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INNOVATION IN TOPICAL PATCH PREPARATIONS BASED ON SHALLOT EXTRACT (*Allium cepa* L.) AS SUPPORTIVE THERAPY MINOR WOUNDS: FORMULATION AND PHYSICAL EVALUATION

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ABSTRACT

A study was conducted on the formulation and evaluation of a shallot (*Allium cepa* L.) extract patch. The purpose of this study was to determine the formulation of a shallot extract patch that meets the preparation requirements and to determine at what concentration the evaluation results of the shallot extract patch meet the preparation requirements. The patch was prepared in three concentrations: FI (2,5%), FII (5%), and FIII (7,5%). The preparation was then evaluated using organileptic tests, pH, weight uniformity, folding resistance, patch thickness, and moisture absorption. Based on the research results, organoleptic test results of shallot patch FI, FII, and FIII have a yellow color, a slight aroma of shallots and menthol, and the texture and surface condition of FI are dry, smooth, flat, flexible, and not sticky, while FII and FIII have a texture and surface condition that is slightly wet, smooth, flat, flexible, and slightly sticky. The average weight uniformity of FI patches is 2.182, FII 2.761, FIII 3.569. The pH measurement of FI, FII, and FIII is the same, namely 6. The fold resistance of the patches is also the same, namely > 300, the thickness of FI patches is 0,80 while FII and FIII are the same, namely 0,82 and the moisture absorption capacity of FI patches is 4,76, FII 5,82 and FIII 7,47.The shallot extract patch that meets the preparation requirements is the patch preparation in FI, where all preparation evaluation results meet the specified preparation requirements.

Keywords: evaluation, formulation, onion, patch.

INTRODUCTION

Minor to moderate wounds are common health problems that can occur due to physical trauma, infection, or irritation (Suwignjo & Darmayanti, 2023). Proper management of minor wounds is crucial to prevent infection and accelerate the healing process (Hidayat et al., 2024). Currently, topical therapies such as ointments and creams are widely used. However, these dosage forms have disadvantages such as being cumbersome, easily removed, and requiring repeated application, which can reduce treatment effectiveness and patient compliance (Lima et al., 2021).

One promising alternative dosage form is the topical patch. Patches offer advantages in terms of ease of application, formulation stability, and the ability to provide controlled release of active ingredients (Prausnitzetal., 2008). This preparation is also able to maintain a moist environment in the wound and prevent external contamination.

Shallots (*Allium cepa* L.) are a widely known herbal plant in Indonesia and have great potential as a natural active ingredient for topical applications (Edy et al., 2022). Shallot extract contains compounds such as flavonoids (especially quercetin), sulfur compounds, and phenolic compounds, which have been shown to have anti-inflammatory and antimicrobial activity and accelerate wound healing (Griffiths etal., 2002; Kianianetal.,

2021). A study by Ighodaro and Akinloye (Ighodaro etal., 2018) showed that quercetin has the ability to reduce inflammation and accelerate tissue regeneration.

The concentration range of 2.5%, 5%, and 7.5% in the shallot extract patch plaster was chosen as a scientific strategy for formula optimization, finding the most effective and safe dose for minor wound healing applications, assuming a positive correlation between increasing extract concentration and increasing therapeutic effects until it reaches the optimal point and provides the best efficacy for minor wound healing.

However, the use of shallot extract in modern pharmaceutical preparations, particularly topical patches, is still very limited. The majority of research still focuses on traditional forms such as ointments or topical oils. Therefore, further research is needed to formulate and evaluate the physical characteristics of shallot extract-based patches to address the need for practical and effective modern herbal products.

METHODS

Time and place of research

This research was conducted in August 2025 to November 2025 in the Pharmaceutical Biology Laboratory, Pharmaceutical Chemistry Laboratory and Pharmaceutical Laboratory of Alauddin State Islamic University, Makassar.

Research tools and materials

The tools used are The tools used in this study were glassware, desiccators,oven, digital scales, Petri dishes, rotary evaporators, water baths,blenders, glass jars, and vernier calipers. The materials used in this study were shallot bulbs (*Allium cepa* L.) (obtained from the Sai Bima area), distilled water, HPMC (Hypromellose), PVP (Poly vinyl pyrrolidone), menthol, propylene glycol, PEG 400 (polyethylene glycol 400), and 96% ethanol.

Researchprocedure

a. Test Material Collection
   The shallot test material was obtained from Sai Village, Soromandi District, Bima Regency, West Nusa Tenggara.
b. Making shallotextract (*Allium Cepa* L.)
   The obtained samples were then collected, washed thoroughly, andchopped, then driedin a dryer at 40°C for 25 hours. Then, they were ground to obtain shallot powder.Theywere weighed and stored in a tightly closed container (Hasibuan & Edrianto, 2021).
c. Procedure for Making Plaster Patch
   HPMC was dissolved in hot distilled water as much as 20 times the weight of HPMC, after dissolving, PVP was added which had previously been dissolved in hot distilledwater as much as 10 times the weight of PVP while stirring. The amount of distilled water used was adjusted to each concentration ratio of the polymer used. Shallot extract and menthol were dispersed in a mortar separately using sufficient 96% ethanol, the dispersed extract and menthol were added to the mixture of HPMC and PVP, then stirred until homogeneous. Propylene glycol and PEG 400 were added, then added with 96% ethanol to 10 mL, let stand for a while until the foam disappeared. Next, the mixture of materials was molded into a petri dish, allowed to cool and stored in a desiccators containing silica gel for 24 hours at room temperature. The film was removed from the mold, cut to a size of 3x5cm and attached to an ultrafix plaster (Julianti et al., 2024).
d. Patch Preparation Evaluation
   1. Organoleptic Test
      This is done by observing changes including shape, color, taste, and odor in the

preparation (Wardani &Saryanti, 2021).

2. Test pH
   The patch was placed into a porcelain dish containing 5 ml of distilled water (pH 6.5) and allowed to expand for 2 hours at room temperature and the pH was determined by placing pH paper on the surface of the patch. The average value was calculated and then the standard deviation was calculated, the safe pH range for topical use is pH 4.5-7 (Tiensi & Sulaiman, 2018).
3. Weight Uniformity Test
   The patch weights were measured using an analytical balance. Three patches were weighed individually, then the average weight, standard deviation, and coefficient of variation were determined. Patch weights were considered uniform if the coefficient of variation was ≤5% (Wardani & Saryanti, 2021).
4. Folding Durability Test
   Folding endurance tests on patches were performed repeatedly with the same fold position. The number of folds that met the standard was > 200 folds (Julianti et al., 2024).
5. Patch Thickness Test
   Patch thickness testing for each formula was performed by measuring the thickness of three patches individually. Patch thickness measurements were performed using calipers at three different points. Thickness plays a role in the physical properties of the patch; thinner patches are more acceptable in use (Prabhakara et al., 2010). Patch thickness should not exceed 1 mm (Julianti et al., 2024).
6. Moisture Absorption Test
   The patches stored at room temperature in a desiccator for 24 hours were weighed first, then exposed to 40°C for 24 hours and weighed again. Previous research has shown that the moisture absorption percentage ranges from 3.52 to 9.79% (Patel et al., 2009).

RESULT AND DISCUSSION

Based on the results of the research that has been carried out, the results obtained are: organoleptic evaluation, weight uniformity, thickness, folding resistance, pH and moisture absorption capacity of the patch were carried out after the preparation was stored for 24 hours.

Table 1. Organoleptic Test Results of Shallot Patches

Formulas	Form	Color	Scent	Texture and Surface Condition
FI	Film	Yellow	A slight aroma of shallot andmenthol	Dry, smooth, even, flexible, non-sticky
FII	Film	Yellow	A slight aroma of shallot andmenthol	Slightly wet, smooth, even, flexible, slightly sticky
FIII	Film	Yellow	A slight aroma of shallot andmenthol	Slightly wet, smooth, even, flexible, slightly sticky

Description:
FI =Topical Patch containing Shallot extract at a concentration of 2,5%
FII =Topical Patch containing Shallot extract at a concentration of 5%
FIII =Topical Patch containing Shallot extract at a concentration of 7,5%

Table 2. Results of the Shallot Patch Weight Uniformity Test

Number	Patch Weight Uniformity (g)		
	FI	FII	FIII
1	2.184	2.761	3.569
2	2.183	2.760	3.570
3	2.181	2.762	3.568
Average	2.182	2.761	3.569

Table 3. Results of the pH Measurement Test of the Shallot Patch

Number	pH measurement		
	FI	FII	FIII
1	6	6	6
2	6	6	6
3	6	6	6

Table 4. Results of the Folding Resistance Test of Shallot Patches

Number	Patch Folding Resistance		
	FI	FII	FIII
1	>300	>300	>300
2	>300	>300	>300
3	>300	>300	>300

Table 5. Results of the Shallot Patch Thickness Test

No	Patch Thickness (mm)		
	FI	FII	FIII
1	0,80	0,83	0,83
2	0,80	0,83	0,82
3	0,80	0,82	0,82
Average	0,80	0,82	0,82

Table 6. Results of the Moisture Absorption Test of the Shallot Patch

No	Patch Moisture Absorption Power(%)		
	FI	FII	FIII
1	4,76	5,83	7,48
2	4,76	5,83	7,47
3	4,76	5,82	7,48
Average	4,76	5,82	7,47

In organoleptic testing, the texture and surface condition of FI, FII, and FIII were nearly identical, but FI's texture and physical condition were better to the other formulas. FI had a dry, smooth, even, flexible, and non-sticky surface. The optimal characteristics of the FI patch were attributed to the sufficient amount of distilled water used during HPMC development, coupled with the moderate amount of extract dispersion, which prevented aeration and wrinkles, resulting in a smooth texture (Wardani & Saryanti, 2021).

The less optimal texture and surface condition of FIII patch was found to be slightly wet, smooth, even, flexible, but stickier. The strength and flexibility of the patch preparation were influenced by PEG 400, which acts as a plasticizer. PVP is hygroscopic and can attract water, resulting in a sticky patch (Arfiani & Marianti, 2019).

However, the presence of PVP also plays a role in increasing elasticity, adhesion time, and forming a film layer on the patch (Wahid, 2020). Based on the evaluation data, it can be seen that there are organoleptic differences, which occur because the variation factors

of the extracts used influence each other on the physical characteristics, especially in the color and condition of the patch surface between FI, FII, and FIII.

In pH testing, all transdermal patch formulas containing shallot bulb ethanol extract had a pH compatible with skin pH, namely 4.5-7 (Hariningsih, 2019). The pH values for patches FI (6), FII (6), and FIII (6) were 6. Formulas FI, FII, and FIII did not experience an increase in pH.The shallot patch plaster does not experience an increase in pH or remains stable after storage due to the presence of natural buffer compounds (such as phytohormones auxin, allithiamin, and gibberellin) as well as the acid content in the shallot extract.Chemical reactions that can occur during storage are one factor causing an increase in the pH of a preparation.

Furthermore, weakly acidic additives, except for polymers, can also affect the pH of the patch preparation. The concentration of HPMC and PVP polymers did not significantly affect the pH of the preparation, as HPMC and PVP have a pH close to neutral, with HPMC pH ranging from 5-8 and PVP pH ranging from 3-7 (Julianti et al., 2024).

The pH value for topical preparations should not be too acidic as it can cause skin irritation, while too alkaline can cause scaly skin (Wardani &Saryanti, 2021). Based on the analysis of pH measurement data, it was found that there was no significant difference between FI, FII, and FIII.

In the weight uniformity test, each transdermal patch formula containing shallot tuber ethanol extract, FI (2182 mg), FII (2761 mg), and FIII (3569 mg), met the requirements for good weight uniformity. A smaller coefficient of variation indicates homogeneous data, while a larger coefficient of variation indicates more heterogeneous data (Julianti et al., 2024).

Each formula had different patch weights. This difference may be due to the role of the extract. Higher concentrations of the extract increase the weight of the patch preparation, which results in increased patch weight for each patch. The FIII patch weight uniformity test results were the highest due to the higher concentration of extract used.

In the folding endurance test, the folding endurance evaluation was carried out manually by hand by folding the patch in the same place repeatedly. The results of the folding endurance test on the FI; FII and FIII patches are in accordance with good folding endurance standards where FI produces endurance of >300 folds, proving that PEG 400 which acts as a plasticizer can work optimally in maintaining patch elasticity so as to reduce patch damage when combined with different polymers (Julianti et al., 2024).

The evaluation results obtained are in accordance with the literature where the folding endurance test on the patch was carried out repeatedly with the same folding position. The number of folding endurances that meet the standard is > 300 folds. (Julianti et al., 2024).

In the patch thickness test, the FI (0.80 mm), FII (0.82 mm), and FIII (0.82 mm) formulas have met the patch thickness test requirements with the results of digital caliper measurement tools, the accuracy at three patch points, namely the right, middle, and left, obtained measurement figures <1 mm. Each patch has almost the same thickness, this can occur because it uses the same polymer combination in each formula.

In addition, it is also influenced by several factors such as mixing, transfer of materials to the mold, the size of the mold, the amount of solution and the drying process. FI and FII patches have a fairly close thickness size, only a difference of 0.2 results can be caused by the concentration between the extract and the solvent which makes both stable. All FI, FII, and FIII patch formulas have met the requirements, but the best patch thickness size is in FI because it has the lowest thickness size based on the patch thickness requirement value. Based on statistical analysis of patch thickness. Overall data between FI, FII, and FIII does not show significant differences.

In the moisture absorption test, the moisture absorption data for FI patches were 4.59%), FII patches 5.53%), and FIII patches 7.48%. The FI, FII, and FIII patches had moisture absorption values that met the requirements, namely <10%. The lower the moisture percentage, the more stable the patch obtained, because the amount of water contained in the patch will extend the shelf life of the preparation and reduce the risk of contamination from microorganisms (Novia & Noval, 2021).

This is related to the effect of increasing the concentration of extract and solvent in a formula will increase the moisture absorption value of the patch (Arifin & Marianti, 2019). This statement is in accordance with the results of the moisture absorption obtained in this study, seen from the percentage of absorption that increased based on the addition of higher solvent concentrations in each formula causing FII and FIII patches with the use of more extract to have the highest percentage value compared to other formulas.

Too high humidity will cause the patch preparation to be too wet and increase the risk of microbial contamination in the patch preparation, while too low humidity will cause the patch to become dry and brittle (Novia &Noval, 2021). Based on analysis of patch moisture absorption data, it was found that there were significant differences between FI, FII, and FIII extract combinations.

CONCLUSION

Based on the research results, organoleptic test results of shallot patch FI, FII, and FIII have a yellow color, a slight aroma of shallots and menthol, and the texture and surface condition of FI are dry, smooth, flat, flexible, and not sticky, while FII and FIII have a texture and surface condition that is slightly wet, smooth, flat, flexible, and slightly sticky. The average weight uniformity of FI patches is 2.182, FII 2.761, FIII 3.569. The pH measurement of FI, FII, and FIII is the same, namely 6. The fold resistance of the patches is also the same, namely > 300, the thickness of FI patches is 0,80 while FII and FIII are the same, namely 0,82 and the moisture absorption capacity of FI patches is 4,76, FII 5,82 and FIII 7,47.

Based on the research results it can be concluded that the formulation of a shallot extract patch plaster that meets the preparation requirements is a patch plaster with the appropriate polymer material weighing and the use of the correct solvent. The shallot extract patch plaster preparation that has evaluation results that meet the preparation requirements is the FI patch plaster preparation where all preparation evaluation results meet the specified preparation requirements.

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