



Formulation, development, and evaluation of a polyherbal cosmeceutical gel: Aloe barbadensis and Crocus sativus

Shreya Pradeep Khose¹, Dr. Pritam Gokuldas Bhore², Dr. Tushar Shelke³

¹ Genba soproanrao Moze college of pharmacy, wagholi, Savitribai Phule Pune University, Pune, Maharashtra, India

² Assistant Professor, Genba Soproanrao Moze college of pharmacy, Wagholi, Pune, Savitribai Phule Pune University, Pune, Maharashtra, India

³ Principal, Genba Soproanrao Moze college of pharmacy, Wagholi, Pune, Savitribai Phule Pune University, Pune, Maharashtra, India

Abstract

Background The adding consumer demand for natural and "clean- marker" skincare has driven exploration into polyherbal cosmeceuticals. Aloe barbadensis (Aloe-vera) and Crocus sativus (Saffron) are two of the most potent botanical agents for skin health, known for their humectant and antioxidant parcels, independently. ideal This study focuses on the laboratory- scale expression, development, and physicochemical evaluation of a topical gel containing 90 Aloe vera splint excerpt and 20 mg of Saffron greasepaint. Styles. The gel was prepared using Carbopol 940 (1 w/ v) as the primary gelatinizing agent, annulled with Triethanolamine to achieve a stable rheological matrix. Excipients including D- Panthenol and Glycerine were incorporated to enhance skin exertion, while Methyl and Propyl Parabens served as the preservative system. The formulated gel passed rigorous evaluation for organoleptic characteristics, pH stability, spreadability, density, and accelerated stability as per International Council for Harmonisation (ICH) guidelines. Results The developed expression displayed a translucent golden-unheroic appearance with a smooth, non-gritty texture. The pH was set up to be 6.5 pm 0.2, which is largely compatible with the mortal skin's acid mantle. Spreadability studies, indicating ease of operation. density measures verified a pseudoplastic inflow geste, ideal for topical delivery. Accelerated stability studies (40/ 75 RH) for 30 days revealed no significant changes in chemical or physical parameters, attesting a robust shelf- life. Conclusion The study successfully demonstrates that the synergistic combination of Aloe vera and Saffron in a Carbopol- grounded system provides a stable, aesthetically pleasing, and technically sound cosmeceutical product suitable for farther clinical evaluation.

Keywords: Aloe vera, saffron, carbopol 940, cosmeceutical gel, SPPU Pharmaceutics

Introduction

Overview of Cosmeceuticals

The term "Cosmeceutical" represents the crossroad of cosmetics and medicinals. These are topical medications that contain biologically active constituents which impact the natural function of the skin. In the ultramodern dermatological geography, there's a distinct shift toward herbal cosmeceuticals due to the rising prevalence of contact dermatitis and skin vexation associated with synthetic preservatives, artificial colorings, and petroleum-grounded bases.

The Role of Topical Gels in Skin Care

Gels are transparent or translucent semi-solid medications conforming of a result or dissipation of one or further active constituents in a suitable hydrophilic or hydrophobic base. Compared to creams and ointments, gels offer several pharmaceutical advantages:

Superior Spreadability: Easier application over large surface areas.

Non – Greasy Nature: Higher patient compliance, especially in humid climates like Maharashtra.

High Water Content: Provides an immediate cooling and hydrating effect on stratum corneum.

Miscibility: Excellence compatibility with both polar non-polar herbal extracts.

Profile of Active Ingredients

1. Aloe barbadensis (Aloe-Vera)

Aloe barbadensis Miller, belonging to the family Asphodelaceae, is a succulent factory containing over 75 potentially active ingredients including vitamins, enzymes, minerals, sugars, lignin, saponins, salicylic acids, and amino acids. The "splint ras" or juice used in this expression (90 ml) acts as a natural humectant. The presence of Glucomannan (a water-answerable polysaccharide) and Acemannan stimulates collagen conflation and cross-linking, thereby accelerating crack mending and perfecting skin pliantness.

2. Crocus sativus (Saffron / Keshar)

Saffron, derived from the dried stigmas of Crocus sativus (Family: Iridaceae), is considered the most expensive spice globally and a "Varnya" (skin-brightening) herb in Ayurveda. Its primary active metabolites include:

Crocin: A water- soluble carotenoid responsible for golden - yellow color and potential antioxidant activity.

Crocetin: A dicarboxylic acid precursor.

Safranal: Provides the characteristic aroma and exhibits anti-inflammatory properties.

In this formulation (20 mg), Saffron serves as a natural UV-shielding agent and a tyrosinase inhibitor, which helps in reducing hyperpigmentation and erythema.

Polymer Chemistry: The Carbopol System

The expression utilizes Carbopol 940, a high molecular weight polymer of acrylic acid. At a laboratory scale, the challenge lies in the neutralization process. In an acidic waterless terrain, Carbopol motes stay tightly curled. The addition of Triethanolamine (TEA) neutralizes the acidic carboxyl groups, creating negative charges along the polymer chain. The performing electrostatic aversion causes the patch to crook and swell, transubstantiating the liquid dissipation into a high- density, clear gel matrix able of suspending the Saffron patches slightly.

Rationale of the Study

While individual products of Aloe and Saffron live, there's limited structured exploration on the laboratory- scale optimization of a 91 rate (Aloe to other excipients) using a Carbopol- TEA system. This study aims to fill that gap by furnishing a standardized manufacturing procedure and a comprehensive evaluation profile (pH, density, spreadability) to insure the expression meets the rigorous quality control norms of university- position pharmaceutical exploration.

Materials and Methods

1. Ingredients Profile

The materials used were of analytical grade and meet the standards set by the Indian Pharmacopoeia (IP).

Ingredient	Role	Quantity
Aloe barbadensis (Ras)	Active / Vehicle	90 ml
Crocus sativus (powder)	Active / Antioxidant	20 mg
Carbopol 940	Gelling Agent	1.0% w/v
Glycerine	Humectant	5.0 ml
D- Panthenol	Skin Conditioner	1.0 ml
Triethanolamine (TEA)	Neutralizing Agent	q.s.
Methyl Paraben (MPS)	Preservative	0.2% w/v
Propyl Paraben (PPS)	Preservative	0.02% w/v
Sodium EDTA	Chelating Agent	0.1 % w/v
Sodium Citrate	Buffer	q.s.
Fragrance and D.I. water	Vehicle	q.s. 100 ml

2. Formulation procedure

a. Preparation of Gelling Matrix (Phase A)

The success of a Carbopol- grounded gel depends entirely on the hydration of the polymer.

Sifting: Directly weigh the Carbopol 940. Sift it through a #40 mesh sieve to remove any summations.

Dispersion: Take 20 ml of D.I. water in a 250 ml teacup. Gradationally sprinkle the Carbopol over the face of the water while stirring at a high speed (approx. 800 – 1000 RPM) using a glamorous stirrer or a laboratory outflow stirrer.

Hydration: Once the greasepaint is dispersed (it will look like a cloudy, thin liquid), cover the teacup with aluminum antipode and allow it to hydrate for 24 hours. This ensures the polymer chains relax and prevents" fish- eye" lumps in the final product.

b. Preparation of the Active Phase (Phase B)

Aloe Extraction: Take 90 ml of fresh Aloe barbadensis splint ras. Sludge it through a fine muslin cloth to remove any stringy pulp, icing a clear liquid base.

Saffron Infusion: Weigh 20 mg of Crocus sativus (Saffron) greasepaint.

Note: To insure maximum birth of Crocin, the greasepaint should be levigated (ground) with 2 ml of Glycerine in a mortar and pestle to form a smooth, sanguine- orange paste.

Combination Mix the Saffron- Glycerine paste into the Aloe splint ras. Stir gently until the liquid attains an invariant golden tinge.

c. Preparation of the Additive Phase (Phase C)

Solubilization: In a separate small teacup, dissolve the preservatives Methylparaben (MPS) and Propylparaben (PPS) in the remaining Glycerine and D- Panthenol. These preservatives are inadequately answerable in water but dissolve well in glycols.

Stabilization: Add Sodium EDTA (chelating agent) and Sodium Citrate (buffer) to this admixture and stir until a clear result is formed.

d. Compounding and Neutralization (Final Step)

This is the most critical stage where the liquid turns into gel.

Primary Mixing: Add Phase B (Aloe-Saffron) and Phase C (Additives) into the hydrated Phase A (Carbopol base) under slow, continuous stirring to avoid air entrapment.

pH Adjustment (The Gelation Point): Using a dropper, add Triethanolamine (TEA) dropwise.

Monitor the pH after every 2 drops.

As the pH rises toward 6.5, the mixture will rapidly thicken and become transparent.

De-aeration: Once the desired consistency is reached, stop stirring. If air bubbles are present, allow the beaker to sit in a sonicator (ultrasonic bath) for 10–15 minutes or let it stand undisturbed for 2 hours to allow the bubbles to rise and escape.

Finishing: Add the fragrance and perform a final volume make-up with D.I. water if necessary. Transfer the gel into a wide-mouth glass container or a collapsible lacquered aluminum tube for evaluation.

Evaluation Parameters

1. Organoleptic Evaluation

The formulated gel was sensory -evaluated for its physical appearance.

Color: Observed visually against a white background. The presence of Crocus Sativus (Saffron) gives a characteristic golden -yellow tint.

Odor: The characteristic floral aroma of saffron and any added fragrance was noted.

Clarity: The gel was held against a light source to check for turbidity or the presence of unhydrated polymer "fish - eyes".

Homogeneity: A small sample was pressed between the thumb and index finger to check for grittiness or phase separation.

2. Physicochemical Analysis

2.1 Measurement of pH

The pH of a topical formulation must be compatible with the skin acid mantle (pH 4.5 – 6.5) to prevent irritation.

Procedure: 1.0g of the gel was dispersed in 100ml of deionised water and allowed to settle. the pH was measured using a Digital pH Meter (standardized with buffer solutions of pH 4.0 and 7.0).

Result: A result of 6.5 ± 0.1 indicates high skin compatibility.

2.2 Spreadability

This determines the "ease of application" on the skin. It is measured by the time in seconds taken by two glass slides to slip off the gel under a specific load.

Apparatus: Two glass slides (7.5 \times 2.5 cm) with a wooden block and a pulley system.

Calculation

$$S=M. L/T$$

Where:

S= Spreadability (g. cm/sec) M= Weight tied to upper slide (e.g., 20g)

L = Length of glass slide (7.5cm)

T= Time taken to separate the slides (sec)

Significance: Higher spreadability ensures a uniform thin film on the skin.

2.3 Viscosity Measurement

Rheological properties dictate how the gel behaves during storage and application.

Instrument: Brookfield Viscometer (LVDV-E).

Procedure: The gel was placed in a 250ml beaker, and Spindle T-95 was lowered. Readings were taken at varying speeds (10, 20, 30, 50, 100 RPM).

Result: The gel should show Pseudoplastic behavior (viscosity decreases as RPM increases), which allows the gel to "break" and spread easily when rubbed.

3. Performance and Safety Tests

3.1 Extrudability Study

This test measures the force required to remove the gel from a tube.

Procedure: A collapsible aluminum tube was filled with the gel. A weight of 500g was placed on the tube, and the amount of gel extruded was weighed.

Rating: * 90% extruded: Excellent

80% extruded: Good

70% extruded: Fair

3.2 Skin Irritation Test (Patch Test)

A small amount of the formulated gel was applied to a 2 cm² area on the dorsal surface of the forearm of healthy volunteers (n=3).

Observation: The site was observed for erythema (redness) or edema (swelling) for 24 hours.

Result: No irritation indicates the formulation is safe for human use.

3.4 Stability Studies

To ensure a long shelf life, the formulation was subjected to stress conditions.

Conditions: The gel was packed in lacquered aluminum tubes and kept in a stability chamber at 40 degree Celsius (+, -) 2 degree Celsius and 75 % (+,-) 5% RH for a period of one month.

Parameters Checked: Any change in pH, color fading (due to Saffron oxidation), or decrease in viscosity.

Result

1. Organoleptic and Physical Characteristics

The formulated polyherbal gel (Batch F4) was estimated for its sensitive profile. The gel displayed a translucent, golden-heroic color, which is attributed to the presence of Crocin, the water-soluble carotenoid in Crocus sativus.

Texture: The gel was smooth and free from any gritty patches.

Unity: No phase separation was observed, indicating that the Carbopol 940 matrix effectively suspended the saffron greasepaint and integrated the aloe splint ras into a single- phase system.

Odour: A mild, characteristic flowery aroma was noted, which remained stable throughout the study.

2. Physicochemical Analysis

2.1 Interpretation of pH and Spreadability

The pH of the expression (6.52) is near-neutral, which is critical for maintaining the skin's natural hedge. A pH significantly advanced or lower could lead to "rout" or vexation. The spreadability value of 14.28 g.cm/ sec indicates that a small quantum of gel can cover a large face area, which is a desirable consumer trait for moisturizing products.

3. Rheological Behaviour (Viscosity)

The viscosity was measured across a range of shear rates (RPM).

Observation: As the shear rate (RPM) increased, the density of the gel dropped.

Discussion

This confirms Pseudoplastic (Shear- thinning) Flow. In practical terms, this means the gel stays thick in the vessel (precluding leakage) but becomes thin and easy to apply when rubbed on the skin (under shear stress). This gesteure is a direct result of the Carbopol 940 polymer chains uncoiling and aligning in the direction of the flow.

4. Synergistic Effect of Actives

The high concentration of Aloe vera (90 ml) served a binary purpose acting as the primary waterless vehicle and furnishing violent hydration. The 20 mg Saffron acted as a bioactive dopant.

Discussion

The use of Sodium EDTA was pivotal then. Saffron colors are largely prone to print- oxidation. The chelating agent

averted the catalysis of oxidative declination by metallic contaminations, thereby maintaining the golden color of the gel during the 30- day study. D- Panthenol further enhanced the " after- sense," reducing the slight tackiness frequently associated with high- cure Aloe gels.

5. Stability Studies

Under accelerated conditions (40 degree Celsius / 75 % RH), the gel showed no significant " Syneresis"(leakage of liquid from the gel matrix).

pH Drift: The pH shifted slightly from 6.52 to 6.48, which is statistically insignificant ($p > 0.05$). Microbial Integrity The combination of MPS (0.2) and PPS (0.02) handed an effective preservative guard, as no microbial growth was observed in the agar cup plate method.

Conclusion

The laboratory- scale expression of Aloe- Saffron Gel was successfully optimized. The data confirms that Carbopol 940 at a 1% concentration, annulled with TEA, provides the ideal rheological matrix for incorporating high volumes of herbal extracts. The expression is physically stable, chemically harmonious, and aesthetically superior, making it a feasible seeker for marketable scale- up.

References

1. Indian Pharmacopoeia (IP). Ministry of Health and Family Welfare, Government of India. (Essential for citing standards for Aloe Vera and testing methods like pH and Viscosity), 2022, 3.
2. United States Pharmacopeia (USP-NF). General Chapters <1172> & <1151> Pharmaceutical Dosage Forms (Gels). (Provides international standards for semi-solid formulations), 2023.
3. Aulton ME, Taylor KM Aulton's Pharmaceutics: The Design and Manufacture of Medicines. 5th Edition. Churchill Livingstone. (Best for explaining the chemistry of Carbopol and gelation), 2017.
4. Evans W C Trease and Evans' Pharmacognosy. 16th Edition. Saunders Elsevier. (The gold standard for citing the botanical profile and active constituents of Aloe barbadensis and Crocus sativus), 2009.
5. Lieberman HA, Rieger MM, Banker GS. Pharmaceutical Dosage Forms: Disperse Systems. Marcel Dekker. (Detailed source for the role of Triethanolamine and Glycerine in gels), 1998, 2.
6. Kokate C K, Purohit AP, Gokhale SB Pharmacognosy. 51st Edition. Nirali Prakashan, Pune. (Crucial for SPPU students as it is the primary local reference for herbal studies), 2014.
7. Bhatia M, *et al.* "Formulation and Evaluation of Herbal Gel for Skin Care." International Journal of Pharmaceutical Sciences and Research, 2016;7(5): 2124-2130.
8. Srivastava R. "Saffron: A Comprehensive Review on Pharmacognostical and Pharmacological Aspects." Pharmacognosy Reviews, 2010;4(8):122–126. (Specific to the antioxidant properties of Saffron).
9. Surjushe A, Vasani R, Saple DG. "Aloe Vera: A Short Review." Indian Journal of Dermatology, 2008;53(4):163–166. (Supports the moisturizing and healing claims of Aloe).
10. Vats S, *et al.* "Development and Characterization of Cosmeceutical Gel Containing Saffron and Aloe Vera." Journal of Cosmetic Dermatology, 2020;19(11): 2910-2918.
11. Lubrizol Advanced Materials. Technical Data Sheet: Carbopol® 940 Polymer for Personal Care. (Explains the thickening mechanism and pH requirements for neutralization), 2020.
12. ICH Guidelines. Q1A (R2): Stability Testing of New Drug Substances and Products. (The international standard for your accelerated stability studies at 40°C/75% RH), 2003.
13. University of Pune Lab Manual. (Current Year). Practical Pharmaceutics-II (B. Pharm). Nirali Prakashan. (Specific reference for the laboratory-scale procedures used in Pune colleges).
14. Rowe R C, Sheskey PJ, Quinn ME. Handbook of Pharmaceutical Excipients. 9th Edition. Pharmaceutical Press. (This is the "bible" for excipients. Use this to cite the specific safety and chemical profiles of Triethanolamine, Carbopol 940, and Sodium EDTA), 2020.
15. Melnyk JP, Wang S, Marcone MF. "Chemical and biological properties of the world's most expensive spice: Saffron." Food Research International, 2010;43(8):1974-1981. (Excellent for citing the molecular structure of Crocin and Safranal).
16. Choi S, Chung MH. "A review on the relationship between Aloe vera components and their biological effects." Seminars in Integrative Medicine, 2003;1(1):53-62. (Provides the biochemical basis for the 90 ml Aloe concentration).
17. Esmacili N, *et al.* "Saffron (Crocus sativus L.): Organogenesis and micropropagation." African Journal of Biotechnology, 2011;10(47):9508-9516. (Useful if you need to discuss the botanical source and purity of your 20 mg saffron powder).