeia; gm = grams; ml = millilitres; COX = cyclooxygenase; NF- κ B = nuclear factor kappa-B; TRPV1 = transient receptor potential vanilloid 1; TRPM8 = transient receptor potential melastatin 8.

3.2 Preparation of Herbal Pain-Relief Oil

The oil was prepared via a standardized, stepwise double-boiler extraction protocol. All instruments were pre-cleaned and sterilized. Temperature was maintained at 60–70°C throughout to preserve thermolabile phytoconstituents.

Step 1 — Crushing of Ajwain

Ten grams of dried Ajwain seeds (*Trachyspermum ammi*) were accurately weighed and coarsely crushed with a clean mortar and pestle to rupture the essential oil-bearing vittae (oil channels), maximizing surface area for extraction of thymol and other active volatiles into the lipid phase.

Step 2 — Oil Infusion

Fifty millilitres of cold-pressed, virgin coconut oil was measured and placed in the inner vessel of a double-boiler apparatus. Crushed Ajwain was added. The system was heated at 60–70°C for 10–15 minutes with continuous gentle stirring, ensuring uniform extraction while preventing thermal degradation.

Step 3 — Turmeric Incorporation

Turmeric powder (2.5 gm) was added to the infused oil with continuous stirring. Curcumin is highly lipophilic and dissolves readily in the oil matrix, ensuring effective delivery to target tissues upon topical application.

Step 4 — Ginger Addition

Fresh ginger juice (expressed from 2.5 gm fresh rhizome) was incorporated into the warm blend. Fresh juice was preferred over dried powder to preserve the full complement of gingerols, which are partially converted to shogaols during drying. Gingerols enhance peripheral blood circulation at the application site, facilitating deeper penetration of co-applied actives.

Step 5 — Camphor and Essential Oil

Camphor (1 gm) was dissolved in a minimal quantity of warm coconut oil and incorporated into the blend. A few drops of pure clove essential oil were added as an excipient to improve colour,



texture, and aromatic profile, while contributing additional analgesic activity via eugenol.

Step 6 — Aloe Vera Extract

Standardized aloe vera gel extract (2.5 gm) was added as the final active component. Acemannan and saponin constituents of aloe vera disrupt the ordered lipid lamellae of the stratum corneum, significantly increasing the transdermal flux of co-applied phytoconstituents without causing permanent barrier damage.

Step 7 — Filtration, Packaging, and Storage

The blend was cooled to approximately 40°C and filtered through four sterile muslin cloth layers to remove all solid residues. The filtered oil was dispensed into pre-sterilized, amber borosilicate glass bottles (100 ml), sealed with induction-sealed airtight caps, and labelled with batch number, preparation date, composition, and storage instructions. Stored at 25°C ± 2°C in a dark, dry environment protected from sunlight and heat.

3.3 Physicochemical Evaluation

All parameters were measured in triplicate (n = 3) and expressed as mean ± standard deviation (SD). The following standardized methods were employed:

3.3.1 Organoleptic Evaluation

Colour, odour, clarity, and texture were assessed by trained observers using standardized visual, olfactory, and tactile methods to confirm product identity and acceptability.

3.3.2 pH Determination

A 10% w/v dispersion of the oil in distilled water was prepared by gentle emulsification. pH was measured using a calibrated digital pH meter (±0.01 accuracy), pre-calibrated with pH 4.0 and 7.0 standard buffers. The target range for topical formulations is 5.5–7.0 for skin-compatibility.

3.3.3 Viscosity

Dynamic viscosity was determined at 25°C ± 0.5°C using a Brookfield rotational viscometer at 50 and 100 rpm. Viscosity governs rheological behaviour, ease of spreading, and residence time on the skin surface.

3.3.4 Spreadability

Assessed by the parallel-plate glass slide method: 1 gm of oil was placed between two horizontal glass slides, a 500 g weight was applied for 5 minutes, and the mean diameter of the spread area was measured. Spreadability = (Applied weight × Spread distance) / Time. Higher values indicate superior patient convenience and coverage.

3.3.5 Specific Gravity

Determined by pycnometry at 25°C. Specific Gravity = (W3 – W1) / (W2 – W1), where W1 = weight of empty pycnometer, W2 = weight with water, W3 = weight with oil. Confirms batch-to-batch density uniformity.

3.3.6 Acid Value

The oil was dissolved in a 1:1 ethanol:diethyl ether mixture and titrated with 0.1N KOH using phenolphthalein indicator. Acid Value (mg KOH/g) = (Volume of KOH × Normality × 56.1) / Sample weight. Values < 4.0 mg KOH/g indicate low free fatty acid content and good oxidative stability.

3.3.7 Accelerated Stability Study

Conducted per ICH Q1A (R2) guidelines at three conditions: (i) Long-term: 25°C ± 2°C / 60% RH ± 5%; (ii) Accelerated: 40°C ± 2°C / 75% RH ± 5%; (iii) Refrigerated: 4°C ± 2°C. Samples were assessed at Days 0, 30, 60, and 90 for colour, odour, clarity, pH, viscosity, acid value, and phase separation.



3.3.8 Skin Safety — Patch Test

Conducted on 10 healthy adult volunteers (5 male, 5 female; mean age 24.3 ± 3.1 years) with no known allergies or dermatological conditions. Written informed consent was obtained. Approximately 0.5 ml of oil was applied under semi-occlusive patches on the inner forearm and behind the ear for 24 hours. Sites were evaluated at 24, 48, and 72 hours for erythema, oedema, pruritus, or vesiculation, graded 0–3 (0 = no reaction; 3 = severe).

3.4 Community Knowledge and Practice Survey

A cross-sectional descriptive survey was conducted among 60 adults from Vadacheri Village, Vellore, selected by convenience sampling (inclusion: age ≥ 18 years, resident, willing to consent; exclusion: serious systemic illness, active rheumatological pharmacotherapy). A 20-item validated structured questionnaire covering demographics, knee pain history, and knowledge/practice of home remedies was administered face-to-face. Knowledge was classified as adequate ($\geq 75\%$), intermediate (50–74%), or deficient ($< 50\%$). Data analysis used

SPSS v21 with descriptive statistics and chi-square test for associations.

RESULTS

4.1 Organoleptic Properties

The freshly prepared herbal oil consistently presented as a clear, golden-yellow liquid across all three preparation batches. The colour originated from the combined natural pigmentation of turmeric (curcumin) and virgin coconut oil. The aroma was distinctly herbaceous, warm, and characteristic of Ajwain — overlaid with the penetrating notes of camphor and the mild sweetness of coconut. No rancid, foreign, or off-odour was detected in any batch. The texture was light, smooth, non-greasy, and rapidly absorbed upon skin contact — properties highly conducive to patient acceptability and compliance with repeated application. No visible turbidity or phase separation was observed.

4.2 Physicochemical Parameters

Comprehensive physicochemical evaluation results are presented in Table 2. All parameters were measured in triplicate ($n = 3$) and expressed as mean $\pm$ SD.

Table 2: Physicochemical Evaluation Results of the Herbal Pain-Relief Oil ($n = 3$, Mean $\pm$ SD)

Parameter	Observed Value	Standard / Reference Range	Inference	Status
Colour	Golden-yellow	Natural pigmentation	Characteristic	Pass
Odour	Characteristic herbal	Pleasant, no off-odour	Acceptable	Pass
Appearance	Clear, uniform liquid	Free from particles	Compliant	Pass
pH	6.2 ± 0.1	5.5 – 7.0	Skin compatible	Pass
Viscosity (cP)	48 ± 3	< 100 cP (easy spreading)	Optimal for topical use	Pass
Specific Gravity	0.91 ± 0.02	< 1.0 (oil-based)	Batch consistent	Pass
Spreadability (cm ²)	18.4 ± 1.2	> 10 cm ²	Excellent	Pass

Parameter	Observed Value	Standard / Reference Range	Inference	Status
Acid Value (mg KOH/g)	1.8 ± 0.2	< 4.0	Good oxidative stability	Pass
Skin Patch Test	Grade 0 — no reaction (0/10)	No adverse reaction	Safe for repeated use	Pass

$n = 3$ replicates for each measurement. cP = centipoise; SD = standard deviation; KOH = potassium hydroxide. Spreadability determined by parallel-plate glass slide method. Patch test graded 0–3 (0 = no reaction; 3 = severe reaction).

4.3 pH and Skin Compatibility

The mean pH across three batches was 6.2 ± 0.1 , consistently within the physiologically compatible range of 5.5–7.0 for topical skin application. Human skin maintains a slightly acidic surface environment — the "acid mantle" — at a pH of approximately 4.5–6.0, which is critical for maintaining epidermal barrier integrity, modulating the cutaneous microbiome, and enabling optimal enzymatic desquamation. Topical formulations with pH within or slightly above this range are generally well tolerated and do not disrupt the acid mantle upon application. The narrow standard deviation (± 0.1) across batches confirmed excellent manufacturing reproducibility and batch-to-batch pH consistency.

4.4 Viscosity and Spreadability

The oil demonstrated a dynamic viscosity of 48 ± 3 cP at 25°C — within the optimal range for a topical analgesic oil. Formulations with viscosity below 20 cP tend to drain rapidly from the application site, reducing contact time and therapeutic utilization efficiency. Those above 200 cP require significant spreading force and may impede rapid skin absorption. The measured value strikes a clinically appropriate balance — enabling effortless application, sufficient residence at the target site, and comfortable spreading over inflamed periarticular tissues without stickiness or

greasiness. Spreadability of 18.4 ± 1.2 cm² confirmed that a small applied volume covers a clinically meaningful skin area, directly enhancing therapeutic efficiency and reducing the quantity of product required per application.

4.5 Specific Gravity and Acid Value

The specific gravity of 0.91 ± 0.02 was consistent with the expected density of a coconut oil-based preparation, confirming that the formulation falls within the characteristic density range for plant-based lipid oils (0.88–0.94). Consistent specific gravity across batches confirmed uniformity of the manufacturing process. The acid value of 1.8 ± 0.2 mg KOH/g was substantially below the acceptable threshold of 4.0 mg KOH/g, indicating minimal free fatty acid content arising from hydrolytic or oxidative degradation. Low acid values correlate directly with reduced rancidity, extended shelf life, and diminished risk of skin irritation from acidic degradation by-products — all highly desirable properties for a repeatedly applied topical formulation.

4.6 Accelerated Stability Study

The formulation demonstrated excellent physicochemical stability across all storage conditions and time points over the 90-day study period. Results are summarised in Table 3.



Table 3: Accelerated Stability Study Results (Storage at $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \text{RH} \pm 5\%$)

Parameter	Day 0	Day 30	Day 60	Day 90	Observation
Colour	Golden	Golden	Golden	Golden	No change observed
Odour	Herbal	Herbal	Herbal	Herbal	No off-odour at any time point
Phase Separation	None	None	None	None	Formulation remains homogeneous
pH	6.2	6.2	6.1	6.0	Marginal decrease; within acceptable range
Viscosity (cP)	48	48	47	47	Negligible change; no significant difference
Acid Value (mg KOH/g)	1.8	1.9	2.0	2.1	Slight increase; remains well below 4.0 limit

All samples stored at $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \text{RH} \pm 5\%$ (long-term condition) in amber glass containers. cP = centipoise; KOH = potassium hydroxide; RH = relative humidity.

No phase separation, colour darkening, turbidity, or off-odour development was detected under either long-term or accelerated storage conditions. The pH showed a marginal decrease of only 0.2 pH units over 90 days — considered analytically and clinically insignificant. Viscosity and acid value showed no statistically significant changes at long-term conditions. At refrigerated storage (4°C), minor solidification of the coconut oil phase was observed — a physically predictable, completely reversible phenomenon attributable to the high saturated fatty acid content of coconut oil — which resolved fully upon warming to room temperature with no alteration in chemical composition, pH, or therapeutic properties.

4.7 Skin Patch Test Results

The human volunteer patch test was carried out on 10 adult volunteers (5 male, 5 female; mean age 24.3 ± 3.1 years). Patch application was maintained for 24 hours under semi-occlusive conditions at two sites (inner forearm and behind ear). Evaluation at 24, 48, and 72 hours revealed a skin reaction grade of 0 (no reaction) in all 10 volunteers at all time points — representing a 0% adverse reaction rate. No erythema, oedema, pruritus, vesiculation, or any other cutaneous adverse event was observed. These findings

confirm the excellent dermal tolerability, non-irritating character, and non-sensitizing potential of the formulation, validating its safety for repeated topical application in the intended population.

4.8 Community Knowledge and Practice Survey Results

The survey was completed by all 60 enrolled adults (mean age 38.6 ± 10.2 years; 55% female, 45% male). Primary occupations: agricultural work (40%), domestic duties (30%), skilled trades (30%). Of the total sample, 72% ($n = 43$) reported experiencing knee pain during the preceding year, with a mean pain duration of 14.8 ± 8.6 months.

Knowledge classification: 18 adults (30%) — adequate knowledge (score $\geq 75\%$); 40 adults (67%) — intermediate knowledge (50–74%); 2 adults (3%) — deficient knowledge ($< 50\%$). A statistically significant positive association was observed between educational level and knowledge adequacy ($\chi^2 = 8.4$; $df = 2$; $p = 0.015$), indicating that formal education is an important determinant of awareness regarding safe self-management practices for knee pain.

Regarding home remedy practices: 36 participants (60%) reported applying hot water fomentation as their primary modality; 10 (17%) regularly



consumed ginger and turmeric tea; 8 (13%) used cold pack application; and 6 (10%) engaged in therapeutic exercise and walking. Notably, 42% of respondents ($n = 25$) reported no prior knowledge of topical herbal oils as a modality for knee pain management, underscoring a significant awareness gap that the present formulation is positioned to address.

DISCUSSION

The present study reports the rational formulation and multi-parameter evaluation of a novel herbal pain-relief oil designed for topical management of knee pain in young adults. The formulation was developed on a robust pharmacological basis — exploiting the complementary, synergistic mechanisms of six carefully selected natural ingredients — and subjected to a rigorous quality evaluation framework consistent with modern pharmaceutical standards and ICH guidance.

5.1 Pharmacological Rationale and Synergistic Mechanisms

Ajwain (*Trachyspermum ammi*) constitutes the principal analgesic ingredient, with thymol (comprising 35–60% of its essential oil) as the key bioactive constituent. Thymol inhibits prostaglandin biosynthesis through competitive inhibition of both COX-1 and COX-2 enzymes — a mechanism mechanistically analogous to conventional NSAIDs but without their associated gastrointestinal and cardiovascular toxicity at the concentrations present in topical herbal formulations. Thymol has additionally been reported to modulate voltage-gated sodium channels in nociceptive peripheral nerve fibres, contributing a local anaesthetic-like component to its analgesic activity. The carvacrol, p-cymene, and gamma-terpinene constituents of Ajwain provide supplementary anti-inflammatory, antispasmodic, and antimicrobial support.

Curcumin, the principal bioactive polyphenol of turmeric (*Curcuma longa*), is among the most extensively characterized natural anti-inflammatory compounds in pharmacological literature. Its multi-modal mechanism encompasses: simultaneous inhibition of COX-2 and 5-lipoxygenase (5-LOX) enzymes — thereby reducing both prostaglandin and leukotriene production; suppression of the master inflammatory transcription factor NF- κ B, which governs the expression of a broad array of pro-inflammatory genes; downregulation of pro-inflammatory cytokines including TNF- α , IL-1 β , and IL-6; and potent free-radical scavenging antioxidant activity. Multiple randomized controlled trials have confirmed curcumin's efficacy in reducing knee pain and improving functional outcomes in osteoarthritis patients, with an anti-inflammatory potency comparable to ibuprofen at equivalent doses but with substantially superior gastrointestinal tolerability. In the topical context, curcumin's high lipophilicity ($\log P \approx 3.29$) is pharmacokinetically advantageous, facilitating ready dissolution in the coconut oil matrix and efficient partitioning into the lipid-rich stratum corneum for localized tissue delivery.

Gingerols and shogaols from ginger (*Zingiber officinale*) contribute to the formulation's anti-inflammatory profile through inhibition of both prostaglandin and leukotriene biosynthesis, suppression of TNF- α and IL-1 β expression, and inhibition of platelet-activating factor — collectively reducing the overall inflammatory mediator load at the application site. A clinically distinctive pharmacological property of ginger constituents is peripheral vasodilation: gingerols induce relaxation of arteriolar smooth muscle, increasing local microvascular blood flow at the topical application site. This enhanced peripheral circulation produces a dual therapeutic benefit — increasing the local concentration of circulating



immune cells and reparative growth factors at the injured tissue, while simultaneously facilitating the clearance of accumulated inflammatory mediators (prostaglandins, bradykinin, substance P) that perpetuate pain sensitization.

Camphor (*Cinnamomum camphora*) provides a pharmacologically unique analgesic mechanism through counter-irritation — operationally grounded in the "gate control theory" of pain modulation proposed by Melzack and Wall. By acting as a potent agonist at TRPV1 (transient receptor potential vanilloid 1, mediating warm sensation) and TRPM8 (mediating cooling sensation) ion channels in sensory nerve endings, camphor generates competing non-nociceptive thermal sensory input that activates inhibitory interneurons in the dorsal horn of the spinal cord, effectively blocking the transmission of nociceptive pain signals to higher brain centres. The US FDA formally recognises topical camphor at concentrations of 3–11% as a safe and effective external analgesic. The concentration of camphor in the present formulation (approximately 1.5% w/v) is well within the established safe range, avoiding the neurotoxicity and hepatotoxicity associated with systemic absorption at higher concentrations.

Virgin coconut oil (*Cocos nucifera*) was selected as the primary base vehicle for multiple pharmacological and pharmaceutical reasons. Its saturated fatty acid composition — principally lauric acid (C12:0, $\approx$ 48%), caprylic acid (C8:0, $\approx$ 7%), and capric acid (C10:0, $\approx$ 7%) — imparts inherent anti-inflammatory and broad-spectrum antimicrobial activity. Lauric acid has demonstrated prostaglandin synthesis inhibition and in vitro anti-inflammatory activity comparable to aspirin in several experimental models. As a pharmaceutical vehicle, the lipophilic nature of coconut oil directly enhances the percutaneous absorption of co-formulated lipophilic phytoconstituents (thymol, curcumin, camphor)

by providing a thermodynamically compatible, miscible matrix that reduces the energetic barrier to partitioning across the lipid-enriched stratum corneum. Coconut oil also forms a protective, occlusive film on the skin surface that reduces transepidermal water loss (TEWL) and provides an emollient effect, improving the overall skin feel and tolerability of the formulation.

Aloe vera (*Aloe barbadensis*) extract performs dual therapeutic and pharmaceutical functions in the formulation. Therapeutically, its acemannan (beta-1,4-acetylated mannan) polysaccharides, anthraquinone derivatives (aloin, emodin), and salicylate compounds collectively deliver anti-inflammatory, analgesic, and tissue-soothing properties. Pharmaceutically, aloe vera is among the best-documented natural percutaneous penetration enhancers in the topical drug delivery literature. Its mechanism involves transient, reversible disruption of the ordered lipid lamellae within the stratum corneum — mediated by the interaction of aloe saponins and polysaccharides with the intercellular lipid bilayers — significantly increasing the permeability coefficient and transdermal flux of co-applied active compounds, without inducing permanent barrier damage, irritation, or sensitization. This penetration-enhancing activity was a key rationale for including aloe vera extract in the present formulation, as it directly augments the bioavailability of all five co-applied active ingredients at the target periarticular tissues.

The synergistic interplay among these six pharmacologically diverse ingredients — each targeting complementary, non-redundant steps in the nociceptive and inflammatory pathways — produces a multi-modal analgesic and anti-inflammatory effect that substantially exceeds what any single ingredient could achieve independently. This multi-target phytotherapeutic approach is consistent with the theoretical framework of combinatorial herbal medicine and



mirrors the mechanistic basis of several successful commercial topical analgesic preparations currently available in the market. The observed absence of adverse reactions in the patch test further validates the safety of this multi-ingredient combination at the employed concentrations.

5.2 Physicochemical Properties — Clinical Implications

The pH of 6.2 is clinically significant from a dermatological perspective. The skin's physiological acid mantle (pH 4.5–6.0 at the surface) is fundamental to the structural integrity of the epidermal barrier, maintaining the compactness of corneocyte-lipid lamellar architecture, regulating the activity of epidermal serine proteases involved in desquamation and barrier repair, and sustaining a skin surface microenvironment that inhibits pathogenic colonization by *Staphylococcus aureus* and other opportunistic organisms. Topical formulations with $\text{pH} \leq 7.0$ are generally considered non-disruptive to the acid mantle. The formulation pH of 6.2 — slightly alkaline to the acid mantle but well within the compatible range for topical products — minimizes the risk of barrier disruption, TEWL elevation, or sensitization reactions, even with frequent and repeated application over the course of chronic pain management.

The viscosity of 48 cP represents an optimal rheological profile for a topical analgesic oil intended for self-application to the knee area. The low viscosity enables effortless, one-handed application without requiring warming between the palms, while maintaining sufficient body to remain at the application site for an adequate contact duration to enable active ingredient partitioning across the stratum corneum. The high spreadability ($18.4 \pm 1.2 \text{ cm}^2$) confirms that a small applied volume — approximately 0.5–1.0 ml — adequately covers the entire periarticular surface

area of the knee, making the formulation both economically efficient and practically convenient for routine daily use. The non-greasy, rapidly absorbing texture observed during organoleptic evaluation further reinforces patient acceptability and compliance.

5.3 Stability — Shelf-Life Considerations

The 90-day stability data provide a robust foundational evidence base for an initial conservative shelf-life claim of at least three months under ambient storage conditions. The marginal, statistically non-significant decreases in pH (−0.2 units) and increases in acid value (+0.3 mg KOH/g) over 90 days at accelerated conditions (40°C / 75% RH) are characteristic of the natural, low-level oxidative and hydrolytic processes expected in any oil-based preparation and do not represent clinically meaningful deterioration. The oxidative stability of the formulation is notably augmented by two intrinsic mechanisms: firstly, the high saturated fatty acid content of coconut oil ($\approx 90\%$ saturated) renders it inherently resistant to oxidative rancidity compared with polyunsaturated oil bases; and secondly, curcumin's potent free-radical scavenging activity acts as a natural antioxidant within the oil matrix, retarding lipid peroxidation and extending the functional shelf life of the product. Prospective long-term stability studies extending to 12–24 months, and validated quantitative assays for key phytoconstituents (thymol, curcumin content) at specified time points, are recommended to support an extended shelf-life claim for commercial product registration.

5.4 Survey Findings — Public Health Implications

The survey results reveal a community knowledge profile that is predominantly intermediate (67%), with a significant minority lacking awareness of appropriate self-management strategies for knee



pain. The strong association between educational attainment and knowledge adequacy ($\chi^2 = 8.4$; $p = 0.015$) underscores the critical role of health literacy and formal education in enabling informed, safe, and effective self-management of chronic musculoskeletal conditions. The finding that 42% of respondents were entirely unaware of topical herbal oil preparations as an option for knee pain management represents a substantial unmet need in community health education and points to a clear opportunity for pharmacist-led counselling, community health awareness campaigns, and integration of validated herbal topical products into primary care and community pharmacy practice.

The dominant role of hot water fomentation (60%) in self-management practice is consistent with well-established thermotherapy physiology: local heat application increases microvascular blood flow, reduces muscle spasm through thermoception-mediated reflex relaxation, and decreases the viscosity of synovial fluid — all beneficial effects in the context of mechanical knee pain. The herbal oil formulation, when applied warm or when combined with gentle massage, would synergistically augment these thermotherapy effects through the additional analgesic and anti-inflammatory activity of its phytoconstituents. This complementarity between the dominant existing practice and the proposed herbal intervention is an important facilitating factor for community acceptance and adoption of the new product.

5.5 Comparison with Published Literature

The physicochemical and safety findings of the present study align closely with and independently corroborate the results reported in the existing literature on herbal topical oil formulations for musculoskeletal pain. Gore et al. (2024) and Manwar et al. (2024) reported comparable pH values (5.8–6.4), spreadability profiles, and skin

safety data for Ajwain-based herbal pain-relief oils. Zarshenas et al. (2013) comprehensively documented the therapeutic application of medicated herbal oils in traditional Persian medicine for musculoskeletal conditions, validating the ethnopharmacological rationale for the present formulation. Tiwari and Tiwari (2021) highlighted the role of natural excipients in enhancing the bioavailability of herbal actives in topical preparations — consistent with the penetration-enhancing strategy employed in the present study through inclusion of aloe vera extract and coconut oil as base vehicle. The convergence of physicochemical, safety, and mechanistic evidence across independent research groups strengthens the overall evidence base for the safety, quality, and therapeutic potential of the present formulation.

CONCLUSION

The present study successfully achieved its primary scientific and clinical objectives — formulating and comprehensively evaluating a novel herbal pain-relief oil comprising Ajwain, virgin coconut oil, turmeric, ginger, camphor, and aloe vera extract for the topical management of knee pain in young adults. The formulation was prepared by a reproducible, standardized double-boiler extraction protocol and demonstrated excellent performance across all evaluated physicochemical parameters: a skin-compatible pH of 6.2 ± 0.1 ; optimal viscosity (48 ± 3 cP) and spreadability (18.4 ± 1.2 cm²) for topical application; consistent specific gravity (0.91 ± 0.02); and a low acid value (1.8 ± 0.2 mg KOH/g) confirming oxidative stability. Accelerated stability testing over 90 days confirmed the formulation's physicochemical integrity across all storage conditions, with no clinically significant deterioration in any parameter.

The mechanistic synergy among the six phytochemical ingredients — targeting



COX/LOX-mediated prostaglandin synthesis, NF- κ B inflammatory signalling, peripheral vascular tone, TRP channel-mediated counter-irritant analgesia, and stratum corneum penetration enhancement — provides a compelling and comprehensive pharmacological rationale for the formulation's therapeutic efficacy in knee pain management. The complete absence of adverse cutaneous reactions in the patch test (0/10 volunteers; 0% reaction rate) confirms the excellent dermal safety and tolerability of the preparation. The community survey revealed a significant gap in awareness of herbal topical alternatives for knee pain (42% unawareness), underscoring the public health importance of making validated, quality-controlled herbal formulations available within community healthcare channels.

In summation, this herbal pain-relief oil represents a safe, stable, cost-effective, and mechanistically well-supported natural alternative to synthetic topical analgesics, with significant translational potential for use in community healthcare, pharmacy, and self-care settings for young individuals experiencing mild to moderate knee pain. Future research directions of priority include: randomized double-blind placebo-controlled clinical trials for definitive efficacy evaluation; pharmacokinetic studies quantifying transdermal absorption of key phytoconstituents; nanoemulsion-based reformulation to further enhance bioavailability; extended 12–24 month stability studies; and commercial scale-up with validated quality control protocols for regulatory submission.

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Conflict of Interest

The authors declare that there is no conflict of interest — financial, personal, or professional — associated with this research work. No relationship exists that could have influenced the design, conduct, data collection, interpretation, or reporting of findings presented in this manuscript.

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