FORMULATION AND PHYSICAL STABILITY TEST OF THE PREPARATION *HAIR TONIC* STAR FRUIT LEAF EXTRACT WULUH (*Averrhoa blimbi* L.*)*

Melindasari S. Datulamban[1)], Srimuliani Arbie [2)], Rini Daud Supu[3)]
[1.2.3)] Bina Mandiri University Gorontalo
E-Mail: ms8912433@gmail.com

ABSTRACT

This study aims to determine the effect of Formula I, II, and III on the physical stability of Hair tonic preparations. The research method used is a true experimental laboratory that aims to see or determine the best proportion of active ingredients in making hair tonic preparations with variations in the concentration of star fruit leaf extract, namely F1 (5%), F2 (10%), and F3 (15%), using the Physical Stability test parameters of the preparation, which include Organoleptic tests, homogeneity, pH, and Viscosity. The results of physical stability studies show that in organoleptic tests, F1, F2, and F3 have the same shape, aroma, and taste. Moreover, there are color differences. In the F1 homogeneity test, F2 and F3 have homogeneity. In the pH test of hair tonic preparations, the extract of Wuluh star fruit leaf at F1 (5%) before the cycling test averaged 4.50, while after the cycling test it averaged 4.57. F2 (10%) before the cycling test averaged 4.56; after the cycling test averaged 4.82; before the cycling test averaged 5.97; after the cycling test averaged 6.13. The viscosity value before the cycling test averaged 16183, while after the cycling test it averaged 15133. F2 (10%) before the cycling test averaged 16533, while after the cycling test it averaged 15433. F3 (15%) before the cycling test averaged 16866, while after the cycling test it averaged 15666.

Keywords: *Hair tonic, Cycling test,* Star Fruit Wuluh Leaf Extract

INTRODUCTION

The hair on the head is a part of the body that is always known as the crown by humans because hair is one part of the body that is known to increase human confidence levels both among men and women. Hair is a part of the body that can be easily modified, therefore, humans usually take care of hair in various ways to produce the desired hair state by humans. Basically, the hair care process is very easy, namely by cleaning the hair at least once every two days and treating continuously if you have problems with the hair or scalp [7].

Hair or what is often referred to as fur is an organ of the human body that has a thread-like shape that grows on the skin of animals and humans. Hair grows in almost every part of the human and animal body except on the palms and feet, eyelids and lips. One of the parts of the body organ that is most overgrown by hair is the head [16].

There are several factors that cause changes in the condition of the hair and scalp, such as old age, stress (depression), decreased activity of oil glands (sebum) on the scalp, disorders of blood vessels, disruption of hormones, the influence of cosmetic use, intensive exposure to Ultraviolet (UV) rays and intake of less nutritious foods for the benefit of hair growth [5]. The most common hair problems encountered in humans are acute loss, thinning hair slowly to baldness.

One of the problems that often occurs is hair loss. Hair loss usually occurs when a

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person experiences prolonged and repeated psychological stress.When under stress, people will experience hormonal imbalances and these immune reactions will come out when stress lasts for a long time, which will cause loss, causing hair to stop growing in the body on epithelial cells and skin mesenchyma [5].

Hair loss is a condition where there is a disorder or disorder in the hair that grows on the scalp or body skin that can interfere with the function of various biological functions of hair in the body. *Alopecia areata* is the loss of about 120 strands of hair per day. During the period of hair growth, hair is influenced by several factors, namely physiological factors such as hormones, metabolic disorders, nutritional deficiencies, aging (aging) and blood vessels [20].

The problem of hair loss in the *United States* affects about 50 million people and 20 million people among them are women, the cause of this condition is classified into two factors, namely endogenous and exogenous. Endongen is a condition that occurs due to systemic, hormonal, nutritional status, intoxication and heredity (genetic). As for exogenous groups such as conditions caused by stimuli from the environment or due to the use of hair cosmetics. The use of cosmetics is one of the consequences of hair loss that is commonly found in women in African-American countries [19].

Cosmetics are substances or preparations used outside the human body (cuticle, hair, nails, lips and genitals (genital organs)) or teeth and oral mucosa and are mainly used to cleanse, fragrance, and change the appearance and or correct odors that exist on the body or protect or maintain the body in good condition [22]

Traditional cosmetics are cosmetics whose ingredients are ingredients derived from nature and the processing method is still done in the traditional way. In addition, there are also types of semi-traditional cosmetics, namely traditional cosmetics whose actions are carried out in a modern way where the method is carried out by mixing synthetic chemicals into preparations. For example, preservatives, emulsifiers and others. The function of this cosmetic in medical science is both in the maintenance of health on the skin and for treatment but still requires further research [22].

The use of materials that function as hair straighteners can cause hair loss to damage about 95% of its use in America and 53% in Nigeria [19].

As many as 31% of students at Universitas Airlangga campus B experienced hair loss [18]. A total of 30 or 0.6% of the total patients who came to the Cosmetic Division of the Medical Cosmetic Division of the Outpatient Unit (URJ) Skin and Genital Health RSUD dr. Soetomo Surabaya in 2012-2016 complained of baldness or Apolesia [13]. One of the pharmaceutical preparations that can overcome hair loss is the preparation of *Hair Tonic*.

Hair Tonic is one of the cosmetic preparations derived from a mixture of chemicals or herbs with other ingredients [4]. The use of *Hair Tonic* is to help increase blood circulation to the scalp to prevent hair loss, can increase hair growth, prevent dandruff and itching, and provide a cold sensation on the skin [15]. With the current shift in the pharmaceutical world, many pharmaceutical preparations are not only derived from synthetic ingredients but many pharmaceutical preparations in circulation come from natural ingredients.

Plants that are known to have activity as hair fertilizers, one of which is the Wuluh star fruit plant. Carambola. Star fruit is used as one of the active ingredients in the manufacture of *Hair Tonic* preparations, where star fruit extract contains flavonoids and phenol compounds that have antibacterial activity that can reduce scalp problems, especially dandruff [23]. In addition, *Hair Tonic* preparations with star fruit active substances can also function as hair fertilizers.

Star fruit leaf extract is known to be effective in hair growth in rabbit test animals. From the results obtained, the best concentration in overcoming hair loss is 10% [12].

Stability in pharmaceutical preparations is one of the qualifications or standards that are very important in order to obtain good production results. Stability is a product application that aims to maintain the properties and characteristics of the preparation to be the same as those stipulated in the limits of use. Instability of natural ingredients tends to cause a decrease to loss of efficacy of a preparation, drugs can turn toxic, or physical changes occur in the preparation (including color, smell, taste, consistency and others). Preparations derived from natural ingredients have many compounds that can affect each other so that there is instability of the preparation which will result in changes that greatly affect the efficacy of the preparation itself. The stability of a pharmaceutical preparation can be known from changes in the physical preparation, chemical changes and changes in terms of the appearance of the preparation [10]

Based on this background, researchers are interested in conducting further exploration related to Wuluh Starfruit Leaves (*Averrhoa bilimbi* L.) which is formulated in the dosage form of *Hair tonic*.

RESEARCH METHODS

Tools and materials

Tools used maceration tools, ovens, refrigerators, pH meters, viscometers, spray container bottles, beakers, measuring cups, erlenmeyers, funnels, watch glasses, porcelain cups, stirring rods, horn spoons, spatulas, analytical scales.

The ingredients used are star fruit leaf extract, ethanol 96%, menthol, sodium metabisulfate, methyl paraben, propyl paraben, propylenglycol, aquadest.

How it Works

1. Sampling

The sample used in this study was star fruit leaves obtained from South Tombulabuto Village, Dungingi District, Gorontalo City.

2. Simplisia Processing Techniques

Simplisia processing techniques consist of sample processing, namely wet sorting, washing, draping, drying, dry sorting as well as packing and storage.

3. Sample Extraction Process

The extraction of star fruit leaf samples was carried out by means of simplisia that had been mashed extracted using the maceration method (soaking), where the samples were soaked using 96% ethanol with a ratio of sample and solvent of 1: 4 (b / v) in a tightly closed container for 3x24 hours (for 3 days) with all stirring. After the sample has been soaked for 3 days, filtration is carried out to obtain filtrate. The filtrate from the filtrate is evaporated using an evaporator device that is modified to produce thick star fruit leaf extract [8]. The evaporation device modified in this study is a stool commonly used in the evaporator process. After that, the yield value is calculated.

4. Manufacture of *Hair Tonic Preparations*

a. Hair Tonic *Formula Design*

Table 1. Formula Design

Material	F1 (%)	F2 (%)	F3 (%)	Information
Star Fruit Wuluh Leaf Extract	10	20	30	Active Substances
Ethanol 96%	60	60	60	Solvent
Propilene Glycol	5	5	5	Humektan
Metil paraben	0,01	0,01	0,01	Preservatives
Propil parabe	0,02	0,02	0,02	Preservatives

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Na.metabisluf at	**0,01**	**0,01**	**0,01**	**Antioxidant**
Mnthol	**1,0**	**1,0**	**1,0**	**Penetration**
Aquadest	**Ad 60 ml**	**Ad 60 ml**	**Ad 60 ml**	

Modified from Akib's Research, et al., (2020).

b. Manufacture of *Hair Tonic Preparations*

The process of making hair tonic preparations is carried out by weighing all ingredients in the formula, after that dissolving the extract in some 96% ethanol, stirring until homogeneous. In the second container, dissolve propyl paraben and methyl paraben in a portion of 96% ethanol and stir until homogeneous. In the third container, dissolve menthol using the remaining 96% ethanol until homogeneous. After that, mix all the ingredients that have previously been dissolved in one place then add propilenglikol gradually and stir until homogeneous. Then add aquadest and stir until homogeneous. After that, the *hair tonic* preparation is put into a pipette bottle-shaped container.

c. Physical evaluation of the preparation

The stability test of *hair tonic* preparations is carried out using the cycling test method *by observing the presence or absence of changes in the physical character of the preparation both before and after the* cycling test. The sample is stored in the refrigerator at 4oC for 24 hours and then transferred to the oven (40oC; 24 hours), counting as one cycle. The cycle of *cycling test on* hair tonic *hair preparations* is carried out as many as 6 cycles. By parameters to be observed include:

1) Organoleptic Test

Organoleptic tests are carried out by observing the shape, smell, taste (in the skin) and color of the preparation.

2) Homogeneity Test

Organoleptic tests are carried out by observing the shape, smell, taste (in the skin) and color of the preparation.

3) pH Test

pH testing is carried out using a pH meter (pH stick) by dipping the tip of the stick into a hair tonic preparation and then matching it to the color on the universal pH indicator to determine the pH of the preparation.

4) Viscosity Test

Test the viscosity of the preparation using a viscometer, using rotor number 6 at a speed of 20 rpm.

RESEARCH RESULTS

From the results of the research conducted get results.

Table 2. Extract Yield Results

Sample	Dry simplisia weight	Maceration viscous extract weight	Yield
Star fruit leaves wuluh	1000 grams	159 grams	15,9%

Source : Data processed, 2023

Table 3. Organoleptic Test

Formula	*Cycling test*	Shape	Color	Aroma	Taste
F1 5%	Before	Liquid	Bright green	Typical Extracts and Mint	There is a cold sensation in the skin
	After	Liquid	Bright green	Typical Extracts and Mint	There is a cold sensation in the skin
F2 10%	Before	Liquid	Dark green	Typical Extracts and Mint	There is a cold sensatio

					n in the skin
	After	Liquid	Dark green	Typical Extracts and Mint	There is a cold sensation in the skin
F3 15%	Before	Liquid	Blackish green	Typical Extracts and Mint	There is a cold sensation in the skin
	After	Liquid	Blackish green	Typical Extracts and Mint	There is a cold sensation in the skin

Source : Data processed, 2023

The table above is a table of organoleptic test results of *hair tonic preparations of* star fruit leaf extract where F1, F2 and F3 produce almost the same preparation, there are only differences in the color of the extract. The higher the concentration of the extract used, the darker the color of the resulting preparation.

Table 4. Homogeneity Test

Formula	Cycling test	Homogeneity
F1 (5%)	Before	Homogeneous in the absence of precipitate
	After	Inhomogeneous there are deposits
F2 (10%)	Before	Homogeneous in the absence of precipitate
	After	Inhomogeneous there are deposits
F3 (15%)	Before	Homogeneous in the absence of precipitate
	After	Inhomogeneous there are deposits

Source : Data processed, 2023

From the table above, it can be seen that the homogeneity test results *of star fruit leaf extract* hair tonic preparations produce *hair tonic preparations* that are not homogeneous with the presence of deposits after *a cycling test*.

Table 5 pH Test

Formula	Cycling test	Ph
F1 (5%)	Before	4,50
	After	4,57
F2 (10%)	Before	4,56
	After	4,82
F3 (15%)	Before	5,97
	After	6,13

Source : Data processed, 2023

In the table of pH test results of *hair tonic* preparations of star fruit leaf extract, it can be seen that the pH is in accordance with the pH of the skin, which is between 3-7. So it can be concluded that *hair tonic* preparations made have good acidity characteristics

Table 6. Viscosity Test

Formula	Cycling test	Viscosity
F1 (5%)	Before	16183
	After	15133
F2 (10%)	Before	16533
	After	15433
F3 (15%)	Before	16866
	After	15666

Source : Data processed, 2023

The table above is a table of viscosity test results, viscosity values in previous studies that were good for *Hair tonic* preparations were 15.733 [21].

DISCUSSION

Hair tonic is one of the cosmetic preparations whose use is intended for scalp and hair care used when the scalp and hair are clean. *Hair tonic* is a cosmetic preparation in liquid form which is a mixture of chemicals or other ingredients that function to help improve growth, help strengthen and maintain hair condition in good condition [11].

1. **Sample Setup**

   The star fruit leaf samples used in this study were star fruit leaves taken directly from South Tombulabuto Village, Dungingi District, Gorontalo City. Star fruit leaves taken in the form of fresh leaves and in good condition (not hollow).

2. **Extract Creation**

Extraction is the process of extracting chemical compounds contained in natural materials or in cells by using appropriate and appropriate solvents and methods [3]. In this study, the type of extraction used was maceration (soaking) by obtaining an extract yield of 15.9%, the yield results can be seen in table 1. Yield is a comparison between the results of the many metabolites obtained after the extraction process with the weight of the sample used. According to [6], a good yield result is a yield that is not less than 10%.

3. Manufacture of *Hair Tonic Preparations*

Making *hair tonic preparations of* star fruit leaf extract wuluh in this study made as many as 3 formulas with the use of the same active substances and additives. However, there are differences in the concentration of the active substance of star fruit leaf extract, where the concentrations used are, 5% (FI), 10% (F2), 15% (F3). The existence of variations in the concentration of active substances aims to determine the difference in physical stability of the preparation of each concentration. From the results of the study, the formula that is closest to the requirements *for the best hair tonic* is formula 3 with an active substance concentration of 15%.

As for some reasons for the use of excipient in *hair tonic preparations*. 96% ethanol is used in the preparation as an antimicrobial and co-solvent, besides that some of the ingredients used in the preparation are more soluble in ethanol. Propyl paraben and methyl paraben in the preparation are used as preservatives. The combined use of preservatives aims to obtain effective preservatives. Sodium metabisulfate in the preparation is used as an antioxidant, the use of antioxidants in the preparation aims to prevent the occurrence of oxidation processes that may occur in the preparation. Menthol is used in preparations as penetration, so that the preparation is able or easier to absorb into the scalp. In addition, the use of menthol in the preparation is also able to give aroma to the preparation. Propilenglikol in preparations is used as a moisturizer (humectant) that can maintain skin moisture at the time of use. In addition, the use of propilenglikol can also help increase the viscosity of the preparation so that it can maintain the preparation on the surface of the skin [14].

4. Physical Evaluation of *Hair Tonic Preparations*

Physical evaluation of preparations is carried out to assess the suitability of preparations with existing literature. The physical evaluation of the preparation carried out includes organoleptic tests, homogeneity tests, pH tests, .viscosity tests.

1) Organoleptic Test

Organoleptic tests are performed to see the physical appearance of the preparation with the naked eye. Physical appearance observed includes aroma, color, taste and form of the preparation using the human senses. In the results of the preparation observed to have the aroma, taste and shape of each formulation has similarities where the distinctive aroma of menthol and star fruit leaf extract wuluh, coldness on the skin when sprayed and has a liquid form. While the color of the preparation in each formulation is different. In F1 (5%) it has a bright green color, in F2 (10%) it has a dark green color and in F3 (15%) it has a blackish green color. The color change is caused by the addition of extract concentration, the higher the extract concentration, the more concentrated the color of the preparation produced [9]. However, even though the color is different, this is still in accordance with SNI 16-4955-1998 where *a good*

hair tonic preparation is a preparation that has a color like an extract [16]. The results of organoleptic tests can be seen in table 2.

2) Homogeneity Test

The homogeneity test is carried out to see the presence of insoluble particles in *hair tonic preparations*. The homogeneity test is carried out by observing the preparation whether there are deposits in the preparation or there are insoluble particles. From the results of research conducted on *hair tonic* preparations, homogeneous preparations were produced before cycling tests, but after *cycling tests* there were deposits in each formula. This is not in accordance with the requirements for *a good hair tonic preparation according to SNI 16-4995-1998, it is said that a good* hair tonic preparation is a homogeneous preparation. The presence of deposits after *cycling tests* occurs due to temperature changes during the *cycling test*. In addition to temperature that affects the homogenization process, namely stirring or agitation which is a process that shows the movement produced in a material or mixture where in this process will form a circulation pattern [2].

3) pH Test

Acidity check or pH test is a test parameter that aims to determine whether the preparation made is in accordance with the pH of the skin or not. The preparation must be in accordance with the range of pH values because acidity can affect the absorption of the preparation on the skin. If the preparation is too acidic it will cause the skin to experience irritation while if it is too alkaline it can cause scaly skin [19]. pH tests can be performed using a pH stick or pH meter. The results in table 4.4 in each formulation have different values where formula 3 (15%) is the highest pH value, the higher the extract concentration, the higher the pH value. In addition, there is a difference in pH before and after the *cycling test* where there is an increase in pH, pH changes can occur because during the storage process there is an interaction between the active substance in the extract with additional ingredients in *hair tonic* preparations [1]. However, from the pH value obtained in each formula is normal or falls into the range of pH values of hair tonic preparations *according to SNI 16-4995-1998 it is said that the pH value of* hair *tonic preparations is* 3-7 or in accordance with the pH of the skin [4].

In this study, the statistical analysis used was the F test to see the influence of variable X (independent variable) and variable Y (dependent variable). From the results of the analysis carried out, it was obtained that the sig value of 0.000 < 0.05 and the calculated F value of 21.705 > of the F value of the table, which is 3.55. So it can be concluded that if the sig value < 0.05 or the F value is calculated > F table, there is a simultaneous influence between variable X and variable Y. So in this case it is concluded that there is an influence of extract concentration in the tonic preparation formula on the pH level of the preparation.

In the *post hoc duncan* test to see the difference between formulas 1, 2 and 3 it was found that there was a significant difference in pH values between formulas 1, 2 and 3.

4) Viscosity Test

Dosage viscosity test is a test that aims to see the viscosity level of a preparation. The viscosity test on *the hair tonic* preparation was carried out using a brookfiled *viscometer at* a speed of 20 rpm using rotary number 6.

From the results of *hair tonic* viscosity star fruit leaf extract has increased at each concentration, the higher the concentration of extract, the higher the viscosity value of the preparation [1]. In addition, there was a decrease in viscosity value after *the cycling test*. This happens because after *cycling test* the preparation experiences a precipitate which causes the preparation to become thinner [21]. Changes in viscosity during storage are the main criteria for preparation stability [1]. The viscosity value in Formulation 3 (15%) has the closest value to the viscosity value of *hair tonic preparations*, which is 15.733 Cp.

In this study, the statistical analysis used was the F test to see the influence of variable X (independent variable) and variable Y (dependent variable). From the results of the analysis carried out, it was obtained that the sig value of 0.000 < 0.05 and the calculated F value of 206,602 > of the F value of the table, which is 3.55. So it can be concluded that if the sig value < 0.05 or the F value is calculated > F table, there is a simultaneous influence between variable X and variable Y. So in this case it is concluded that there is an influence of extract concentration in the tonic preparation formula on the pH level of the preparation.

In the *post hoc duncan* test to see the difference between formulas 1, 2 and 3, it was found that there was no significant difference in viscosity values between formulas 1, 2 and 3.

CONCLUSION

Based on the results of the study, it can be concluded that

1. The hair tonic preparation formula in this study consisted of star fruit leaf extract (5%, 10% and 15%) as active substances, methyl paraben (0.01%) and propyl paraben (0.02%) as preservatives, ethanol 96% (60%) as solvent, menthol (1.0%) as penetration, propilenglikol (5%) as humectant and sodium metabilsulfate (0.01%) as antioxidant.
2. From the results of statistical tests conducted in the study, it can be concluded that there is an influence on the physical stability of the preparation of *Hair tonic* star fruit leaf extract wuluh (*Averrhoa bilimbi* L.) Formula 1, Formula 2 and Formula 3.

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