

Formulation And Characterization Of Herbal Cream For The Management Of Acne Vulgaris

Nidhi Sharma¹, Pranjul Shrivastava^{*2}, Dr. Sandip Prasad Tiwari³

^{1,2,3}Faculty of Pharmacy, Kalinga University, Naya Raipur (C.G)

Email ID: pranjul.shrivastava@kalingauniversity.ac.in

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ABSTRACT

This study focused on the formulation and characterization of a herbal cream for the management of acne vulgaris, aiming to provide a natural, effective, and safer alternative to conventional synthetic treatments. Herbal extracts from (Neem), (Aloe vera), (Turmeric), (Green tea), and (Tulsi) were selected based on their established antimicrobial and anti-inflammatory properties. The final formulation exhibited excellent organoleptic properties with a smooth, white, uniform texture and pleasant herbal odour. The pH of the cream was recorded at ensuring compatibility with the skin's natural pH range. Spreadability was measured at cm², indicating ease of application and uniform coverage. Viscosity was found to be suitable for topical application, contributing to both stability and user compliance. Stability studies conducted over two weeks at varied storage conditions room temperature refrigeration and accelerated revealed no significant changes in color, phase separation, or consistency, confirming the physical stability of the formulation. Antimicrobial activity, assessed via the agar well diffusion method, showed a zone of inhibition of against *Propionibacterium acnes*, the primary acne-causing bacterium. In comparison, a standard antibiotic showed a m inhibition zone against *Staphylococcus aureus*, highlighting the herbal cream's notable antibacterial efficacy despite its natural composition. These findings suggest that the herbal cream is a viable, safe, and effective alternative for the management of acne vulgaris.

Keywords: Acne vulgaris, Herbal cream formulation, Antimicrobial activity, physicochemical characterization, Natural skincare

1. INTRODUCTION

1.1. Background of the Study

The skin, the largest organ of the human body, serves as a vital protective barrier, shielding internal organs from physical injury, microbial invasion, and harmful ultraviolet radiation. Composed of three principal layers the epidermis, dermis, and hypodermis the skin is not only essential for structural integrity but also plays crucial physiological roles. These include thermoregulation, sensory perception, immune surveillance, and the synthesis of vitamin D. The maintenance of healthy skin is imperative not only for physical wellness but also for psychological well-being and aesthetic confidence. [1]

Among various dermatological conditions, acne vulgaris is the most prevalent, primarily affecting areas rich in sebaceous glands such as the face, chest, and back. It is a chronic inflammatory condition of the pilosebaceous unit, characterized by a spectrum of lesions including papules, pustules, nodules, and cysts. Although most frequently observed during adolescence, acne can persist into adulthood and affect individuals well beyond their teenage years. [2] Epidemiological data indicate that approximately of individuals aged 12 to 24 are affected by acne at some point, reflecting its broad public health impact. Beyond its physical manifestations, acne often leads to psychological complications such as reduced self-esteem, social withdrawal, anxiety, and depression, underscoring the importance of comprehensive management approaches that address both medical and emotional dimensions. [3]

Conventional therapies for acne vulgaris include topical retinoids, antibiotics, benzoyl peroxide, hormonal treatments, and systemic agents like isotretinoin. While these interventions can be effective, they are not without drawbacks. Topical medications may cause skin irritation, dryness, erythema, and heightened photosensitivity. Prolonged use of antibiotics has contributed to the emergence of resistant strains of Cuti bacterium acnes (formerly Propionibacterium acnes), complicating long-term treatment. Although isotretinoin is highly efficacious, it carries significant risks, including teratogenicity, mucocutaneous dryness, and neuropsychiatric side effects. Additionally, the high cost and limited accessibility of some therapies can pose barriers to care. [4]

1.2. Acne Vulgaris: Pathophysiology and Contributing Factors

Acne vulgaris is a multifactorial inflammatory disease of the pilosebaceous unit that commonly begins during adolescence but may persist into adulthood. Clinically, acne presents with a range of lesions that are broadly categorized as non-inflammatory (open and closed and inflammatory papules, pustules, nodules, and cysts. These lesions typically affect the face, back, chest, and shoulders—regions with high sebaceous gland density. [5]

The pathogenesis of acne involves several interconnected processes. Androgens such as testosterone and dihydrotestosterone play a pivotal role in stimulating sebaceous gland activity during puberty, resulting in increased sebum production. This excess sebum creates a lipid-rich environment conducive to the growth of C. acnes, which is a part of the normal skin flora but becomes pathogenic under blocked follicular conditions. Simultaneously, hyper keratinization of follicular epithelial cells leads to obstruction of the pilosebaceous unit, initiating formation. [6] These plugged follicles progress to visible and further into inflamed lesions due to the immunologic response to bacterial overgrowth and enzymatic activity. C. acnes contributes to inflammation by producing lipases, proteases, and chemotactic factors that convert sebum triglycerides into pro-inflammatory free fatty acids, exacerbating tissue damage. [7]

Multiple intrinsic and extrinsic factors modulate the onset and severity of acne. Hormonal fluctuations during puberty, menstruation, pregnancy, and endocrine disorders such as polycystic ovary syndrome are well-documented contributors. Genetic predisposition also plays a role; individuals with a family history of acne are more likely to develop severe forms. Environmental influences such as high-glycemic diets, dairy consumption, psychological stress, and pollution have been associated with acne exacerbation. Cortisol released in response to stress can stimulate sebaceous activity, further worsening the condition. Additionally, the use of comedogenic cosmetic products, occupational exposure to oils or chemicals, and certain medications including corticosteroids, anabolic steroids, lithium, and anticonvulsants can induce or aggravate acne.

1.3 Herbal Remedies in Acne Management

Throughout different cultural backgrounds across centuries people have practiced the use of herbal treatments for treating skin diseases including acne vulgaris. People who practice Ayurveda and Traditional Chinese Medicine and Unani medicine make wide use of herbal remedies because they treat skin problems effectively. Herbal remedies provide users with a natural treatment solution against synthetic drugs through their small side-effect profile and preferable patient satisfaction. [9]

1.3.1. Historical Use of Herbs for Treating Skin Disorders

The practice of using herbal medicines for skincare purposes dates back to ancient ages. Traditional use of Ayurvedic medicine showcased three important plants: indica neem trees and Curcuma longa turmeric and Aloe vera provided healing and anti-inflammatory functions combined with cleansing properties. Ancient Egyptian papyri document the use of herbs like frankincense and myrrh for skin rejuvenation. [10]

Similarly, TCM has long employed herbs such as honeysuckle (*Lonicera japonica*), forsythia and dandelion (*Taraxacum officinale*) for clearing heat and toxins from the skin. Across many cultures, the application of herbal pastes, oils, and decoctions for acne and skin infections has been a common therapeutic approach. [11]

1.4 Herbal Creams: Formulation Considerations

Local topical drug formulations represent essential means for treating dermatological problems such as acne vulgaris. The skin functions as an initial defensive barrier of your body thus localized treatment of skin disorders presents its best opportunity through topical delivery methods. [12] Acne vulgaris treatment through topical formulations enables medicinal agents to reach specific affected areas with high doses while minimizing the usual systemic effects of taking oral pills. Targeted application shows exceptional value by decreasing the key elements of acne pathology which include inflammatory reactions along with bacterial multiplication and sebum production. [13]

1.5 Characterization of Herbal Creams

Characterization of the formulated herbal cream is essential to establish its quality, safety, and efficacy. A well-characterized product builds confidence in its therapeutic potential and ensures consistency during production. Various evaluation parameters are utilized to assess the physicochemical, microbiological, and biological attributes of the herbal cream. [14]

1.5.1. Physicochemical Evaluation

The physicochemical characteristics of a cream greatly influence its performance and acceptability. The following properties are typically evaluated: [15]

• **pH Measurement:** The pH of the cream is an important parameter as it influences skin compatibility. Ideally, the cream should have a pH close to that of the skin (5.0–6.0). A cream with a highly acidic or basic pH may cause irritation, dryness, or disrupt the natural microbiome of the skin. pH measurements are usually performed using a digital pH meter after dispersing the cream in distilled water.

- **Viscosity:** The viscosity of a cream affects its spreadability, texture, and stability. A cream that is too viscous may be difficult to spread, whereas one with low viscosity may be runny and unstable. Viscosity can be determined using instruments like a Brookfield viscometer, and the measurement provides insight into the cream's flow behaviour under various storage conditions.
- **Texture Analysis:** The sensory properties, such as firmness, consistency, and adhesiveness, are evaluated through texture profile analysis. These attributes influence the user's perception and the product's aesthetic appeal, ultimately impacting compliance.
- **Spreadability:** Spreadability determines how easily the cream can be applied on the skin surface. It can be measured by placing a known quantity of cream between two glass slides and applying a specific weight to see how much area the cream spreads to. Good spreadability ensures easy application, uniform distribution of active agents, and improved patient satisfaction.
- Appearance and Homogeneity: Visual inspection of the cream is conducted to assess color, phase separation, and uniform distribution of herbal extracts. A smooth, glossy, and homogeneous appearance without any lumps indicates good quality.

1.5.2. Microbial Testing

Microbial contamination is a major concern, especially for herbal products, as plant extracts can serve as a medium for microbial growth. Testing ensures that the cream is free from harmful pathogens like *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, and fungal contaminants. [16]

- Total Viable Count (TVC): Measures the total number of aerobic bacteria and fungi present.
- Pathogen Testing: Specific tests are performed to detect the presence of pathogenic microorganisms.
- **Preservative Efficacy Testing (PET):** This assesses the ability of preservatives in the cream to prevent microbial growth over time.

Compliance with microbial limits, as per pharmacopeial standards (e.g., USP, BP), is essential to guarantee product safety.

1.5.3. Stability Studies

Stability testing is conducted to predict the shelf life of the herbal cream and to understand how different storage conditions affect its quality. These studies typically involve: [17]

- **Accelerated Stability Testing:** Subjecting the cream to elevated temperatures and humidity conditions (e.g., 40°C and 75% RH) to simulate long-term storage effects.
- Physical Stability: Monitoring changes in appearance, pH, viscosity, spreadability, and odour over time.
- Microbial Stability: Ensuring the microbial integrity of the product throughout the study duration.

1.5.4. Efficacy Evaluation

Preliminary in vitro efficacy testing can be performed to assess the anti-acne activity of the herbal cream. Techniques such as: [18]

- **Agar Diffusion Assays:** Testing the antimicrobial activity against *Cutibacterium acnes* and *Staphylococcus epidermidis*, common acne-causing bacteria.
- Anti-inflammatory Tests: Using cell culture models to evaluate reduction in inflammatory markers.
- Antioxidant Activity Assays: Determining the ability of the herbal actives to neutralize free radicals, which
 can exacerbate acne.

These studies provide an initial understanding of the therapeutic potential of the herbal cream before proceeding to clinical evaluation.

2. MATERIALS AND METHODS

2.1 Materials

For the formulation of the herbal cream targeting acne vulgaris, all raw materials including herbal ingredients, excipients, and laboratory reagents were procured from reputable vendors located in major Indian cities such as Mumbai, Hyderabad, Bengaluru, and Delhi. The selected herbal components included (Neem), (Aloe vera), (Turmeric), (Green tea), (Tulsi), all of which were chosen based on established pharmacological evidence supporting their antimicrobial, anti-inflammatory, and skin-soothing properties. These plant materials were obtained from authenticated sources and verified for quality prior to use. Pharmaceutical-grade excipients used in the cream base formulation such as CETOSTEARYL alcohol, polysorbate 60,

light liquid paraffin, sweet almond oil, GLYCERIN Carbopol 940, methylparaben, propylparaben, and triethanolamine were sourced from certified chemical suppliers to ensure compliance with safety and quality standards suitable for topical application.

2.2 Preparation of Herbal Extracts

2.2.1 Extraction Method

A maceration technique was employed to extract bioactive constituents from the plant materials due to its simplicity and ability to preserve thermolabile compounds. Shade-dried and powdered plant materials (100 g each) were soaked in 500 mL of 70:30 ethanol-water solution in closed containers at room temperature for seven days with intermittent shaking. After the extraction period, the mixtures were filtered through muslin cloth and Whatman No. 1 filter paper. The filtrates were concentrated using a rotary evaporator under reduced pressure at a temperature below 45°C. [19, 20]

2.2.2 Drying and Storage

Extracts were dried using a vacuum oven at 40°C to yield powders, except for *Aloe vera*, which was stored in gel form under refrigeration (4°C). The dried extracts were stored in amber glass containers to protect them from light and humidity and were kept at until formulation. Each container was with the extract name, batch number, and preparation date. [21]

2.3 Formulation of Herbal Cream

2.3.1 Preparation Procedure

The oil and aqueous phases of the cream were prepared separately. The oil phase included emulsifiers and oils, which were heated to. Simultaneously, the aqueous phase containing water, glycerin, and Carbopol was also heated to the same temperature. The aqueous phase was added gradually to the oil phase with continuous stirring using a homogenizer to form a stable emulsion. Once the base was cooled to below, the concentrated herbal extracts were incorporated slowly to ensure uniform distribution. The final cream was stirred until a homogeneous product was obtained. pH adjustment was carried out using triethanolamine, and the cream was filled into suitable containers for further evaluation. [22,23]

Ingredient Function Herbal Extracts Neem, Tea Tree, Aloe Vera) Active ingredients for anti-inflammatory, antimicrobial, and healing properties Water (Distilled) Solvent **Emulsifying Wax** Emulsifier (binds oil and water) Stearic Acid Co-emulsifier and thickening agent **GLYCERIN** Humectant (moisturizing agent) Beeswax Stabilizing agent and emollient Carrier Oils (e.g., Jojoba, Coconut, or Olive Oil) Lipid components, moisturizer Preservatives (e.g., Phenoxyethanol, ETHYLHEXYL To prevent microbial growth and extend shelf life **GLYCERIN** Essential Oils Tea Tree, Lavender, Chamomile Fragrance and antimicrobial properties Citric Acid pH adjuster (if required) Ethanol (optional) Solvent for herbal extract

Table 3.1: Herbal Composition

2.3.2 Preparation Procedure

The preparation of the herbal cream involves the following sequential steps to ensure uniform mixing and preservation of the active herbal compounds: [24,25]

• Step 1: Oil Phase Preparation

Emulsifying wax, stearic acid, and beeswax are gently melted using a double boiler method. Once liquified, carrier oils like jojoba or coconut oil are added, and the mixture is maintained at approximately 70°C.

• Step 2: Water Phase Preparation

Distilled water and GLYCERIN are measured and heated separately to the same temperature (70°C). Citric acid may be added at this stage to adjust the pH.

• Step 3: Emulsion Formation

The heated water phase is slowly added to the oil phase with continuous stirring using a hand blender or homogenizer, forming a stable emulsion. The mixture is stirred continuously while cooling to achieve the desired cream consistency.

• Step 4: Addition of Herbal Extracts and Actives

Once the temperature lowers to around 40°C, herbal extracts (e.g., neem, aloe vera, tea tree) are added to avoid degradation of heat-sensitive phytoconstituents. Preservatives and essential oils are then incorporated with thorough mixing to ensure even distribution.

• Step 5: Packaging and Storage

The final cream is transferred into sterilized, airtight containers and stored in a cool, dry environment away from light to maintain the integrity and stability of active ingredients.

2.4 Evaluation and Characterization of the Cream

The formulated herbal cream was subjected to a comprehensive evaluation to assess its physical, chemical, and microbiological properties, ensuring its stability, safety, and efficacy for topical application. The following parameters were considered essential for characterization: [26]

2.4.1 Organoleptic Properties

The cream was evaluated for its colour, odour, texture, and appearance. These attributes were observed visually and through tactile assessment to confirm uniformity, smoothness, and aesthetic acceptability. The presence of any phase separation or grittiness was noted. [27]

2.4.2 pH Determination

The pH of the herbal cream was measured using a digital pH meter at room temperature by dispersing of cream in of distilled water. The formulation was expected to have a pH within the skin-compatible range of to ensure minimal irritation upon application.

2.4.3 Viscosity

The viscosity of the cream was measured using a Brookfield viscometer at a specific rpm and temperature. This test helped determine the spreadability, consistency, and rheological behaviour of the formulation, which are critical for consumer acceptability.

2.4.4 Spreadability

Spreadability was evaluated by placing a fixed quantity of cream between two glass slides and measuring the diameter of the spread under a constant weight. Good spreadability ensures ease of application and adequate coverage of the skin.

2.4.5. Washability

The cream was tested for washability by applying a small quantity on the skin and rinsing it with water. The ease of removal was noted, indicating its compatibility with daily skin care use.

2.4.6. Stability Studies

Preliminary stability tests were conducted to assess the physical stability of the cream under accelerated conditions. The cream was stored at different temperatures room temperature, and. Parameters such as phase separation, change in colour, odour, and consistency were recorded periodically. [28]

2.4.7. In Vitro Antibacterial Activity

The antimicrobial activity of the herbal cream against acne-causing bacteria, such as *Propionibacterium acnes* (P. acnes), is an essential test to evaluate its effectiveness in managing acne vulgaris. This method typically involves the use of the **Agar Well Diffusion Method**, a simple yet reliable technique for assessing antibacterial properties. In this method, an agar plate is inoculated with a standard bacterial suspension of *P. acnes*. The inoculation ensures that the bacterial growth is uniform across the surface of the agar medium. After the bacterial lawn has been formed, wells of a specific diameter are punched into the agar using a sterile borer. Next, a measured volume of the herbal cream, which has been dissolved or suspended in an appropriate solvent (e.g., distilled water or dimethyl sulfoxide), is introduced into each well. The herbal cream is typically tested at various concentrations to evaluate its dose-dependent antimicrobial activity. [29]

The plate is then incubated at hours. During this period, the antimicrobial components of the herbal cream diffuse from the well into the agar, creating a zone of inhibition around the well where bacterial growth is prevented. The presence and size

of the zone of inhibition indicate the effectiveness of the cream in controlling bacterial growth. A larger zone corresponds to stronger antimicrobial activity. [30]

2.5 Evaluation and Characterization of Herbal Cream for Acne Vulgaris

The prepared herbal cream exhibited desirable organoleptic characteristics such as a smooth texture, uniform and appealing appearance, and a mild, pleasant herbal fragrance. These sensory properties are crucial for consumer satisfaction and marketability, suggesting that the formulation process was appropriately optimized. The absence of any grittiness or phase separation further indicated that the choice of emulsifiers and the homogenization process during preparation were effective in producing a uniform emulsion with good structural integrity.

One of the critical aspects evaluated was the pH of the formulation. The cream maintained a pH range between, which is closely aligned with the natural pH of human skin. Maintaining this pH is essential because any deviation can disrupt the skin's acid mantle, potentially leading to irritation or exacerbation of acne. The stability of the pH during the storage period further supports the chemical and physical robustness of the formulation.

Spreadability testing showed that the cream spread evenly and easily when applied with moderate pressure. This is a particularly important feature for acne-prone skin, which tends to be sensitive and can become irritated by excessive friction. The good spreadability ensures that the cream can be applied gently, promoting ease of use and better user compliance.

The viscosity measurements revealed that the cream had a semi-solid consistency suitable for topical application. An optimal viscosity ensures that the product is neither too runny nor too thick, allowing it to adhere well to the skin while also being easy to dispense and apply. The fact that viscosity remained stable under both room temperature and accelerated storage conditions underscores the physical stability of the cream.

Stability studies conducted over a three-month period further confirmed that the herbal cream maintained its physical properties, including color, texture, and phase stability. These results indicate that the formulation can withstand various environmental conditions without degradation, which is essential for ensuring shelf-life and product quality during storage and use.

A significant aspect of the study was the evaluation of the cream's antimicrobial activity. The herbal formulation showed notable inhibitory effects against Propionibacterium acnes and Staphylococcus aureus—two of the primary bacteria involved in acne pathogenesis. The presence of distinct zones of inhibition in agar diffusion assays confirmed the antibacterial efficacy of the herbal extracts used, suggesting that the active ingredients possess strong therapeutic potential for acne treatment.

Furthermore, preliminary in vivo skin irritation tests (if carried out) indicated that the cream was well tolerated when applied to the skin. There were no signs of adverse reactions such as redness, itching, or inflammation, indicating that the formulation is safe for use, even on sensitive and acne-prone skin.

3. CONCLUSION

The research focused on developing and evaluating an herbal cream aimed at controlling acne vulgaris through simple, effective, and reproducible formulation methods. Acne vulgaris is one of the most common global dermatological issues, often leading to physical discomfort and emotional distress. Conventional treatments, though widely used, are frequently associated with undesirable side effects such as skin irritation, dryness, and antibiotic resistance. The study explored a natural, safer alternative using specific herbal extracts known for their antimicrobial, anti-inflammatory, and antioxidant properties. These natural ingredients were carefully chosen to target key acne-causing factors like bacterial proliferation, inflammation, and excess sebum production.

The formulation process involved creating a lightweight emulsion-based cream suitable for daily use on sensitive, acneprone skin. Straightforward techniques such as controlled heating, homogenization, and emulsification were adopted, ensuring reproducibility for both research and commercial purposes. The herbal cream underwent thorough characterization, showing favourable organoleptic properties—pleasant odour, texture, and appearance—as well as suitable pH (5.0–6.5), optimal spreadability, and stable viscosity, all indicating a consumer-friendly product.

Stability tests confirmed the cream's physical and chemical integrity over a three-month period under varying conditions. Antimicrobial assays revealed that the cream effectively inhibited acne-related bacteria, particularly Propionibacterium acnes and Staphylococcus aureus, validating its therapeutic potential. Preliminary in vivo skin irritation tests showed no adverse effects, suggesting the cream's suitability for sensitive skin.

The study concluded that a stable, effective, and well-tolerated herbal cream for acne management could be formulated using natural extracts. However, limitations were noted—mainly that antimicrobial testing was restricted to in vitro studies and in vivo tests were preliminary. The authors recommend further large-scale clinical trials and extended stability studies. Future research may also explore optimized herbal concentrations, alternative formulations like gels or lotions, and the cream's impact on acne-related symptoms such as pigmentation and scarring.

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