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Formulation and characterization of dermal patch containing mangosteen (*Garcinia mangostana* L.) peel extract using ethyl cellulose and polyvinylpyrrolidone polymers

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ABSTRACT

Mangosteen peel extract (*Garcinia mangostana* L.) shows strong potential in treating diabetic ulcers. Topical applications via dermal patches enable direct delivery of active compounds while protecting wounds from contaminants, preventing bacterial invasion, and maintaining moisture factors essential for promoting effective wound healing in diabetic patients. The dermal patches of mangosteen peel extract were developed using a combination of EC and PVP K-30 polymers. Previously, the mangosteen peels were extracted utilizing the ultrasound-assisted extraction method. Subsequently, the dermal patches were prepared utilizing solvent casting techniques, employing a combination of ethyl cellulose and polyvinyl pyrrolidone in ratios of 1:3 (F1), 1:2 (F2), and 1:1 (F3). The dermal patches were assessed for their physicochemical properties, including organoleptic characteristics, thickness, weight uniformity, folding endurance, moisture uptake, moisture loss, and pH values. The content of alpha-mangostin was analyzed using UV spectrophotometry, while the interactions between the active ingredient and excipients were examined through Fourier Transform Infrared Spectroscopy. The crystallinity profiles were analyzed using an X-ray diffractometer. Surface morphologies were assessed using scanning electron microscopy. The dermal patches were thin, light yellow, smelled of menthol, uniform in size, and exhibited good folding endurance (>300 folds). The moisture uptake and moisture loss were minimal. The pH values ranged from 6.99 to 7.24. The total xanthone concentrations in patches F1, F2, and F3 were 95.26% ± 0.47, 71.42% ± 1.99, and 78.54% ± 0.47, respectively. It showed no chemical interaction between active ingredients and excipients and had amorphous forms. The surface morphologies displayed smoothness for F1, whereas F2 and F3 exhibited solid spots. It was concluded that formulation F1, which contained ethyl cellulose and polyvinyl pyrrolidone in a 1:3 ratio, was the optimal formulation.

Keywords: Dermal Patch, Ethyl Cellulose, *Garcinia mangostana* (L.), Polyvinylpyrrolidone K-30

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INTRODUCTION

In Indonesia, mangosteen plants (*Garcinia mangostana* L.) Clusiaceae are widely cultivated, and their production continues to increase annually (Syahputra et al., 2021). Mangosteen peels make up over 50% of the fruit's total weight and are commonly treated as waste. However, peels have traditionally been used in medicine, especially in Southeast Asia (Syahputra et al., 2021). Compared to other fruit peels, mangosteen peel is particularly rich in compounds with strong antioxidant properties (Bi et al., 2023). The primary secondary metabolites found in mangosteen are xanthones, with 68 types identified in the entire fruit and 50 specifically concentrated in the peel (Gondokesumo et al., 2019, 2020). These bioactive compounds make mangosteen peel a promising candidate for diabetic ulcer treatment, as they have been shown to accelerate wound healing and inhibit bacterial growth, thereby reducing the risk of infection (Gondokesumo et al., 2023; Shafy et al., 2019). Topical treatments for diabetic ulcers, including the use of dermal patches, have demonstrated significant effectiveness (American Diabetes Association, 2024).

Dermal patches designed to treat diabetic ulcers protect wounds from external contaminants, block bacterial migration, and keep wounds moist, which aids healing (Holl et al., 2021). Patches are preferred over ointments or creams because they adhere better to the skin, which improves patient compliance with home care (Kavitha, 2014). A modern type of patch, known as a film patch, is commonly used for wounds and is particularly suitable for early-stage diabetic ulcers. The film patch allows the passage of water vapor, oxygen, and carbon dioxide, but acts as a barrier to water and microorganisms, making it ideal for superficial ulcers (Polk et al., 2021).

Previous research on mangosteen peel extract patches used bacterial cellulose (*Acetobacter xylinum*) as a film former, resulting in wet patches that were conducive to microbial growth (Gondokesumo et al., 2023). Mangosteen peel extract patches were also developed using chitosan and Na-alginate (Wijaya et al., 2023). Chitosan and Na-alginate are hydrophilic polymers (Herdiana et al., 2022; Samani et al., 2015). A different study revealed that the combination of chitosan and HPMC in the preparation of mangosteen peel extract patches resulted in high moisture content (13–23%), mainly due to the hygroscopic nature of HPMC (Azzahra et al., 2023). Patch matrix formulations using hydrophilic polymers, including hydroxypropyl methylcellulose (HPMC) or polyvinylpyrrolidone (PVP), often require the incorporation of hydrophobic polymers such as ethyl cellulose (EC) to achieve optimal physicochemical characteristics (Oktaviani & Sukmawati, 2024). The integration of hydrophobic and hydrophilic polymers allows the formation of a more balanced matrix system, as the complementary properties of each polymer can offset the limitations of the other. This dual polymer strategy is generally more effective than single polymers, which can result in less-than-optimal matrix properties. The recommended combination is EC and PVP, with a higher proportion of PVP to increase hydrophilicity and improve overall matrix performance (Oktaviani & Sukmawati, 2024).

Ethyl cellulose, a cellulose derivative, contributes to the structural integrity of the patch through its inherent hardness and flexibility and by increasing viscosity. On the other hand, PVP plays a vital role in forming a uniform film layer, offers excellent skin compatibility, and is highly soluble in various solvents. Specifically, PVP K-30 has been shown to improve penetration, modulate drug absorption, and stabilize active pharmaceutical ingredients (Fuziyanti et al., 2022) . The combination of EC and PVP as film-forming agents not only results in a well-formed and drier film layer but also reduces the risk of microbial growth due to lower moisture retention (Zakaria et al., 2018). Research on polymer blends has further highlighted that such combinations can significantly influence critical matrix properties, including resistance to wrinkling, uniformity in weight and thickness, degree of shrinkage during drying, and water absorption capacity (Fuziyanti et al., 2022). This research focuses on formulating a patch that integrates mangosteen peel extract with a combination of EC and PVP K-30 to achieve optimal physicochemical properties, employing a solvent casting method followed by characterization testing.

MATERIALS AND METHODS

Materials

Mangosteen peels, simplicia powder *Garcinia mangostana* (L.), were purchased from PT. Indonesian Herbal Borobudur (Magelang, Indonesia). Other materials, such as alpha-mangostin p.a and EC p.a, were purchased from GLPBIO, PVP K-30 (Boai NKY), propylene glycol (DOW Chemical Pacific), menthol (Brataco), and ethanol 96% p.a (Merck). The equipments that have been used in this study were the analytical balance (Ohaus PA 224), ultrasonic bath (Branson 1510), hot plate and macnetic bar (Cimarec NH), oven (Mamert), UV-visible spectrophotometer (Shimadzu 1800), pH meter (Horiba), and micrometer screw gauge (Mitutoyo), fourier transform infrared spectroscopy (Aligent Cary), X-ray diffractometer (X'pert pro), and scanning electron microscopy (Hitachi).

Methods

Extraction of mangosteen peel

50 grams of the mangosteen peel simplicia powder were weighed and put into a glass beaker after being sieved through a 45-mesh sieve. Then, 500 mL of 96% ethanol was added, maintaining a solute-to-solvent ratio of 1:10. The mixture was stirred using a magnetic stirrer for 1 hour, followed by sonication at 55°C for 45 minutes to obtain a liquid extract. The resulting liquid extract was then filtered using Whatman No. 41 filter paper until no precipitate remained. The obtained extract was stored at room temperature for use in subsequent tests (Gondokesumo et al., 2020).

Determination of total xanthon content

A stock solution containing 100 µg/mL of alpha-mangostin was prepared by dissolving 5.0 mg of the substance in 50 mL of ethanol p.a. Concentrations of 2, 3, 4, 5, 6, 7, and 8 µg/mL were obtained by further diluting this solution (Mayefis et al., 2019). The absorbance of each standard solution at the maximum wavelength was measured to create a linear regression equation. 50 mL of ethanol p.a. was used to dissolve 0.1 mL of mangosteen peel extract. After that, 10 mL of ethanol was added to 0.5 mL of this solution to dilute it further. The linear regression equation obtained from the standard curve was used to calculate the absorbance of the solution and the total xanthone content (Aisha et al., 2013; Andayani & Verawati, 2015; Wijaya et al., 2023).

Formulation of dermal patch

The dermal patches were prepared using ethyl cellulose (EC) and polyvinylpyrrolidone K-30 (PVP K-30) at 1:1, 1:2, and 1:3 ratios, as shown in Table 1. The mixing process was conducted with the aid of a magnetic stirrer on a hot plate set at 50°C. EC was first dissolved in 96% ethanol in a beaker and stirred at medium speed for ± 3 minutes until fully dissolved (blend 1). Separately, PVP K-30 was dissolved in ethanol, combined with propylene glycol and menthol, and stirred at medium speed for ± 3 minutes (blend 2). After that, blend 2 was poured to blend 1 and stirred for ± 2 minutes to form a homogeneous polymer base. Subsequently, mangosteen peel extract was incorporated into the mixture. The final formulation was poured into molds with a diameter of 4 cm. Due to the thermolabile nature of the active ingredients, evaporation at high temperatures or using an oven was avoided. Therefore, drying was conducted at ambient temperature (Fauzana & Azhari Herli, 2021). The time required for the patches to dry was 72 hours.

Table 1. Dermal Patch Formulation with Variations of EC and PVP K-30

Formula	Concentration (%)					
	Extract Mangosteen	EC	PVP K-30	Propylene glycol	Menthol	Ethanol 96%
F1 (1:3)	1.62	3.20	9.62	1.78	0.26	83.44
F2 (1:2)	1.62	4.27	8.55	1.78	0.26	83.44
F3 (1:1)	1.62	6.41	6.41	1.78	0.26	83.44

The formula patch utilized a combination of EC: PVP K-30 in the ratios of 1:3 (F1), 1:2 (F2), and 1:1 (F3).

Evaluation of dermal patch

Organoleptic observations

Organoleptic testing involves visual and sensory assessment of the product. This was a preliminary evaluation to ensure the product meets certain physical characteristics. Typically, transdermal patches are expected to be thin and smooth in texture, with a uniform size throughout (Saundharya et al., 2022).

Thickness

The patch's thickness was determined using a micrometer screw gauge. Measurements were conducted at three different points on each patch, and the average value was calculated for determining the patch's overall thickness (Santi et al., 2022).

Weight uniformity

For weight uniformity, every patch was weighed separately using an analytical device. Each patch's weight was compared to the mean weight of all patches in the formula to ensure consistency (Santi et al., 2022; Syarifah & Nabila, 2023).

Folding endurance

In this test, the patch was folded repeatedly at the same point until cracks appeared. This evaluates the patch's folding resistance, and a good patch typically withstands more than 300 folds without breaking (Parkash et al., 2024; Syarifah & Nabila, 2023).

Moisture uptake

Following a full day in a desiccator at ambient temperature, the patches were weighed. They were then weighed once more after spending an additional day in an oven set at 40°C. Ideally, the moisture uptake should be less than 15%, as found in previous studies. By calculating the difference between the final and initial weights and dividing that difference by the initial weight, the moisture uptake % was determined (Equation 1). The method was modified from prior research (Latif et al., 2021).

$$\text{Moisture Uptake} = (\text{Final weight} - \text{Initial weight})/\text{Initial weight} \times 100\% \quad \text{.....(1)}$$

Moisture loss

Each patch was weighed individually before and after drying to determine moisture loss. Initially, the patch was kept for 24 hours in a desiccator containing silica gel, after which it was reweighed. The percentage of moisture loss was determined by calculating the ratio of the weight difference between the initial and final measurements to the initial weight (Equation 2). The method was modified from previous research. This process was repeated three times for each formula to ensure accuracy. A good-quality patch generally shows a moisture loss of about 10% (Latif et al., 2021; Shabbir et al., 2017).

$$\text{Moisture Uptake} = (\text{Initial weight} - \text{Final weight})/\text{Initial weight} \times 100\% \quad \text{.....(2)}$$

Surface pH

The surface pH was evaluated by immersing the sample for 2 hours in 15 mL of distilled water, followed by measurement using a calibrated pH meter (Rozza et al., 2021).

Total xanthon content in dermal patches

The dermal patch was solubilized in 50 mL of 96% ethanol using a volumetric flask. The resulting solution was stirred for 24 h continuously in an incubator shaker, followed by sonication for 15 min to ensure complete dissolution. Subsequently the solution was suitably diluted with 96% ethanol to achieve the target absorbance range. The absorbance was recorded at the maximum wavelength by utilizing a UV-Vis spectrophotometer, and the total xanthone content was quantified using the linear regression equation derived from the standard calibration curve. Following the

determination of total xanthone content in the patch, the percentage recovery of xanthone was subsequently calculated (Equation 3) (Aisha et al., 2013; Latif et al., 2021; Wijaya et al., 2023; Zakaria et al., 2018).

% Total xanthon recovery = Calculated concentration/Theoritical concentration x 100 .....(3)

Fourier Transform Infrared (FT-IR)

The patches were examined utilizing Fourier Transform Infrared (FTIR) Spectroscopy within a spectral range of 4000 to 650 cm^{-1}, with a resolution of 4 cm^{-1}. FT-IR was applied to both the raw materials and the final patch formulations (F1, F2, F3) to identify key functional groups (Kriplani et al., 2021; Kusumawati et al., 2024; Suksaeree et al., 2014).

X-ray Diffraction (XRD)

Compatibility of polymers and menthol in the patch was evaluated through X-ray diffraction, run at 40 kV and 30 mA, with an angle range of 5°–40° (Suksaeree et al., 2014; Zaman et al., 2017).

Scanning Electron Microscopy (SEM)

Scanning electron microscopy (SEM, Hitachi) at a high voltage of 20 kV and 3000x magnification was employed to provide an overview of the surface structure and morphology of the patch components (Zaman et al., 2017).

Data Analysis

Results were reported as the mean ± standard deviation (n = 3) and analyzed utilizing one-way ANOVA was used to analyze patch thickness, weight uniformity, moisture loss, moisture uptake, and surface pH. Additionally, post hoc tests were applied to analyze alpha-mangostin content, with a p-value less than 0.05 was regarded as statistically significant. Statistical analysis was undertaken by using SPSS software version 27.

RESULT AND DISCUSSION

Extraction of mangosteen peel

Mangosteen (*Garcinia mangostana* L.) peel extract was acquired utilizing the Ultrasound-Assisted Extraction (UAE) method, yielding 340 mL of extract (Figure 1). UAE employs ultrasonic waves to disrupt plant cell walls, enhancing the expulsion of secondary metabolites into the solvent. This method was chosen for its efficiency, shorter extraction time, and lower solvent usage than conventional techniques (Setiawan et al., 2023). The extraction used 96% ethanol, selected for its low toxicity and effectiveness in extracting active compounds while minimizing unwanted components (Wahyuningsih et al., 2024). The resulting extract was a dark brown liquid with a distinctive aroma and a bitter, slightly astringent taste. Total xanthone content was determined using alpha-mangostin as the marker compound (Socaciu et al., 2020). The total amount of xanthone yielded by mangosteen peel extract was (26.49 ± 1.6) mg in 1 mL of extract.

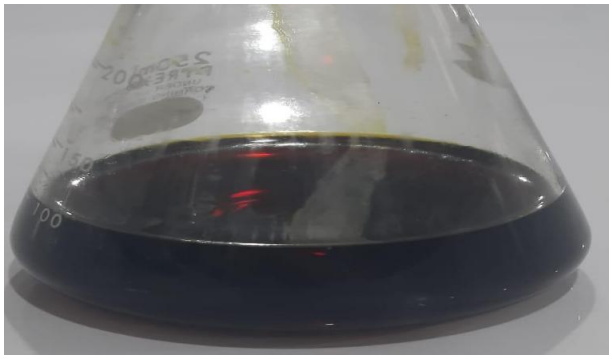

Figure 1. Mangosteen peel extraction results

The formulation of dermal patches

The physical appearance that could be observed in dermal patches is illustrated in Figure 2. The dermal patch formulation containing *Garcinia mangostana* (L.) mangosteen peel extract was prepared in three different formulas (F1-F3), each with varying ratios of EC and PVP K-30 polymers. Solvent evaporation was used in the mangosteen peel extract dermal patch formulation. The polymers used were ethyl cellulose and polyvinylpyrrolidone K-30. Ethyl cellulose has hydrophobic properties, which were combined with polyvinylpyrrolidone K-30, which has hydrophilic properties, to regulate the release of active ingredients gradually. Hydrophilic polymers can provide rapid release at the initial stage, and lipophilic polymers will provide gradual release for a longer effect (Franco & De Marco, 2020).

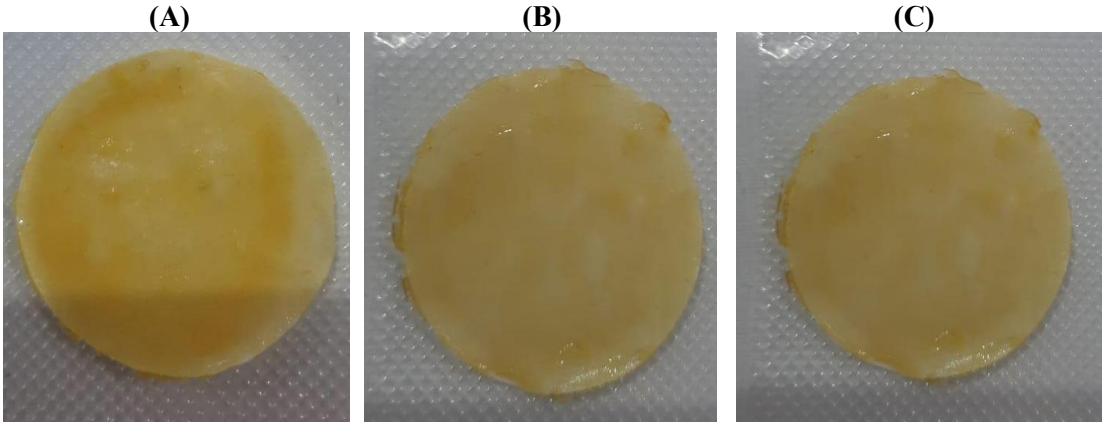

Figure 2. Mangosteen peel extract patch. Patches with EC and PVP K-30 ratio (A) 1:3 (F1); (B) 1:2 (F2); (C) 1:1 (F3).

Evaluation of dermal patch

The organoleptic properties of the patches, including their shape, texture, color, and surface condition, were evaluated for each formula. The results of these observations are summarized in Table 2, which details the physical characteristics of the prepared patches. The patch appears light yellow, changing from the original brown or purplish-red anthocyanins into mangosteen peel when combined with other ingredients. Since the patch was designed for single-dose administration, uneven distribution of the active ingredient was not expected to affect the total dose delivered. The formulation has a menthol scent to mask any unpleasant odors from the extract (Saundharya et al., 2022). The texture of F1, F2, and F3 patches showed slight moisture because of the hygroscopic properties of PVP K-30, menthol, and bioactive compounds in mangosteen peel extract (Socaciu et al., 2020). The visible blotches observed on the surface of the transdermal patch were attributed to the high viscosity of the matrix mixture. Viscous solutions are less capable of spreading uniformly over the substrate surface before solvent evaporation. As the solvent evaporates, the viscosity of the polymer-containing mixture increases further, leading to uneven surface formation, which manifests visually as spots or blotches (Felton, 2013).

Table 2. Organoleptic of the mangosteen peel patch

Formula	Shape	Texture	Color	Smell	Surface
	Thin Layer	Dryness	Light yellow	Special smell of menthol	Smoothness
F1	+	+	+	+	+
F2	+	+	+	+	+
F3	+	+	+	+	+

(+): Conforms to specifications; (-): Does not comply with specifications.

The folding endurance of patches was examined for folding resistance with folding repeatedly them at the same spot until they cracked or broke. All patches demonstrated excellent folding endurance, withstanding over 300 folds without failure (Parkash et al., 2024). It is essential in dermal patch formulation, showing that the patch can integrate with skin folds and resist tearing during use (Latif et al., 2021). Plasticizers are critical for flexibility, as they prevent the patch from cracking; without them, the patch would be brittle. The backing membrane also helps to improve folding endurance (Nandi & Mondal, 2022).

Thickness and weight uniformity Table 3 were observed, with a low standard deviation of ≤5%, indicating good thickness (less than 1 mm) and weight uniformity. A low standard deviation ≤5% indicates that the preparation method used is skillful for patch development with little variability (Nandi & Mondal, 2022). Thickness and weight uniformity will affect flexibility, compactness, and brittleness (Santi et al., 2022; Wijaya et al., 2023). In this study, the low moisture uptake (no more than 15%) and loss values (no more than 10%), Table 3 indicate the patch remains stable during long-term storage and does not become brittle (Latif et al., 2021; Shabbir et al., 2017). Low moisture uptake prevents the patch from microbial contamination (Santi et al., 2022). The formulated patch's surface pH Table 3 was determined to assess the potential for skin irritation because acidic or basic pH can be irritating. The pH test on the dermal patch found the highest pH value in F3, which was 7.24, and the lowest pH in F1, which was 6.99. The influence of pH is important in wound healing, such as in diabetic wounds. Increasing the pH in the wound area to a more alkaline pH of up to 8.5 will be an optimal environment for the growth of bacteria that trigger wound infections (Fu et al., 2022). Conversely, a pH that is close to neutral can accelerate the wound-healing process. A clinical study on wounds, including diabetic wounds, showed that a wound pH value lower than 7.5 will accelerate the wound healing process, and the wound environment tends to become more acidic during the healing process (Mcardle et al., 2014).

The analysis of total amount of xanthones in the patch formulations Table 3 was carried out to determine the amount of active compound remaining after the formulation. The test results revealed the recovery percent of the patch F1, F2, and F3 were 95.26%, 71.42%, and 78.54%, respectively. The reductions in F2 and F3 were thought to be because of the higher viscosity of the mixture compared to F1, resulting in poor flow during the casting process, which causes incomplete transfer of the formulation into the mold and further loss of active compounds (Martin et al., 2011). These findings indicate that controlling the viscosity of the formulation and optimizing the casting process were needed to minimize the loss of active compounds and ensure the uniformity and effectiveness of the final dermal patch.

Table 3. Thickness, weight uniformity, moisture uptake, surface pH, and the recovery of total xanthone of the patch

Formula	Thickness (mm)	Weight Uniformity (g)	Moisture Uptake (%)	Moisture Loss (%)	Surface pH	The Recovery of Total Xanthone (%)
F1	0.67 ± 0.05	0.61 ± 0.03	7.03 ± 1.43	1.59 ± 0.08	6.99 ± 0.14	95.26 ± 0.47
F2	0.68 ± 0.09	0.64 ± 0.04	7.96 ± 1.30	1.59 ± 0.07	7.01 ± 0.14	71.42 ±1.99
F3	0.71 ± 0.03	0.64 ± 0.03	6.37 ± 1.30	1.48 ± 0.05	7.24 ± 0.14	78.54 ± 0.47

The FTIR spectra of the EC, PVP K-30, propylene glycol, menthol, and patches F1, F2, and F3 Figure 3 were investigated to investigate potential interactions between active ingredients and excipients. The mangosteen peel extract spectrum showed characteristic peaks at 1045.51 cm^{-1} for C-O ether groups, 1664.25 cm^{-1} for (C=C) stretching, 1701.52 cm^{-1} for C=O stretching, 2974.41 cm^{-1} and 2929.68 cm^{-1} for (CH-) stretching, and 3307.42 cm^{-1} for (-OH) stretching (Rohman et al., 2020; Tejamukti et al., 2020). The EC spectrum exhibited characteristic peaks at 1051.10 cm^{-1} and

1278.47 cm^{-1} for C-O-C stretching, 2870.05 cm^{-1} and 2972.55 cm^{-1} for C-H stretching, and 3369.57 cm^{-1} and 3479.46 cm^{-1} for O-H stretching (Nandi & Mondal, 2022). The PVP K-30 spectrum showed peaks at 1168.52 cm^{-1} and 1285.93 cm^{-1} for C-N stretching, 1638.16 cm^{-1} for C=O amide bond absorption, 2948.32 cm^{-1} for C-H bonds, and 3309.87 cm^{-1} and 3399.33 cm^{-1} for O-H stretching from absorbed water (Febriyenti et al., 2020). The FTIR spectra revealed several peaks within the formulations, confirming no chemical interaction between the active ingredients of mangosteen extract and the excipients (Latif et al., 2021).

The XRD analysis presented in Figure 4 was performed to assess the crystal structure of the material. The mangosteen peel extract was in liquid form. Consequently, its crystallinity was not assessed through XRD analysis. The XRD pattern showed a high peak at the 2-theta diffraction angle, indicating high crystallinity of menthol. In contrast, the X-ray diffraction spectra of the polymers EC and PVP K-30 showed no significant peaks, reflecting their amorphous nature. The diffraction spectra for formulations F1, F2, and F3 showed similar characteristic peaks as EC and PVP K-30, but with reduced intensity, as indicated by the broadened peak shape. The XRD patterns for F1, F2, and F3 had no sharp peaks, which confirmed the amorphous form. The decrease in peak intensity on the diffractograms indicates that the active ingredients were well dispersed in the polymer matrix (Sharma & Pancholi, 2012).

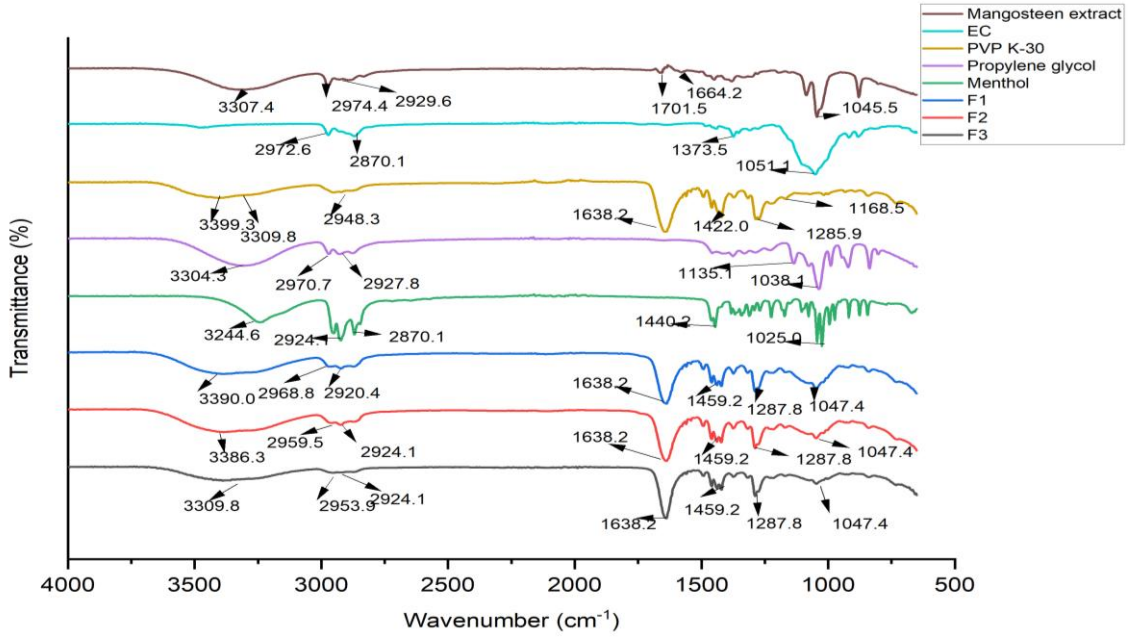

Figure 3. FT-IR spectra of mangosteen extract, EC, PVP K-30, propylene glycol, menthol, F1, F2, and F3

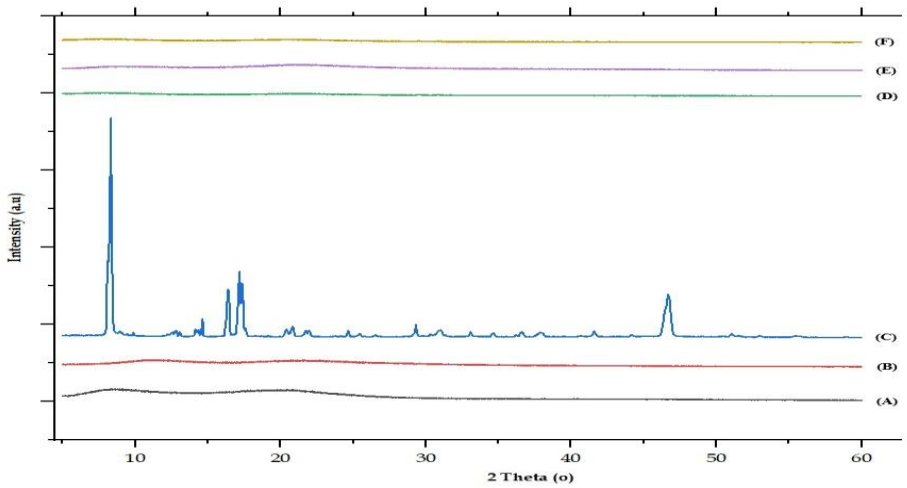

Figure 4. X-ray diffractogram of (A) EC, (B) PVP K-30, (C) menthol, (D) F1, (E) F2, (F) F3

SEM was conducted to examine the surface morphology of the patches. The results, presented in Figure 5, revealed that a smoother and less porous surface was observed in F1, while a rougher surface was observed in F2 and F3. This was attributed to the higher concentration of PVP K-30 polymer in formula F1 compared to other formulations. Hydrophilic polymers such as PVP K-30 in patch formulations serve to prevent recrystallization through two mechanisms: exhibiting intermolecular hydrogen bonds with the active ingredients and occupying voids in the saturated matrix solution. In addition, they contribute to reducing the nucleation rate, effectively preventing crystallization (Chatterjee et al., 2022).

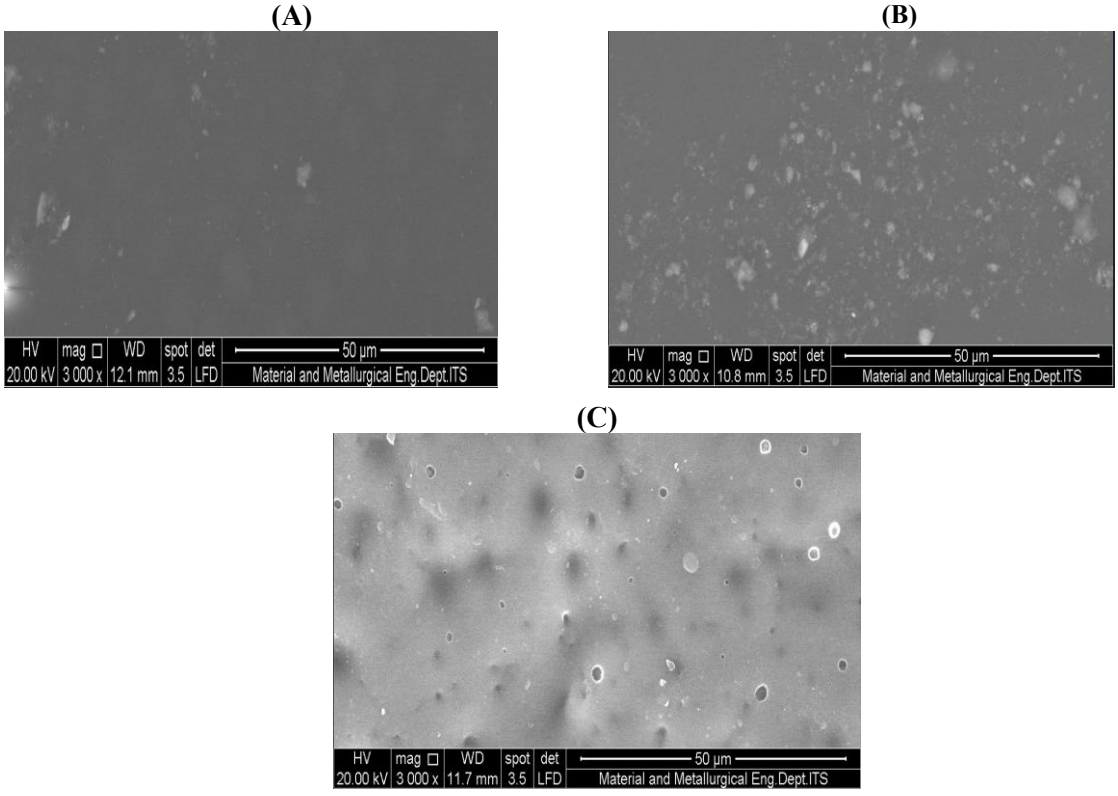

Figure 5. Surface morphology of the dermal patch (A) F1, (B) F2, and (C) F3 at a magnification of 3000x

CONCLUSION

Dermal patches containing mangosteen peel extract (*Garcinia mangostana* L.) utilizing a polymer combination of EC and PVP K 30 were successfully developed. Among all of the patch formulations, F1, utilizing a combination of EC and PVP K 30 in a 1:3 ratio, was identified as the optimal formula due to its physicochemical characteristics and smooth surface morphology.

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