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Research Article

Formulation and Stability Assessment of Herbal Cream Prepared from Datura Leaves for Wound Healing

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The present study focuses on the formulation and stability assessment of a herbal cream prepared from leaves of Datura stramonium for wound healing applications. The plant extract was obtained using ethanol as a solvent through Soxhlet extraction. The herbal cream was formulated using an oil-in-water (O/W) emulsion base and evaluated for its physicochemical properties, including organoleptic characteristics, pH, viscosity, spreadability, homogeneity, washability, and skin irritation potential. The formulated cream exhibited acceptable color, pleasant odor, smooth texture, and good consistency. The pH of the cream was found to be within the range suitable for skin application, indicating minimal irritation risk. Viscosity and spreadability results confirmed ease of application and uniform distribution on the skin surface. The formulation showed good homogeneity and was easily washable. Stability studies revealed that the cream remained physically and chemically stable under various storage conditions without significant changes in its properties. The findings suggest that the formulated Datura herbal cream is stable, safe, and holds potential as a topical wound healing agent.

Keywords: *Datura stramonium*, herbal cream, wound healing, stability studies, topical formulation.

INTRODUCTION

Background of wound healing

Wound healing is the body's natural, coordinated response to restore the integrity of damaged tissue after injury, mainly in the skin but also in internal organs. It involves a tightly regulated sequence of overlapping stages in which multiple cell types, signaling molecules, and extracellular matrix components interact to close the defect and regain barrier function [1, 2]. Descriptions of wound treatment date back to ancient civilizations such as Egypt, Greece, and India, where practitioners already emphasized wound cleansing, foreign-body removal, suturing, and protection from infection. In the 18th–19th centuries, figures such as John Hunter and Alexis Carrel advanced understanding by describing granulation tissue, neovascularization, and the importance of minimizing tissue trauma to promote quicker healing [3, 4]. Wound healing is replacement and functional restoration of damaged or missing cellular structures and tissue layers, typically beginning immediately after injury and continuing for days to months. In normal physiology, the process is self-limited and aims to re-establish a protective epithelial barrier while minimizing structural distortion (scarring) [5, 1, 2].

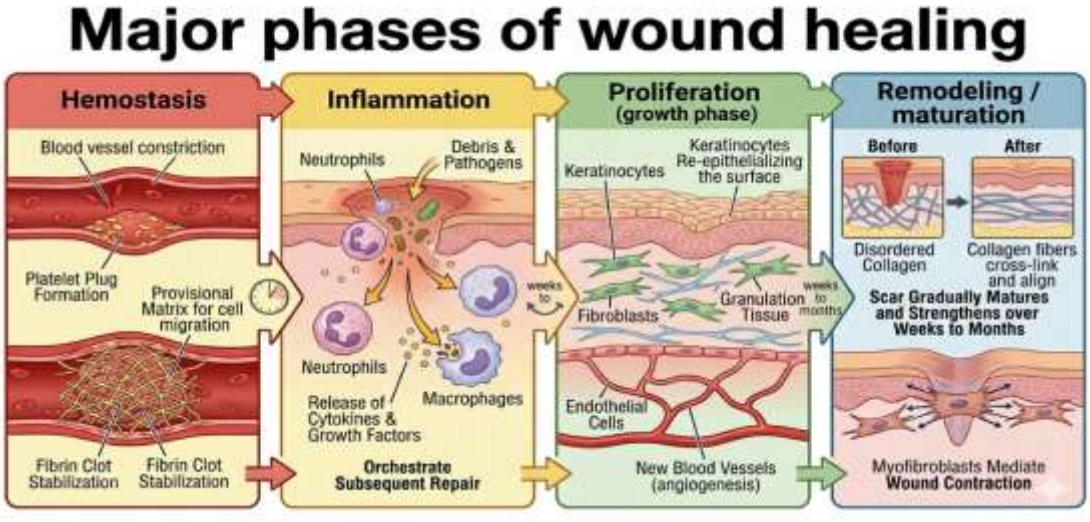


Figure No. 1 Major phases of wound healing [1, 2, 4, 5].

Role of herbal formulations in wound management

Herbal formulations play an important adjunctive role in wound management by modulating inflammation, limiting infection, and enhancing tissue repair and regeneration, often with fewer side effects than conventional synthetic drugs. They are widely used in both traditional systems of medicine and modern research-oriented wound-care products (ointments, gels, dressings, and biopolymer-based systems) [6, 7, 8, 9, 10].

Main mechanisms of action

i. Anti-inflammatory and antioxidant effects: Many medicinal plants (e.g., *Curcuma longa*, *Calendula officinalis*, *Aloe vera*, *Glycyrrhiza glabra*) reduce pro inflammatory cytokines (TNF α, IL 6) and oxidative stress, thereby shortening the inflammatory phase and protecting regenerating cells [7, 10].

ii. Antimicrobial activity: Extracts from plants such as *Azadirachta indica*, Allium sativum, Melaleuca alternifolia, and honey containing polyherbal preparations help control microbial load at the wound bed, reducing infection driven delays in healing [7, 10, 11].

iii. Pro repair and pro angiogenic effects: Bioactives such as curcumin, quercetin, and triterpenoids from *Centella asiatica* and *Boerhavia diffusa* stimulate fibroblast proliferation, collagen deposition, granulation tissue formation, and neovascularization [7, 8, 12].

Forms and types of herbal formulations

i. Monoherbal products: Single-plant extracts (e.g., *Aloevera* gel, *Calendula* ointments, *Kaempferia galangal* preparations) are extensively studied in rodent and clinical settings and shown to accelerate wound-contraction rate, epithelialization, and tensile strength [7, 12].

ii. Polyherbal formulations: Combinations of herbs (e.g., *Centella* + *Curcuma* + *Azadirachta*-based gels/ointments) often show synergistic effects, improving wound contraction, antimicrobial coverage, and remodeling while lowering the risk of resistance or toxicity compared with single-drug regimens [7, 11].

iii. Advanced herbal-loaded systems: Modern biopolymeric dressings (chitosan, alginate, cellulose, hyaluronic acid, etc.) incorporating herbal bioactives such as curcumin, *Aloe vera*, and *Vinca* alkaloids provide sustained release, moisture retention, and matrix support for cell migration [8, 13].

Herbal formulations are increasingly used for difficult-to-heal wounds (diabetic ulcers, burns, pressure sores) because they address multiple pathological components—hyperglycemia-related

oxidative stress, chronic inflammation, and impaired angiogenesis—through a "multi-target" action [7, 9]. Their relatively safer profile and lower cost make them attractive for topical development (e.g., gels, creams, emulsions) in preclinical pharmacology and translational dermatology, especially in resource-limited settings [7, 14].

Therapeutic potential of *Datura stramonium* leaves

Datura stramonium (thorn-apple, Jimson weed) leaves show notable but narrowly circumscribed therapeutic potential, primarily due to tropane alkaloids such as atropine and hyoscyamine, but their use is heavily limited by toxicity and narrow safety margins [16].

Key pharmacological activities of the leaves

i. Analgesic and anti-inflammatory effects: Leaf extracts have demonstrated dose-dependent analgesia in rodent models (writhing and hot-plate tests), likely mediated partly via opioid-like and anticholinergic mechanisms; they also reduce inflammatory mediators and edema in topical-use models [17, 18, 19].

ii. Antimicrobial and wound-care potential: Crude leaf extracts show activity against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and other wound-associated bacteria, suggesting a possible adjunctive role in infected or contaminated wounds when used as topical poultices or ointments [16, 17, 20].

iii. Respiratory and antispasmodic use: Traditionally, roasted or smoked leaves are used to relieve bronchospasm and asthma-like symptoms, exploiting the antimuscarinic (bronchodilator) effect of atropine and scopolamine [17, 21].

Chemical basis and traditional uses

Leaves contain tropane alkaloids (atropine, hyoscyamine, scopolamine), plus tannins, flavonoids, and phenolic compounds, which together contribute antinociceptive, antispasmodic, and moderate antioxidant effects. In folk medicine, they are applied externally as poultices for pain, boils, abscesses, bruises, swellings, and skin infections, and internally (with extreme caution) for asthma, cough, and some gastrointestinal complaints [16, 17, 18, 19, 20]. Because even small oral doses can cause severe anticholinergic toxicity (delirium, tachycardia, hyperthermia, seizures, coma), therapeutic use of *D. stramonium* leaves is restricted mainly to topical, low-dose, or highly standardized preparations, often under ethnopharmacological supervision. For research-oriented work, any development of leaf-based formulations (e.g., gels or ointments for wound pain or inflammation) must rigorously address [16, 20].

i. Standardization of alkaloid content.

ii. Route-dependent toxicity and dermal-systemic absorption.

iii. Safety margins and regulatory implications.

MATERIALS AND METHODS

MATERIALS

Fresh leaves of Datura stramonium were collected for the study. All chemicals used in the formulation, including stearic acid, cetyl alcohol, liquid paraffin, glycerin, triethanolamine, methyl paraben, propyl paraben, and distilled water, were of analytical grade and procured from standard suppliers.

Collection of Plant Material

Fresh, healthy leaves of *Datura stramonium* were collected from local areas Jagatpura, Jaipur Rajasthan, India, during the appropriate growing season. The collected leaves were washed thoroughly with tap water followed by distilled water to remove dust and contaminants, and then shade-dried at room temperature.

Preparation of Plant Extract

The dried leaves were coarsely powdered using a mechanical grinder. The powdered material was subjected to extraction using the Soxhlet extraction method with 95% ethanol as a solvent. The extraction process was continued for 6–8 hours until complete extraction was achieved. The extract was then concentrated using a rotary evaporator and dried to

obtain a semisolid mass, which was stored in an airtight container at 4°C for further use.



Figure No. 2 Soxhlet extraction assembly of Dhatura leaves

Formulation of Herbal Cream

Step 1: Gel Base: Add Carbopol 934 in distilled water slowly with constant stirring, add Propylene Glycol and mix well.

Step 2: Oil Phase: Take stearic acid, cetyl alcohol, and liquid paraffin in a beaker. Heat to 70–75°C until completely melted.

Step 3: Aqueous Phase: Dissolve methyl paraben in distilled water and heat at 70–75°C.

Step 4: Emulsion Formulation: Slowly add the aqueous phase into oil phase with continuous stirring to form a uniform emulsion.

Step 5: Add the prepared gel base (Carbopol gel) slowly into emulsion formulation and add Datura extract.

Table No. 1: Composition of Herbal Cream Formulated with Datura stramonium Leaf Extract

Ingredient	Quantity	Role
Datura leaf extract	2 g	Active ingredient
Carbopol 934	0.5g	Thickening Agent
Stearic acid	5 g	Emulsifier
Cetyl Alcohol	2 g	Stabilizer
Liquid Paraffin	8 ml	Emollient
Propylene Glycol	5 ml	Humectant
Methyl paraben	0.15 g	Preservative
Distilled water	q.s.	Vehicle
Perfume	q.s.	Fragrance



Figure No. 3 Dhatura leaves herbal cream

Evaluation of Formulated Cream

i. Organoleptic Properties: The formulated cream was evaluated for color, odor, texture, and appearance by visual inspection.

ii. pH Determination: The pH of the cream was determined using a calibrated digital pH meter. Approximately 1 g of cream was dispersed in 10 mL of distilled water and measured at room temperature.

iii. Viscosity: The viscosity of the formulation was measured using a Brookfield viscometer at controlled temperature with appropriate spindle selection.

iv. Spreadability: Spreadability was determined by placing a fixed amount of cream between two glass slides and applying a known weight. The time required to separate the slides was recorded and used to calculate spreadability.

v. Homogeneity: The cream was tested for homogeneity by visual inspection and by touch to detect the presence of aggregates or lumps.

vi. Washability: Washability was evaluated by applying a small amount of cream on the skin and observing the ease of removal with water.

vii. Stability Studies

a. Physical Stability: The formulated cream was subjected to stability studies under different storage conditions such as room temperature (25±2°C), intermediate (30±2°C), and accelerated temperature (40±2°C) for a period of up to 1 month. The samples were evaluated periodically for changes in color, odor, phase separation, and consistency.

b. Chemical Stability: Chemical stability of the cream was assessed by evaluating the retention of active constituents and pH over time. The samples were analyzed at regular intervals to detect any degradation of phytoconstituents present in the *Datura* extract.

RESULTS AND DISCUSSION

i. Organoleptic Properties

The formulated herbal cream exhibited a buff colored characteristic of the plant extract, with a mild herbal odor and smooth creamy texture. The appearance was uniform and free from any visible impurities. These properties indicate good patient acceptability and aesthetic appeal, which are important for topical formulations.

ii. pH Determination

The pH of the cream was found to be 7.12, which is close to the natural pH of the skin. This suggests that the formulation is compatible with skin and unlikely to cause irritation upon application. Maintaining an appropriate pH is crucial for preserving the skin barrier and promoting wound healing.

iii. Viscosity

The viscosity measurements indicated 1,03,182 cP, hence the cream possessed optimal thickness, ensuring that it remains at the site of application without being too stiff or too fluid. Proper viscosity contributes to better residence time on the skin, enhancing the therapeutic effect of the active constituents.

iv. Spreadability

The formulation demonstrated good spreadability i.e. 1.16 g cm/sec^{-1}, indicating that it can be easily applied over the skin surface with minimal effort. Good spreadability ensures uniform distribution of the active ingredients, which is essential for effective wound healing.

v. Homogeneity

The cream showed excellent homogeneity with no phase separation or grittiness observed during the study period. This indicates proper mixing of ingredients and stability of the emulsion system.

vi. Washability

The cream was easily washable with water, suggesting that it does not leave excessive residue on the skin. This property improves user compliance and convenience.

Stability Studies

Physical Stability

During the stability study period, the cream remained stable under different storage conditions (room temperature, and elevated temperature). No significant changes in color, odor, consistency, or phase separation were observed. This indicates that the formulation possesses good physical stability.

Chemical Stability

The chemical stability evaluation showed no significant change in pH or degradation of active constituents over time. This suggests that the phytochemicals present in Datura stramonium extract remained stable within the formulation, ensuring sustained therapeutic efficacy.

Table No. 2: Chemical stability assessment of cream

Study Type	Temperature	Relative Humidity	Duration	Parameter
Day of manufacturing	25 ± 2 °C	45 ± 5% RH	Day 0	**pH-** 7.12
				Viscosity- 1,03,182 cP
				Spreadability-1.16 g cm/sec^{-1}
Accelerated	40 ± 2 °C	75 ± 5% RH	1 months	**pH-** 7.10
				Viscosity- 1,33,307 cP
				Spreadability- 1.10 g cm/sec^{-1}
Intermediate	30 ± 2 °C	65 ± 5% RH	1 months	**pH-** 7.11
				Viscosity- 1,59,328 cP
				Spreadability- 1.04 g cm/sec^{-1}

DISCUSSION

The results demonstrate that the formulated herbal cream meets all essential criteria for a stable and effective topical preparation. The physicochemical parameters were within acceptable limits, and the absence of irritation indicates its safety. The stability studies further confirm that the formulation can maintain its integrity over time under various environmental conditions. The wound healing potential of *Datura stramonium* is attributed to its bioactive constituents such as alkaloids, flavonoids, and tannins, which are known for their antimicrobial, anti-inflammatory, and tissue-regenerating properties. The incorporation of these phytoconstituents into a stable cream base enhances their applicability as a topical therapeutic agent.

CONCLUSION

The present study successfully demonstrated the formulation and evaluation of a stable herbal cream prepared from leaves of Datura stramonium for potential wound healing application. The formulated cream exhibited desirable physicochemical properties, including appropriate pH, good viscosity, excellent spreadability, and homogeneity, making it suitable for topical use. The absence of skin irritation further confirms its safety profile. Stability studies indicated that the formulation remained physically and chemically stable under various storage conditions, with no significant changes in its characteristics. The presence of bioactive phytoconstituents in *Datura stramonium* contributes to its therapeutic potential, particularly in promoting wound healing through antimicrobial and anti-inflammatory effects. Overall, the developed herbal cream can be considered a promising, cost-effective, and safe alternative to conventional wound healing formulations. However, further in vivo and clinical

studies are recommended to establish its efficacy and safety on a larger scale.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this research work.

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