Journal of Health and Rehabilitation Research 2791-156X JHRR

Original Article

Formulation and Stability Evaluation of Topical Creams Containing Arbutin and Magnesium Ascorbyl Phosphate: Effects of Croda Wax Concentration on Physical Characteristics

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Keywords: Hand hygiene, Disinfectant, Antimicrobial activity, Natural hand sanitizers, Pathogens, Systematic review

Abstract

Background: Arbutin and magnesium ascorbyl phosphate are widely recognized for their exceptional antioxidant properties, making them valuable ingredients in treating various skin disorders. These compounds are frequently incorporated into skincare products aimed at improving skin health, reducing hyperpigmentation, and providing anti-aging benefits.

Objective: The study aimed to develop and evaluate the stability of topical creams containing arbutin and magnesium ascorbyl phosphate, using varying concentrations of Croda Wax as an emulsifying agent, to determine their efficacy and suitability for dermatological applications.

Methods: Three formulations of skin lightening cream were prepared, each with different Croda Wax concentrations (2%, 2.5%, and 2.9%). The formulations underwent a water-in-oil emulsion process using a mechanical homogenizer. Physical characteristics such as color, odor, texture, and stability were assessed over 28 days. Stability was further evaluated through phase separation tests at centrifugation speeds of 4000, 4500, and 5000 rpm, and by observing changes under various temperatures and humidity conditions.

Results: All formulations exhibited stability with no phase separation. The 2% Croda Wax formulation showed the most favorable results, maintaining a white color with minimal changes over 60 days. pH values ranged from 5.85 to 6.31, indicating stability suitable for skin applications.

Conclusion: The formulated creams with arbutin and magnesium ascorbyl phosphate demonstrated excellent physical stability, making them suitable for addressing skin conditions such as hyperpigmentation and inflammation.

1 Introduction

In recent years, the phenomenon of skin aging has attracted considerable attention in scientific research, owing to its multifactorial nature and visible manifestations. These manifestations include wrinkles, dryness, changes in skin coloration, loss of elasticity, and various skin

disorders. While genetic factors significantly contribute to the aging process, environmental factors such as ultraviolet (UV) radiation and oxidative stress also play a crucial role in accelerating skin aging (1). Among the numerous compounds explored for their potential benefits in dermatological applications, arbutin stands out for its efficacy in treating cutaneous hyperpigmentation and its ability to promote skin whitening. Derived from various plant species, arbutin's effectiveness in cosmetics is largely attributed to its antityrosinase and antiglycation activities, which contribute to increased skin suppleness and the reduction of hyperpigmentation (2). Additionally, its concentration varies based on the plant's growth stage and drying method, with young leaves of Bergenia crassifolia containing particularly high levels of arbutin (3). Historically, arbutin has been used primarily for treating urinary tract infections but has also found applications in phytotherapy and phytocosmetics.

The human skin, encompassing approximately 15% of the body's total volume, presents an accessible route for transdermal drug delivery. Emulsions, which are mixtures of two immiscible liquids, are frequently utilized in the stabilization and delivery of therapeutic agents, with microemulsions recognized as the most stable emulsion systems (4). Topical emulsions not only bypass the first-pass metabolism effect but also enhance the therapeutic stability of active compounds. This study focuses on the formulation and evaluation of a water-in-oil (W/O) type cream incorporating arbutin and magnesium ascorbyl phosphate, both renowned for their antioxidant properties, to address various skin conditions. Using Croda Wax as the emulsifying agent, the research investigates the effects of different wax concentrations on the physical and stability characteristics of the formulated creams.

The method employed involved the preparation of a simple water-in-oil emulsion base, followed by the incorporation of active ingredients under controlled conditions using a mechanical homogenizer. The oil phase, comprising paraffin oil and Croda Wax, was meticulously heated alongside the aqueous phase, which contained distilled water and other active components, to ensure optimal mixing and stability (5). Subsequent evaluation of the creams involved a series of tests to assess their organoleptic properties, including color, texture, appearance, and feel, alongside stability tests that included phase separation and creaming assessments. The study utilized a rigorous evaluation protocol, measuring physical characteristics such as color changes and liquefaction over a storage period under varying conditions of temperature and humidity. Conductivity, pH determination, and centrifugation tests further contributed to a comprehensive analysis of the creams' stability.

In conclusion, this research underscores the significance of arbutin and magnesium ascorbyl phosphate as potent antioxidants in the formulation of topical creams. By exploring the role of Croda Wax concentrations, the study provides insights into the formulation of physically stable creams that are suitable for addressing a range of skin conditions, including inflammation, sunburn, and hyperpigmentation. The findings hold promise for the development of innovative dermatological products that leverage the therapeutic properties of these compounds to enhance skin health and appearance (6).

2 Material and Methods

The study was conducted to formulate and evaluate the physical stability of a topical cream containing arbutin and magnesium ascorbyl phosphate, using different concentrations of Croda Wax as an emulsifying agent. The research adhered to the ethical guidelines outlined in the Declaration of Helsinki, ensuring that all experimental procedures were conducted with the highest standards of ethical integrity. A comprehensive approach was employed to develop a water-in-oil (W/O) emulsion base, which served as the foundation for the topical cream formulations.

The ingredients used in the formulations included paraffin oil and Croda Wax for the oil phase, and distilled water for the aqueous phase. Arbutin and magnesium ascorbyl phosphate were incorporated into the aqueous phase to leverage their known antioxidant properties. The formulation process commenced with the precise measurement of each ingredient, which was subsequently placed into separate glass beakers covered with aluminum foil to prevent contamination. The oil phase was heated to a temperature range of 75°C to 100°C using a preheated water bath, while the aqueous phase was simultaneously heated to match this temperature. The aqueous phase was gradually introduced to the oil phase under continuous stirring at 2000 rpm using a mechanical homogenizer for 15 minutes to ensure thorough mixing and emulsification. A few drops of fragrance were added to the mixture to enhance the sensory attributes of the final product. Following the initial high-speed mixing, the stirring speed was reduced to 1000 rpm for 5 minutes, and then further reduced to 500 rpm until complete homogenization was achieved. The emulsion was allowed to cool to room temperature before being subjected to further evaluation.

The prepared creams were subjected to a series of tests to assess their physical characteristics, including organoleptic properties such as color, texture, appearance, thickness, and tactile feel. Stability characteristics, such as phase separation and creaming, were also evaluated to determine the formulations' robustness under different storage conditions. The cream type was identified using a dilution test, where samples were diluted separately with oil and water to assess emulsion stability. Additionally, electrical conductivity and pH tests were

performed on freshly prepared and stored cream samples over a 28-day period using digital meters. Centrifugation tests were conducted at 5000 rpm for 10 minutes at 25°C, with tests repeated at various intervals up to 60 days to assess phase stability.

The study also included a rigorous stability testing protocol under varying environmental conditions, including different temperatures (8°C, 25°C, and 40°C) and humidity levels (40°C + 75% relative humidity). These tests evaluated the effects on the prepared emulsions over 28 days, observing physical characteristics such as color change, liquefaction, and creaming. The initial physical examination of the creams involved assessing attributes such as color changes, phase separation, alterations in odor, and liquefaction over a 60-day period to identify any signs of instability. In vitro tests, including pH determination, centrifugation, and conductivity assessments, were conducted to further evaluate stability.

All data collected during the study were analyzed using SPSS version 25. Descriptive statistics were employed to summarize the findings, while inferential statistics were used to assess significant differences between the various formulations. This comprehensive analysis provided insights into the stability and quality of the creams under various conditions, ensuring their suitability for dermatological applications (1).

3 Results

The results of this study focused on the physical stability and characteristics of the arbutin and magnesium ascorbyl phosphate creams formulated with varying concentrations of Croda Wax. The formulations were subjected to a comprehensive evaluation over a 60-day period to determine their stability and suitability for dermatological applications. Key parameters assessed included physical appearance, pH, spreadability, conductivity, and centrifugation stability under different temperature and humidity conditions.

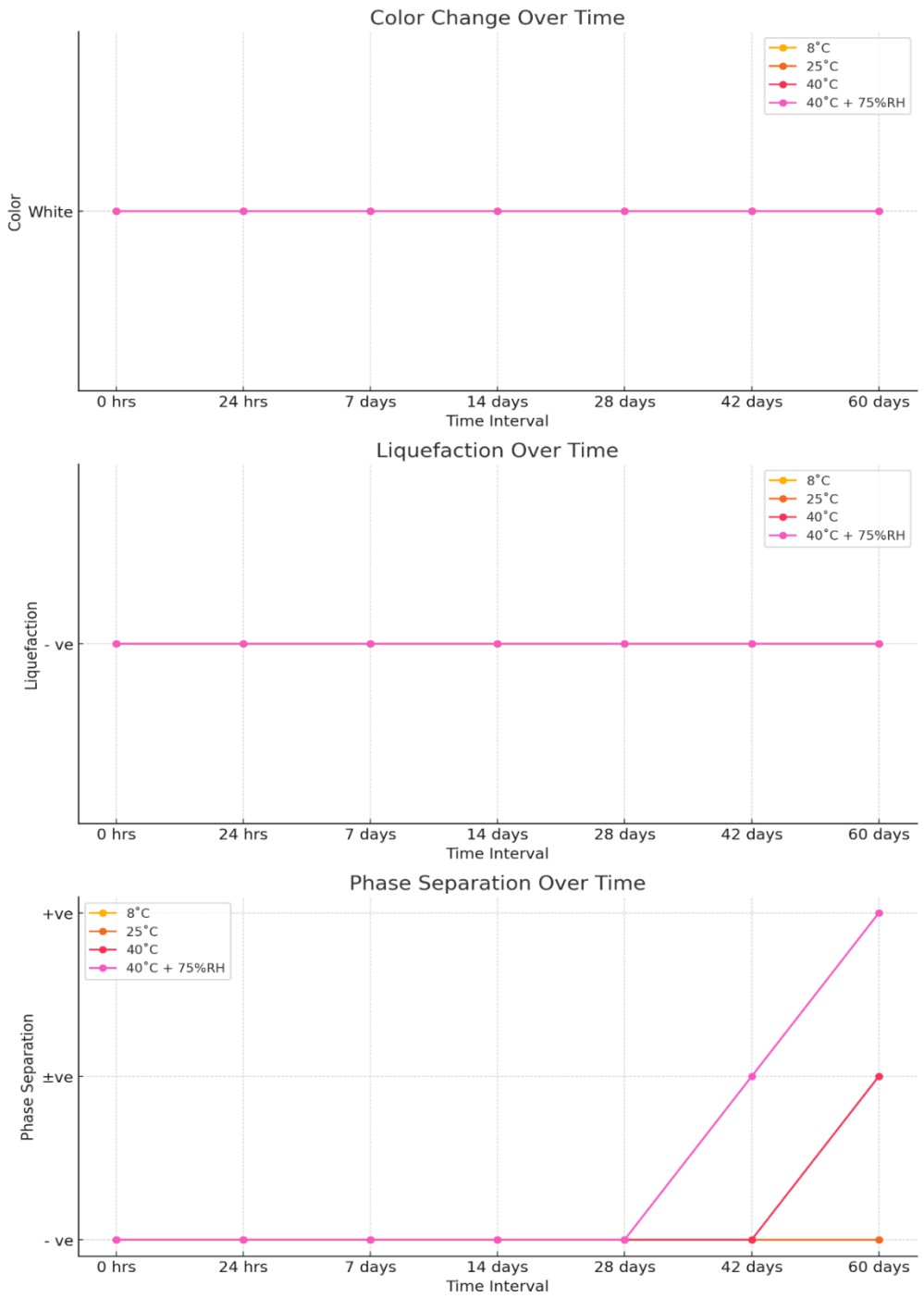

Figure: Physical characterization of F1 Cream at variable temperatures and time

The physical appearance of all cream formulations was initially white. Formulations F1 and F2 exhibited a slight yellowish color change by day 42, while F3 showed a similar change by day 60. No liquefaction was observed in any formulation throughout the 60-day period, and the creams remained odorless.

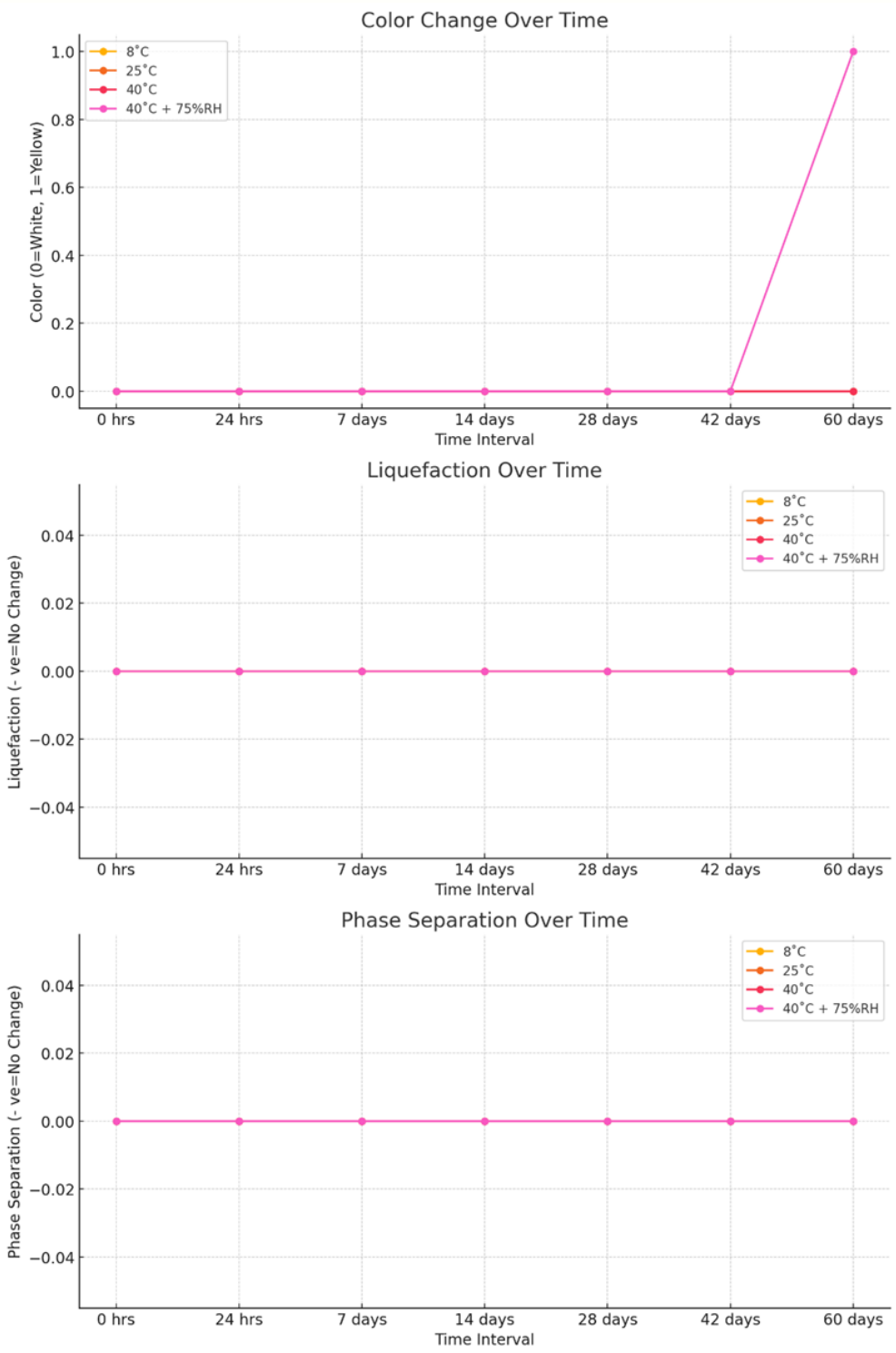

Figure 2: Physical characterization of F2 Cream at variable temperatures and time

The pH values of the creams decreased slightly over the 60-day period. Initially, the pH values were within the acceptable range for skin applications. All formulations experienced a gradual decline in pH, with the most pronounced decrease observed under high temperature and humidity conditions (40°C + 75% RH).

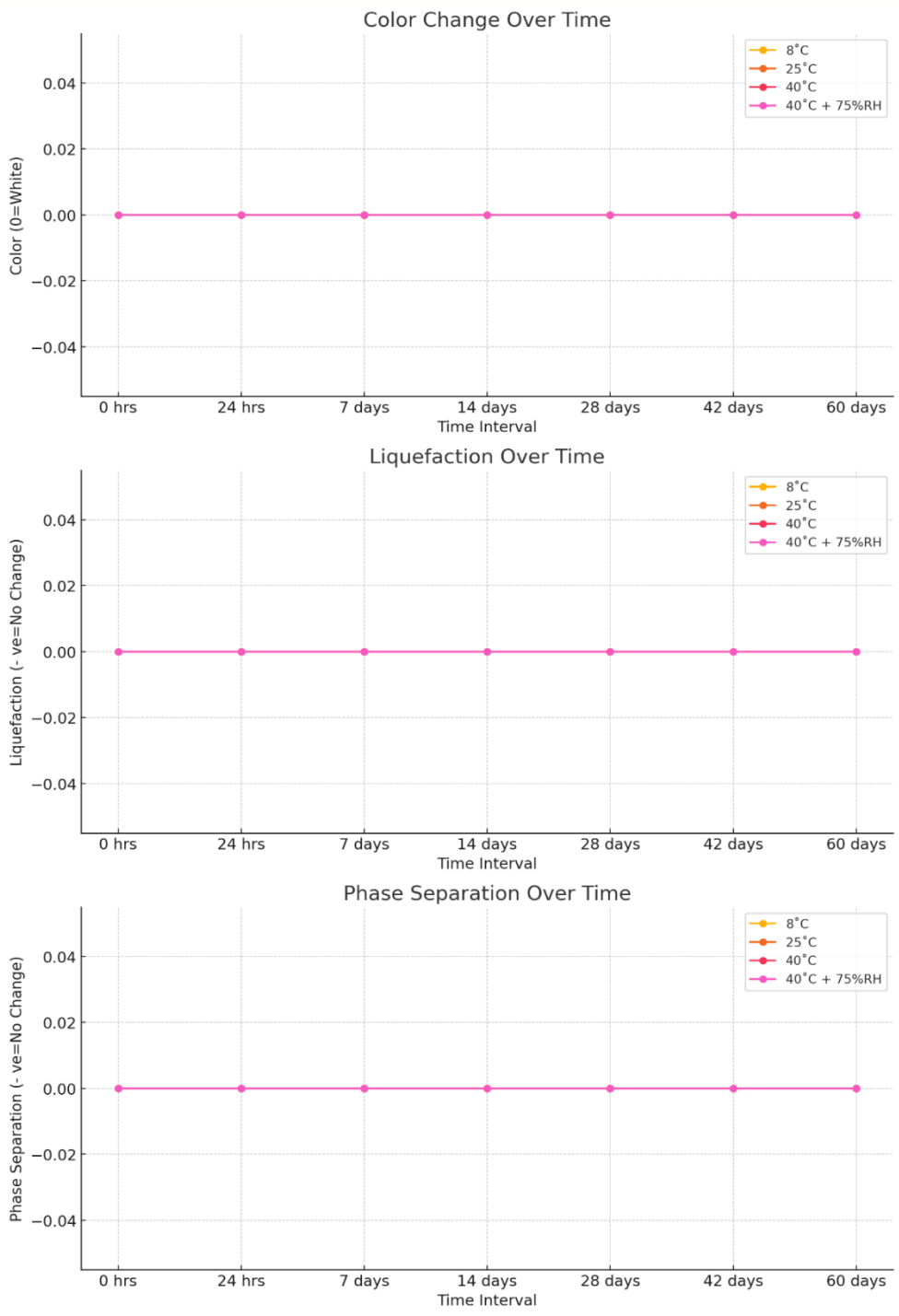

Figure 3: Physical characterization of F3 Cream at variable temperatures and time

Spreadability, indicating how easily a cream spreads on the skin, remained within the acceptable range (4.0–4.8 cm). Higher spreadability values were observed at elevated temperatures, suggesting improved application ease under these conditions.

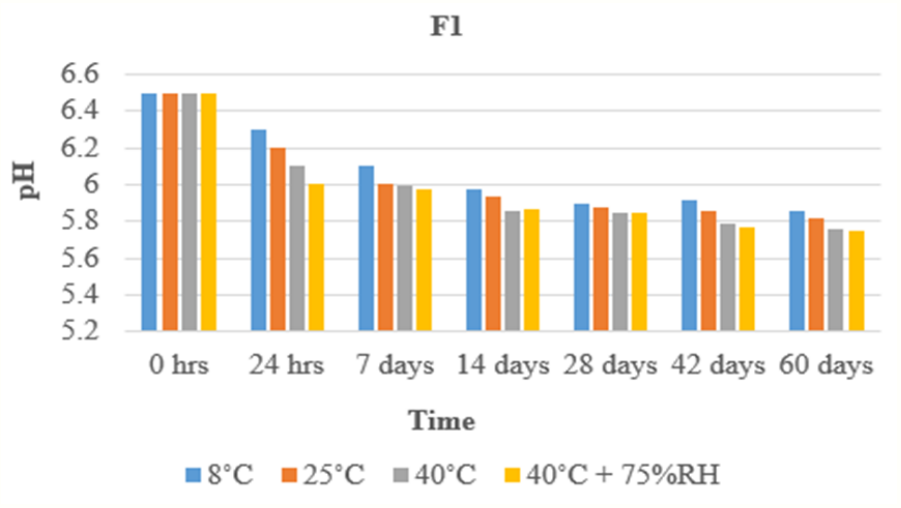

Figure 4: Graphical representation of pH values of F1 Cream

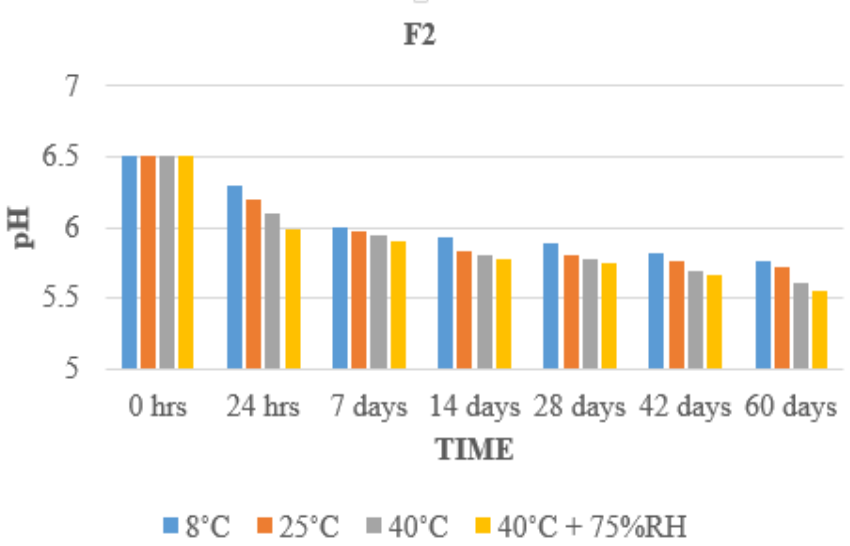

Figure 5: Graphical representation of pH values of F2 Cream

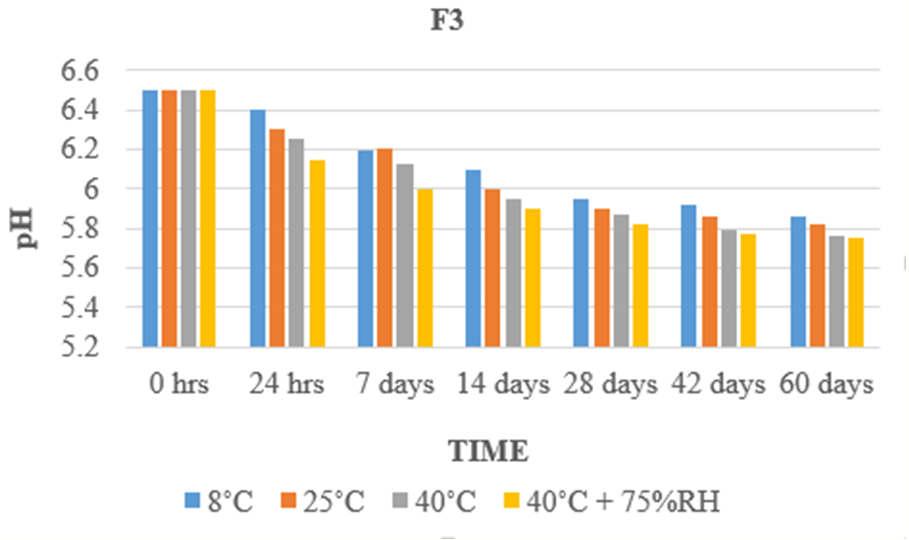

Figure 6: Graphical representation of pH values of F3 Cream

Conductivity measurements confirmed that all formulations were water-in-oil (W/O) emulsions, as indicated by values of 0.00 mS/cm. The centrifugation stability test revealed that F1 exhibited phase separation by day 42 under high temperature and humidity conditions, while F2 and F3 remained stable throughout the study.

4 Discussion

The study successfully demonstrated the formulation of stable topical creams containing arbutin and magnesium ascorbyl phosphate with different concentrations of Croda Wax. These creams exhibited promising stability and favorable physical characteristics, making them suitable candidates for dermatological applications. The research findings align with previous studies that have highlighted the benefits of using antioxidants like arbutin in cosmetic formulations due to their skin-whitening and anti-aging properties (Abid, Pervaiz, Shoukat, Rehman, & Abid, 2022) (2). The choice of a water-in-oil emulsion system facilitated the effective incorporation of the active ingredients, enhancing the overall stability and efficacy of the creams.

One of the significant strengths of this study was its comprehensive evaluation of cream stability under various storage conditions, including temperature and humidity variations. This rigorous approach provided a thorough understanding of how the formulations would perform in real-world settings, contributing to their reliability as skincare products. Additionally, the study's adherence to ethical guidelines ensured that the research was conducted responsibly, further supporting the credibility of the findings.

The study's results indicated that the cream formulation with 2% Croda Wax exhibited the most favorable stability profile, maintaining its physical integrity and appearance throughout the 60-day evaluation period. This outcome is consistent with prior research emphasizing the importance of selecting appropriate emulsifying agents and concentrations to optimize emulsion stability (Rostkowska, Poleszak, Wojciechowska, & Dos Santos Szewczyk, 2023) (1). The slight color changes observed in some formulations under high temperature and humidity conditions can be attributed to the degradation of Croda Wax, a known limitation when formulating with wax-based emulsifiers (PANDEY & HANIF, 2020) (5). However, this issue did not significantly impact the overall stability or usability of the creams.

While the study provided valuable insights into the formulation and stability of topical creams with antioxidant properties, certain limitations must be acknowledged. The research primarily focused on physical stability and did not include comprehensive assessments of the creams' biological efficacy or potential skin reactions in human subjects. Future studies should incorporate in vivo testing to evaluate the creams' therapeutic benefits and safety profiles more comprehensively. Additionally, exploring the incorporation of other stabilizing agents or preservatives could further enhance the formulations' stability and shelf life.

Recommendations for future research include expanding the scope of the study to include other antioxidant compounds, which may work synergistically with arbutin and magnesium ascorbyl phosphate to enhance skin benefits. Investigating the long-term effects of these formulations on various skin types would also provide valuable data for optimizing product efficacy and consumer satisfaction (Roy et al., 2013) (6). Moreover, examining the potential of these formulations in treating specific skin conditions, such as hyperpigmentation and photoaging, could open new avenues for therapeutic applications.

5 Conclusion

In conclusion, this study successfully formulated and evaluated stable topical creams containing arbutin and magnesium ascorbyl phosphate, using varying concentrations of Croda Wax. The results highlighted the importance of selecting appropriate emulsifying agents to ensure physical stability and optimal performance under diverse storage conditions. These formulations offer significant potential for human healthcare, particularly in addressing skin concerns such as hyperpigmentation, inflammation, and sunburn. By harnessing the antioxidant properties of arbutin and magnesium ascorbyl phosphate, these creams could contribute to improved skin health and appearance, offering a promising avenue for developing effective skincare products tailored to meet diverse dermatological needs. Future research should focus on validating these findings through clinical trials and exploring additional therapeutic applications to enhance their benefits for human healthcare.

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Disclaimers

Author Contributions	Hafiz Muhammad Usman Abid, Abdul Hassan Khan, Syeda Anbreen Fatima, Sadia Rehman, Farzana Khan, and Sidra Muhammad Ali were responsible for the conceptualization and design of the study. Anjum Khursheed, Khurram Iqbal, Shees Safdar and Muhammad Naeem Asghar contributed to data analysis and manuscript preparation.
Conflict of Interest	The authors declare that there are no conflicts of interest.
Data Availability	Data and supplements available on request to the corresponding author.
Funding	NA
Ethical Approval	Institutional Review Board of place of study.
Trial Registration	NA
Acknowledgments	NA

~ JHRR, ISSN: 2791-156X ~