Design and evaluation of Biphasic Bigel containing Colloidal Oatmeal and Frankincense Oil as an Adjuvant for treatment of atopic dermatitis

Mrs. Deepika A. Jagadale[1*], Ms. Sharvari Molkar[2], Ms. Anjali Karande[3], Ms. Ananya Chowdhary[4], Ms. Rudrakshi Bhamburkar[5], Mr. Rasik Kshirsagar[6]

[1-6]AISSMS College of Pharmacy, RB Motilal Kennedy Rd, Near RTO, Pune, Maharashtra, India-411001

[1]deepikapharale@gmail.com
[2]sharvarimolkar@gmail.com
[3]anjalikarande93@gmail.com
[4]ananyachowdary553@gmail.com
[5]rudrakshibhamburkar2003@gmail.com
[6]Rasikkshirsagar52376@gmail.com

Abstract

The growing demand for natural skincare formulations has prompted the exploration of innovative ingredients that offer both therapeutic and cosmetic benefits. This research investigates the formulation of a bigel containing colloidal oatmeal and frankincense oil, aimed at enhancing skin hydration and providing anti-inflammatory properties. Colloidal oatmeal, known for its skin-soothing effects, is integrated into the bigel matrix to improve its moisturizing capabilities, while frankincense oil is incorporated for its antiseptic and rejuvenating properties. Various formulation parameters, including stability, texture, and release kinetics, were systematically evaluated. The results indicate that the bigel formulation maintains structural integrity, exhibits favorable sensory attributes, and demonstrates enhanced skin hydration in vitro. Furthermore, the synergistic effect of colloidal oatmeal and frankincense oil reveals promising potential for managing conditions such as dryness and irritation. This study provides significant insights into the development of multifunctional skin formulations that leverage natural ingredients and could pave the way for more effective and appealing skincare solutions.

Keywords: *Bigels, Colloidal oatmeal, Frankincense oil, Eczema, Atopic dermatitis*

1. Introduction

As consumer interest in natural skincare continues to grow, the search for effective and safe ingredients has become increasingly vital in the cosmetic industry. Natural formulations are increasingly favored for their multifaceted benefits, which seamlessly combine therapeutic efficacy with aesthetic appeal. Among the wide array of available options, colloidal oatmeal

and frankincense oil have emerged as particularly promising candidates, celebrated for their remarkable soothing, moisturizing, and healing properties. Colloidal oatmeal has a long history of use due to its skin-soothing characteristics, making it a preferred ingredient in addressing issues like dryness and irritation [1]. In parallel, frankincense oil is recognized not only for its antiseptic qualities but also for its ability to promote skin rejuvenation, thus providing a holistic approach to skincare [2]. This study aims to investigate the formulation of a bigel—a novel emulsion system—incorporating both colloidal oatmeal and frankincense oil. By optimizing formulation parameters, we strive to enhance skin hydration and explore the anti-inflammatory effects these natural ingredients can offer. Ultimately, this research aspires to contribute to the development of effective skincare solutions that harness the synergistic potential of natural components, providing consumers with innovative options that prioritize skin health without compromising on quality or sensory experience.

2. Material and Methodology

Colloidal oatmeal was obtained from *Blend It Raw Apothecary(purchased)*. Frankincense essential oil was procured from *Earth N Pure* (purchased). All other reagents and solvents employed were of analytical grade.
The bigel was developed using a systematic approach that involved creating both a hydrogel and an organogel, which were subsequently combined to produce the final bigel formulation.

2.1 Preparation of Hydrogel phase

Preparation of the Hydrogel Phase involved the initial dispersion of colloidal oatmeal, glycerin, lactic acid, and Carbopol 940 using a mortar and pestle to achieve a uniform blend of all powdered and semi-solid ingredients. This process facilitated the initial swelling of the polymer and ensured proper wetting of the active components. The resulting mixture was then transferred to a clean beaker and continuously stirred with a magnetic stirrer. Triethanolamine (TEA) was added dropwise while maintaining constant agitation to neutralize the Carbopol and promote the formation of a turbid, homogeneous gel. Stirring continued until a stable hydrogel with the desired consistency was achieved [3].

2.2 Preparation of the Organogel Phase

In a separate beaker, the lipid components—beeswax, coconut oil, and Span 80—were combined and heated in a water bath at a temperature range of 60–70 °C. The heating process was sustained until the beeswax was entirely melted, resulting in a uniform lipid mixture. Once the lipid base appeared clear and homogeneous, frankincense essential oil and phenoxyethanol were incorporated while continuously stirring. This process ensured the even distribution of the active ingredient and preservative within the lipid matrix. The resulting mixture was then allowed to cool gradually to room temperature while maintaining continuous stirring. This cooling and agitation promoted the gelation of the lipid system, leading to the formation of the organogel [3].

2.3 Formation of the Bigel

To create the bigel, the organogel was slowly introduced to the preformed hydrogel while stirring moderately. This gradual incorporation was essential to prevent phase separation and to guarantee an even distribution of the lipid phase within the aqueous gel base. Following the complete addition, the mixture underwent high-speed homogenization to achieve a stable and uniform bigel. The homogenization process was crucial to ensure consistency [3].

Table 1. Formulation Table

Sr. No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	**Water (ml)**	**35**	**35**	**35**	**35**	**35**	**35**	**35**	**35**	**35**
2	**Carbopol (g)**	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**
3	**Tri-ethanolamine (ml)**	**0.22**	**0.22**	**0.22**	**0.22**	**0.22**	**0.22**	**0.22**	**0.22**	**0.22**
4	**Colloidal oatmeal (g)**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**
5	**Glycerine (ml)**	**2**	**2**	**0.5**	**2**	**1.98**	**1.98**	**0.5**	**2**	**1.98**
6	**Lactic acid (ml)**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**
7	**Frankincense Oil (ml)**	**0.57**	**0.57**	**0.57**	**0.57**	**0.57**	**0.57**	**0.57**	**0.57**	**0.57**
8	**Beeswax (g)**	**1**	**1.5**	**0.5**	**0.5**	**0.5**	**1**	**1.5**	**1**	**1.5**
9	**Coconut oil (ml)**	**1.6**	**1.6**	**1.6**	**1.6**	**1.6**	**1.6**	**1.6**	**1.6**	**1.6**
10	**Span 80 (ml)**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**
11	**Phenoxyethanol (ml)**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**	**0.25**

3. Design of experiment

Using Design-Expert software (version 13), a 3^2 factorial design was implemented to optimize the bigel formulation.

The impacts of two independent variables were methodically evaluated through this statistical technique:

Concentration of glycerine (%)
Concentration of beeswax (%)

Two dependent responses were analyzed to see how these variables influenced them:

Hardness (measured in grams)
Particle size (nm)

A total of nine formulations were developed, featuring all possible combinations of the two variables at three different levels (low, medium, and high). This design facilitated a better understanding of the interaction between glycerine and beeswax, enabling the selection of the optimal formulation with the desired levels of hardness and particle size.

Table 2. Optimization table for DOE

Run	Factor1: Glycerine (ml)	Factor2: Beeswax (g)	Response 1: Hardness (g)	Response 2: Particle size (nm)
1	2	1	28.6	483.7
2	2	1.5	36.4	1100
3	0.5	0.5	23.4	316.1
4	2	0.5	30.6	500
5	1.98	0.5	29.1	850
6	1.98	1	33.4	354.4
7	0.5	1.5	40.4	574.4
8	2	1	32.9	442.2
9	1.98	1.5	42.6	1150

Table 3. Statistical models

Parameter	Model	R^2	Adequate Precision	Model F Value	P-Value
Hardness(g)	**2F1**	**0.7852**	**6.4911**	**10.96**	**0.0099**
Particle size (nm)	**2F1**	**0.9067**	**8.6899**	**9.72**	**0.0245**

Hardness=33.04+6.76B1−1.41B2

Particle size=594.93+113.29A1+189.87A2+346.54B1−306.98B2

A – Glycerin B – Beeswax

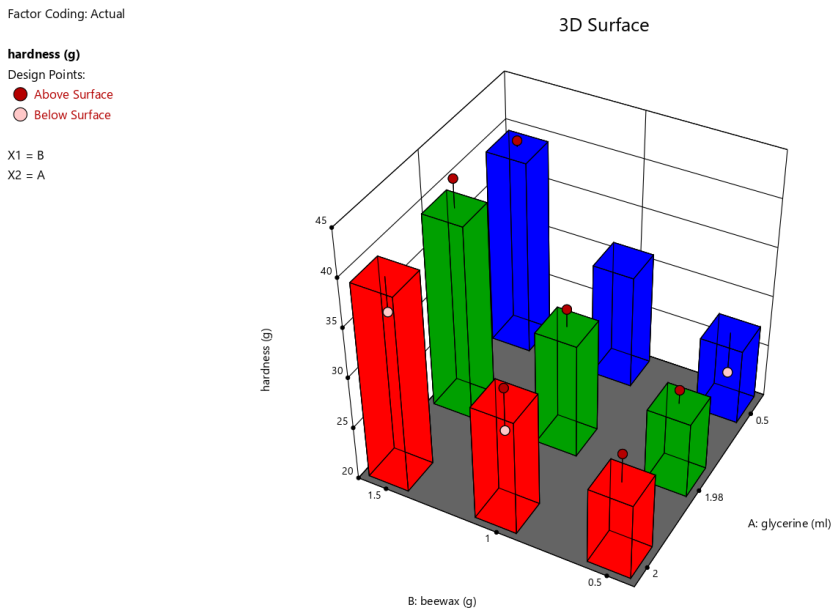

Figure 1. 3D Surface graph for hardness

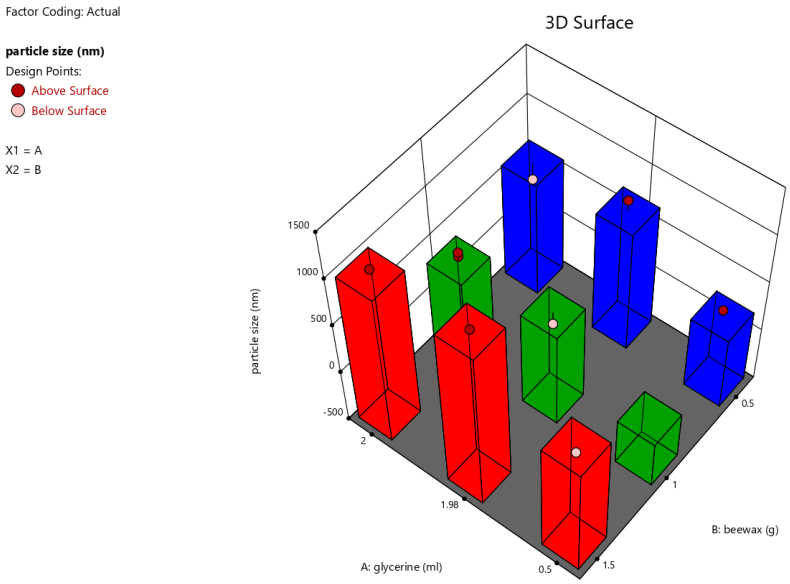

Figure 2. 3D Surface graph for Particle size

4. Evaluation Parameters

4.1Oganoleptic Properties

Color, odor, taste, and texture are all examples of an organoleptic property of a bigel formulation that are sense-perceived and are essential to the sensory experience and acceptance of the product. The sample (organogel, hydrogel, bigels) was applied to a glass slide in a 2–4 mm layer in order to analyze the sensory parameters of color, odor, consistency and feel [4].

4.1.1Color

The components utilized, including the color of the hydrogel and organogel components and any additional colorants, might affect a bigel's color.

4.1.2Odor

The volatile molecules in a bigel's formulation—which may come from the hydrogel, organogel, or additional ingredients—determine its odor. A good sensory experience can be enhanced by a suitable and pleasant scent.

4.1.3Texture

The texture of a bigel, which refers to how it feels in the mouth or on the skin, is a significant organoleptic characteristic. This encompasses elements like smoothness, creaminess, or the presence of any particulates.

4.1.4Feel

The sensation of a bigel on the skin or in the mouth is another vital organoleptic attribute. It should strike a balance, being neither overly greasy nor excessively sticky. Sensory evaluation of the formulated bigels indicated that they were uniform semi-solid systems, with color varying based on the quantity of organogel used. Coconut oil possesses distinct traits that affect the typical sensory profile of various products. Every sample exhibited a scent reminiscent of frankincense.

4.2 Homogeneity

Homogeneity evaluation involves examining the even distribution of active compounds and excipients in a formulation, guaranteeing consistency in dosage forms, effectiveness, and stability of pharmaceutical and cosmetic products [5].

4.3 Texture Analysis

Texture analysis is an important factor in examining the mechanical properties of bigels, which are important for their spreadability, stability, and consumer acceptability in pharmaceutical and cosmetic applications [6]. The analysis provides quantitative measurements of the gel’s hardness, adhesiveness, resilience, cohesiveness, and stringiness and these factors contribute to both the sensory and functional properties of the gel. In this study Texture Profile Analysis (TPA) was performed using a Brookfield Texture Analyzer, in compression mode. During the test, a probe was lowered to a controlled weight on the gel samples to measure hardness (resistance to deformation), adhesiveness (work to overcome attractive forces), resilience (the ability to return to shape), and stringiness (the extent of stretching before breaking) [7] [8].

4.4 Spreadability Studies

An excess of bigel was placed between two glass slides and compressed to a consistent thickness using weight (in grams) for five minutes to assess its spreadability. Weights (in grams) were added to a pan. The spreadability is determined by the time required to separate the two slides, during which the upper slide moves over the lower slide. This procedure was repeated three times for each bigel. The formula $(m \times l) / t = S$ represents spreadability, where S stands for spreadability, m denotes the weight of the upper slide, l is the distance traveled by the upper glass slide, and t is the time taken [9].

4.5 pH

The pH was assessed by dissolving a precisely measured amount of bigel in 10 ml of distilled water, after which the pH of the resulting dispersion was recorded using a digital pH meter at room temperature. This process was repeated three times for each bigel [9].

4.6 Particle Size Analysis

Particle size analysis, is an important parameter in determining the physical stability, dispersion uniformity, and bioavailability of bigel formulations. Particle size and particle size distribution will influence the texture, spreadability, the full range of drug release and stability of the formulation [10].

In this study, Dynamic Light Scattering (DLS) was used to determine the Z-average particle size (d. nm), polydispersity index (PdI), and intensity distribution of bigel samples. DLS determined light scattering fluctuations associated with the Brownian motion of the particles, which allowed particle size to be determined based on the Stokes-Einstein equation.

The Z-average diameter means intensity-weighted mean particle size and the PdI provides an indication of the uniformity of the particle size distribution. A low PdI (≤ 0.3) indicates a more homogeneous dispersion, while a high PdI (>0.5) is indicates polydispersity and the potential for phase separation over time. Recognizing the particle size distribution is important for optimizing stability and performance characteristics of bigels while preserving similarities that are important for use in pharmaceutics [11].

4.7 Zeta Potential Analysis

An important metric for assessing the colloidal stability of bigel formulations is zeta potential analysis. It provides information about the surface charge, stability, and possible aggregation behavior of dispersed particles in a liquid media by measuring their electrokinetic potential. Higher absolute values of the zeta potential suggest stronger electrostatic repulsion between particles, which lowers the chance of aggregation and affects the bigel's physical stability [12].

In this study, a Zetasizer in aqueous dispersion was used to perform Zeta Potential Analysis. The device uses the Smoluchowski equation to determine the zeta potential and monitors the electrophoretic mobility of charged particles in the presence of an applied electric field. Zeta potential (mV), peak distribution, zeta deviation, and conductivity (mS/cm) are among the important metrics that were noted.

A high negative or positive zeta potential value (greater than ±30 mV) suggests a stable formulation with good particle dispersion, whereas values closer to zero indicate weak repulsion, increasing the risk of flocculation or phase separation [13].

4.8 Viscosity

The viscosity of the prepared gels was measured using a Brookfield viscometer (Brookfield DV-II+ Pro). The samples were gathered for analysis in a 100 ml beaker. The samples' viscosity was measured using spindle number 94. The test was run six times on each sample, and the average outcome was determined. The experiment was carried out at room temperature with an angular velocity of 4 rpm [14].

4.9 In vitro drug release studies

In vitro drug release was assessed using a Franz diffusion cell for a bigel formulation containing colloidal oatmeal and frankincense oil. The diffusion membrane was placed in the receptor compartment filled with phosphate buffer at pH 5.5, which was maintained at a temperature of 32±0.5°C for 8 hours to achieve equilibrium. The diffusion cell was set up on a magnetic stirrer along with the diffusion membrane that separates the donor and receptor compartments. A bigel sample weighing 50 mg was placed on the membrane in the donor compartment. The contents were stirred at a rate of 50 rpm using the magnetic stirrer, and 1 ml aliquots were taken from the release medium at various time intervals: 0, 1, 2, 3, 4, 5 ,6,7 and 8 hours. Each withdrawn sample was replaced with an equal volume of fresh medium. The absorbance of these samples was measured at 249 nm using a UV-Visible double beam spectrophotometer (**Make: Jasco, Model: V730)** [15].

While the absorbance was shown along the Y axis, the concentration was plotted along the X axis [16].

Table 4. Absorbance Colloidal Oatmeal

Concentration	Absorbance
100	0.2738
200	0.3739
300	0.6874
400	0.6666

500	1.1724
600	1.2499
700	1.4766
800	1.6122

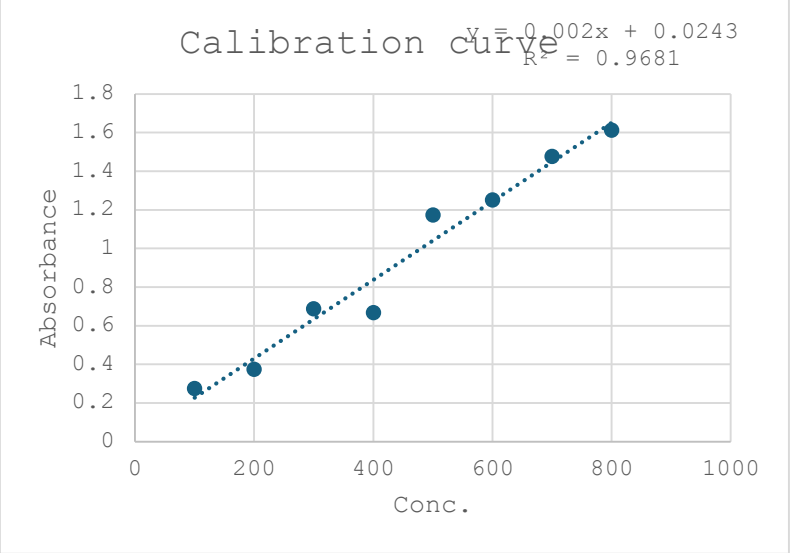

Figure 3. Calibration curve for colloidal oatmeal using UV spectrophotometry

4.10 Bigel Stability studies determination.

Stability studies for the bigel were conducted over the course of one month at 4°C (refrigerated stability), 25°C (long-term stability), and 40°C (accelerated stability). A glass container was filled with each of the formulated gels. The packaged gels were then kept under the various specified temperature and environmental conditions. After the tests, phase separation, content, viscosity, and pH were assessed [17].

5. Results and discussion

Table 5. Observed results

Sr. No	Parameters	F3	F6	F7
1	**Color**	White	White	White
2	**Odour**	Pleasant	Pleasant	Pleasant
3	**Consistency**	Semisolid	Semisolid	Semisolid
4	**Texture**	Smooth	Smooth	Smooth
5	**Feel**	Creamy, smooth, soft spreadable	Creamy, smooth, soft spreadable	Creamy, smooth, soft spreadable texture, leaving a light

		texture, leaving a light occlusive film without greasy residue	texture, leaving a light occlusive film without greasy residue	occlusive film without greasy residue
6	**Homogeneity**	Consistent appearance, no phase separation, clumping, or visible aggregates	Consistent appearance, no phase separation, clumping, or visible aggregates	Consistent appearance, no phase separation, clumping, or visible aggregates
7	**Hardness (g)**	23.4	33.4	40.4
8	**Spreadability (g.cm/s)**	300	275	155
9	**pH**	6.2	5.4	6.0
10	**Particle Size (nm)**	316.1	354.4	574.4
11	**Zeta Size (mv)**	-33.6	-18.7	-21.4
12	**Viscosity (c.p)**	65,500	71,250	75,950

14) In-vitro drug release studies

Table 6. % Drug release of F3

Time(hr)	**Absorbance**	**Concentration (µg/mL)**	**% drug release**
0	0	0	0
1	0.092	33.85	3.385
2	1.08	527.85	52.785
3	1.18	577.85	57.785
4	1.27	622.85	62.285
5	1.35	662.85	66.285
6	1.41	692.85	69.285
7	1.57	772.85	77.285
8	1.65	812.85	81.285

Table 7. % Drug release of F6

Time (hr)	Absorbance	Concentration (µg/mL)	%drug release
0	0	0	0
1	0.089	32.35	3.235
2	0.098	36.85	3.685
3	1.06	517.85	51.785
4	1.17	572.85	57.285
5	1.27	622.85	62.285
6	1.35	662.85	66.285
7	1.42	697.85	69.785
8	1.59	782.85	78.285

Table 8. % Drug release of F7

Time (hr)	Absorbance	Concentration (µg/mL)	%drug release
0	0	0	0
1	0.078	26.85	2.685
2	0.087	31.35	3.135
3	0.099	37.35	3.735
4	1.09	532.85	53.285
5	1.15	562.85	56.285
6	1.22	597.85	59.785
7	1.29	632.85	63.285
8	1.38	677.85	67.785

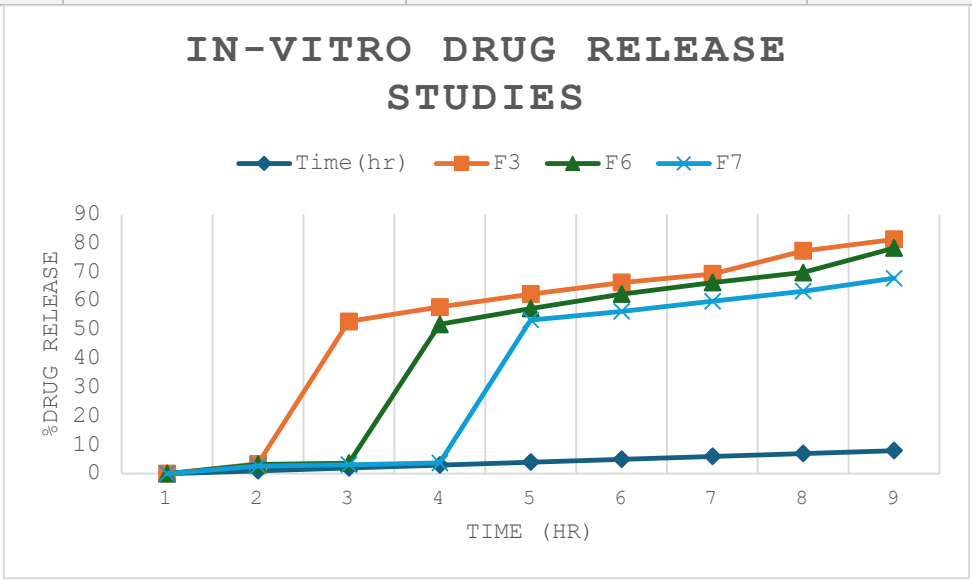

Figure 4. Graph for in-vitro drug release studies for formulation F3, F6 and F7

Table 9. Kinetic models for F3, F6 and F7

Model	F3 (R^2)	F6(R^2)	F7(R^2)
Zero order	0.8837	0.8621	0.8468
First order	0.8005	0.9319	0.8468
Higuchi model	0.9281	0.9147	0.7419
Korsmeyer-peppas model	0.754	0.8635	0.8589

The developed bigel formulations (F3, F6, and F7) were thoroughly assessed for their physicochemical attributes, mechanical properties, drug release capabilities, dermal compatibility, and stability.

Organoleptic Characteristics and Uniformity

Each formulation displayed a consistent white, semi-solid appearance accompanied by a smooth, creamy texture and a pleasant fragrance from the frankincense oil. The sensory assessment indicated excellent uniformity, with no signs of phase separation, aggregation, or clumping.

Texture Assessment and Mechanical Properties

The Texture Profile Analysis indicated hardness values of 23.4 g for F3, 33.4 g for F6, and 40.4 g for F7, suggesting that a higher concentration of beeswax improved the mechanical strength of the bigels.

pH Evaluation

The pH levels of the formulations were found to be between 5.4 and 6.2, which is consistent with the skin's physiological pH range (5.0–6.5). This indicates a low likelihood of causing irritation or disturbing the natural skin barrier during topical use.

Particle Size and Zeta Potential Analysis

Dynamic Light Scattering (DLS) assessments showed that the particle sizes ranged from 316.1 nm to 574.4 nm. The zeta potential readings were moderately negative (–18.7 to –33.6 mV), indicating sufficient electrostatic repulsion and stability of the colloid. Formulation F3 displayed the smallest particle size along with the highest zeta potential magnitude, suggesting enhanced stability in dispersion.

Rheological Attributes

Viscosity assessments indicated an increase with greater beeswax proportions, ranging from 65,500 c.p (F3) to 75,950 c.p (F7). This rheological behavior illustrates the dual-phase composition of bigels, where the oleogel component (beeswax and coconut oil) plays a crucial role in developing the viscoelastic characteristics.

In Vitro Drug Release Evaluations

The drug release profiles indicated that F3 exhibited the highest total drug release after 8 hours, followed by F6 and F7. The enhanced release observed with F3 could be linked to its lower concentration of beeswax, which allows for a less compact matrix and fosters rapid diffusion of the active ingredients. These findings emphasize the importance of achieving an optimal balance between the hydrogel and oleogel phases to enhance permeation properties.

Kinetic models

The formulations analyzed show varied drug release kinetics. Formulation F3 exhibits a release profile that is controlled by diffusion, aligning with the Higuchi model.

Stability Studies

When the formulations were subjected to stability conditions recommended by the ICH (4°C, 25°C, and 40°C), no significant changes in color, odor, or phase separation were detected.
• Under refrigerated conditions (4°C), a minor decrease in viscosity and spreadability was observed.
• In accelerated conditions (40°C), an increase in spreadability and improved drug release was noted, likely due to the softening of the gel matrix.
Overall, all three formulations showed physicochemical stability throughout the one-month evaluation period, with only slight acceptable variations in viscosity, hardness, and pH.

Conclusion

In conclusion, this research successfully formulated and optimized a bigel containing colloidal oatmeal and frankincense oil for the topical treatment of atopic dermatitis, utilizing a 3^2 factorial design. Among the nine formulations tested, F3 emerged as the most effective, demonstrating excellent spreadability, appropriate hardness, stable particle size, and a sustained drug release of 81.2% over 8 hours, without any indications of skin irritation. Stability assessments conducted under ICH guidelines affirmed its physical and chemical integrity. In comparison to traditional therapies such as corticosteroids and calcineurin inhibitors, this bigel presents a safer, more natural option that enhances hydration, repairs the skin barrier, and minimizes the likelihood of adverse effects. The dual-phase formulation facilitates extended drug release and better compatibility with the skin. Future research should prioritize clinical

validation, long-term stability assessments, and scaling up for potential applications in other dermatological issues, including psoriasis, xerosis, and wound healing.

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