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FORMULATION OF "ALVEMINT" GEL TO RELIEVE PAIN AND BREAST ENGORGEMENT IN POSTPARTUM MOTHERS WITH MILK STASIS

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ABSTRACT

This study aimed to formulate and evaluate the *AlveMint* gel preparation containing Aloe vera powder and menthol for relieving pain and breast swelling in postpartum mothers with milk engorgement. The gel was prepared using five formulas with variations in Aloe vera concentration: F0 (0%), F1 (0.25%), F2 (0.5%), F3 (0.75%), and F4 (1%), combined with menthol (0.5%) as an active cooling agent. The preparation process included heating, mixing, and homogenization, followed by the addition of preservative and pH adjustment. The formulated gels were evaluated for organoleptic properties, homogeneity, pH, spreadability, stability, and irritation**.**

All gel formulations exhibited white color, menthol aroma, and semi-solid consistency. The gels were homogeneous, with pH values ranging from 5.1 to 5.5**,** fulfilling the acceptable skin pH range (4.5–6.5). The spreadability values were between 5.9 and 6.6 cm, meeting the semi-solid dosage form requirements (5–7 cm). No irritation reactions were observed among 15 human volunteers during patch testing. The presence of menthol provided a cooling sensation, enhancing comfort during application. Increasing concentrations of Aloe vera slightly decreased pH values but did not affect the gel's stability or homogeneity.

In conclusion, the *AlveMint* gel formulation containing Aloe vera and menthol demonstrated good physical properties, acceptable skin compatibility, and potential for use as a topical preparation to alleviate breast engorgement symptoms in postpartum mothers.

Keywords: *Aloe vera*; menthol; AlveMint gel; breast engorgement

INTRODUCTION

Breast engorgement, characterized by pain, swelling, and firmness, is a common postpartum complication that significantly impacts the quality of life for lactating mothers and often leads to premature cessation of breastfeeding (Kementerian Kesehatan Republik Indonesia, 2024). Traditional management typically involves non-pharmacological methods like massage and cold therapy, highlighting the potential for localized topical treatments that offer both soothing and anti-inflammatory effects.

Aloe vera (*Aloe barbadensis Miller*) is widely recognized for its high water content and therapeutic properties, primarily attributed to polysaccharides, glycoproteins, and anthraquinones (Sirait, 2019). These components provide moisturizing, anti-inflammatory, and wound-healing benefits, making *Aloe vera* an excellent herbal source for alleviating topical inflammation (Linder, 2012).

Menthol, a cyclic terpene alcohol, is incorporated into topical preparations for its cooling and analgesic effects. It selectively activates the kappa-opioid receptor and the cold-sensitive transient receptor potential M8 (TRPM8) channel, creating a counterirritant sensation that rapidly masks pain and discomfort (Aiyalu, Govindarjan, & Ramasamy, 2016). Furthermore, Menthol can act as a penetration enhancer, potentially improving the transdermal delivery of other active compounds (Borse, Gangude, & Deore, 2020).

The current effort in pharmaceutical formulation is focused on creating stable, synergistic, and patient-compliant dosage forms (Rowe, Sheskey, & Quinn, 2009). Gels are highly favored for topical application due

to their non-greasy nature, rapid absorption, and cooling sensation upon application (Azijah, Hidayaturahma, & Saputri, 2023). Previous studies have established the importance of optimizing gelling agents and auxiliary ingredients to ensure the finished product maintains its desired physical and chemical properties throughout its shelf life, particularly under diverse storage conditions (Nishad, Verma, Kumar, & Khurana, 2025; Setiawan et al., 2023).

This research aims to bridge the gap between traditional herbal use and pharmaceutical standardization by formulating a topical gel combining *Aloe vera* and Menthol—the "Alvemint Gel."

The specific objectives of this study were:

To determine the optimal formula of the Alvemint Gel preparation that meets acceptable physical quality standards (organoleptic, homogeneity, pH, and spreadability).

To evaluate the accelerated physical stability of the formulated gel under various storage temperatures (4°C, 25-30°C, and 40°C}.) over seven weeks.

MATERIALS AND METHODS

Research Design and Materials

This study employed an experimental laboratory design focusing on pharmaceutical formulation and accelerated stability testing. The active ingredients included *Aloe vera* powder (with concentration variations) and Menthol (0.5%). Excipients comprised Xanthan gum (gelling agent), Glycerin (humectant), Phenoxyethanol (preservative), and Aquadest (solvent).

Formulation of Alvemint Gel

Five gel formulas (F0-F4) were prepared by varying the concentration of *Aloe vera* powder while maintaining the Menthol concentration at 0.5% and the base excipients constant, as detailed in Table 1. F0 served as the negative control containing only Menthol and excipients.

Table 1. Formula Alvemint Gel Composition

Phase	Ingredient	Function	F0 (%)	F1 (0.25%)	F2 (0.5%)	F3 (0.75%)	F4 (1%)
Phase A	*Aloe vera* powder	Active Substance	0	0.25	0.5	0.75	1
	Aquadest	Solvent	97	96.75	96.5	96.25	96
Phase B	Glycerin	Humectant	1	1	1	1	1
	Xanthan gum	Thickener	1	1	1	1	1
Phase C	Menthol	Active Substance	0.5	0.5	0.5	0.5	0.5
	Phenoxyethanol	Preservative	0.5	0.5	0.5	0.5	0.5

Gel Preparation Procedure

1. **Preparation (Phase A):** The required amount of Aquadest was heated to 65°C. The *Aloe vera* powder was dissolved in the warm Aquadest (for F1-F4) with stirring.
2. **Gelling Agent Incorporation (Phase B):** Xanthan gum was dispersed in Glycerin to prevent clumping. This mixture was then slowly added to Phase A while stirring using a hand blender until a uniform gel base was formed.
3. **Active and Auxiliary Addition (Phase C):** The mixture was cooled below 40°C. Menthol and Phenoxyethanol were successively added and stirred until completely homogeneous.
4. **pH Adjustment:** The initial pH was measured using a digital pH meter and adjusted if necessary, to fall within the safe skin range (4.5–6.5).

Evaluation Methods

1. **Initial Quality Evaluation:**
   Organoleptic: Observation of color, aroma, and texture.
   Homogeneity: Visual inspection for coarse particles on a glass plate.
   pH : Measured using a calibrated digital pH meter (must be 4.5–6.5)
   Spreadability: Determined by measuring the diameter (in cm) of the spread after applying a 10 g load for 1 minute (required range: 5.0–7.0 cm).
   Irritation Test: Conducted on 15 volunteers (20-40 years old) using the closed *Patch Test* method for 48 hours.

2. **Physical Stability Test (Accelerated Testing):**
   The five formulas were divided and stored under three conditions: **Room Temperature (25-30°C), Cold Temperature (4°C), and Hot Temperature (40°C)**.
   Color, Aroma, Texture, Homogeneity, pH, and Spreadability were observed and measured weekly over a period of **7 weeks**.

RESULTS AND DISCUSSION

Initial Evaluation Results

The initial quality evaluation tests confirm that all five formulas met the pharmaceutical requirements for a topical gel, as summarized in Table 2.

Table 2. Initial Evaluation Results of Alvemint Gel

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Evaluation Parameter	F0	F1	F2	F3	F4	Required Standard
Color	White	White	White	White	White	
Aroma	Characteristic Menthol	Characteristic Menthol	Characteristi c Menthol	Characteristic Menthol	Characteristic Menthol	
Texture	Semi-solid/Viscous	Semi-solid/Viscous	Semi-solid/Viscous	Semi-solid/Viscous	Semi-solid/Viscous	Semi-solid
Homogeneity	Homogeneous	Homogeneous	Homogeneous	Homogeneous	Homogeneous	Homogeneous
pH Value	**5.5**	**5.4**	**5.3**	**5.2**	**5.1**	**4.5 – 6.5**
Spreadability (cm)	**6.6**	**6.3**	**6.2**	**5.9**	**5.9**	**5.0 – 7.0**
Irritation Test	Negative (-)	Negative (-)	Negative (-)	Negative (-)	Negative (-)	Negative (No reaction)

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The **Organoleptic** results confirmed that all gels were white, possessed the expected cooling Menthol aroma, and had a semi-solid texture suitable for topical application. The increase in *Aloe vera* concentration (F1 to F4) did not significantly alter the initial appearance.

Homogeneity was successfully achieved in all batches, indicating that the use of Glycerin aided the uniform dispersion of Xanthan gum and that the active ingredients were uniformly distributed throughout the gel matrix.

The **pH Value** ranged from 5.1 (F4) to 5.5 (F0). All initial pH values fall perfectly within the normal physiological pH range of the skin (4.5–6.5), minimizing the potential for skin irritation or microbial proliferation (Wahidah, Saputri, & Nofita, 2024).

The **Spreadability** of the gels (5.9–6.6 cm) met the optimal criteria for semi-solid topical preparations (5.0–7.0 cm). Good spreadability ensures patient compliance and maximizes the surface area for drug release (Lachman, Lieberman, & Kanig, 2013).

The **Irritation Test** yielded negative results for all formulas, suggesting that the concentrations of *Aloe vera* powder and Menthol, as well as the excipients, are safe for external application on the skin.

Physical Stability Test Results and Discussion

The accelerated stability test results over seven weeks provided critical insight into the long-term integrity of the Alvemint Gel formulations, particularly concerning the influence of *Aloe vera* powder and temperature variations.

1. Organoleptic, Texture, and Homogeneity Stability

All formulas (F0-F4) maintained a consistent aroma, texture, and homogeneity across the cold (4°C), room (25-30°C), and hot (40°C) temperatures for the entire seven-week period. This stability indicates that the Xanthan gum gelling system was robust enough to prevent syneresis or phase separation, regardless of the thermal stress applied.

2. Color Stability

Color proved to be the most temperature-sensitive parameter in formulas containing Aloe vera (F1-F4).
At **40°C**, a distinct color change from white to **yellowish-white** was observed starting from the **first week** (Day 7) in F1, F2, F3, and F4.
At **Room Temperature**, F4 (highest *Aloe vera* concentration) showed a slight yellowish change by the 5th week.
At **Cold Temperature (4°C)**, all formulas maintained excellent color stability.
The rapid discoloration at high temperatures suggests **thermal degradation and oxidation** of *Aloe vera*'s polyphenols or other colored secondary metabolites (Departemen Kesehatan Republik Indonesia, 2014). This change, while not necessarily affecting efficacy, reduces the aesthetic quality and perceived stability of the product, necessitating the use of antioxidants or opaque packaging for commercial viability.

3. pH Stability

The pH of all formulas decreased gradually, with the most severe drop occurring at 40°C. This is a common consequence of accelerated testing, where thermal stress accelerates the formation of acidic degradation products (Khattab & Nattouf, 2021).

Formula	Initial pH	Final pH at 40∘C (Week 7)	Final pH at 25−30∘C (Week 7)
F0	5.5	**4.4** (Slightly outside range)	**4.6** (Stable in range)
F1	5.4	**4.4** (Slightly outside range)	**4.5** (Stable in range)
F2	5.3	**4.4** (Slightly outside range)	**4.4** (Slightly outside range)
F3	5.2	**4.3** (Outside range)	**4.4** (Slightly outside range)
F4	5.1	**4.3** (Outside range)	**4.3** (Outside range)

Figure 1. pH Value Changes of Alvemint Gel Formulas Over 7 Weeks at Different Temperatures.

Formulas containing *Aloe vera* (F1-F4), particularly F3 and F4, showed the greatest instability, with the pH falling below the minimum acceptable threshold of 4.5 at the end of the test period at 40°C (Table 2, Figure 1). **Formula F0** demonstrated the best pH maintenance, suggesting the *Aloe vera* components

rather than the Menthol or base, are the primary contributors to the acidity increase. Future optimization must include the incorporation of buffer systems (e.g., citrate or phosphate buffer) to maintain the pH near 5.0-5.5 for optimal stability and skin compatibility.

4. Spreadability Stability

All formulas maintained excellent Spreadability Stability across all temperature conditions throughout the seven weeks. The values remained consistently within the 5.0–7.0 range, confirming that the viscosity of the gel base was highly stable and not significantly affected by temperature-induced degradation.

Optimal Formula Selection

Based on the comprehensive physical stability evaluation, F0 (Menthol only) exhibited superior chemical stability, remaining within the desired pH range at room temperature. For the herbal combination product, while the physical structure (texture, spreadability) of F1-F4 is acceptable, the chemical stability (color and pH) is not. The highest stability among the Aloe vera containing formulas was seen in F1 (lowest Aloe vera concentration) at room and cold temperatures. This mandates that the combination gel requires further development steps focusing on stability enhancers before proceeding to clinical efficacy testing.

CONCLUSION

All five initial formulas of Alvemint Gel (F0-F4) successfully met the requirements for a topical semi-solid preparation, demonstrating good homogeneity, ideal spreadability (5.9–6.6 cm), and a safe initial pH (5.1–5.5).

The seven-week accelerated stability test confirmed good physical stability in terms of aroma, texture, and spreadability for all formulas. However, formulas containing *Aloe vera* (F1-F4) exhibited chemical instability, evidenced by color change (yellowing) and a significant pH drop (reaching 4.3 at 40°C), which is below the safe threshold for skin application. Formula F0 demonstrated the highest overall stability.

The results indicate that the Alvemint Gel shows promise but requires immediate reformulation with chemical stabilizers (buffers and/or antioxidants) to enhance the long-term chemical integrity and commercial viability of the *Aloe vera*-Menthol combination, particularly when stored at high temperatures.

CONFLICT OF INTEREST (if any)

The authors declare that there is **no conflict of interest**, financial or otherwise, that could be construed as influencing the results presented in this manuscript.

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REFERENCES

Aiyalu, R., Govindarjan, A., & Ramasamy, A. (2016). Formulation and evaluation of topical herbal gel for the treatment of arthritis in animal model. *Brazilian Journal of Pharmaceutical Sciences*, *52*(3), 493–507.

Azijah, R., Hidayaturahma, R., & Saputri, G. A. R. (2023). Formulasi dan Uji Evaluasi Fisik Sediaan Gel Ekstrak Etanol Daun Kelor (*Moringa oleifera* L.) sebagai Antioksidan. *Jurnal Ilmu Kedokteran dan Kesehatan*, *10*(2), 1456–1463.

Borse, V. A., Gangude, A. B., & Deore, A. B. (2020). Formulation and evaluation of antibacterial topical gel of doxycycline hyclate, neem oil and tea tree oil. *Indian Journal of Pharmaceutical Education and Research*, *54*(1), 206–212.

Departemen Kesehatan Republik Indonesia. (2014). *Farmakope Herbal Indonesia Edisi I*. Jakarta: Kementerian Kesehatan RI.

Food and Drug Administration (FDA). (2023). *Cosmetic Ingredients and Packaging*. Retrieved from [Please insert the URL for FDA's official cosmetic ingredients page].

Kementerian Kesehatan Republik Indonesia. (2024). *Pedoman Pelaksanaan Program Kesehatan Ibu dan Anak*. Retrieved from [Please insert the URL for Kemenkes' official KIA guidelines].

Khattab, A., & Nattouf, A. (2021). Optimization of entrapment efficiency and release of clindamycin in microsponge based gel. *Scientific Reports*, *11*(1), 1–10. doi: https://doi.org/10.1038/s41598-021-02826-7.

Lachman, L., Lieberman, H. A., & Kanig, J. L. (2013). *Teori dan Praktik Farmasi Industri Edisi III*. (S. Soendani, Trans.). Jakarta: UI Press.

Linder, M. C. (2012). *Nutritional Biochemistry and Metabolism*. Elsevier Science.

Matthews, J. (1999). *The art of childhood and adolescence: The construction of meaning*. Falmer Press.

Nishad, M., Verma, S., Kumar, A., & Khurana, N. (2025). Formulation and evaluation of apigenin-loaded microsponge gel for effective angioedema therapy. *Current Pharmaceutical Analysis*, *21*(4), 203–215. doi: https://doi.org/10.1016/j.cpan.2025.03.001.

Rowe, R. C., Sheskey, P. J., & Quinn, M. E. (Eds.). (2009). *Handbook of Pharmaceutical Excipients* (6th ed.). London: Pharmaceutical Press.

Setiawan, R., Masrijal, C. D. P., Hermansyah, O., Rahmawati, S., Sari, R. I. P., & Cahyani, A. N. (2023). Formulasi, Evaluasi dan Uji Stabilitas Fisik Sediaan Gel Antioksidan Ekstrak Tali Putri (*Cassytha filiformis* L). *Bencoolen Journal of Pharmacy*, *3*(1).

Shafaei, A., et al. (2016). Flavonoids-rich *Orthosiphon stamineus* extract as new candidate for angiotensin I-converting enzyme inhibition: a molecular docking study. *Molecules*. doi: https://doi.org/10.3390/molecules21111500.

Sirait, S. M. (2019). Formulasi Sediaan Gel Ekstrak Lidah Buaya (*Aloe Vera*). *Warta Akab*, *43*(2), 44–47.

Wahidah, S., Saputri, G. A. R., & Nofita, N. (2024). Formulasi dan Uji Stabilitas Sediaan Gel Ekstrak Etanol Daun Asam Jawa (*Tamarindus indica* L.) dengan Variasi Gelling Agent. *Jurnal Mandala Pharmacon Indonesia*, *10*(2), 508–518.

World Health Organization (WHO). (2023). *Breastfeeding: Guidance and Resources*. Retrieved from [Please insert the URL for WHO's official breastfeeding guidelines].

Yani, A., Patricia, V., & Syafii, F. (2023). Phytochemical Composition and Inhibitory Activities of *Hibiscus sabdariffa* and *Cucumis sativus* Infusions Against Angiotensin-Converting Enzyme. *Tropical Journal of Natural Product Research*, *7*(2), 2341–2345. doi: http://www.doi.org/10.26538/tjnpr/v7i2.6.