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Research article

Formulation and Evaluation of Transdermal Patch Preparations from Ethanol Extract of Green Tea Leaves (*Camellia sinensis* (L.) Kuntze)

Imas Maesaroh[1*], Sri Anjani[1]

[1]Faculty of Pharmacy, Health and Science, Universitas Muhammadiyah Kuningan, Kuningan, Indonesia

*Corresponding Author: imasmaesaroh0205@gmail.com

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Abstract

Green tea (*Camelia sinensis* (L.) Kuntze) contains secondary metabolites such as polyphenols, flavonoids, tannins, and catechins (−) -Epigallocatechin gallate (EGCG). An ethanol extract of green tea is formulated into a transdermal patch to bypass the first-pass effect and maintain the drug's bioavailability in the plasma. This study aims to determine the optimal concentration combination of HPMC (Hydroxypropyl Methylcellulose) and PVP (Polyvinylpyrrolidone) that yields the best physical stability of the transdermal patches. Green tea was extracted using the maceration method with 70% ethanol. Transdermal patches are made by first optimizing the base using a combination of HPMC and PVP polymer bases in F1 (1:3), F2 (2:2), and F3 (3:3). The patch preparations obtained were tested, including organoleptic evaluations, pH levels, weight consistency, thickness, and fold resistance. The results obtained show that the most optimal formula to be used as a transdermal patch preparation is formula 3 (F3), with a ratio of HPMC and PVP (3:1) and an average weight of (0.08 g ± 0) and an average thickness of the patch is (0.16 m ± 0), and has met the patch fold resistance test, namely ≥ 200 folds and has a stable pH of 6. This study concludes that green tea ethanol extract can be formulated into a transdermal patch preparation with a combination of HPMC and PVP (3:1), which has the best physical stability.

Keywords: *Camellia sinensis* (L.) Kuntze.), HPMC-PVP, transdermal patch

Introduction

Herbal medicine is becoming increasingly popular among the public because it is considered safer and has fewer side effects than synthetic drugs. The use of traditional medicinal plants in the health care system is also in line with the global trend towards the use of sustainable natural materials [1]. One of the plants that has long been used in traditional medicine is green tea (*Camellia sinensis* (L.) Kuntze) leaves. Green tea is characterized by a high content of polyphenols, which is produced from the tea plant *Camellia sinensis*. (−) -Epigallocatechin gallate (EGCG) is regarded as the most abundant compound in tea leaves with excellent bioactivities, such as antibacterial, antioxidant, and anti-inflammatory [2,3].

The pharmacological activities as antibacterial, antioxidant, and anti-inflammatory of green tea leaves make it a potential candidate for topical formulation. Various studies have explored its use in cream, ointments, and gel form, but studies regarding its application in modern drug delivery systems such as transdermal patches are still limited [4-6]. The application of herbal transdermal patches may be able to deliver therapeutic substances locally and continuously to the wound site, aiding in the healing process and lowering inflammation.

The formulation of herbal transdermal patches involves selecting appropriate herbs that have wound-healing properties and incorporating them into a patch. The herbs can be in the form of extracts, oils, or powders, and are typically combined with a polymer matrix to form the patch. The patch is applied to the skin over the site of the wound, where it slowly releases the herbal agents into the body [7].

Patch is one of the transdermal preparations that functions as a drug delivery system by attaching it to the skin. Some of the advantages of this transdermal preparation include: providing a long-term drug effect, releasing drugs at a constant dose, being easy to use, and reducing the frequency of drug administration [8]. Some other potential advantages

of transdermal drug delivery are controlled absorption, uniform plasma levels, improved bioavailability, reduced side effects, painless and simple application, and the flexibility of stopping drug delivery by simply removing the patch from the skin [9].

In transdermal preparations, patches are included in the matrix system, which consists of two main components, namely the backing layer and the matrix [10]. In this system, the drug in the excipients, such as polymers, plasticizers, permeation enhancers, and adhesives, is formulated into one, which is then allowed to dry to form a matrix. Furthermore, the matrix is attached to the backing layer. The advantage of the matrix system is that it will form a thin patch so that it is comfortable to use [11].

From the description above, green tea leaves contain catechin compounds, especially Epicatechin Gallate (ECG), which has the effect of accelerating the formation of blood vessels in the wound area, making it useful in distributing strong nutrients for wound healing. With these ingredients, the author is interested in making a transdermal patch preparation from ethanol extract of green tea leaves (*Camellia sinensis* (L.) Kuntze) to help heal cut wounds, made with a combination of HPMC and PVP matrices. One of the basic components of a patch is a polymer. Polymers play an important role in producing patch preparations with good physical properties. Water-soluble (hydrophilic) polymers can expand and form a gel-like consistency. The combination of hydrophilic polymers in making patches will support water absorption, expand to form pores, making it easier for active substances to diffuse, while also becoming a barrier in regulating the release of active substances. Hydroxy Propyl Methyl Cellulose (HPMC) and PVP are a combination of hydrophilic polymers that are suitable for formulation into patch preparations. This is because the HPMC polymer can form a clear film, is easily hydrated, and has good matrix swelling power, thereby increasing the speed of drug release [12]. This research aims to find out whether the ethanol extract of green tea leaves can formulated into a transdermal patch preparation, determine the effect of the combination of HPMC and PVP based on the physical properties of transdermal patch preparations, and find out the best formula for transdermal patch preparations from combination of HPMC and PVP bases.

Materials and Methods

Materials

The materials used in this study are green tea leaf extract, HPMC (Dipa Husada Persada Ltd.), PVP (Dipa Husada Persada Ltd.), propylene glycol (Dipa Husada Persada Ltd.), DMSO (Nitra Kimia Ltd.), ethanol 95% pro analysis (Hikam Abadi Indonesia Ltd.), Zn powder (Nitra Kimia Ltd.), Hydrochloric acid 2N (Nitra Kimia Ltd.), Amyl alcohol (Nitra Kimia Ltd.), $FeCl_3$ (Nitra Kimia Ltd.), and Gelatin 1% (Nitra Kimia Ltd.).

Methods

Making simplicia and extraction

Young green tea leaves are sorted, which includes wet sorting, washing, drying, dry sorting, and grinding and sieving using a number 40 sieve. Extraction of green tea leaves using the maceration method using 70% alcohol solvent. Simplicial powder weighing 250 grams was soaked in 70% alcohol using a ratio of simplicia and solvent 10:75 for 24 hours, then remaceration was carried out using the same ratio of solvent for two days while stirring occasionally.

Phytochemical screening of extracts

Phytochemical screening of the extract was carried out by placing 10 drops of extract into a test tube, adding 2 mL of distilled water, then adding 0.2 grams of Zn Powder and 1 mL of 2N hydrochloric acid. Heated over a water bath and filtered. Then the filtrate is added 1 mL of amyl alcohol, and then shaken vigorously. The presence of flavonoids will produce a red, yellow, or orange filtrate, which can be extracted with amyl alcohol. Next, 10 drops of the extract are added to 10 mL of distilled water, heated, and filtered. The filtrate was diluted with distilled water until colorless. In the $FeCl_3$ method, 2 mL of the filtrate is taken, and then 3-4 drops of $FeCl_3$ reagent are added. The formation of a black-blue color indicates the presence of polyphenols. The gelatin method involves taking 2 mL of the filtrate and then adding 3-4 drops of 1% gelatin solution. The presence of white deposits indicates that there are tannins [13].

Transdermal patch formulation

The transdermal patch formula containing ethanol extract of green tea leaves (*Camellia sinensis* (L.) Kuntze) was made with 3 formulas using HPMC and PVP polymer bases to optimize the bases listed in Table 1. For the transdermal patch formula, the most optimal formula was made from the base optimization results as shown in Table 2.

Table 1. Basic optimization formula

Material Name	Formula Concentration			Utility
	F1	F2	F3	
Ethanol extract of green tea leaves	70%	70%	70%	Herbal ingredients
HPMC	1%	2%	3%	Polymer
PVP	3%	2%	1%	Polymer
Propylene glycol	0.5 mL	0.5 mL	0.5 mL	Plasticizers and Preservatives
DMSO	0.1 mL	0.1 mL	0.1 mL	Enhancer
Ethanol 95%	ad 10 mL	ad 10 mL	ad 10 mL	Solvent

Table 2. Transdermal patch formula

Material Name	Formula Concentration	Utility
	F3	
Ethanol extract of green tea leaves	70%	Herbal ingredients
HPMC	3%	Polymer
PVP	1%	Polymer
Propylene glycol	0.5 mL	Plasticizers and Preservatives
DMSO	0.1 mL	Enhancer
Ethanol 95%	ad 10 mL	Solvent

Formulation of green tea leaf ethanol extract transdermal patch

The PVP is crushed in a mortar, then HPMC is added, and crushed until homogeneous, then 1 mL of distilled water is added, and stirred until homogeneous, and a gel is formed. Add a little 95% ethanol, stir until completely dissolved, then add the little ethanol extract of green tea leaves, then add propylene glycol until homogeneous, then add DMSO, and stir until homogeneous. 95% ethanol is added to 10 mL, then the remaining ethanol extract of green tea leaves is added, then stirred until the preparation is mixed well, after that the preparation is poured into a mold, namely a petri dish that has been coated with alumunium foil at the bottom, left for 24 hours to remove the solvent then preparation is placed in an oven at 50°C. After the patch has dried, it is removed from the petri dish by peeling it off, and then the patch is cut to a size of 3x1 cm^2 (LxW), Once it is ready, the patch is attached to a hypafix plaster with a size of 5x2 cm^2 (LxW).

Evaluation of transdermal patch formula

Pourability test

The transdermal patch formula base that has been left for 24 hours is poured into a mold and the pourability is observed [14].

Speed of drying time

The transdermal patch formula base that has been made is dried in an oven (Memmert) at a temperature of 50°C with varying drying times (30, 60, 90, 120, 150, 180, 210, and up to 240 minutes), observed the surface of the transdermal patch until dry [14].

Organoleptic test

Transdermal patch produced, using transdermal patches stored at temperatures of 1°- 4°C, 25°C- 28°C, and 40°C on days 0,7, 14, 21, and 28. This organoleptic test was carried out with the help of five which consist of the sense of sight, sense of smell, and sense of touch [15]. The use of polymers usually affects the appearance of the resulting transdermal patch [16].

Weight uniformity test

The weight of the transdermal patch is weighed using an analytical balance, weighing each of the 4 patches and determining the average weight. The weight of the transdermal patch is said to be uniform if the standard deviation value is ≤ 0.05 [17]. The purpose of weight uniformity testing is to assess consistency in the production process to ensure that the resulting product has uniformity [18].

pH test

This test is carried out to ensure that the surface pH of the transdermal patch is suitable for use on the skin. This test is carried out by adding 10 mL of CO_2-free distilled water to the transdermal patch and leaving it for 1 hour. This test is carried out using a pH paper indicator universal (suncare) in contact with the surface of the transdermal patch. In the test, the desired pH is the same as the skin pH is the same as the skin pH, namely 4.5-6.5, at temperatures of 1°-4°C, 25°-28°C, and 40 °C on days 0,7, 14, 21, and 28 [15].

Thickness test

Testing the thickness of the transdermal patch for each formula is done by measuring the thickness of three patches one by one. Measurement of the thickness of the transdermal patch uses a scrub micrometer (tricle brand) and is carried out at 3 different points. Thickness plays a role in the physical properties of transdermal patches; thin patches will be easier to use [4]. The thickness of each patch is not may be less or more than 0.5-1.0 mm significantly [19].

Folding resistance test

Testing for resistance to folding is carried out with the transdermal patch repeatedly in the same position. The number of folds is considered the value of the resistance to folding. Increasing the folding resistance of a patch indicates that the patch has a good film consistency, so it does not break or tear easily during storage [4]. The requirement for good folding durability is more than 200-fold [20].

Data analysis

Analysis of the data obtained includes organoleptic tests, weight uniformity tests, pH tests, thickness tests, and folding resistance tests.

Results and Discussion

Preparation of green tea leaf ethanol extract

From the maceration process of green tea leaves, a filtrate weighing 1,180 grams was obtained. Next, evaporation was carried out over a water bath (Memmert) at a temperature of 60 °C to obtain the extract. With the results from 250 grams of powder, 40 grams of extract was obtained with an extract yield of 16%. With the characteristics of a blackish-brown extract and a distinctive tea smell.

Phytochemical screening of extracts

From the results of research that has been carried out, it can be proven that green tea leaves contain secondary metabolites, namely polyphenols, flavonoids, and tannins, as shown in Table 3.

Table 3. Results of the phytochemical screening test of green tea leaf extract

Compound Class	Observation Results	Information
Flavonoids	The filtrate is orange	+
Polyphenols	The filtrate is black	+
Tannin	There is a white precipitate	+

In previous studies, the results of the secondary metabolite compound content in green tea contained flavonoids, tannins, saponins, and alkaloids [21]. Flavonoids and tannins are part of polyphenol compounds; the polyphenol components of green tea can act as antioxidants. Epicatechin, epicatechin gallate, epigallocatechin, and epigallocatechin gallate are among the main antioxidant compounds in green tea, one of which can increase collagen volume so that it can help heal wounds [22].

Formulation of green tea leaf ethanol extract transdermal patch

Transdermal patches are made by first optimizing the base using HPMC and PVP polymer bases in F1 (1:3), F2 (2:2), and F3 (3:3). Then a base evaluation is carried out to find out the most optimal formula based on an evaluation of the preparation base including tests of pourability and drying time speed. With the result that F3 is the most optimal formula. So, F3 with a ratio of HPMC and PVP polymer (3:1) is an advanced formula that will be tested in the physical evaluation of the preparation.

Evaluation of transdermal patch formula base

Evaluation of the base formula is carried out to determine the concentration of the transdermal patch formula that can form a good transdermal patch preparation and meet the standards or requirements that have been determined, namely ease of pourability and speed of drying time. The formula base is the main part of the patch, which is used to deliver the active substance to a specific site and to optimize drug delivery due to longer contact [23].

Pourability

Table 4 shows that the pourability of Formula 1 (F1) was not observed due to a worse result in mixing. Therefore, observations of the pourability and time speed could not be carried out. Formula 2 (F2) produces a good preparation that is very easy to pour, and Formula 3 (F3) produces a preparation that is easy to pour. A good pouring power test is not difficult to pour [23].

Table 4. Pourability results

Formula (F)	tability
F1	-
F2	Very easy to pour
F3	Easy to pour

Dry time speed

The drying time speed parameter was observed when the patch was dried using a variation in drying time, starting from 30 minutes until the patch of each formula dried. In Table 5, the results of the drying time speed at F2 are ≥ 240 minutes; the resulting preparation does not form a good patch surface, and the preparation breaks and sticks to the aluminum foil. Then at F3, the drying time is 240 minutes, which is within the provisions for variations in drying time, namely variations in drying time between 30 to 240 minutes [14]. Increasing the amount of polymer in the preparation will cause an increase in water absorption into the matrix.

Thus, from the results of the evaluation of the base formula for the transdermal patch, namely the pourability, and speed of drying time, it was found that F3 with a ratio of HPMC and PVP (3:1) was the best preparation based on the evaluation of the base formula compared to F1 and F2. Research conducted by Nia Nitiariksa (2020) also shows that the ratio of HPMC and PVP (3:1) yields a suitable preparation for patch formulation. This Formula is used as a follow-up Formula for transdermal patch preparations, which will then carry out a physical evaluation of the transdermal patch preparations [24].

Table 5. Dry time speed results

Formula (F)	Speed of drying time (minute)
F1	-
F2	≥ 240
F3	240

Physical evaluation of transdermal patch preparations

The physical evaluation of the transdermal patch preparation aims to determine the stability of the preparation at various temperatures over several days of storage. The formula was tested for 28 days, with testing carried out every week. Physical evaluation of transdermal patch preparations using the most optimal formula based on basic evaluation, with the results of F3 being the best preparation compared to F1 and F2.

Organoleptic test

The results of organoleptic observations of transdermal patch preparations from ethanol extract of green tea leaves (*Camellia sinensis* (L.) Kuntze) at cold temperatures (1°- 4°C) during 28 days storage of formula 3 (F3) experienced changes only in shape, where the texture was previously chewy and elastic, it became rough and shriveled and somewhat elastic, but the smell and color did not change. In organoleptic observations at room temperature (24°C- 28°C) for 28 days, the transdermal patch preparation from ethanol extract of green tea leaves (*Camellia sinensis* (L.) Kuntze) experienced changes in shape, namely from a chewy texture to a rough one, but in color and odor remains the same.

Based on organoleptic observations, the hot temperature (40°C) during storage 28 experienced changes only in shape, namely from a chewy and elastic texture to a rough, slightly elastic, and shriveled texture, the color remained the same, namely blackish brown, and the odor had the characteristic smell of tea leaves.

Weight uniformity test

The weight uniformity of the transdermal patch from the ethanol extract of green tea leaves (*Camellia sinensis* (L.) Kuntze) in Table 6 shows that Formula 3 (F3) has an average weight of 0.08 grams with a standard deviation of 0. From the results of weight uniformity measurements, formula 3 (F3) meets the standard deviation requirements, which is based on literature standards, a good standard deviation (SD) is ≤ 0.05 [17].

Table 6. Weight uniformity test results

Weight Uniformity Test (F3)	Weighted (Mean ± SD)	Information
0.09 0.09 0.08 0.08	0.08 ± 0	qualify

pH test

Observation results on pH testing of transdermal patch at cold temperatures (1°-4°C), room temperatures (24°-28°C), and hot temperatures (40°C), during 28 days of storage was showed in Table 7. Formula 3 (F3) did not experience changes in pH, and remained stable at pH 6. This formula still meets the established skin pH standards, namely 4.5-6.5 [17]. These results have met the requirements to be formulated into a transdermal patch preparation because it has a stable pH within the specified pH requirements.

Table 7. pH test of transdermal patch preparation

Formula (F)	Day	pH	Information
F3	0	6	qualify
	7	6	
	14	6	
	21	6	
	28	6	

Transdermal patch thickness test

Table 8 shows the measurement of the thickness of the transdermal patch uses a scrub micrometer and is carried out at three different points. Thickness plays a role in the physical properties of transdermal patches, thin patches will be easier to use [4].

Table 8. Transdermal patch thickness results

Patch Thickness Test (F3)	Weighted Mean ± SD	Information
0.17 0.17 0.17 0.16	0.16 ± 0	qualify

The results of measuring the thickness of the transdermal patch show that Formula 3 (F3) has a patch thickness with an average of 0.16 µm and a standard deviation of 0. The thickness of the transdermal patch is caused by the hygroscopic nature of PVP, which increases the weight of the transdermal patch, which also increases the thickness of the transdermal patch [24]. The higher the concentration of polymer base used, the thicker the preparation will be, and vice versa.

Transdermal patch crease resistance test

Testing for resistance to folding is carried out with the transdermal patch repeatedly in the same position. The number of folds is considered the value of resistance to folding. An increase in the folding resistance of a patch indicates that the patch has a good film consistency, so it does not break or tear easily during storage [4]. The requirement for good folding durability is more than 200 folds [20]. Use of PVP as a soluble polymer in water causes the release of dissolved materials faster and reduces the swelling index in patches. Threfore the texture of the patch is not easily brittle and hard [25]. Table 9 shows a patch crease resistance test results. Test results on the increased resistance of the transdermal patch from ethanol extract of green tea leaves (*Camellia sinensis* (L.) Kuntze) showed that formula 3 (F3) had a crease resistance of more than 200 folds, and the transdermal patch still looked good. Thus, based on the test results on the foldability of the transdermal patch from the ethanol extract of green tea leaves, F3 has met the requirements for patch crease resistance.

Table 9. Patch crease resistance test results

Patch Folding Durability Test (F3)	Weighted Mean ± SD	Information
200 200 200 200	200 ± 0	qualify

Conclusion

This research concludes that the ethanol extract of green tea leaves can be formulated into transdermal patch preparations. The influence of the combination of HPMC base, which is lipophilic, and PVP, which is hygroscopic on the physical properties of the transdermal patch preparation influences the thickness and weight of the patch. Selecting the base formula with the best HPMC and PVP (3:1) was the best preparation, with results in pourability and time speed of good drying and has an average weight of (0.08 g ± 0), and an average patch thickness (0.16 µm ± 0).

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