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FORMULATION AND EVALUATION OF THE PHYSICAL QUALITY OF NIACINAMIDE GEL PREPARATIONS USING PVP AS A GELLING AGENT

Formulasi dan Evaluasi Mutu Fisik Sediaan Gel Niacinamide Menggunakan PVP Sebagai Gelling Agent

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ABSTRAK

Niacinamide adalah bentuk amida dari vitamin B3. Bentuk lain dari vitamin B3 termasuk niacin (asam nikotinat). Polivinilpirolidon (PVP) adalah polimer biodegradable dan larut dalam udara yang berasal dari monomer N-vinilpirolidon. Gell merupakan sediaan yang mengandung banyak air dan mempunyai potensi yang lebih baik sebagai sediaan pemberian obat secara topikall dibandingkan salep karena tidak lengket, memerlukan energi yang rendah selama formulasi, stabil dan mempunyai nilai estetika. Tujuan penelitian ini adalah untuk mengevaluasi mutu fisik dari sediaan gel niacinamide berbasis PVP berdasarkan parameter mutu fisik meliputi uji organoleptik, uji homogenitas, uji pH, uji viskositas, uji daya lekat, dan uji daya sebar. Metode yang digunakan dalam penelitian ini adalah metode eksperimental yang dilakukan untuk mengetahui mutu fisik gel yang baik. Hasil penelitian menunjukkan sediaan gel niacinamide berbasis PVP yang dihasilkan memiliki tekstur gel kental, warna transparan, tidak berbau, homogen, nilai rata – rata pH sebesar 6,6, nilai rata - rata viskositas sebesar 2673,6 - 2179,6, nilai rata – rata daya sebar sebesar 6,2 – 6,3, dan nilai rata-rata daya lekat sebesar 4,67 – 4,46. Berdasarkan hasil tersebut sediaan gel niacinamide berbasis PVP memiliki mutu fisik yang memenuhi persyaratan sesuai kriteria baik.

***Kata kunci**: gel, mutu fisik, niacinamide, PVP*

ABSTRACT

Niacinamide is the amide form of vitamin B3. Other forms of vitamin B3 include niacin (nicotinic acid). Polyvinylpyrrolidone (PVP) is a biodegradable and air-soluble polymer derived from the monomer N-vinylpyrrolidone. Gels are water-rich preparations and have better potential as topical drug delivery preparations compared to ointments because they are non-sticky, require low energy during formulation, are stable, and have aesthetic value. The purpose of this study was to evaluate the physical qualities of PVP-based niacinamide gel preparations based on physical quality parameters, including organoleptic test, ligninogenicity test, pH test, viscosity test, adhesiveness test, and spreading power test. The method used in this study was an experimental method carried out to determine the physical qualities of a good gel. The results of the study showed that the PVP-based niacinamide gel preparation produced had a thick gel texture, transparent color, odorless, homogeneous, an average pH value of 16.6, an average viscosity value of 2673.6 - 2179.6, an average spreadability value of 6.2 - 6.3, and an average adhesiveness value of 4.67 - 4.46. Based on these results, the PVP-based niacinamide gel preparation had physical quality that met the requirements according to good criteria.

Keywords: gel, niacinamide, physical quality, PVP

INTRODUCTION

Niacinamide is the amide form of vitamin B3. Other forms of vitamin B3 include niacin (nicotinic acid). Vitamin B3 is an essential water-soluble vitamin that is not stored in the body. Vitamin B3, primarily in the form of niacin or nicotinamide, is found in various foods, including poultry, beef, fish, legumes, nuts, cereal products, mushrooms,

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yeast extracts, and coffee. Niacinamide is a relatively safe and inexpensive compound with minor side effects. There are no reports of teratogenicity. Reported side effects include nausea, vomiting, headache, and fatigue, although these are rare. When developed as a topical preparation, particularly in cosmetics, niacinamide concentrations ranging from 0.0001% to 4% are generally well tolerated and do not cause irritation or photosensitivity. [1]

Niacinamide is the active, water-soluble form of vitamin B3 that offers various benefits for skin health. It is a potent antioxidant agent that works by protecting keratinocytes from free radicals, reducing the induction of photocarcinogenesis, and providing protection against UV-induced immunosuppression. Niacinamide is an essential nutrient for both the body and the skin. The use of 5% niacinamide has been shown to inhibit melanosome transfer by approximately 35–68%, significantly reduce hyperpigmentation, and improve skin brightness. Niacinamide can be formulated into topical preparations and is suitable for all skin types, including oily, normal, dry, and combination skin.[2]

Gel formulations have greater potential as topical drug delivery systems compared to ointments because they are non-greasy, require less energy during formulation, are stable, and offer better aesthetic qualities. A gel is a semi-solid material that can be transparent or opaque, containing a high ratio of solvent and gelling agents. Gels are typically smooth, elegant, non-oily, and provide a non-greasy feel while enhancing drug release compared to other semi-solid formulations.[3]

Gel is a pharmaceutical dosage form characterized by a high water content and superior drug delivery properties compared to ointments. This formulation offers several advantages, including ease of application, uniform spreading on the skin, a cooling sensation, good absorption, non-staining properties, and user convenience. To achieve an optimal gel formulation, a suitable base is required to ensure high stability and compatibility, low toxicity, and prolonged contact time with the skin. The gelling agent serves as the key component responsible for the gel's viscosity and structural integrity. It consists of high molecular weight polymers formed by interconnected molecular chains that create a three-dimensional network, providing the gel with its semi-solid consistency. Various types of polymers are commonly utilized in pharmaceutical gel formulations, including natural polymers such as gelatin, pectin, gellan gum, sodium alginate, xanthan gum, and carrageenan; semisynthetic polymers such as *methylcellulose (MC), hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), sodium carboxymethyl cellulose (NaCMC), and hydroxypropyl methylcellulose (HPMC);* and *synthetic polymers such as carbomers* and *polyvinyl alcohol (PVA)*.[4]

Polivinilpirolidon (PVP), also known as povidone or polyvidone, is a biodegradable and water-soluble polymer derived from the monomer N-vinylpyrrolidone. In addition to its hydrophilic nature, PVP exhibits excellent solubility in a wide range of solvents with varying polarities, as well as strong binding capacity and significant stabilizing effects for suspensions and emulsions. Recognized as a biocompatible and non-toxic polymer, PVP has been approved for safety by the Food and Drug Administration (FDA). Consequently, it is widely utilized in the food industry, as well as in medical and cosmetic fields, particularly in pharmaceutical and biomedical applications.

PVP possesses unique physicochemical characteristics, including chemical inertness, colorlessness, heat resistance, and stability across a wide pH range. To date, PVP has been employed in

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pharmaceutical and biomedical research to develop various drug delivery systems, including oral, topical, transdermal, and ophthalmic applications. [5]

Based on the above considerations, niacinamide was formulated into a gel preparation using PVP as the gelling agent. The formulated gel was subsequently evaluated to determine the influence of the gel formulation on niacinamide and to assess whether the resulting niacinamide gel exhibits acceptable physical quality characteristics.

METHODS

Research Design

This study employed an experimental method aimed at determining the physical quality of an optimized niacinamide gel formulation. The research was conducted in October 2024 at the Laboratory of STIKES Tujuh Belas, Karanganyar.

Materials and Equipment

The materials used in this study included niacinamide as the active ingredient, polyvinylpyrrolidone (PVP) as the gelling agent, propylene glycol as the solvent, methyl paraben as the preservative, and Aquadest as the aqueous phase. The equipment utilized included a stirring apparatus, a set of glassware, porcelain dishes, a mortar and pestle, an analytical balance, a viscotester, a spreadability tester, an adhesion tester, a stirring rod, and a measuring cylinder.

Sample Collection

Niacinamide samples were obtained from *Toko Cipta Kimia*, totaling 100 grams of pure niacinamide (100% purity). Other materials used for hydrogel formulation were sourced from the Laboratory of STIKES Tujuh Belas, Karanganyar.

Characterization of Niacinamide

The characterization of niacinamide was performed to confirm the authenticity of the active ingredient based on the Certificate of Analysis (CoA) received. According to the Indonesian Pharmacopeia (FI) VI Edition, niacinamide or nicotinamide is described as a white crystalline powder, odorless or practically odorless, with a slightly bitter taste. Its aqueous solution is neutral to litmus paper. Niacinamide is freely soluble in water and ethanol, and soluble in glycerin.[6]

Manufacturing Procedure

Table 1. Formulation of Niacinamide Gel

Ingredients	Composition (% b/v)
Niacinamide	3
PVP	4
Propylene glycol	5
Methyl paraben	0,18
Distilled water (ad)	100

In this study, the formulation used was based on Table 1. The preparation began by dissolving 3 grams of niacinamide in distilled water. Separately, 4 grams of PVP were mixed with a portion of the distilled water using a mechanical stirrer. Subsequently, 5 grams of propylene glycol and 0.18 grams of methyl paraben were added to the mixture. The niacinamide solution and the remaining distilled water were then added gradually with continuous gentle stirring until a homogeneous gel was formed. The gel was stored in a closed container at room temperature and evaluated for its physical quality over a period of 14 days.

Organoleptic Test

Organoleptic testing was performed by direct observation of the gel's appearance, color, and odor over 14 days, on days 1, 7, and 14.[7]

Homogeneity Test

Samples were taken from three different points of the gel and spread onto a transparent glass plate. The gel was considered homogeneous if no coarse particles were observed. The homogeneity test was also conducted on days 1, 7, and 14 during the 14-day observation period.

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pH Test

The pH test was conducted by turning on the pH meter and immersing its electrode in the gel formulation that had been diluted with distilled water.[7] The recommended pH range for topical preparations is between 4.5 and 8.0.[8]. The pH measurement was carried out over a 14-day period on days 1, 7, and 14, with three replications performed for each measurement.

Viscosity Test

Viscosity was measured using a viscometer equipped with spindle number 4 at a rotation speed of 60 rpm. A good gel formulation is expected to have a viscosity value between 2000–4000 cps.[9] The viscosity test was performed on days 1, 7, and 14, with three replications for each test.

Spreadability Test

A small amount of gel was placed between two glass plates, and a 125 g weight was placed on the top plate. After 1 minute, the diameter of the spread area was measured. The expected spread diameter ranged between 5–7 cm. The spreadability test was conducted on days 1, 7, and 14, with three replications [7]

Adhesion Test

Approximately 0.25 g of gel was placed on a glass slide and covered with another glass slide. The sample was pressed using a 1 kg weight for 5 minutes. The slides were then mounted on an adhesion test apparatus and subjected to a load of 80 g. The adhesion time was recorded as the duration required for the two slides to detach. A good adhesion time should be no less than 4 seconds.[10] The adhesion test was conducted on days 1, 7, and 14, with three replications.

Data Analysis

The data obtained from the physical quality evaluation of the gel were first tested for normality to determine whether the data followed a normal distribution. Data were considered normally distributed if $p > 0.05$. Subsequently, a homogeneity test was performed to assess whether the data were homogeneous, where $p > 0.05$ indicated homogeneity. After confirming normality and homogeneity, the results were analyzed statistically using One-Way ANOVA at a 95% confidence level.[11]

HASIL

Table 2. Organoleptic test results

Observation Day	Test results
Day 1	Gel, viscous, transparent, odorless
Day 7	Gel, viscous, transparent, odorless
Day 14	Gel, viscous, transparent, odorless

The results of the organoleptic test presented in Table 2, conducted over 14 days, showed that the gel had a viscous consistency, was transparent, and odorless. The results of the homogeneity test presented in Table 3, also conducted over 14 days, indicated that the gel preparation was homogeneous, with no visible particles or granules observed.

Table 3. Homogeneity Test Results

Observation Day	Test Result
Day 1	Homogeneous
Day 7	Homogeneous
Day 14	Homogeneous

The results of the pH test presented in Table 4, conducted over a 14-day period, showed that the average pH value on day 1 was 6.6, on day 7 was 6.6, and on day 14 was also 6.6.

Viscosity test results in table 5. which has been done in 14 days shows that the results for the 1st day were obtained on average of 2673.6, the 7th day was obtained on average of 2532, and the 14th day was obtained on average of 2179.6.

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Table 4. pH Test

Observation Day	Test Result			Average
	Replication 1	Replication 2	Replication 3	
Day 1	7	6	7	6,6
Day 7	7	6	7	6,6
Day 14	7	6	7	6,6

Table 5. Viscosity Test

Observation Day	Test Result			Average	p-value
	Replication 1	Replication 1	Replication 1		
Day 1	3101	2380	2540	2673,6	
Day 7	2786	2360	2450	2532	,137
Day 14	2119	2310	2110	2179,6	

Table 6. Spreadability Test

Observation Day	Test Result				p-value
	Replication 1	Replication 2	Replication 3		
Hari 1	6,1	6,1	6,2	6,2	
Hari 7	6,1	6,2	6,4	6,23	,609
Hari 14	6,2	6,3	6,4	6,3	

The results of the spreadability test presented in Table 6, conducted over a 14-day period, showed that the average spread diameter on day 1 was 6.2 cm, on day 7 was 6.23 cm, and on day 14 was 6.3 cm.

Table 7. Adhesion Test

Observation Day	Test Result			Average	p-value
	Replication 1	Replication 2	Replication 3		
Hari 1	4,7	4,5	4,8	4,67	
Hari 7	4,5	4,3	4,6	4,46	,258
Hari 14	4,5	4,3	4,6	4,46	

The results of the adhesion test presented in Table 7, conducted over a 14-day period, showed that the average adhesion time on day 1 was 4.67 seconds, on day 7 was 4.46 seconds, and on day 14 was 4.4 seconds

DISCUSSION

Niacinamide, also known as Vitamin B3 (Nicotinamide or Nicotinic Acid Amide), is the amide form of pyridine-3-carboxylic acid. It is a water-soluble vitamin that can be obtained from dietary sources such as nicotinamide, nicotinic acid, and tryptophan. Niacinamide is considered a relatively safe, inexpensive compound with minimal side effects. When developed as a topical formulation, particularly in cosmetics, concentrations ranging from 0.0001% to 4% are generally well-tolerated and do not cause irritation or photosensitization.[1]

Niacinamide is an essential nutrient for both the body and the skin. The use of topical niacinamide at a concentration of 5% has been shown to inhibit melanosome transfer by 35–68%, significantly reduce hyperpigmentation, and increase overall skin brightness. Niacinamide formulations are suitable for various skin types, including oily, normal, dry, and combination skin.[2] A clinical study found that applying a 4% niacinamide topical preparation for eight weeks significantly improved skin hydration in the intervention group compared to the placebo group. This improvement became evident by the fourth week and continued through the eighth week. Moreover, topical niacinamide was found to be safe and did not cause any significant adverse effects.[12] Another study comparing three niacinamide formulations in an oil-in-water base concluded that formulations mimicking the skin barrier were more effective in enhancing niacinamide accumulation, even when the initial

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concentration was lower. Similarly, other research demonstrated that encapsulating niacinamide molecules within lipid vesicles and suspending them in a hydrogel improved skin accumulation while minimizing systemic absorption, making it an effective and safe approach for topical application.[13]

Polyvinylpyrrolidone (PVP), also known as povidone, is a biodegradable polymer derived from the monomer N-vinylpyrrolidone. PVP is used as a gelling agent due to its excellent solubility, stability across a wide pH range, and compatibility with niacinamide. In addition to its hydrophilic properties, PVP exhibits outstanding solubility in various solvents with different polarities, strong binding capacity, and significant stabilizing effects for suspensions and emulsions.

n this study, a niacinamide gel formulation was prepared containing 3 grams of niacinamide as the active ingredient. The prepared niacinamide gel was then evaluated for its physical quality, including organoleptic properties, homogeneity, pH, viscosity, spreadability, and adhesion. Each test was conducted in triplicate to ensure the reliability of the physical quality assessment.

The organoleptic test was performed by direct observation of the gel's physical characteristics, including its appearance, color, and odor.[7] Based on the tests conducted over 14 days, the niacinamide gel formulation demonstrated a stable physical appearance, characterized by a viscous, transparent, and odorless gel. It is known that gel preparations containing PVP as a gelling agent, along with varying concentrations of active ingredients, can exhibit differences in physical characteristics. The resulting color, ranging from clear to slightly tinted, may be influenced by the type of active substance used, while the texture may vary from moderately viscous to highly viscous.

This phenomenon occurs due to the mechanism of gel formation, in which polymer chains undergo aggregation and cross-linking, forming an interconnected three-dimensional network structure. This network traps or immobilizes water within its matrix, resulting in a strong and rigid structure. The gel formation properties can vary depending on the type and concentration of the gelling agent used.[4]

The homogeneity test aims to observe any significant changes in the physical uniformity of the final formulation. The test was performed by placing the sample between two glass slides and examining it visually for uniformity. A good gel formulation should be homogeneous and free from visible aggregates or particles.[14] The results of the 14-day observation showed no coarse particles in the formulation, indicating good homogeneity. A homogeneous gel is characterized by a uniform color and texture, as well as an even distribution of its components during application on the skin. The uniform dispersion of the active ingredient ensures that the niacinamide is evenly distributed within the polymer matrix, allowing for optimal release and effective skin penetration, thereby maximizing its pharmacological effect.[4]

The pH evaluation was carried out to determine and ensure the stability of the pH during 14 days of storage, as well as to confirm that the pH value remains within the acceptable range for topical formulations, which is between 4.5 and 8.0.[8] The results showed that the gel maintained a stable average pH of 6.6 throughout the testing period. This value is within the safe range for topical application and indicates good formulation stability. The acidity level (pH) is an important aspect in evaluating formulation stability and safety. The pH test helps to determine whether the gel is compatible with the skin's natural pH, as deviations can affect user comfort and safety. A formulation that is too

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acidic may cause skin irritation, while one that is too alkaline may lead to dryness. Minor fluctuations in pH may occur due to the presence of PVP as a gelling agent or due to environmental factors such as temperature and storage duration, which could lead to hydrolysis over time. [4]

The viscosity of a gel formulation influences its ease of application and spreadability. An ideal viscosity range for topical gels is between 2000 and 4000 cps.[9] According to the results, the niacinamide gel exhibited an average viscosity ranging from 2179.6 to 2673.6 cps, which falls within the acceptable range for a stable gel formulation. The addition of propylene glycol was found to decrease the structural strength of the gel network. As the concentration of propylene glycol increases, the viscosity tends to decrease due to the weakening of the gelling agent's structural interactions.[2] Viscosity is defined as a measure of a fluid's resistance to flow; the higher the viscosity, the greater the resistance encountered during movement. The viscosity of a gel or solution can be influenced by several factors, including the stirring speed and mixing conditions during formulation, the choice of gelling base and humectant, as well as the amount of extract incorporated. These factors may also indirectly affect the pH value and overall stability of the final product.[15]

The spreadability test evaluates the ability of the gel to spread uniformly on the skin when applied. An ideal gel formulation should have a spreadability value in the range of 5–7 cm. The results showed that the niacinamide gel had an average spreadability of 6.2–6.3 cm, indicating that it met the standard requirements for good gel formulations. The use of PVP as a gelling agent played a significant role in determining the spreadability results. As the concentration of the gelling agent increases, the dispersibility of the gel tends to decrease, resulting in higher resistance to flow and reduced spreading ability.[4]

The adhesive strength test was conducted to measure the duration of the gel's ability to adhere to the skin surface. The longer the adhesion time, the better the ability of the gel to ensure optimal absorption of the active ingredient. The minimum standard for gel adhesion time is 4 seconds.[16] Based on the test results, the niacinamide gel exhibited an adhesion time ranging from 4.46 to 4.67 seconds, which meets the acceptable standard for topical gel formulations. The adhesive strength of a gel is closely related to its spreadability; the smaller the spreadability value, the longer the adhesion time, whereas a larger spreadability value generally corresponds to a shorter adhesion time due to lower gel consistency. [16] In general, an increase in the concentration of the gelling agent leads to longer adhesion time, as higher polymer content reduces the free water fraction in the formulation. The surface area of application also affects drug absorption — the wider the area and the longer the contact duration, the greater the amount of active substance absorbed through the skin.[17]

This study demonstrates the successful formulation of a niacinamide gel with physical quality parameters that meet the standard requirements for a good gel formulation. Moreover, the use of a safe and skin-beneficial active ingredient supports its potential application in cosmetic preparations. However, this study has certain limitations, as it primarily focuses on the physical quality evaluation of the gel without including long-term stability testing or pharmacological effectiveness studies.

The findings suggest that the developed niacinamide gel formulation has potential as a base for further development of topical cosmetic products. Future studies are recommended to include long-term stability testing and clinical or

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pharmacological evaluations to further confirm the safety and efficacy of the formulation.

CONCLUSION

Based on the results of the formulation and evaluation of the niacinamide gel using PVP as a gelling agent, it can be concluded that the preparation met the required physical quality parameters, including organoleptic properties, homogeneity, pH, viscosity, spreadability, and adhesion, all of which fell within acceptable standards. This indicates that the niacinamide gel formulation is physically stable and suitable for use as a topical cosmetic preparation, particularly as a skin-brightening agent.

The study was conducted with three replications and evaluations performed over 14 days (day 1, 7, and 14). For future research, it is recommended to increase the number of replications and extend the duration of the stability study to obtain more comprehensive results. It is also advisable to include stability testing under elevated and reduced temperature conditions to assess the formulation's robustness under varying environmental factors.

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