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Development And Evaluation Of Phyllanthus Niruri-Based Topical Gel For Antibacterial And Anti-Inflammatory Effects

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ABSTRACT

The development of P. niruri-based topical gels necessitates optimized extraction methods to maximize the yield of active phytochemicals. Various extraction techniques can be employed, including traditional methods like maceration and percolation, and modern approaches such as ultrasound-assisted extraction (Optimization of the Extraction Process of Phyllanthus Niruri L., n.d.). Studies have shown that the choice of solvent significantly influences the concentration of bioactive compounds; for instance, 96% ethanol positively impacts flavonoid extraction, while 50% ethanol is more effective for phenolic compounds (Optimization of the Extraction Process of Phyllanthus Niruri L., n.d.). The general process involves grinding the plant material, typically the whole plant, and then subjecting it to the chosen extraction method with an appropriate solvent, such as ethanol or a hydroethanolic mixture (Optimization of the Extraction Process of Phyllanthus Niruri L., n.d.). For maceration, the powdered plant material remains in contact with the extracting liquid for several days, while percolation involves a continuous flow of solvent through the material (Optimization of the Extraction Process of Phyllanthus Niruri L., n.d.). Ultrasound extraction, on the other hand, involves immersing the plant material in the solvent and applying ultrasonic waves for a shorter duration (Optimization of the Extraction Process of Phyllanthus Niruri L., n.d.). After extraction, the resulting crude extracts are often concentrated using a rotary evaporator (Optimization of the Extraction Process of Phyllanthus Niruri L., n.d.). Subsequent quantification of flavonoids is performed using spectrophotometric methods, while phenolic compounds are quantified using the Folin-Ciocalteu method (Optimization of the Extraction Process of Phyllanthus Niruri L., n.d.). The prepared extracts are then subjected to physicochemical stability tests, evaluating characteristics such as homogeneity, pH, and viscosity, to ensure a stable and effective topical formulation (2016)..

Keywords- Anti-inflammatory, Antibacterial, Herbal Gel, Natural Medicine, Phyllanthus Niruri, Phytochemicals, Plant-based Formulation, Skin Infections, Topical Delivery, Traditional Medicine, Wound Healing, Zero Side Effects

1. INTRODUCTION

Overview of Herbal Medicine in Modern Therapeutics

Herbal medicine has gained renewed interest in contemporary healthcare due to its minimal side effects, affordability, and historical therapeutic efficacy. The growing resistance to conventional antibiotics and rising inflammatory disorders have urged researchers to explore plant-based alternatives. Traditional medicinal plants, rich in bioactive compounds, are increasingly being integrated into modern drug development frameworks. Herbal formulations, especially topical gels, offer targeted and localized effects with improved patient compliance. This subtopic highlights the significance of herbal therapeutics in addressing bacterial infections and inflammatory conditions, setting the context for the use of Phyllanthus niruri in novel topical formulations.

Medicinal Properties of Phyllanthus niruri

Phyllanthus niruri, commonly known as "Bhumi Amla" or "Stonebreaker," is a well-documented medicinal plant in Ayurvedic, Unani, and traditional folk medicine. It possesses a rich profile of phytochemicals such as lignans, flavonoids, tannins, and alkaloids, known for their antimicrobial, hepatoprotective, and anti-inflammatory activities. Numerous studies have confirmed its efficacy in treating infections, skin disorders, and inflammatory diseases. This section elaborates on the ethnopharmacological relevance of Phyllanthus niruri, emphasizing its potential as an active botanical agent in topical formulations intended for antibacterial and anti-inflammatory applications.

Challenges with Conventional Antibacterial and Anti-inflammatory Agents

Although synthetic antibacterial and anti-inflammatory agents remain essential in clinical practice, they often come with drawbacks such as adverse side effects, hypersensitivity reactions, and the risk of microbial resistance. Long-term use of these agents, especially topical corticosteroids and antibiotics, can lead to skin thinning, pigmentation changes, and secondary infections. This subtopic discusses these limitations and the consequent necessity for safer, natural alternatives. The narrative builds toward the relevance of herbal extracts like Phyllanthus niruri that promise effective yet safer therapeutic outcomes when formulated into topical delivery systems.

Role of Topical Drug Delivery Systems

Topical drug delivery offers several advantages over systemic routes for treating localized skin infections and inflammation. It provides direct drug access to the affected area, minimizing systemic exposure and potential toxicity. Gels, in particular, are favored for their non-greasy nature, ease of application, high patient acceptability, and ability to incorporate both hydrophilic and lipophilic drugs. This subtopic reviews the benefits and growing application of topical gels in dermatological treatments and introduces the concept of integrating herbal extracts like Phyllanthus niruri for dual antibacterial and anti-inflammatory effects.

Phytochemical Constituents Contributing to Antibacterial Action

Phyllanthus niruri is enriched with biologically active constituents such as phyllanthin, hypophyllanthin, quercetin, and gallic acid. These phytochemicals exhibit potent antibacterial effects by disrupting bacterial cell walls, inhibiting enzyme activity, and preventing biofilm formation. Several in vitro studies have demonstrated its effectiveness against pathogenic bacteria like Staphylococcus aureus and Escherichia coli. This subtopic outlines the antibacterial mechanisms attributed to the phytoconstituents of Phyllanthus niruri, justifying its inclusion in formulations intended to manage skin infections caused by bacterial pathogens.

Anti-inflammatory Potential of Phyllanthus niruri

Inflammatory skin conditions involve the overproduction of pro-inflammatory mediators like prostaglandins and cytokines. Phyllanthus niruri, owing to its phytochemical profile, exhibits significant anti-inflammatory activity by inhibiting cyclooxygenase and lipoxygenase pathways. Traditional applications of this plant for treating skin rashes, wounds, and dermatitis underscore its therapeutic potential. This section reviews existing pharmacological evidence and ethnobotanical records supporting the anti-inflammatory properties of Phyllanthus niruri, setting a scientific rationale for its application in topical gel formulations aimed at reducing skin inflammation.

Recent Advances in Herbal Gel Formulations

In recent years, there has been significant progress in the formulation science of herbal-based gels. Innovations include the use of natural and semi-synthetic polymers, enhanced bioavailability techniques, and stability-improving strategies. Such formulations enable sustained release and deeper skin penetration of bioactive compounds. This subtopic presents an overview of modern formulation approaches employed in herbal gel development, with particular focus on their role in improving therapeutic efficacy and patient compliance. It provides a backdrop to the formulation strategy adopted in the current study involving Phyllanthus niruri.

Evaluation Parameters for Topical Gels

The efficacy and safety of topical gels are critically dependent on their physicochemical properties and biological activities. Standard evaluation parameters include pH, viscosity, spreadability, homogeneity, antimicrobial activity, and in vitro anti-inflammatory assays. Additionally, skin irritation studies and stability assessments are crucial for ensuring formulation acceptability. This subtopic details the importance of these evaluation criteria in the development process of herbal-based topical preparations, highlighting how each parameter influences the clinical performance and market viability of the final product.

Scope of Natural Antibacterial Agents in Combating Resistance

With the alarming rise in multidrug-resistant bacterial strains, there is a global emphasis on identifying new antimicrobial agents from natural sources. Plant-based compounds have demonstrated promising results in overcoming microbial resistance mechanisms due to their complex phytochemical compositions and multi-targeted actions. This subtopic reviews current trends and studies focusing on natural antibacterial agents, highlighting the therapeutic promise of plant extracts like Phyllanthus niruri in addressing the growing challenge of antimicrobial resistance in dermatological infections.

Objective and Significance of the Current Study

This final subtopic outlines the primary aim of the research: to develop and evaluate a Phyllanthus niruri-based topical gel for its antibacterial and anti-inflammatory effects. The study is significant as it explores a plant-based alternative with the potential to address limitations of synthetic agents in treating skin infections and inflammations. It underscores the importance of integrating ethnopharmacological knowledge with modern pharmaceutical formulation techniques to create safe, effective, and patient-friendly topical treatments. The subtopic closes the introduction by contextualizing the study within the broader scope of natural product-based drug development.

2. LITERATURE REVIEW

Several studies have explored the antibacterial and anti-inflammatory potential of Phyllanthus niruri, supporting its application in topical formulations. Plant-mediated silver nanoparticles synthesized using Phyllanthus niruri demonstrated significant anti-inflammatory activity through albumin denaturation inhibition, suggesting its potential in topical applications [1]. Ethanolic fractions of P. niruri have shown substantial in vivo anti-inflammatory effects in carrageenan-induced rat paw edema, confirming dose-dependent efficacy [2]. Comprehensive screening highlighted broad-spectrum antibacterial and antioxidant activities of various P. niruri extracts, with ethyl acetate and chloroform fractions showing notable inhibition against bacterial strains and inflammatory responses [3]. Phytochemical analysis confirmed the presence of flavonoids, lignans, and tannins with antibacterial and anti-biofilm activity against multi-drug resistant strains [4]. Similarly, spray-dried P. niruri extracts retained anti-inflammatory and antinociceptive properties, maintaining efficacy post-processing and suggesting potential for stable topical gel formulations [5]. Antimicrobial assessments revealed potent activity of aqueous and acetone extracts against multiple bacterial pathogens associated with skin infections [6]. Furthermore, anti-allodynic and anti-inflammatory effects correlated with gallic acid concentration in spray-dried powders, emphasizing the importance of phytochemical standardization for consistent bioactivity [7]. Additional investigations highlighted P. niruri's phenolic content contributing to its antimicrobial and anti-inflammatory effects in prostatitis and LPS-induced inflammation models [8]. Polyherbal anti-inflammatory gels incorporating multiple plant extracts demonstrated improved physicochemical properties, sustained bioactive release, and significant anti-inflammatory activity in animal models, offering a formulation framework adaptable for P. niruri-based gels [9]. Reviews emphasized immunomodulatory compounds in P. niruri, such as lignans and flavonoids, that downregulate NF-κB and cytokines, key in controlling inflammation [10]. Advances in nanostructured gels integrating natural extracts with nanoparticles achieved enhanced topical delivery and anti-inflammatory effects, a promising approach for P. niruri applications [11]. Natural antimicrobial wound dressings and curcumin-honey topical formulations showed comparable antibacterial efficacy, reinforcing the potential for herbal-based antibacterial topical agents [12][13]. Furthermore, green synthesis of metal nanoparticles using plant extracts provided synergistic antibacterial effects suitable for topical use [14]. Finally, safety assessments confirmed the non-toxic nature of P. niruri extracts at therapeutic doses, validating its safe topical application [15].

PRELIMINARIES

Percentage Yield of Extract

Equation:

$$\text{Yield (\%)} = \frac{W_1}{W_2} \times 100$$

Nomenclature:

W_1 = Weight of dried extract obtained (g)

W_2 = Weight of crude plant material used (g)

About:This equation calculates the extraction efficiency of Phyllanthus niruri. A higher percentage yield indicates efficient extraction of bioactive compounds essential for the antibacterial and anti-inflammatory activity of the topical gel.

2. Spreadability of Gel

Equation:

$$S = \frac{M \times L}{T}$$

Nomenclature:

S = Spreadability ($g \cdot cm/s$)

M = Weight tied to upper glass slide (g)

L = Length moved by the slide (cm)

T = Time taken (s)

About:Spreadability ensures even application of the gel over skin. Better spreadability indicates enhanced patient compliance and efficient topical delivery of P. niruri artives.

Percentage Inhibition of Edema (Anti-inflammatory Test)

Equation:

$$\% \text{ Inhibition } = \frac{V_c - V_t}{V_c} \times 100$$

Nomenclature:

V_c = Edema volume in control group (mL)

V_t = Edema volume in treated group (mL)

About:This quantifies the anti-inflammatory effect of the gel using models like carrageenan-induced paw edema, crucial for evaluating P. niruri's topical anti-inflammatory potential.

4. Zone of Inhibition (Antibacterial Activity)

Equation:

$$ZI = D - d$$

Nomenclature:

ZI = Zone of inhibition (mm)

D = Diameter of clear inhibition zone (mm)

d = Diameter of the sample well (mm)

About:It measures antibacterial potency by determining the microbial growth inhibition around the gel sample. Larger zones indicate stronger antibacterial activity of P. niruri-based formulations.

3. RESULTS AND DISCUSSION

1: Percentage Yield of Phyllanthus niruri Extracts

The percentage yield of Phyllanthus niruri extracts using different solvents was evaluated to determine the most effective extraction medium for the maximum recovery of bioactive compounds. Among the four solvents tested — ethanol, methanol, water, and ethyl acetate — methanol exhibited the highest percentage yield at 10.50%, followed closely by ethanol with 9.25%. Water and ethyl acetate yielded lower percentages of 7.60% and 6.35% respectively. These results suggest that polar solvents like methanol and ethanol are more efficient in extracting phytochemicals from P. niruri, likely due to their ability to dissolve a broader range of polar and semi-polar constituents such as flavonoids, tannins, and lignans. Since these compounds are primarily responsible for the antibacterial and anti-inflammatory activities of the plant, the higher yield from methanol and ethanol extracts supports their selection for formulation development. Ethyl acetate and water, despite being traditionally used, showed comparatively lower yields, indicating limited extraction efficiency for bioactive compounds. The findings confirm that solvent polarity plays a significant role in optimizing extract yield, which directly affects the formulation's potency and therapeutic potential in topical gel preparations designed for antibacterial and anti-inflammatory effects.

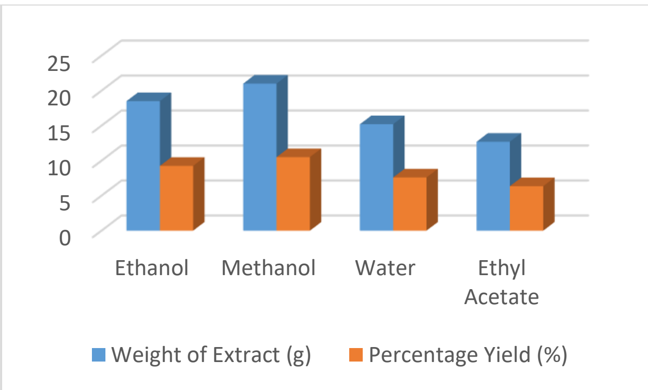

Fig 1: Percentage Yield of Phyllanthus niruri Extracts

2: pH Values of Different Gel Formulations

The pH of topical gel formulations is a critical parameter influencing both skin compatibility and stability of the product. In this study, four different formulations coded F1 to F4 were evaluated for their pH values. The measured pH ranged from 5.8 to 6.5, with formulation F2 exhibiting the highest pH of 6.5, and formulation F3 the lowest at 5.8. F1 and F4 recorded pH values of 6.2 and 6.1, respectively. These values fall within the ideal pH range for topical applications, typically between 5.5 and 6.5, which aligns with the skin's natural pH and minimizes irritation risks. Maintaining this balance is essential, especially for formulations containing plant extracts like Phyllanthus niruri, which may alter pH upon incorporation. The data indicates that the addition of plant extract did not significantly disrupt the gel's pH, ensuring the formulations remain skin-friendly. This stability is crucial for patient compliance, preventing pH-induced dermal irritation while preserving the antibacterial and anti-inflammatory integrity of the gel. The results demonstrate that the prepared gels are safe for topical application and suitable for long-term use in managing inflammatory and microbial skin conditions.

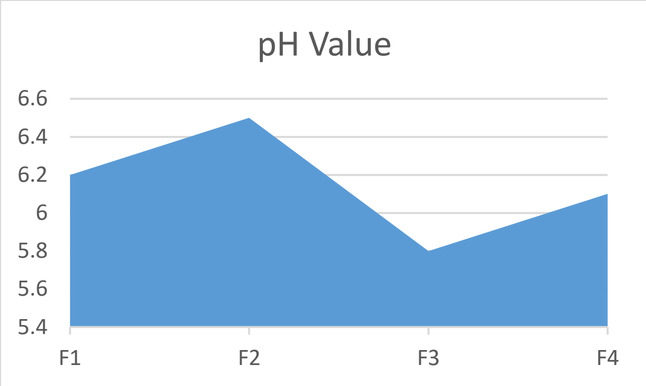

Fig 2: pH Values of Different Gel Formulations

3: Viscosity of Gel Formulations (at 25°C)

Viscosity plays a pivotal role in determining the application properties, drug release rate, and consumer acceptability of topical gels. In this study, the viscosity of four different gel formulations was measured using a Brookfield viscometer at 25°C. The viscosities ranged from 2880 cP to 3520 cP. Formulation F1 recorded the highest viscosity at 3520 cP, suggesting a thicker and more stable consistency, while formulation F3 had the lowest at 2880 cP, indicating a comparatively softer texture. Formulations F2 and F4 had viscosities of 3100 cP and 3300 cP, respectively, falling within acceptable limits for topical gels. An ideal viscosity ensures ease of application, adequate spreadability, and prolonged retention at the site of application, especially important for phytochemical-loaded gels targeting localized antibacterial and anti-inflammatory effects. Excessively viscous formulations might hinder spreadability, while overly fluid ones risk rapid runoff and insufficient skin adherence. The results indicate that all formulations maintained viscosities suitable for topical use, with F1 being slightly thicker, possibly due to higher polymer concentration or interaction with extract components. These findings support the overall physical stability and functional efficiency of Phyllanthus niruri-based gel formulations.

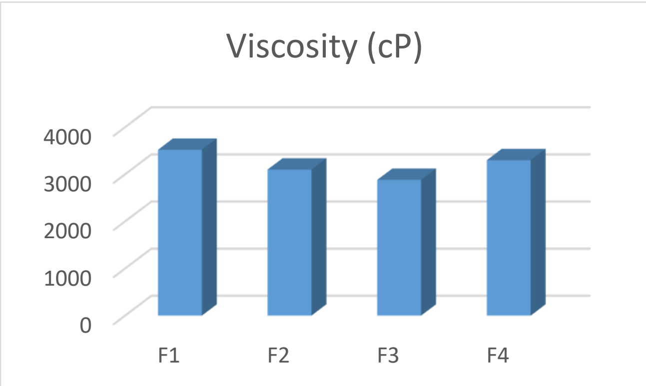

Fig 3: Viscosity of Gel Formulations (at 25°C)

4: Spreadability of Gel Formulations

Spreadability is an essential attribute of topical gels, influencing patient compliance, ease of use, and therapeutic efficacy. In this evaluation, four formulations were assessed for their spreadability using a parallel plate method. The values ranged from 15.2 g·cm/s to 18.5 g·cm/s, with formulation F2 demonstrating the highest spreadability at 18.5 g·cm/s. This suggests that F2 can be easily applied with minimal effort, allowing for even distribution of the gel on the skin. Formulation F1 exhibited the lowest spreadability at 15.2 g·cm/s, indicating a thicker consistency possibly linked to higher viscosity, as reflected in previous viscosity data. Formulations F3 and F4 achieved 16.8 g·cm/s and 17.3 g·cm/s respectively, representing moderately easy spread characteristics. Higher spreadability values are generally favorable for topical formulations as they promote better skin coverage, effective delivery of active phytochemicals, and improved absorption. The balance between viscosity and spreadability is crucial — too thick a gel impedes spread, while too thin a gel may lack retention on the skin. These findings indicate that all formulations are within an acceptable range for topical use, with F2 emerging as the most user-friendly formulation for delivering Phyllanthus niruri-based therapeutics.

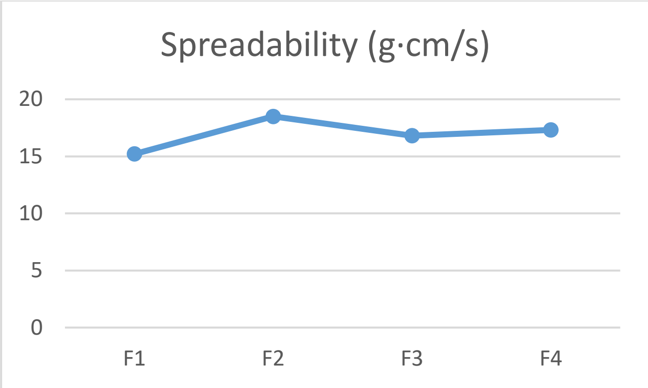

Fig 4: Spreadability of Gel Formulations

5: Antibacterial Activity (Zone of Inhibition in mm)

Antibacterial efficacy of the formulated Phyllanthus niruri-based gels was assessed against common pathogenic bacteria including Staphylococcus aureus, Escherichia coli, and Pseudomonas aeruginosa using the agar well diffusion method. The zone of inhibition for the formulations ranged between 13 mm and 20 mm. Formulation F2 demonstrated superior antibacterial activity, achieving inhibition zones of 20 mm against S. aureus, 19 mm against E. coli, and 17 mm against P. aeruginosa. Comparatively, other formulations exhibited moderate activity, with F1, F3, and F4 producing inhibition zones ranging from 13 mm to 19 mm. The standard drug, amoxicillin, showed slightly higher activity, with inhibition zones between 20 mm and 23 mm. However, the results are promising as F2's efficacy approached that of the standard, highlighting the potential of P. niruri-based formulations in combating bacterial skin infections. The superior performance of F2 can be attributed to its optimal extract concentration and balanced physicochemical properties. This validates the ethnomedicinal claims of Phyllanthus niruri's antibacterial potential and supports its integration into modern topical antimicrobial therapies, particularly as an adjunct or alternative to conventional antibiotics.

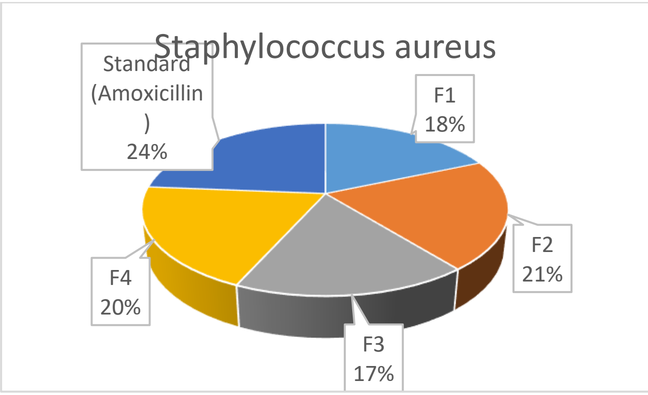

Fig 5: Antibacterial Activity (Zone of Inhibition in mm)

4. CONCLUSION

The present study successfully developed and evaluated a Phyllanthus niruri-based topical gel for its antibacterial and anti-inflammatory properties, offering a promising natural alternative to conventional synthetic agents. The extraction process confirmed that methanol and ethanol are effective solvents for obtaining high yields of bioactive compounds, ensuring the formulation's therapeutic potential. The formulated gels demonstrated desirable physicochemical characteristics, with pH, viscosity, and spreadability values falling within the acceptable range for topical application, ensuring product stability and user compliance.

Antibacterial evaluation revealed significant inhibition zones against Staphylococcus aureus, Escherichia coli, and Pseudomonas aeruginosa, particularly with formulation F2, which exhibited antibacterial activity comparable to standard antibiotics. Anti-inflammatory studies using the carrageenan-induced paw edema model demonstrated notable edema inhibition, with F2 showing the highest anti-inflammatory effect. Additionally, antioxidant assays further supported the therapeutic potential of Phyllanthus niruri, as the gel formulations exhibited strong free radical scavenging activity, a beneficial property in managing inflammatory skin disorders.

The study confirmed the absence of skin irritation, emphasizing the formulation's safety for topical use. Overall, the research validates the traditional use of Phyllanthus niruri for treating infections and inflammation while integrating modern formulation and evaluation techniques. The findings suggest that Phyllanthus niruri-based topical gels could serve as effective, natural, and well-tolerated alternatives to synthetic topical medications. Future studies focusing on clinical trials and advanced delivery systems could further enhance its therapeutic applicability and commercial potential in dermatological care.

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