JNPDD
Journal of Natural Product for Degenerative Diseases
https://journal.univpancasila.ac.id/index.php/Natural

In Vitro Penetration of Curcumin Self-Nanoemulsifying Drug Delivery System (SNEDDS) in Transdermal Gel Formulations

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Received: 17 September 2025 / Accepted: 30 March 2026

ABSTRACT: Curcumin is a natural bioactive compound with potent antibacterial properties; however, its clinical utility is restricted by poor aqueous solubility (BCS Class II) and low systemic bioavailability. This study aimed to overcome these barriers by formulating curcumin into a self-nanoemulsifying drug delivery system (SNEDDS) incorporated into a transdermal gel. Optimization involved a synergistic blend of virgin coconut oil (VCO), Tween 80, and Cremophor RH 40, which spontaneously forms a nanoemulsion upon aqueous contact. The optimized formulation yielded nanoparticles with a size of 257.9 nm, a polydispersity index (PDI) of 0.018, and a zeta potential of − 29 mV. In vitro penetration tests using a Franz diffusion cell with guinea pig skin revealed a significant improvement ($p < 0.05$) in drug delivery. The curcumin SNEDDS gel achieved a cumulative permeation of 187.53 ± 16.27 µg/cm², significantly outperforming the conventional curcumin gel (125.19 ± 8.41 µg/cm²). These findings demonstrate that the SNEDDS-based transdermal approach is a highly effective strategy for enhancing skin penetration and the therapeutic potential of curcumin.

KEYWORDS: Curcumin; in vitro penetration test; nanoemulsion; SNEDDS; and transdermal gel.

1. INTRODUCTION

Curcumin, the main compound of turmeric or *Curcuma longa* L. (Figure 1), exhibits a wide range of pharmacological activities, including antiviral [1], antifungal [2], and antibacterial activities [3]–[5]. In particular, curcumin inhibits the growth of gram-positive bacteria, such as *Staphylococcus aureus, Trichophyton gypseum*, *Salmonella paratyphi*, and *Mycobacterium tuberculosis* [5]. The clinical potential of curcumin is hampered by its physicochemical properties, namely, its very low solubility in water (1.34 ± 0.02 mg/L) and rapid presystemic elimination, resulting in poor oral bioavailability [6]. Despite its potential, curcumin faces a significant "delivery paradox". It possesses excellent lipid membrane permeability (log P 2.56–3.29) but suffers from extremely low water solubility (1.34 mg/L) and rapid metabolism [7]. To bypass first-pass metabolism and provide sustained release, the transdermal route offers a compelling alternative. However, the skin's natural barrier, the stratum corneum, remains a formidable obstacle [8]. To address this, The Self-Nanoemulsifying Drug Delivery System (SNEDDS) is one of the cutting-edge formulation strategies that is effective in improving the solubility and absorption of lipophilic drugs [9]. SNEDDS is an isotropic mixture of oils, surfactants, and cosurfactants that spontaneously forms nanoemulsions with very small droplet sizes (below 200 nm) when mixed with water media [10]. This very small particle size increases the surface area of contact, facilitates the solubilization of curcumin, and allegedly aids penetration through the stratum corneum [11].

This study aimed to optimize the formulation of SNEDDS curcumin and test the penetration ability in vitro of transdermal gel preparations containing curcumin SNEDDS compared to conventional curcumin transdermal gels to confirm the effectiveness of SNEDDS as a superior transdermal delivery system [7], [12]. Penetration tests were performed on transdermal gels to obtain and determine the amount of curcumin nanoemulsions that entered the skin using the abdominal skin of guinea pigs [13]. To ensure the precision

How to cite this article: Prawira SC, Hakim ZR. In Vitro Penetration Test of Transdermal Gel Preparatıons Self-Nanoemulsifying Drug Delivery System (SNEDDS) Curcumin as a Drug Delivery System. JNPDD. 2026; 3(2): 62-71.

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https://doi.org/10.58511/v3i2.9213
ISSN: 3031-6847

and validity of the penetration data, the study also involved the optimization of analytical parameters, including the maximum absorption wavelength (lambda max), stability time, and linear calibration curve.



Figure 1. Turmeric (*Curcuma longa* L.) and curcumin [14]

2. MATERIALS AND METHODS

2.1. Material

The active ingredients used were curcumin (Sigma Aldrich, Germany), virgin coconut oil (Sigma Aldrich, Germany), Cremophor RH 40 (BASF personal care, ULTRUS, USA), Tween 80, propylene glycol (Fluka, Honeywell, USA), NaOH, ethanol 96%, aqua destillata, the skin of the male guinea pig's abdomen (Hampet Center, Bekasi, Indonesia), natrium phosphate dibasic dihydrate ($Na_2HPO_4.2H_2O$), natrium phosphate monobasic dihydrate ($NaH_2PO_4.2H_2O$). Glass tools (Pyrex, USA), drip pipettes, magnetic stirers, analytical scales (ACIS type AD-300H, USA), pH meters (Meterlab PHM201, USA), freezers, spatulas, iron clamps, aluminum foil, particle sizer analyzer (Beckman Coulter, USA), zeta sizer (Beckman Coulter, USA) Transmission Electron Microscope (JEOL JEM-1010, Japan), Scanning Electron Microscope (ZEISS, Germany), hotplate magnetic stirrers(OHAUSS, USA), centrifuses (Kokusan H-103n, Saitama, Japan), peristaltic pumps (Innofluid Co., Ltd, China), PVC pipes, micropipettes (Pipetmann, Gilson, USA), vortexes (DLAB Scientific, China), orbital shakers (Mettler Toledo, Switzerland), Transdermal Diffusion Cells (LOGAN, New Jersey, USA).

2.2. Optimization and Characterization of SNEDDS Curcumin

The SNEDDS formulation was created by mixing pseudo-ternary phase diagrams with variations in the ratio of oil, surfactant, and cosurfactant. The optimal SNEDDS formulation was selected based on its clear visual appearance, fast emulsification time, and stability to freeze–thaw tests. The SNEDDS nanoemulsion formulation was created by mixing virgin coconut oil (VCO), Cremophor RH 40, Tween 80, and propylene glycol in seven different formulations and adding the same amount of curcumin. SNEDDS nanoemulsions were prepared by dissolving curcumin in VCO until it was completely dissolved. Next, the solution was added to Cremophor RH 40, Tween 80, and propylene glycol by stirring using a magnetic stirrer at a speed of 100 rpm at a temperature of 37 °C until a clear emulsion was formed. Distilled water was then placed in a beaker containing SNEDDS and sonicated for 15 min. The proportions of the formulations are listed in Table 1.

Table 1. Composition of ingredients in the manufacture of SNEDDS formula

Materials	Formula SNEDDS (%b/v)						
	I	II	III	IV	V	VI	VII
Curcumin powder	1.5	1.5	1.5	1.5	1.5	1.5	1.5
VCO	27	30	33	36	39	42	45
Tween 80	6	6	6	6	6	6	6
Propylene glycol	20	20	20	20	20	20	20
Cremophor RH 40	27	24	21	18	15	12	9
Aquadest add	200	200	200	200	200	200	200

The optimal characterization of self-nanoemulsifying drug delivery systems (SNEDDS) involves several key physicochemical parameters to ensure stability and performance. Particle size and the polydispersity index (PDI) are commonly determined using photon correlation spectroscopy (PCS) to evaluate the uniformity and distribution of nanosized droplets [15]. Zeta potential is measured using the electrophoretic light scattering method to assess the surface charge and predict the stability of the nanoemulsion system. In addition, particle morphology is typically examined using transmission electron microscopy (TEM) to visualize the shape and structural characteristics of the formed nanoemulsion droplets [16]. Furthermore, the entrapment efficiency (EE) and loading capacity (LC) are calculated using a UV–Vis spectrophotometer to determine the amount of active compound successfully incorporated within the SNEDDS formulation [17].

2.3. Transdermal Gel Preparation and Evaluation

The best SNEDDS formulation of curcumin was then formulated into a transdermal gel using HPMC as a gelling agent. A curcumin transdermal gel without SNEDDS was also manufactured for comparison. Both gel preparations were evaluated for quality, including organoleptic properties, homogeneity, centrifugation test, dispersability, viscosity, flow properties (rheology), and pH [18].

2.4 In Vitro Penetration Test

A penetration test was performed using Franz type transdermal cell diffusion (TDC). The skin membrane of the guinea pig was prepared by removing the subcutaneous fat. The receptor compartment was filled with 0.1 M phosphate buffer solution at pH 7.4, which was adjusted to the skin pH and used as a release medium. Gel preparations were applied to the membranes. Samples were drawn at specific time intervals of 3 h, and the penetrated curcumin concentrations were analyzed using a UV-Vis spectrophotometer at a maximum wavelength of 432 nm. The penetration results were expressed as the cumulative amount of curcumin penetrated per area (μg/cm^2) [19].

2.5. Data Analysis

Characterization of Nanoparticles by the Descriptive Method The penetration test results were analyzed using 1-way analysis of variance to statistically compare the difference in penetration ability between the SNEDDS curcumin transdermal gel and the curcumin transdermal gel [20].

3. RESULTS & DISCUSSION

3.1 Physicochemical Optimization and SNEDDS emulsification enhance

The success of SNEDDS depends heavily on the ratio of its components. Our tests showed that formulas with lower oil concentrations (Formulas 1–4) achieved rapid emulsification in less than 60 s. As the oil phase (VCO) increased, the emulsification time slowed down because lower surfactant concentrations could not efficiently reduce the surface tension at low energy (100 rpm). Visually, Formulas 1 and 2 remained the clearest (Class I), confirming that a higher surfactant-to-oil ratio is essential for maintaining a stable, transparent nanoemulsion. In the preparation of SNEDDS, raw materials are crucial for the quality of the product. The results of the inspection showed that the raw materials included curcumin, VCO, Cremophor RH 40, tween 80, propylene glycol, povidone, and hydroxy propyl methyl cellulose, in accordance with the requirements of the standards (description, solubility, and degree of acidity) in the Handbook of Pharmaceutical Excipients 6th Edition [21]. The emulsification time is used to determine how quickly the SNEEDS formula forms an emulsion; a SNEEDS formula must be able to form an emulsion spontaneously after direct contact with gastric fluid. Based on the results of the emulsification time test, formulas 1–7 were obtained with an emulsification time range of 43 – 102 s. This time can indicate the increasing addition of VCO with the addition of Cremophor RH 4, 0, which can affect the emulsification speed of the formula, as shown in Figure 2. The entire formula is affected by the phase imposition of the oil, and a lower surfactant will require more energy, which lowers the surface tension, while the stirring speed used to emulsify the entire formula is the same; therefore, low energy (100 rpm) takes longer. The faster the emulsification time, the clearer the SNEDDS with a larger percentage of transmitters and the smaller the droplets produced. A good emulsification time requirement for SNEDDS is less than 60 s [22] in formulas 1, 2, 3, and 4, the emulsification time obtained was 24 – 53 s, which is qualifie; however,t in formula 5, 6, and 7, the emulsification time obtainedwass 61 – 91 s, which is not qualified.

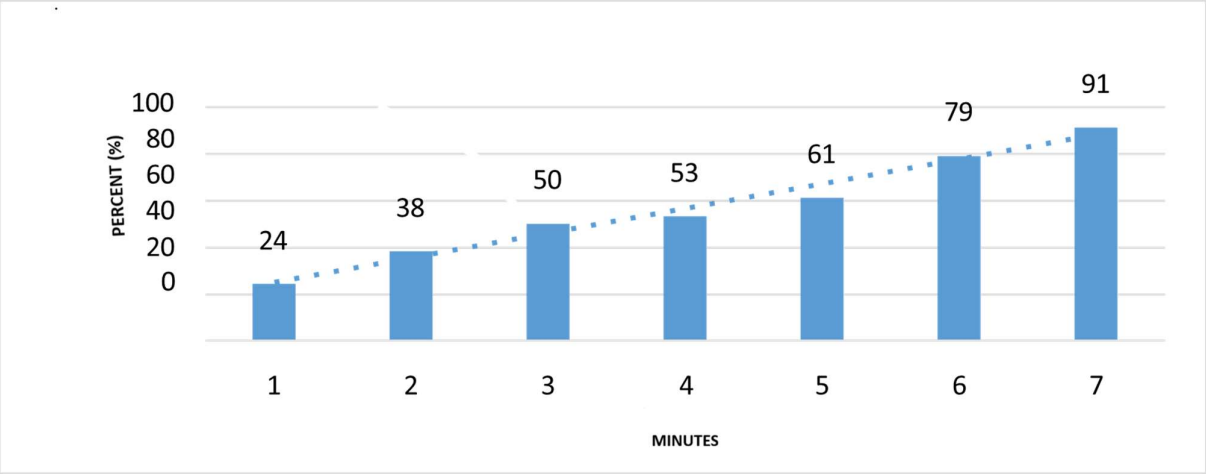


Figure 2. The emulsification time test

3.2 Visual Appearance Examination (Morphology)

The results of the visual appearance examination of curcumin SNEDDS are shown in Figure 3. Based on the visual display test, the results of formula 1.2 are included in class I, formula 3 is included in BCS class II, formula 4.5 is included in class III, and formula 6, 7 is included in class IV. It is known that the SNEDDS formulas that are expected to produce clear nanoemulsions are formulas 1 and 2. There was a decrease in clarity in the emulsion until formula 7, which showed that the more oil phases in the SNEDDS formula, the more turbidity the emulsion produced. This is because of the decreasing percentage of surfactants, which makes it more difficult to prevent the incorporation of dispersed liquid droplets. This decrease in the emulsion grade was directly proportional to the emulsification time.



Figure 3. Visual Appearance of Curcumin SNEDDS

Based on the visual display test, the results of formula 1, 2 were included in class I, formula 3 in BCS class II, formula 4.5 in class III, and formula 6, 7 in BCS class IV. It is known that the SNEDDS formulas that are expected to produce clear nanoemulsions are formulas 1 and 2. There was a decrease in clarity in the emulsion until formula 7, which showed that the more oil phases in the SNEDDS formula, the more turbid the emulsion was. This is because of the decreasing percentage of surfactants, which makes it more difficult to prevent the incorporation of dispersed liquid droplets. This decrease in the emulsion grade was directly proportional to the emulsification time.

https://doi.org/10.58511/v3i2.9213
JNPDD 2026; 3(2): 62-71

3.3 Stability test results with Freeze-thaw

Freeze–thaw testing was performed to determine the resistance of SNEDDS to separation and deposition due to temperature changes. The freeze–thaw test results forf curcumin SNEDDS are shown in Figure 4. It is known that there is no separation in the two formulas tested because if an emulsion of oil and water is frozen, the oil phase will form crystals such that the oil phase will separate during the defrosting process; however, there is a change in color from clear yellow to orange. This is due to the change in the color of the active substance curcumin because an increase in pH causes the degradation of curcumin during freeze–thaw testing [23].



Figure 4. Freeze-thaw test results

3.4 Test results of pseudo-ternary phase diagram

Determination of pseudo-ternary phase diagrams to determine how to compare clear regions so that they can be formulated into SNEDDS. The results of the preparation of the pseudo-ternary phase diagram of curcumin-SNEDDS are shown in Figure 5. According to Hea-Young Cho, the use of surfactants mixed with Cremophor RH 40 and Tween 80 results in a larger emulsion area than the use of Tween 80 alone. It is known that Cremophor RH 40 and Tween 80 can form surfactants that can better prevent the incorporation of dispersed liquid droplets, thus creating a wider area in the pseudo-ternary phase diagram [24].

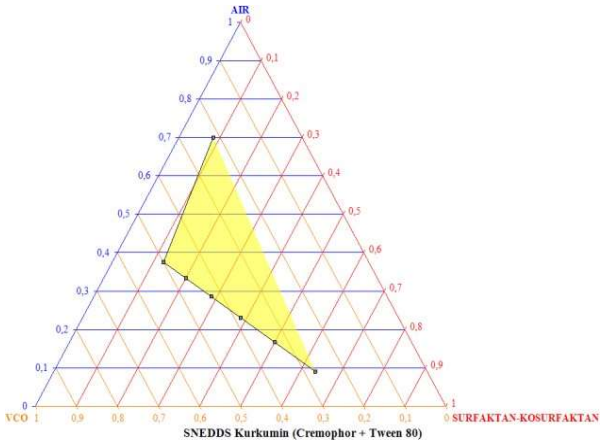


Figure 5. Diagram of the pseudo-ternary phase using mixed surfactants Cremophor RH 40 and Tween 80

3.5 SNEDDS particle size distribution test results

Particle size is an important parameter in the characterization of curcumin nanoparticles because it determines the in vivo distribution, toxicity, release, drug loading, stability, and targeting ability of curcumin nanoparticles, which will affect the uptake rate of curcumin nanoparticles in cells. The smaller the size of the nanoparticles, the larger the surface area of the curcumin nanoparticles; thus, curcumin in the nanoparticles is

more easily exposed to the surface charge in the cell, leading to the rapid release of curcumin in the nanoparticles[25]. The distribution of curcumin SNEDDS particle sizes is shown in Figure 6.

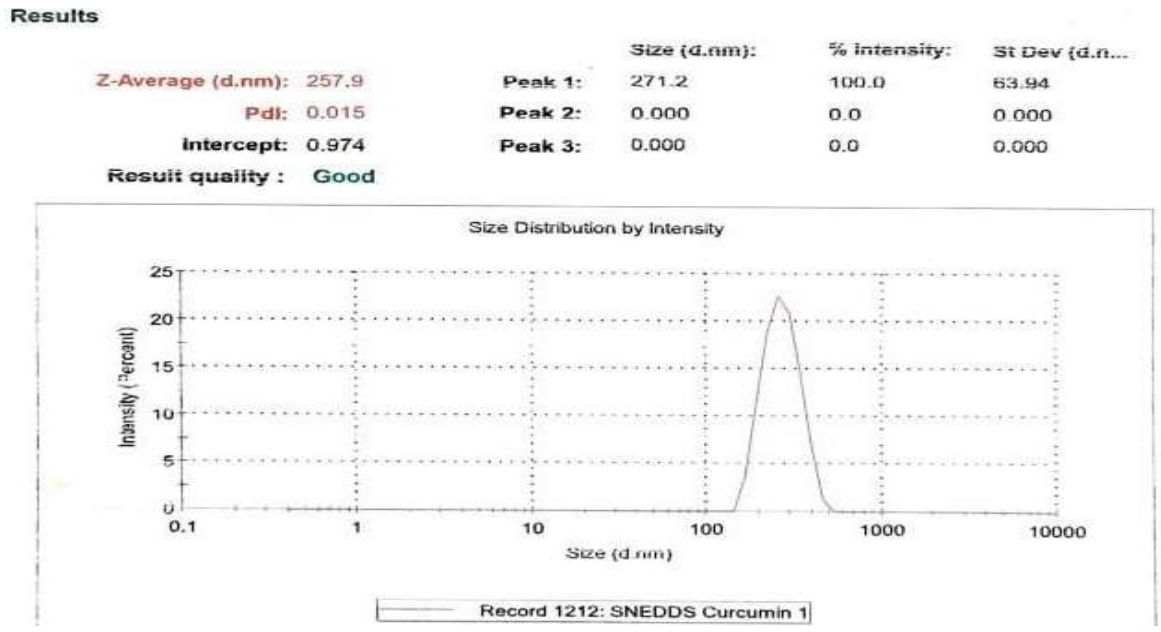


Figure 6. Results of the SNEDDS Curcumin Formula 1 particle size distribution test (Best formula)

As shown in Figure 6, only one peak is observed in the results of the particle size distribution measured with a particle size analyzer (PSA), indicating that the size of the curcumin nanoparticles is uniformly distributed. The results of the curcumin nanoparticle size can be aimed at the delivery of curcumin to the brain and tumor tissues that have a particle size range between 50-200 nm. At a smaller nanoparticle size of approximately 150 nm, nanocarriers can easily exit the systemic circulation through the blood vessels of tumors or cancerous tissues, which increases the level of chemotherapeutic active substances in tumor tissues, especially curcumin, which is also efficacious as an anticancer agent[15, 26]. The optimal curcumin SNEDDS formulation (Formula 1) was successfully developed and demonstrated favorable physicochemical characteristics.

The formulation exhibited a particle size of 257.9 nm with a very low polydispersity index (PDI) of 0.018, indicating a highly monodisperse system with a uniform droplet distribution. In addition, the zeta potential value of −29 mV suggests good electrostatic stability, which helps prevent nanoparticle aggregation due to strong interparticle repulsion. Morphological observations further confirmed that the particles had a spherical shape (Figure 7). Overall, the relatively small particle size combined with a low PDI reflects a homogeneous and physically stable dispersion system, supporting the stability and potential effectiveness of the SNEDDS formulation for curcumin delivery. No phase separation occurred during stability testing (freeze–thaw). However, we observed a color shift from clear yellow to orange. This phenomenon is likely attributed to curcumin degradation triggered by slight pH fluctuations during the temperature cycles

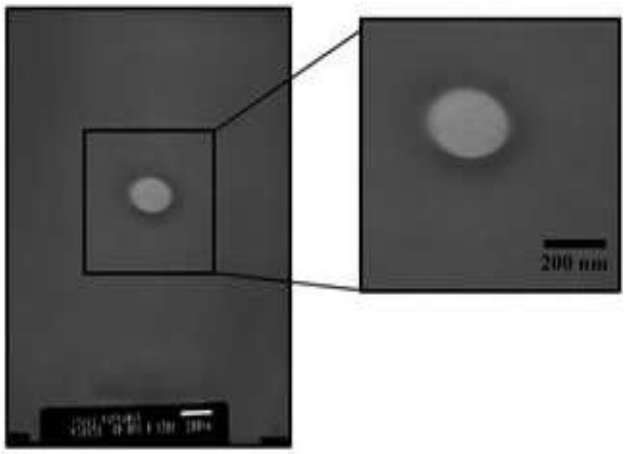


Figure 7. The spherical particles morphology of SNEDDS curcumin

3.6 Evaluation of Physical Quality of Gels

SNEDDS curcumin transdermal gel preparations exhibit plastic ticsotropically flow properties. This property is desirable for topical preparations because the preparation will not flow when stored but will spread easily (shear thinning) and has good penetration when applied to the skin with a sliding force (massage). pH evaluation showed qualified results for topical preparations.

3.7 In Vitro Penetration Test Results

The in vitro penetration data serve as definitive proof of the superiority of the SNEDDS. Within 3 h, the SNEDDS gel delivered 187.53 ± 16.27 µg/cm² of curcumin, a 50% increase over the conventional gel's 125.19 ± 8.41 µg/cm².

Table 2. Penetration result of SNEDDS curcumin

Gel Formula (after 3 hours)	Cumulative Amount of Penetrated Curcumin (µg/cm²)
SNEDDS Curcumin Transdermal Gel (Formula 1)	187.53 ± 16.27
Conventional Curcumin Transdermal Gel (Formula 1)	125.19 ± 8.41

The results of statistical analysis using one-way ANOVA demonstrated a significant difference ($p < 0.05$) in the penetration ability between the curcumin SNEDDS gel and the conventional curcumin gel. Overall, the amount of curcumin that penetrated from the SNEDDS formulation (Formula 1) reached 187.53 ± 16.27 µg/cm², which was substantially higher than that of the conventional gel (Formula 3), which showed only 35.20 ± 4.03 µg/cm². This enhanced penetration can be explained by two primary mechanisms associated with the SNEDDS system. First, SNEDDS improves the solubility of lipophilic curcumin by dissolving it in extremely small oil-phase droplets, thereby increasing the concentration of the drug in a dissolved state, which is a critical factor influencing the rate of skin penetration. Second, the nanoscale particle size provides a carrier effect by increasing the surface area and facilitating interactions with the lipid layers of the stratum corneum. Additionally, the surfactants used in the SNEDDS formulation, such as Tween 80 and Cremophor RH 40, function not only as emulsifying agents but also as penetration enhancers that can modify the skin barrier, thereby promoting greater drug permeation.

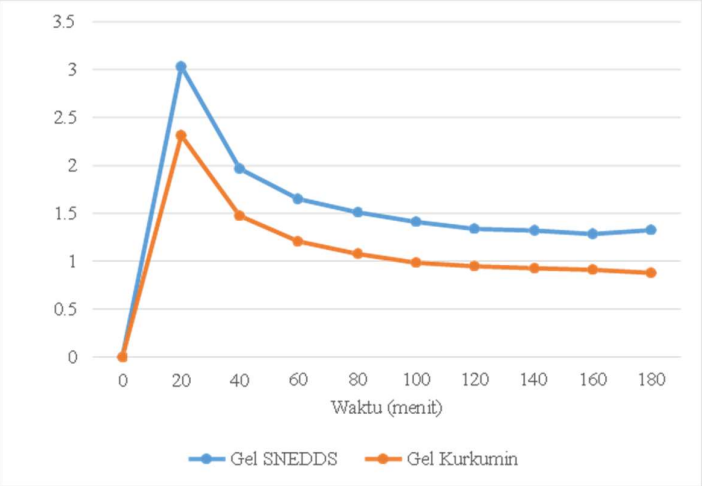


Figure 8. Flux values of SNEDDS curcumin transdermal gel

Flux values passing through guinea pig skin membranes for 3 h from three transdermal gel preparation formulas of curcumin SNEDDS were compared with three curcumin transdermal gel formulas. The largest flux value was observed at the 20th min. Formula 1 transdermal gel SNEDDS curcumin and formula 1 transdermal gel curcumin were 3.03 ± 0.25 µg/cm² and 2.31 ± 0.12 µg/cm² (Figure 8). Formula 2 transdermal gel SNEDDS curcumin and formula 2 transdermal gel curcumin are 2.74 ± 0.24 µg/cm² and 0.89 ± 0.09 µg/cm². Formula 3 transdermal gel SNEDDS curcumin and formula 3 transdermal gel curcumin are 0.68 ± 0.06 µg/cm² and 0.24 ± 0.02 µg/cm². The results showed rapid release of curcumin at 20 min, which may have been caused by saturation of the gel matrix in the early stages, resulting in faster release of curcumin. When the condition becomes unsaturated over time, the release of the active substance slows.

4. CONCLUSION

In this study, we successfully developed an optimized curcumin SNEDDS that yields stable spherical nanoparticles (257.9 nm). By integrating this system into a transdermal gel, we achieved a significant improvement in curcumin's ability to penetrate the skin barrier compared to traditional methods. Although these results are promising, further validation through ex vivo human skin models and clinical antibacterial assays is needed to fully realize curcumin's potential as a modern therapeutic agent.

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