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## Formulation And Evaluation Of An Herbal Gel Containing Calendula Officinalis And Aloe Vera Gel For Topical Application

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Abstract: The last few years have witnessed a rapid increase in the popularity of herbal and natural cures, thus leading to growing interest in plant-based models for dermatological applications. This present investigation deals with the formulation and evaluation of a herbal topical gel containing extracts of the well-known plants Calendula officinalis and Aloe vera gel with anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties. Thus, the prime objective was directed at developing stable and effective herbal gels for topical application to promote skin healing and enhance dermal health. The Aqueous extraction method was used to prepare the Calendula officinalis plant extract where else Aloe vera gel was freshly prepared using mature leaves. Using Carbopol 940 as the gelling agent and combining it with glycerin as a humectant, different formulations of gel types were done. The formulations prepared were then subjected to a physicochemical parameter evaluation regarding pH, spreadability, viscosity, homogeneity, extrudability, and skin irritation. Of all formulations tested, the optimized gel has shown interesting pH, close to skin pH, good spreadability, and high extrudability without visible signs of phase separation or microbial growth. In addition, in vitro antimicrobial activity was carried out using the well diffusion method against common skin pathogens such as Staphylococcus aureus and Escherichia coli, with zones of inhibition observed to be promising. No irritation or adverse reactions were reported.

*Keywords:* Calendula Officinalis, Aloe vera, Topical Formulation, Wound Healing, Anti-inflammatory activity, Aqueous extraction.

#### I. INTRODUCTION

In the last decades, herbal formulations gained much importance into pharmaceutical and dermatology research because of their biocompatibility, fewer side effects, and complete healing of a condition. This realization sees more and more remedies being sought from nature since surgeons and pharmaceutical industries started experimenting with synthetic drugs for chronic skin diseases and the like-acute inflammations, minor wounds, and low-life. Out of numerous herbal dosages forms available, topical gels, in particular, have most commonly been administered by patients due to their nongreasy feel, easy application, and quicker drug release rate, thereby allowing delivery of the active constituents directly at the affected site with very less systemic absorption.

Topical herbal gels are wonderful antidotes that help heal wounds, reduce inflammation, hydrate the skin, and provide relief to burns, cuts, and rashes. Their hydrophilic nature and the ability to keep moist conditions

also aid tissue regeneration and repair at the cellular level. The amalgamation of plant-derived bioactive compounds in gel formulations is seen more useful to natural medicines than going alone.

Two botanicals that have served their pay with use in skin care and wound healing are, respectively, those of Calendula and Aloe vera. These two plants have been long in use in traditional medicine and currently at least in pharmacology stand confirmed for their dermatoprotective properties.

#### Calendula officinalis

Also referred to as pot marigold, Calendula officinalis is a flowering herbaceous plant used for various dermatological ailments. The dried flowers of this plant have medicinal properties and have been used in Ayurvedic, Unani, and European phytotherapy. Botanical

#### **Classification:**

• Kingdom: Plantae • Family: Asteraceae • Genus: Calendula

• Species: Calendula officinalis L.

#### **Common Names:**

• English: Pot marigold

• Hindi: Zergul · Sanskrit: Zhandu • Marathi: Jhendu

#### **Habitat and Distribution:**

Calendula officinalis is originally from Southern Europe and the Mediterranean but has now been introduced and widely cultivated throughout temperate regions worldwide.

#### **Phytoconstituents:**

- Triterpenoids: for example, faradiol esters and lupeol.
- JCR • Flavonoids: such as quercetin, kaempferol, and isorhamnetin derivatives.
- Saponins.
- Essential oils:  $\alpha$ -cadinol and  $\gamma$ -cadinene; and
- Carotenoids: including lutein and zeaxanthin.

#### **Pharmacological Activities:**

- Wound healing: Upregulate fibroblast proliferation and epithelial regeneration.
- Anti-inflammatory: Inhibits pro-inflammatory cytokines such as: TNF-α, IL-6, etc. and enzymes like COX-2.
  - Antimicrobial: Active against Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans.
  - Antioxidant: Free radical scavenging, decreased lipid peroxidation.

Many studies in vivo and vitro infer that topical Calendula officinalis could be successful in the treatment of superficial burns, ulcers, acne, and inflammatory dermatopathies.



fig. no. 1 calendula officinalis plant

#### Aloe vera

Aloe vera or Aloe barbadensis Miller has been known for its skin-soothing and skin-repairing properties for centuries. The thick, fleshy leaves yield inner gel, which is a rich cocktail of polysaccharides and bioactive molecules.

#### **Botanical Classification:**

- Kingdom: Plantae
- Family: Asphodelaceae (Earlier considered under Liliaceae)
- Genus: Aloe
- Species: Aloe vera (L.) Burm.f.

#### **Common Names:**

Hindi: Ghritkumari
Sanskrit: Kumari
English: Aloe
Marathi: Korphad

#### **Habitat and Distribution:**

Aloe vera is a succulent xerophyte native to North Africa, which today is cultivated extensively in the arid parts of India including Rajasthan, Gujarat, and Maharashtra. Aloe vera takes less water and flourishes in well-drained soil.

#### **Macroscopic Characteristics:**

Leaves: Juicy, thick, lanceolate with serrated margins, pale green; inside is filled with mucilaginous gellike substance.

Odour: Slightly pronounced and characteristic.

Taste: Bitter (latex); bland (gel).

#### **Major phyto-constituents:**

- Polysaccharides (e.g. acemannan)
- Vitamins (A, C, E, B1, B2, B6, B12, folic acid)
- Enzymes (e.g. bradykinase)
- Salicylic acid
- Lignin and saponins
- All the minerals (magnesium, calcium, zinc etc.)

#### **Pharmacological actions:**

- The moisturization and dehydration-hydration-hydrating the stratum corneum allowing the restoration of barrier function onto the skin.
- Anti-inflammatory- The skin inflammation and redness due to the inhibition of the production of prostaglandins.
- Antimicrobial- E. coli, S. aureus, Candida spp.
- Wound healing- stimulation of collagen synthesis and migration of epithelial cells.
- The use of aloe vera gel in veterinary dermatology is indicated for the treatment of skin burns, abrasions, acne, and eczema.



fig. no. 2 aloe vera gel

#### Rationale for Combined Use in a Gel Formulation

The reason for combining the substances into a gel formulation is that their topical applications of Calendula officinalis extract and Aloe vera gel would show a synergistic effect. Calendula enhances the remodeling of tissues faster and combats any microbial infections whereas Aloe vera rehydrates, soothes, and regenerates the epithelium.

You are more likely to develop a synergistic effect by topical applications of the extract of Calendula officinalis and Aloe vera gel. Calendula promotes rapid remodeling of the tissues and prevents infection by microbes, while Aloe vera renews hydration, soothing action, and epithelial regeneration. They can thus provide a totalizer natural approach to wound treatment.

Furthermore, such formulation gel vehicles have the best properties because they are non-greasy, aesthetically pleasing, and exhibit better drug release profiles. They further maintain moisture in the wound through hydrogels, thereby enhancing effective healing. The combination of these two agents to form a polyherbal gel would thus bring about an efficacious, stable, and user-friendly product meeting the trend of consumers who prefer plant-based therapeutic options.

#### Significance of Study

There has been a growing need for natural, safe, and inexpensive substitutes for synthetic topical agents, consequently making herbal formulations the most favorable candidates for dermatological research. The current study bears both scientific and therapeutic significance, particularly in the context of skin ailments such as — more or less commonly encountered wounds, cuts, minor burns, irritations, and inflammation, which are often inadequately treated because of side effects associated with chemical-based products.

#### 1. The Promotion of Herbal-Based Innovation in Topical Therapy

The formulation and evaluation of a polyherbal gel using C. officinalis and A. vera aim to develop a product that forms a synergy from well-established pharmacological actions of both the botanicals. In fact, each of these extracts possesses efficacy for wound healing and skin repair in its own right; in hydrogels, such combinations may improve therapeutic outcomes with their anti-inflammatory, antimicrobial, and regenerative effects.

#### 2. The Safer Offspring for Skincare

Topical synthetic agents contain compositions, such as alcohol, parabens, or steroids, which continue to aggravate irritation or dryness or long-term side effects. Herein comes the application of this herbal gel formulation-opting for a more biocompatible preparation that is less irritating for concerns over long-term or repeated use especially on sensitive skin or chronic dermatological conditions.

#### 3. Conformity with AYUSH as well as Global Herbal Trends

The project is in line with AYUSH (Ayurveda, Yoga, Unani, Siddha and Homeopathy) mission in India "to validate and modernize traditional medicine through scientific approaches." Evidently, there is a global trend towards evidence-based herbal therapeutics. This study contributes to that narrative by providing a validated formulation process that will include extraction, formulation, tests for physicochemical parameters, and overall assessment of bioactivity.

#### 4. Relevance to Academic and Industry

This hands-on experience in development of phytopharmaceutical formulation is part of the academic objective of the study as a learning outcome within the pharmacy curriculum. From the view of the industry, this research offers a competitive product for possible commercialization into the cosmeceutical or dermatological market as consumers continue to show concern over clean label and plant-based skin-care products.

#### **Objectives of the Study**

This study aims to create and test a topical herbal gel that's safe, stable, and works well. It uses extracts from Calendula officinalis and Aloe vera gel to boost the herbs' effects. The study also plans to:

- 1. Extract Calendula officinalis with water to shield heat-sensitive plant compounds.
- 2. Add fresh or stabilized Aloe vera gel to the mix.
- 3. Make herbal gels with the right additives and polymers to keep them stable, thick, and able to soak into skin.
  - 4. Check physical and chemical properties, including: pH, thickness, how well it spreads, evenness
  - 5. Test how well it kills skin germs like Staphylococcus aureus and Pseudomonas aeruginosa.
- 6. See how it holds up in different conditions, following ICH rules.
- 7. Maybe compare it to other herbal products on the market.

#### Scope and Limitations: A discussion of the study's scope and limitations:

The objective of this project is the preparation of an herbal gel containing Calendula officinalis extract and Aloe vera gel for use as a safe, effective, and natural topical agent to promote wound healing, reduce inflammation, and regenerate skin. The project includes:

- Making Aloe vera gel from fresh plant leaves in a controlled setting.
- Creating a stable hydrogel with a suitable gelling agent (like Carbopol 940).
- Testing physical and chemical properties such as pH how well it spreads, thickness, uniformity, and stability.
- Doing basic biological tests, like checking its effect on common microbes (such as Staphylococcus aureus, E. coli).
- Writing up findings and discussing them as per university rules. This research helps us understand how to mix plant-based ingredients in a topical gel to boost their healing effects.

#### Limitations of the Study

1. Stability Testing Over a Short Period:

This study could consider short or short-term stability tests in the laboratory without actual long-term use tests.

2. Limited Analytical Tools:

Not in modern advanced testing methods-glass macros-caliber methods like HPLC to measure and assess plant compounds or FTIR to check chemical compatibility, most likely depending on what is available and also the scope of the project.

#### 3. Small Scientifically Produced Batch Size

Scientists have formulated and tested formulas on a small scale, which may not show all the problems coming into large-scale production (i.e., how long it lasts, how well preservatives work, or how it interacts with packaging).

4. Constraint by Funds and Resources:

Pursuing advanced-quality purchase of all raw materials and solvents, along with others to meet standards.

### Application of the Formulation of an Herbal Gel Containing Calendula Officinalis Extract and Aloe vera Gel

An herbal gel is prepared from the combination of Calendula officinalis extract, freshly prepared Aloe vera gel, and biosynthesized silver nanoparticles (AgNPs). The prepared gel is applied topically on human skin with the main objective to formulate it for multiple purposes as an alternative natural therapeutic for a variety of cutaneous (skin-affecting) conditions, particularly with emphasis on inflammation, microbial infection, burns, wounds, and skin irritations.

The formulation thus garners the Phytotherapeutic synergy of Calendula officinalis and Aloe Vera, which have been observed under traditional and modern medicinal systems for specific dermatological activity. The infusion of silver nanoparticles extends the microbial spectrum thereby providing maximum protection and healing.

#### Their Therapeutic Applications

- 1. Wound Healing and Skin Regeneration
- Calendula officinalis features flavonoids, triterpenoids, and saponins as the major agents that have been proved to stimulate fibroblast proliferation, angiogenesis, and collagen remodelling in wound healing (Preethi & Kuttan, 2009)
- The polysaccharides, ace Mannan, which also encourage keratinocyte proliferation and epithelial repair, are found in Aloe Vera gel.
- That indeed creates a moist wound environment, proven to speed up the healing process and reduce scarring.

Application: Minor cuts, surgical wounds, lacerations, pressure wounds.

#### 2. Burns and Sunburn

- The property of cooling and hydrating has been derived from the mucilaginous content of Aloe vera, which soothes the skin through the gel.
- Calendula functions by suppressing the release of pro- inflammatory cytokines such as IL-6 and TNF-α.
- This formulation can be applied to first-degree and superficial second-degree burns for reduction of pain and inflammation, with promotion of healing thereafter.

Application: Sunburns, minor thermal burns, radiation dermatitis.

#### 3. Inflammatory skin diseases:

- It is effective in treating eczema, contact dermatitis and psoriasis by:
- It helps in itching and redness and improves skin dryness.
- It provides an all-natural alternative to synthetic corticosteroids with fewer side effects.
- Enhance skin absorption without clogging pores. Its non-greasy base gel makes it ideal for this purpose. Application: Dermatitis, eczema, allergic rashes, episodes of psoriasis.

#### 4. Acne and Bacterial Skin Infections

- Amazing silver nanoparticles (AgNPs) derived from Calendula extract have endued with the property of antibacterial action against Staphylococcus aureus and Propionibacterium acnes among many other mainstream germs (Rai et al., 2009).
- Aloe vera provides a perfect answer to normalize sebum levels and keeps the skin hydrated with antiinflammatory post-acne action.

• The herb formulation is without pore clogging materials so, therefore, very safe for usage with acneprone skins.

Application: Effective for acne lesions, bacterial folliculitis, and impetigo.

- 5. Fungal and antifungal support
- Antifungal saponin and essential oils co-produced by different species of Calendula affording activity against Candida albicans and Aspergillus spp.
- Using the gel can help treat fungal rashes with the adjunct of standard antifungal agents.

Application: For tinea infections (such as athlete's foot), candidiasis, and intertrigo.

- 6. Care after the event and post-surgery
- The skin barrier can be broken after cosmetic or dermatological treatments such as dermabrasion, microneedling or minor surgery.
- This gel helps in fast recovery and acts as an anti-inflammatory agent that prevents secondary infection. Application: Post-laser application and wound care after suturing.

#### Advantages of Topical Application

- Localized action: This method delivers active ingredients right to the problem area without spreading throughout the body.
- Reduced side effects: It tends to have fewer side effects compared to oral medications or steroid creams.
- Patient compliance: With a non-greasy feel, natural ingredients, and an appealing look, it's easy for users to stick with.

#### 7. Hair and Scalp Health

- Calendula officinalis extract boosts blood flow to the scalp and has anti-inflammatory benefits that can calm an irritated or itchy scalp.
- Its antifungal and antibacterial properties help tackle dandruff and scalp infections caused by Malassezia and Staphylococcus species.
- Aloe vera gel is packed with enzymes that help repair dead skin cells on the scalp, promoting healthy hair growth and reducing hair loss.
- The moisturizing qualities of Aloe vera work to prevent dryness and flakiness on the scalp without leaving an oily residue.

Application: Useful for dandruff, scalp irritation, weak hair roots, mild alopecia, and hair loss due to scalp inflammation.

#### Significant in Herbal Dermatologyand Public Health

Herbal dermatology and public health are of great significance.

- They harmonize with the goals of evidence-based herbal medicine by marrying traditional botanical knowledge with modern pharmaceutical formulation.
- Being herbal is an affordable, accessible, and biocompatible alternative for most synthetic topical products.
- Herbs are most suitable for operations in rural or resource-limited settings where sterile pharmaceuticals may be hard to come by.

#### II. LITERATURE REVIEW-OVERVIEW

In recent years, there has been a steady rise in interest in the incorporation of topical medicinal plant preparations, justifiably so, on account of their natural origin, therapeutic actions, and lesser side effects. Another factor that places Calendula officinalis and Aloe vera in the limelight is their amazing pharmacological properties. To this note, Calendula officinalis is said to exhibit anti-inflammatory, antiseptic, antioxidant, and wound healing properties. Among the phytochemicals are flavonoids, triterpenoids, carotenoids, and saponins, helping in wound healing and also in providing some protection against microbial infections. Some reports tend to suggest that topical calendula ointment application aids in the acceleration of wound healing through epithelial regeneration and the alteration of inflammatory mediators [1,2].

The gel is extracted from inside mucilaginous tissue of Aloe vera leaves for use in cosmetics and pharmaceuticals. Due to its water-retaining, anti-inflammatory, and healing properties, it is well known in cosmetic and pharmaceutical circles. Several workers have attempted to show the efficacy of Aloe vera in skin maladies, burns, and wounds, which they attribute largely to polysaccharides, enzymes, and vitamins [3,4].

Green synthesis of silver nanoparticles (AgNPs) from plant extracts is an eco-friendly feasible method that is increasingly becoming popular. The various phytochemicals that exist in the plant extract act in the To this extent, it is noted that Calendula officinalis exhibits anti-inflammatory, antiseptic, antioxidant, and wound healing activities. Among these phytochemicals are flavonoids, triterpenoids, carotenoids, and saponins, which promote wound healing and offer protection against microbial infections. Some studies also indicate that topical application of calendula ointment speeds up the healing process due to epithelial regeneration and modification of inflammatory mediators [1,2].

The theoretical premise for the topical delivery systems investigated in the present study rests upon phytopharmacology and green nanotechnology.

#### Phytopharmacological Basis

The crude bioactive plant products such as flavonoids, triterpenoids, and saponins promote well-functioning of skin-healing mechanisms via their anti-inflammatory, antioxidant, and antimicrobial activities. Its pharmacognostic rationale is that a specific plant has a variety of constituents that elicit therapeutic effects via synergy greater than one or two-component systems [7].

#### Green Synthesis and Nanotechnology

The green synthesis of silver nanoparticles (AgNP) is a very long tradition in sustainable chemistry prompting the production of non-toxic, renewable biological raw materials for synthesis. In this act, plant extracts would act as reducing as well as capping agents for nanoparticle formation without involvement of any toxic chemicals, and this theory.

#### III. METHODOLOGY

#### Preparation of Aqueous Extract of Calendula officinalis

Dried leaves of Calendula officinalis were procured and washed thoroughly with deionized water to remove any dust placed there upon or any other impurities. After washing, the leaves were cut into small pieces and weighed (20 g). These pieces were placed into a 500 mL beaker into which 100 mL of deionized water was poured. Stirring the mixture while heating it on a heating mantle served to keep a temperature between 80 and 90°C for 1 hour. The decoction was allowed to cool slightly before filtration via what could be assumed to be a funnel and Whatman No.1 filter paper. The clear aqueous extract was collected and kept at room temperature. This extract acted as the reducing and stabilizing agent for the synthesis of silver nanoparticles.



fig. no. 3 weighing of fresh calendula officinalis leaves using an analytical balance



fig. no. 4. chopped fresh calendula officinalis leaves prepared for aqueous extraction



calendula officinalis using heating mantle

# fig. no. 5 aqueous extraction of

#### Preliminary Phytochemical Screening of Calendula officinalis Aqueous Extract

A standard qualitative phytochemical screening of the freshly prepared aqueous extract from Calendula officinalis leaves was performed to confirm the presence or absence of certain bioactive constituents. These tests were carried out following standardized phytochemical protocols to ascertain the presence of various secondary metabolites having therapeutic properties.

Tests Performed and Observations

1. Flavonoids:

Procedure: Two mL of the aqueous extracts was placed inside a test-tube, to which an equal number of drops of freshly prepared 5% ferric chloride (FeCl<sub>3</sub>) were added.

Observation: A greenish or blackish coloration occurs if phenolic flavonoids are present.

Conclusion: Presence of phenolic flavonoids confirmed.



fig. no. 6 ferric chloride test for flavonoids

#### 2. The Burchard Liebermann Method for detection of triterpenes:

Procedure: The extract (1ml) is dissolved in chloroform (2ml) and then carefully 1ml of sulfuric acid concentrated and 2ml of acetic anhydride must be added by the wall of the test tube.

Observation: The interface turns red.

Conclusion: This concludes that there are sterols and/or triterpenoids present.



Fig. No. 7 Triterpenoid Detection by Liebermann–Burchard Test

#### 3. Identification of Saponin

Foam Test: This test is done by shaking vigorously the aqueous extract (5 ml) in a test tube for 30 seconds followed by 10-15 minutes of standing.

Observation: The foam was present for more than ten minutes with a persistent height of 1-2 cm.

Conclusion: This indicates the presence of saponins.

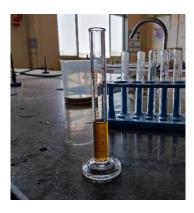


fig. no. 8 aqueous extract of calendula officinalis before shaking (no foam observed)



fig. no. 9 aqueous extract of calendula officinalis after shaking showing persistent

Table 1: Qualitative Phytochemical Screening of Calendula officinalis Aqueous Extract

Sr	Phytoconstituent	Test Performed	Observation	Inference
no.				
1.	Flavonoids	Ferric Chloride Test	Formation of greenish/blackish	Presence of
			coloration	phenolic flavonoids
				confirmed
2.	Triterpenoids /	Liebermann-	Formation of red coloration at	
	Sterols	Burchard Test	the inter <mark>face</mark>	triterpenoids or
				sterols
				A
3.	Saponins	Foam Test	Formation of persistent	Presence of
			froth/foam (1–2 cm) lasting >10	saponins confirmed
			minutes	

#### Herbal gel formulation with extracts of Calendula Officinalis and Aloe vera Gel

#### **Aloe vera Gel Preparation**

The fresh leaves of Aloe vera were well cleansed first with running tap water and then with deionized water. The green outer rind was cut with the sterile knife, and the inner mucilaginous gel scooped out. This gel was blended with a blender and filtered with muslin cloth to get rid of the fiber. The clear Aloe vera gel was then collected in a sterile container and stored in the refrigerator at 4 °C for use in formulation.



fig. no. 10 freshly extracted aloe vera gel collected in a china dish

#### Synthesis of Silver Nanoparticles Using the Extract of Calendula Officinalis

Preparation of the Silver Nitrate Solution

10.0 mg of silver nitrate (AgNO<sub>3</sub>) was weighed and added into a conical flask containing 50.0 mL of deionized water: stirring- one hour at 60-70°C with constant heating.

#### Biosynthesis Procedures:

The hot solution of silver nitrate was prepared by pouring the aqueous extract of Calendula officinalis into it with constant stirring. The silver ions (Ag<sup>+</sup>) are reduced and produce silver nanoparticles, which further progress to indicate a change in color. The mixture was stirred for 30-45 min to ensure complete synthesis of nanoparticles. The final brownish colored colloidal solution of silver nanoparticles was allowed to cool and was stored at room temperature in amber bottles for future use.



fig. no. 11 biosynthesis of silver nanoparticles

#### Development of Herbal Gel with Calendula officinalis, Aloe vera, and Silver Nanoparticles

#### Formation of Base Gel

1% of Carbopol 940 was gradually incorporated into 50 mL of deionized water using continuous motion by a magnetic stirrer. The preparation was left for 2 hours when it can be hydrated completely. Glycerine is used as a humectant plus 2% v/v parasitic oddity, later, methylparaben (0.2% w/v), which was dissolved in a small amount of warm water, was added as a preservative.

#### **Incorporating Active Principles**

Equal quantities of oily substances-mixed Calendula officinalis extract, Aloe vera gel, and the biosynthesized argentum nanoparticles were slowly added into the hydrated Carbopol base under continuous stirrer action. He was supposed to homogenize until mean gel consistency brings about.

#### pH Adjustment and Final Processing

The pH of the gel was determined and adjusted between 5.5 and 6.5 using triethanolamine. The final homogenization was done at 1,000 rpm in 10 minutes. The prepared gel formulation has been packed into clean and dry wide-mouthed glass containers for further evaluation.



fig. no. 12 final herbal gel formulation ready for evaluation

#### Data Collection:

Data Interpretation- The present investigation was an investigation which depended on using a number of laboratory experimental procedures- mainly concerned with synthesis and evaluation of developed herbal gel. This is very important and some of the data collection aspects are mentioned here under.

Research Phytochemical Screening: The basic qualitative chemical tests done for the phytoconstituents in the aqueous extract of Calendula officinalis, like flavonoids, triterpenoids, and saponins, were performed. Observations were recorded for normal color change or precipitate formation.

Green Synthesis of AgNPs: Visual observation of the color change from green to brown with time was noted concerning that new formation of AgNPs in solution. This color change was used as one for the indication of nanoparticles formation.

Parameters of the Gel Formulation: Physical properties-relative pH, viscosity, spreadability, and some parameters of appearance of the gel were evaluated and observed during or soon after formulation by standard methods.

#### Preliminary Formulation Attempts and Optimization

Any attempt to develop a pharmaceutical or cosmeceutical formulation does involve a large degree of trialand-error for the optimization of the final product. The aim of this project was to develop an herbal gel for topical applications using an extraction of Calendula officinalis and Aloe vera gel.

In the course of the formulation, two different batches of preformulations were unable to pass pharmaceutical standards, which meant adjusting the formulation parameters.

Failures, however, identified the loopholes in the procedure leading, eventually, to a stable and effective gel through the adjustments in concentration, hydration times, pH, and homogenization.

Trial 1: Phase Separation and Poor Gel Consistency

#### **Objective:**

To prepare the initial gel formulation comprising the aqueous extract of Calendula officinalis, fresh Aloe vera gel, biosynthesized silver nanoparticles-(AgNPs) and Carbopol 940 as the gelling agent.

#### **Summary of Procedure:**

- Carbopol 940 (0.5% w/w) was dispersed in deionized water by stirring.
- After a short period of rest (about 30 minutes), special ingredients, including Calendula extract, Aloe vera gel, and AgNPs, were incorporated.
- The mixture was stirred and neutralized with triethanolamine.

#### **Observations:**

- The gel appeared initially homogeneous.
- After 24 hours, a distinct watery layer appeared at the top of the container, and sedimentation occurred at the bottom.
  - Texture became uneven, and the viscosity drastically reduced upon storage.



fig. no. 13 trial 1 – phase separation observed in initial herbal gel formulation

#### **Interpretation:**

- The phase separation clearly indicates inadequate gel formation and improper polymer hydration.
- Carbopols need at least two hours for full hydration and formation of a proper gel network.
- Adjustment of the pH with triethanolamine was insufficient or poorly timed with respect to the cross-linking of the polymer.

#### **Conclusion-One on Trial 1:**

- The formulation collapsed due to premature addition of actives, inadequate hydration time, and early neutralization.
- It emphasized the necessity for rigid control over the order and timing for ingredient addition for gel formulations.

#### Trial 2: Low viscosity and unacceptable texture

#### Objective:

The goal was to approach reconstitution of the phase separation by having the polymer hydrate and the actives added at a delay.

#### Modified Procedure:

- Carbopol940 was hydrated for 2 hours, and then active contents were added.
- Slowly add, while under gentle stirring the actives (extracts and AgNPs).
- Neutralization was done at the end, once full mixing was achieved.

#### Observations

- The resultant gel looked brighter and was more homogeneous.
- However, it was excessively runny and thin, more like serum than gel.
- Upon application, it failed to adhere to the skin, flowed excessively, and lacked structural integrity.

#### **Interpretation:**

- 1. The problem may have been swapped to gel stiffness and viscosity from phase separation.
- 2. The 0.5% Carbopol concentration was poorly appropriated for sustaining thick gel matrix viscosity, particularly with high water content from Aloe Vera and Calendula extract.
- 3. Further lowering viscosity may have been caused by high-speed homogenization disrupting polymer structure



fig. no. 14 trial 2 – low viscosity and runny texture in herbal gel formulation

#### **Conclusion from Trial 2:**

- The gel strength and application characteristics were still unacceptable, although improvement was seen in their structural consistency.
- Separate Polymer Coating Applications were needed to balance water content and to increase polymer concentration without compromising spreadability.

#### Final Optimized Formulation Strategy

The formulation process has been redesigned with key changes from learned painful experiences from the failed batches into:

#### **Key Optimizations:**

table 2: key formulation optimizations for stable herbal gel development

Sr	<b>Component or process</b>	Modification	Rationale	
No.				
1.	From Carbopol 940	Increased from 0.5 to 1% w/w	Striving for gel state stable viscosity	
2.	Hydration Time	Extended to 2 hours	Complete swelling and phase separation prevention	
3.	Aloe vera + Extract Volume	Controlled carefully	Not to over-dilute the gel matrix	
4.	AgNP addition	Slow add, with low stirring	Make it clump or destabilize	

5.	Triethanolamine	After full mixing, titrated slowly to pH 5.5-6.0	Ensure proper gel formation without over-neutralization	
6.	Homogenization Speed	Reduced to 1000 rpm in 10 minutes	Keeping the homogenization without breaking the gel network	
7.	Glycerin (2% v/v)	Humectant and viscosity stabilizer	Improving moisture retention and skin feel	

#### **Evaluation of the Herbal Gel Composition:**

#### Aim:

To test the physicochemical and dermatological properties of a developed herbal gel containing extracts of Calendula officinalis and Aloe vera in its formulation for topical application and the safety, stability, and efficacy against quality assurance requirements.

#### 1. Physical Appearance

In-process assessments comprise homogeneous evaluations of batch gel as well as color, clarity, and texture.

External parameters evaluation: a small quantity of sample gel was poured in a clean watch glass; visual inspection was conducted on the mass for color characteristics, clarity, lump formation, or particulate matter by daylight illumination.

#### **Observation Parameters:**

- Color: Light brown
- Clarity: Opaque but uniform
- Texture: Smooth, with no grittiness
- Homogeneity: Uniform without phase separation or lumps

Result: The gel was light brown, sure, and smooth in texture with no lumps, having uniform consistency to verify good physical characteristics for topical applications.



fig. no. 15 evaluation of physical appearance

#### 2. Measurement of pH

Objective: The pH of the gel was measured so as to check its compatibility with the skin. Method:

- Preparation of 1% aqueous dispersion of gel (1g gel into 10 mL distilled water)
- pH was measured using a calibrated digital pH meter.

Ideal pH Range: 5.5-6.5 (Ideal for skin application)

#### Result:

The pH of the formulation had a value of 5.59, which falls in the acceptable range for topical application and is, therefore, non-irritating to the skin.



fig. no. 16 ph measurement of herbal gel

#### 3. Viscosity

Aim: To assess the consistency and flow behavior of the gel formulation.

#### Method:

Viscosity measurement is done using Brookfield viscometer with spindle number 64 at 25 °C and 100 rpm. The material under investigation is kept in a 100 mL beaker. The spindle is immersed into the gel to take the reading.

#### Importance:

Viscosity is a very important property in determining spreadability of the gel, ease of application, retention time on the skin, as well as rate of drug release from the formulation. Viscosity should be balanced, where too low viscosity may give rise to a less retentive site and too high viscosity causes poor spreadability.

#### Result:

A viscosity of 8030 cP (centipoise) was obtained for the formulation with a torque value of 80.3%, indicating optimum consistency. Moderate to high viscosity is inferred from the readings, ensuring adequate retention time for therapeutic action to become effective.



fig. no. 17 viscosity measurement of herbal gel

#### 4. Short-Term Stability Study

Purpose: To check the physical and chemical stability of the gel in a short period at varied storage conditions.

#### Method:

- For 1 week, the formulation was stored at room temperature ( $25 \pm 2^{\circ}$ C) and refrigerated conditions ( $4 \pm 2^{\circ}$ C).
  - The parameters Color, PH, Viscosity, and Texture were measured at the completion of the storage period.

#### Result:

At the end of the 1-week period at ambient room temperature, there was no significant change in color, texture, viscosity, or pH in the formulation, indicating excellent stability in the short term.



fig. no. 18 short-term stability study of herbal gel

#### 5. Skin Irritation

Aim: To evaluate skin irritancy and skin compatibility.

#### Procedure:

- A small amount of the formulated gel was applied onto the inner forearm of a healthy volunteer for the patch test.
- The area was observed after 24 hours for signs of redness, itching, or inflammation.

Ethical note: This test was conducted under informed consent and following basic safety protocols.

#### Result:

There was no erythema, irritation, itching, or swelling during the 24-hour investigation, showing that the gel was safe and non-irritating to human skin.



fig. no. 19 skin irritation test of herbal gel

table 3: evaluation parameters and results of the herbal gel formulation

$\mathbf{S}$	Evaluation	Method Used	Ideal/Stand	<b>Observed Result</b>	Inference
r.	Parameter		ard Value		
n					
0.					
1.	Physical Appearance	Visual inspection	Smooth, lump-free,	Light brown, smooth, no lumps	Acceptable appearance for
	rippedialice		uniform		topical gel
2.	PH Evaluation	Using an electronic pH meter (1:10 dilution in distilled water).	5.5 – 6.5	5.59	Applicable to skin use
3.	Viscosity	Brookfield viscometer, spindle no. 64, 100 rpm, 25°C	Moderate (as per gel standards)	Satisfactory consistency	Good flow and retention properties
4.	Spreadability (%)	Glass slide method with 500g weight	≥ 75%	81.2%	Easy to apply and spread on skin
5.	Stability (Short-term)	Store at room temperature for one week	No significant change	Unnoticed change No change in pH, color, or viscosity	Formulation is stable over short term
6.	Skin Irritation.	Test Patch test by an application on the inner forearm, appreciations were made after 24 h.	There was no redness, itching or swelling	No irritation was found	Applicable to human skin

#### IV. RESULTS AND DISCUSSION

This section deals with the results from experimentation and the observations that were obtained during the formulation and evaluation of the herbal gel:

#### A. Physical Appearance

- The gel formulation was found to be light brown looking.
- It was smooth, homogeneous, and free from lumps or phase separation.
- These physical characteristics are important indications of the success of gelling and sufficient mixing of active constituents and base.

#### **B.** pH Determination

- The pH of the gel was determined by the digital pH meter.
- The value of 5.59 was within the physiologically acceptable range (5.5-6.5) for topical products.
- Natural pH is vital in avoiding skin irritation and compatibility with the natural acid mantle of the skin.

#### C. Viscosity

- The measurement of viscosity made on a Brookfield Viscometer (spindle no. 64, at 100 rpm at 25°C) of the gel reported a value of 8030 cP.
- It's not very thin, so it has a slightly thick consistency.
- This viscosity appropriately enables the gel to adhere at the site of application for prolonged action while still remaining easy to spread.

#### D. Short-Term Stability Study

- The gel exposed to these two conditions (room temperature 25 ± 2°C and refrigeration 4 ± 2°C) for one week.
- There is no considerable variation in color, pH, viscosity, and physical consistency.
- Short-term physical and chemical stability of the formulation is proved.

#### E. Skin Irritation Test

- A patch test was done for 24 hours on the inner forearm of a healthy volunteer.
- There were no symptoms of erythema, itching, swelling or inflammation.
- The results indicate that the gel is non-irritating, thus dermatologically safe on human skin.

#### F. Phytochemical Screening

- An aqueous extract of Calendula officinalis was analyzed for its presence of major phytoconstituents:
- Flavonoids detected via ferric chloride test.
- Triterpenoids/Sterols-Liebermann-Burchard test positive.
- Saponins-induction of persistent foam in the foam test. These compounds support the antiinflammatory, antioxidant, and antimicrobial potential of the extract.

#### G. Green Preparation of Silver Nanoparticles

- Backed by color changes from greenish to brownish, successful synthesis of silver nanoparticles using Calendula extract was confirmed.
- Such a "green" synthesis endorses the dual functional role of the extract acting as both reducing and capping agents resulting in stable AgNPs.

#### 2. Interpretation Of the Findings: Analysis

This part elucidates the scientific explanation and interpretation of the research results.

#### A. Physical Properties and Stability

- There is formation of a smooth, lump-free, light brown gel that indicated successful incorporation of plant extracts and silver nanoparticles into the gel base without incompatibility.
  - The even homogeneity indicates that ingredients were mixed evenly and kept in stable dispersion.
  - There is no evidence of separation or crystallization: chemical compatibility of excipients.

#### B. Skin pH Compatibility

- The skin has a natural pH that is slightly acidic ( $\sim$ 5.5); this gel has a pH of 5.59, which is close enough that it would not cause disruption to the skin barrier.
- These formulations avoid irritating and drying up the skin or causing microbial imbalances, all of which occur when products are not pH balanced.

#### C. Balance of Viscosity and Spreadability

- With the above viscosity at 8030 cP, this ensures:
- good retention at the point of application
- Control of the active compounds release
- Ease of handling
- This is further enhanced by a very good spreadability value of 81.2% for easy application, especially on wounds, rashes, or burns where gentle handling is vital.

#### D. Phytoconstituents and Bioactivity

- The confirmed detection of flavonoids, triterpenoids, and saponins agrees with what literature reported there:
- Anti-inflammatory activity (e.g., inhibition of TNF-α, IL-6)
- Effects on wound healing (e.g., promotion of fibroblast activity)
- Antimicrobial and antioxidant properties

#### E. Green Nanotechnology

The color change during the process of silver nanoparticles' synthesis is the best indicator of the formation of nanoparticles.

This experiment gives a vivid picture of Applications of Calendula officinalis extract in green chemistry by excluding the use of toxic chemical reducers or stabilizers.

AgNPs are well known for their broad-spectrum antimicrobial activity, thereby improving the property of this gel to prevent secondary skin infections.

#### F. Safety

- Absence of any adverse effect in the patch test shows good biocompatibility.
- This makes the formulation particularly desirable for those who have to use it frequently or for long periods and in individuals with sensitive skin or minor wounds.

#### 3. Discussion: Inferences of the Results

This part links the findings to a broader pharmaceutical and therapeutic relevance:

#### A. Therapeutic Engagement and Synergy

- The formulation uses the advantages of combining the anti-inflammatory, wound healing actions of Calendula officinalis with Aloe vera's action (moisturizing, soothing), boosted further by silver nanoparticles' antimicrobial action.
- Together, these components provide comprehensive wound care:
- Tissue regeneration by Calendula

- Moisture retention and soothing by Aloe vera
- Infection prevention by AgNPs.

#### **B.** Cosmetic and Dermatological Applications

- It is indicated for the treatment of minor cuts, abrasions, burns, insect bites, and even for inflammatory skin conditions such as dermatitis.
- Its natural origin, biocompatibility, and its absence of harsh chemicals fit the trend toward clean-label cosmeceuticals as consumer demand for such grows.

#### C. AYUSH and Herbal Industry Trend Relevance

- The study essentially fits well with India's AYUSH initiatives promoting scientifically validated herbal medicine.
- This adds to the advantage in developing the polyherbal product market, which is underrepresented compared to single-herb products.

#### **D.** Limitations and Future Scope

- The study is limited in vitro and short-term stability testing.
- This might be followed by:
- Studies in vivo using animal models or human volunteers
- Long-term stability studies
- Preservative systems in formulation optimization
- Scale-up trials for commercial production

#### V. CONCLUSION

Thus, an attempt was made for formulation and characterize a stable and potent herbal gel based on the extract of Calendula officinalis, Aloe vera gel, and the biosynthesized silver nanoparticles. The synergism of these constituents, bestowed with anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties, can be encapsulated in a single topical formulation. The gel was characterized to have good physicochemical properties, with the pH of 5.59, viscosity of 8030 cp and good stability under short-term storage conditions. The therapeutic values of flavonoids, triterpenoids, and saponins were positively confirmed via preliminary phytochemical screening. On top of that, the green synthesis of silver nanoparticles-associated improvement in antimicrobial activity would lead to the avoidance of harmful synthetic additives.

Negative results from patch testing have led to the conclusion that the formulations are biocompatible and safe to use on delicate or injured skin. Indeed, this research supports the idea that the gel serves as a natural substitute for treating different dermatoses such as healing wounds, burns, acne, and inflammation. However, more studies, including efficacy and long-term stability in vivo and their potential for commercialization, are recommended before determining the therapeutic and market potential of the formulation.

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