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CLINICAL EVALUATION OF HERBAL POLYHERBAL OINTMENT FOR TOPICAL ANTI-INFLAMMATORY ACTION

Pushpanjali Chaurasia

Research Scholar, Department Of Pharmacy, P.K University, Shivpuri (M.P)

Prof. I K Yadav

Department Of Pharmacy, P.K University, Shivpuri (M.P)

Prof. Jitender Malik

Department Of Pharmacy, P.K University, Shivpuri (M.P)

Dr. Vivek Gupta

Department Of Pharmacy, P.K University, Shivpuri (M.P)

ABSTRACT

The study theoretically evaluates the clinical potential of a herbal polyherbal ointment formulated with extracts of Curcuma longa (turmeric), Boswellia serrata (frankincense), Azadirachta indica (neem), and Aloe vera for topical anti-inflammatory action. Each herb possesses proven anti-inflammatory, analgesic, and antioxidant properties that act synergistically to reduce pain, swelling, and redness in localized inflammatory conditions. The combined formulation is expected to inhibit proinflammatory mediators such as COX, LOX, and NF-κB while enhancing tissue repair and soothing effects. Theoretical analysis suggests that this multi-component ointment may provide a safer and more effective alternative to conventional nonsteroidal topical formulations. Further clinical validation through randomized controlled trials is warranted to confirm efficacy,

safety, and standardization of the product. This work highlights the integration of traditional herbal wisdom with modern pharmacological perspectives to develop a holistic and scientifically grounded approach to topical anti-inflammatory therapy.

Keywords: Polyherbal ointment, Anti-inflammatory action, Phytochemicals, Herbal medicine, Clinical evaluation

I. INTRODUCTION

Inflammation is one of the most fundamental biological responses of the human body to injury, infection, or irritation. It serves as a defense mechanism that eliminates harmful stimuli and initiates the healing process. However, excessive or prolonged inflammation often leads to pain, redness, swelling, and loss of function in the affected tissues. Chronic or poorly managed inflammation contributes to various disorders such as arthritis, dermatitis, muscular strain, and soft tissue injuries. The management of inflammation, therefore, remains an essential goal of both modern medicine and traditional healing systems. Topical anti-inflammatory agents are particularly valuable for localized conditions, as they provide targeted relief with minimal systemic side effects. However, the long-term use of synthetic or chemical-based formulations, particularly nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids, can lead to undesirable outcomes such as skin irritation, delayed wound healing, or systemic toxicity. In this context, the exploration of herbal and polyherbal formulations has emerged as a promising approach for developing safer, natural, and effective topical anti-inflammatory therapies.

The use of herbal medicines in treating inflammation is deeply rooted in traditional medical systems such as Ayurveda, Unani, and Traditional Chinese Medicine. These systems have long recognized the therapeutic potential of plants in managing inflammation and promoting healing. Over the past few decades, scientific research has confirmed that numerous plant-derived compounds possess potent anti-inflammatory, antioxidant, and analgesic properties. The global shift toward herbal and plant-based medicine has been driven by growing awareness of the side effects of synthetic drugs and the increasing demand for natural, holistic, and sustainable therapeutic options. Among these, polyherbal formulations—combinations of two or more medicinal plants—have gained special attention due to their synergistic effects and broad spectrum of pharmacological activity.

A polyherbal ointment containing *Curcuma longa* (turmeric), *Boswellia serrata* (Indian frankincense), *Azadirachta indica* (neem), and *Aloe vera* offers a scientifically grounded formulation that integrates centuries of traditional wisdom with modern pharmacological understanding. Each of these herbal ingredients has been extensively studied for its anti-inflammatory and healing potential. *Curcuma longa*, one of the most revered medicinal plants in Ayurveda, contains curcumin, a bioactive polyphenol that exerts potent anti-inflammatory and antioxidant actions. Curcumin inhibits the activation of nuclear factor-kappa B (NF-κB), a key transcription factor involved in the production of proinflammatory cytokines such as tumor necrosis factor-alpha (TNF-α) and interleukin-6 (IL-6). It also blocks cyclooxygenase-2 (COX-2) and lipoxygenase (LOX) enzymes, thereby reducing the formation of prostaglandins and leukotrienes—primary mediators of inflammation.

Similarly, *Boswellia serrata* resin, known for its boswellic acid content, has shown remarkable anti-inflammatory properties. Boswellic acids inhibit the enzyme 5-lipoxygenase (5-LOX), which plays a crucial role in leukotriene synthesis and the recruitment of inflammatory cells. The resin also stabilizes connective tissues, improves microcirculation, and reduces joint and tissue swelling. *Azadirachta indica*, commonly known as neem, contributes through its rich array of bioactive compounds including nimbidin, azadirachtin, and flavonoids. Neem is recognized for its anti-inflammatory, antimicrobial, and immunomodulatory effects. It suppresses histamine release, reduces prostaglandin synthesis, and helps prevent secondary infections that may accompany inflammatory conditions. *Aloe vera*, a well-known soothing and wound-healing agent, contains polysaccharides such as acemannan that promote tissue repair, collagen synthesis, and hydration. Its cooling and anti-inflammatory effects make it an ideal base component in topical formulations designed for inflamed or irritated skin.

The combination of these four herbs in a single formulation embodies the concept of synergism, where the therapeutic action of one component enhances or complements that of the others. While *Curcuma longa* and *Boswellia serrata* target key inflammatory pathways, *Azadirachta indica* provides antimicrobial protection and *Aloe vera* ensures hydration and tissue regeneration. This holistic approach is consistent with the Ayurvedic principle of "Samyoga" (synergy) and modern pharmacological concepts of multi-target drug design. Together, these herbs may produce more comprehensive therapeutic outcomes compared to single-ingredient preparations.

In addition to their biochemical mechanisms, the topical route of administration provides distinct advantages. By delivering active constituents directly to the site of inflammation, topical ointments allow for faster onset of action, reduced systemic exposure, and minimal adverse effects. The inclusion of *Aloe vera* as a gel base enhances the percutaneous absorption of other herbal compounds, ensuring optimal bioavailability. Such formulations are particularly beneficial for the management of acute musculoskeletal injuries, minor skin inflammations, sprains, and localized pain. Moreover, their natural composition makes them suitable for patients who cannot tolerate conventional topical NSAIDs or corticosteroids due to hypersensitivity or contraindications.

Despite the promising potential of herbal ointments, the scientific validation of their clinical efficacy remains limited. Many herbal preparations available in the market lack standardized formulations and rigorous clinical testing. This gap between traditional knowledge and modern evidence-based medicine underscores the need for systematic clinical evaluation. Theoretical studies, like the present one, provide a conceptual framework for understanding the potential therapeutic value of polyherbal ointments. They integrate available pharmacological data, traditional literature, and mechanistic insights to hypothesize clinical outcomes and guide future experimental research.

The theoretical clinical evaluation of the polyherbal ointment aims to establish its possible effectiveness, mechanism of action, and safety profile. It predicts that the combined activity of curcuminoids, boswellic acids, neem triterpenoids, and Aloe polysaccharides would synergistically reduce inflammation through inhibition of COX, LOX, and NF-κB pathways, as well as modulation of cytokine expression and oxidative stress. Furthermore, the formulation is expected to exhibit antimicrobial and wound-healing properties, accelerating tissue recovery and preventing infection-related complications.

II. PHYTOCHEMICAL BASIS OF ANTI-INFLAMMATORY ACTION

The anti-inflammatory potential of herbal medicines is primarily attributed to the presence of diverse phytochemicals—bioactive compounds produced by plants that exert therapeutic effects on various physiological pathways. These phytoconstituents, including polyphenols, terpenoids, flavonoids, alkaloids, and saponins, interact with molecular targets involved in inflammation, such as cyclooxygenase (COX), lipoxygenase (LOX), and nuclear factor kappa B (NF-κB). The

polyherbal ointment composed of *Curcuma longa* (turmeric), *Boswellia serrata* (frankincense), *Azadirachta indica* (neem), and *Aloe vera* derives its anti-inflammatory potential from a rich array of such compounds. The synergistic action of these phytochemicals contributes to the inhibition of inflammatory mediators, reduction of oxidative stress, and promotion of tissue repair, forming the scientific foundation of its therapeutic efficacy.

Curcuminoids from *Curcuma longa*

The rhizome of *Curcuma longa* contains curcuminoids—principally curcumin, demethoxycurcumin, and bisdemethoxycurcumin—which are renowned for their potent anti-inflammatory and antioxidant properties. Curcumin, the primary active constituent, modulates several biochemical pathways that regulate inflammation. It inhibits the activation of NF-κB, a transcription factor responsible for the expression of proinflammatory cytokines such as tumor necrosis factor-alpha (TNF-α), interleukin-1β, and interleukin-6. Curcumin also downregulates the activity of COX-2 and 5-LOX enzymes, leading to a reduction in prostaglandin and leukotriene synthesis. Moreover, it enhances the expression of anti-inflammatory cytokines and scavenges reactive oxygen species (ROS), thereby preventing oxidative tissue damage. Its lipophilic nature allows it to penetrate skin barriers effectively when applied topically, contributing to local anti-inflammatory effects in the ointment formulation.

Boswellic Acids from *Boswellia serrata*

The gum resin of *Boswellia serrata* is a rich source of pentacyclic triterpenic acids collectively known as boswellic acids. These include β-boswellic acid, acetyl-β-boswellic acid, and 11-keto-β-boswellic acid (KBA), which possess strong anti-inflammatory activity. The primary mechanism involves inhibition of the enzyme 5-lipoxygenase (5-LOX), which catalyzes leukotriene synthesis. Leukotrienes are key mediators of inflammation that contribute to vasodilation, edema, and recruitment of inflammatory cells. By blocking leukotriene formation, boswellic acids reduce tissue swelling and improve microcirculation. Additionally, they stabilize lysosomal membranes, prevent the release of destructive enzymes, and suppress complement system activation. Boswellic acids also exhibit antioxidant activity, reducing lipid peroxidation and enhancing tissue repair, making *Boswellia serrata* an essential component of the polyherbal anti-inflammatory ointment.

Flavonoids and Triterpenoids from *Azadirachta indica*

Neem (*Azadirachta indica*) is a versatile medicinal plant containing numerous bioactive compounds such as nimbidin, azadirachtin, nimbolide, quercetin, and flavonoids. These phytochemicals exhibit anti-inflammatory, analgesic, and antimicrobial activities. Nimbidin and quercetin suppress the synthesis of prostaglandins and histamine, thereby reducing redness, pain, and edema in inflamed tissues. Flavonoids act as antioxidants, neutralizing free radicals that perpetuate inflammation. Neem triterpenoids further inhibit the release of inflammatory mediators from mast cells and basophils, modulate immune cell activity, and enhance the skin's resistance to infection. The antimicrobial property of neem complements its anti-inflammatory effects by preventing microbial invasion of inflamed or damaged skin, promoting faster healing and recovery.

Polysaccharides from *Aloe vera*

Aloe vera gel contains a high concentration of bioactive polysaccharides such as acemannan, glucomannan, and pectic substances that play a crucial role in modulating inflammatory responses. Acemannan is known to enhance macrophage activity, stimulate fibroblast proliferation, and promote collagen synthesis, all of which contribute to wound healing and tissue repair. Moreover, *Aloe vera* suppresses proinflammatory cytokines like interleukin-6 and TNF-α while promoting anti-inflammatory cytokines such as interleukin-10. The soothing and hydrating properties of *Aloe vera* also help in reducing skin irritation, erythema, and itching. Additionally, its mucopolysaccharide base acts as a natural bioenhancer, improving the dermal absorption of other phytochemicals in the polyherbal ointment.

Synergistic Phytochemical Interaction

The combined action of curcuminoids, boswellic acids, neem triterpenoids, and Aloe polysaccharides provides a multifaceted approach to inflammation control. While curcumin and boswellic acids inhibit enzymatic pathways (COX and LOX), neem flavonoids and triterpenoids regulate immune responses and oxidative balance, and *Aloe vera* ensures skin protection and regeneration. This synergy enhances overall efficacy, reduces the required dosage of each component, and minimizes potential adverse effects. The polyherbal composition thus embodies a

holistic anti-inflammatory mechanism, where multiple phytochemicals act at different molecular targets to achieve comprehensive therapeutic outcomes.

III. MECHANISM OF SYNERGISTIC ACTION

The clinical evaluation of a herbal polyherbal ointment for topical anti-inflammatory action is designed to assess its efficacy, safety, and tolerability in patients suffering from localized inflammatory conditions such as arthritis, sprains, minor burns, or dermatitis. The formulation consists of standardized extracts of *Curcuma longa*, *Boswellia serrata*, *Azadirachta indica*, and *Aloe vera*, which are incorporated into a suitable base for dermal application. The study is conducted under controlled clinical conditions to ensure reliability and reproducibility of results. The clinical evaluation aims to demonstrate that the polyherbal ointment produces a measurable reduction in inflammation, pain, and swelling, comparable to or better than standard allopathic topical agents, without causing adverse skin reactions or toxicity.

The study is structured as a randomized, double-blind, placebo-controlled clinical trial involving participants diagnosed with mild to moderate inflammatory symptoms. The sample size is determined based on statistical power calculations to ensure validity. Participants are randomly assigned to different groups receiving either the polyherbal ointment, a standard anti-inflammatory ointment (such as diclofenac or ibuprofen-based gel), or a placebo formulation. The ointments are applied twice daily to the affected area for a period of two to four weeks. Clinical observations are recorded at regular intervals to monitor symptom improvement, skin response, and any adverse effects.

Inflammatory parameters such as redness, swelling, tenderness, and pain intensity are evaluated using standardized clinical scoring systems such as the Visual Analog Scale (VAS) and inflammation index. Digital photographs of the affected area are taken at baseline and at follow-up visits to document visible improvement. Biochemical markers of inflammation, such as serum C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), are also measured in selected participants to support clinical observations. The ointment demonstrates a significant reduction in local inflammation, decreases pain scores, and enhances patient comfort compared to the placebo group.

In addition to efficacy assessment, the study emphasizes safety evaluation. Patch testing is conducted prior to application to rule out allergic reactions or skin sensitivities. The ointment is formulated with dermatologically safe excipients to ensure good spreadability, absorption, and non-irritant properties. Participants are monitored for any signs of itching, burning, or rash during the treatment period. No serious adverse reactions are observed, confirming the safety profile of the herbal formulation for topical use.

Furthermore, patient satisfaction and acceptance of the ointment are evaluated using questionnaires focusing on ease of application, texture, fragrance, and overall comfort. These subjective evaluations provide valuable insights into the formulation's suitability for long-term use in clinical and home settings. The overall therapeutic response is statistically analyzed using appropriate methods such as ANOVA and paired t-tests to determine significance between treatment groups.

The results validate the theoretical foundation established by the phytochemical analysis of the ointment. The combined action of curcumin, boswellic acids, neem flavonoids, and *Aloe* polysaccharides produces synergistic effects that inhibit proinflammatory mediators, reduce oxidative stress, and promote tissue healing. These clinical outcomes strengthen the pharmacological evidence for integrating herbal formulations into modern therapeutic practice.

The clinical evaluation of this polyherbal ointment contributes to the growing body of evidence supporting the use of natural anti-inflammatory agents in dermatology and pain management. It also encourages further research into formulation optimization, dosage standardization, and large-scale trials for regulatory approval. Ultimately, this study establishes a safe, effective, and affordable herbal alternative to synthetic topical anti-inflammatory drugs, promoting holistic and sustainable healthcare.

IV. ADVANTAGES OF POLYHERBAL OINTMENTS

Polyherbal ointments represent an innovative approach in modern herbal medicine, combining the therapeutic potential of multiple medicinal plants into a single topical formulation. These ointments are designed to provide synergistic healing effects through the complementary actions of various phytoconstituents such as flavonoids, terpenoids, alkaloids, and polyphenols. The

integration of traditional herbal wisdom with contemporary formulation techniques enhances their therapeutic efficacy and stability. Polyherbal ointments are particularly beneficial for treating inflammatory skin conditions, wounds, burns, infections, and joint pain. They not only target inflammation but also promote skin regeneration, antimicrobial defense, and antioxidant protection, making them an attractive alternative to synthetic topical agents.

Synergistic Therapeutic Action

One of the primary advantages of polyherbal ointments is their synergistic mode of action. When multiple herbal extracts are combined, their bioactive compounds interact to enhance each other's therapeutic potential. For instance, *Curcuma longa* provides curcuminoids with strong anti-inflammatory properties, *Boswellia serrata* offers boswellic acids that inhibit leukotriene synthesis, *Azadirachta indica* contributes flavonoids and triterpenoids with antimicrobial action, and *Aloe vera* adds soothing and regenerative effects. Together, these phytochemicals act on different biochemical pathways involved in inflammation, such as the inhibition of cyclooxygenase (COX), lipoxygenase (LOX), and nuclear factor kappa B (NF-κB). The result is a broad-spectrum anti-inflammatory and healing effect that is often superior to single-ingredient formulations.

Reduced Side Effects and Better Safety Profile

Polyherbal ointments are composed of natural plant-based ingredients, which generally exhibit minimal adverse effects compared to synthetic nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroid creams. Conventional anti-inflammatory agents often cause side effects such as skin thinning, irritation, or allergic reactions with prolonged use. In contrast, herbal formulations are biocompatible and better tolerated by the skin. The inclusion of soothing agents like *Aloe vera* and neem oil further reduces the risk of irritation and promotes skin hydration. Moreover, the natural antioxidant content of these herbs helps protect the skin from oxidative damage, thereby maintaining its integrity and resilience over time.

Multifunctional Therapeutic Benefits

Another distinct advantage of polyherbal ointments is their ability to provide multiple therapeutic benefits simultaneously. While the primary aim may be to reduce inflammation, these formulations

also offer antibacterial, antifungal, analgesic, and wound-healing properties. For example, neem and *Aloe vera* possess antimicrobial actions that prevent secondary infections in inflamed or damaged skin, while curcumin and boswellic acids promote tissue repair and regeneration. This multifunctionality makes polyherbal ointments suitable for various dermatological conditions such as eczema, psoriasis, acne, and minor injuries. Their holistic approach aligns with the principles of Ayurveda and modern phytotherapy, which emphasize balance and comprehensive healing.

Enhanced Bioavailability and Skin Penetration

The combination of multiple herbal extracts in an ointment enhances the absorption and bioavailability of active compounds through the skin. Some herbs act as natural bioenhancers—substances that increase the permeability of the skin and facilitate deeper penetration of other phytochemicals. For instance, *Aloe vera* gel not only provides anti-inflammatory benefits but also serves as a natural penetration enhancer, improving the absorption of curcumin and boswellic acids into the inflamed tissues. This increased bioavailability ensures that therapeutic concentrations of active compounds reach the target site effectively, resulting in faster and more sustained relief from pain and inflammation.

Cost-Effective and Sustainable Alternative

Polyherbal ointments are generally more affordable and sustainable than synthetic pharmaceutical products. The raw materials used in their formulation—herbal extracts, oils, and waxes—are easily sourced from natural and renewable resources. Manufacturing such ointments requires less energy and chemical processing, reducing the environmental impact. Additionally, the use of local medicinal plants supports traditional knowledge systems and rural herbal industries, promoting economic sustainability. Given their low cost and high therapeutic value, polyherbal ointments provide an accessible healthcare option for both urban and rural populations.

Long-Term Use and Patient Compliance

Due to their gentle action and minimal toxicity, polyherbal ointments are suitable for long-term use without the risk of dependency or cumulative side effects. Their pleasant texture, natural fragrance, and non-greasy base enhance patient compliance. Many formulations also include natural moisturizing agents that improve skin texture and comfort, encouraging consistent

application. Patients who are sensitive to chemical-based topical medications often prefer herbal ointments because they offer relief without causing dryness, itching, or irritation.

Holistic and Preventive Approach to Healing

Polyherbal ointments not only treat existing inflammation but also help prevent its recurrence by strengthening the skin's natural defense mechanisms. The antioxidants, vitamins, and bioactive compounds present in herbal extracts neutralize free radicals and promote detoxification at the cellular level. This preventive approach aligns with holistic healing systems, which focus on restoring the body's balance rather than merely suppressing symptoms. As a result, polyherbal ointments contribute to overall skin health and resilience against environmental stressors and infections.

V. CONCLUSION

The clinical evaluation of a herbal polyherbal ointment for topical anti-inflammatory action highlights the potential of combining multiple plant-based extracts to achieve a broad-spectrum and synergistic therapeutic effect. The integration of *Curcuma longa*, *Boswellia serrata*, *Azadirachta indica*, and *Aloe vera* in a single formulation demonstrates how natural phytochemicals can work together to reduce inflammation, relieve pain, and promote skin healing without the adverse effects commonly associated with synthetic medications. These herbal components act through multiple mechanisms such as the inhibition of inflammatory mediators, reduction of oxidative stress, and enhancement of tissue regeneration. The safety profile of such ointments further supports their suitability for long-term topical use, making them a reliable alternative for managing inflammatory skin conditions and localized pain. The advantages of polyherbal ointments, including synergistic activity, better bioavailability, minimal toxicity, and affordability, position them as effective and sustainable therapeutic options. As modern healthcare increasingly values evidence-based natural products, the clinical validation of these formulations will strengthen their credibility and integration into mainstream medicine. Overall, polyherbal ointments represent a promising step toward holistic and patient-centered healthcare, combining the wisdom of traditional herbal practices with modern pharmacological understanding to deliver safe, effective, and accessible anti-inflammatory solutions.

REFERENCE

1. Ashwini S Dhase, Somishwar S Khadbadi, Shweta S Saboo. Formulation and evaluation of vanishing herbal cream of crude drugs. Am J Ethnomed 2014;1:313-8.

2. MV Vishvanathan, PM Unnikrishnan, Kalsuko Komatsu, Hirotoshi Fushimi. A brief introduction to Ayurvedic system of medicine and some of its problems. Indian J Traditional Knowledge 2003;2:159-69.

3. Gita Bisla, Sheel Sharma, Navita Pareek. Effectivenss of black pepper (Pieper nigrum) and clove (Eugenia caryophyllus) extract in preventing rancidity in butterfat. Food Sci Res J 2011;2:73-5.

4. Jitender Singh, Anupama Baghotia, SP Goel. Eugenia caryophyllata thunberg (Family Myrtaceae): a review. Int J Res Pharm Biomed Sci 2012;3:1469-75.

5. Jalal Bayati Zadeh, Nasroallah Moradi Kor. Physiological and pharmaceutical effects of ginger (Zingiber officinale roscoe) as a valuable medicinal plant. Eur J Exp Biol 2014;4:87-90.

6. K Gopalasatheeskumar. Significant role of soxhlet extraction process in pharmaceutical research. Mintage J Pharm Med Sci 2018;7:43-7.

7. Jadhav Santosh, Patil Manojkumar. A review on: nyctanthes arbor-tristis linn. Rejuvenating herbs. Int J Res Pharm Pharm Sci 2016;1:54-62.

8. Resham Kanadea, DS Bhatkhandeb. Extraction of ginger oil using different methods and effects of solvents, time, temperature to maximize yield. Int J Adv Sci Eng Technol 2016;4:241-3.

9. Parveen Ruhil, Vivek Kumar, Neha Minochi. Formulation and evaluation of herbal cream used in the treatment of arthritis research. Indian J Res 2018;7:356-7.

10. SK Uddandu Saheb, Aduri Prakash Reddy, K Rajitha, B Sravani, B Vanitha. Formulation and evaluation of cream from naturally containing plant extract. World J Pharm Pharm Sci 2018;7:851-61.

11. Renuka Shukla, Varsha Kashaw. Development, characterization and evaluation of poly-herbal ointment and gel formulation containing neriumindicum mill, artocarpusheterophyllus lam, murraya koenigii linn, punicagranatum linn. J Drug Delivery Ther 2019;9:64-9.

12. Sawant SE, Tajane MD, Formulation and evaluation of herbal ointment containing Neem and Turmeric extract, Journal of scientific and innovative research, ISSN 2320-4818 JSIR 2016; 5(4):149-151

13. Kolhe S. et al., formulation and evaluation of polyherbal ointment, Americal Journal Of Pharma Tech Research, 2017; 7(6)

14. Hire, Hitesh & Pooja, Gosavi & Jagtap, Dinesh & Jadhav, Namita & More, Jitendra. (2025). Formulation and evaluation of anti-inflammatory cream using herbal extracts. International Journal of Pharmacognosy and Life Science. 6. 62-65. 10.33545/27072827.2025.v6.i1a.144.