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Evaluation of the physical properties of andaliman (*Zanthoxylum acanthopodium* DC) fruit extract tablets using polyvinylpyrrolidone as a binder agent

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ABSTRACT

Background: *Zanthoxylum acanthopodium* DC, also known as andaliman, is a traditional herb utilized predominantly as a spice. It is rich in bioactive compounds such as alkaloids, flavonoids, tannins, saponins, and terpenoids, which exhibit analgesic activities.

Objective: This study aims to develop a tablet formulation of andaliman fruit extract, employing polyvinyl pyrrolidone (PVP) K-30 as a binder, utilizing the wet granulation method.

Method: The andaliman fruit was processed to extract its components using 96% ethanol. The extract, at a concentration of 100 mg, was then formulated into three different tablet formulations, varying in PVP K-30 concentration: F1 (1%), F2 (3%), and F3 (5%). These formulations were analyzed for granule characteristics and physical properties of the tablets.

Results: Granule testing confirmed that all formulations met the requirements for quality granules. Among the formulations, F1 (1% PVP concentration) demonstrated superior physical properties: size uniformity of 1.22±0.00 cm, weight uniformity of 518.53±10.15 mg, friability of 0.45±0.01%, hardness of 6.34±0.05 kg, and disintegration time of 9.42±0.90 minutes.

Conclusion: The tablet formulation of Andaliman fruit extract with 1% PVP K-30 exhibited the most favorable physical properties, suggesting its potential viability for further development and testing. This study lays the groundwork for exploring Andaliman fruit-based analgesic tablets.

Keywords: andaliman fruit, binder agent, polyvinyl pyrrolidone, tablet

Introduction

The andaliman fruit (*Zanthoxylum acanthopodium* DC), also known as Batak peppercorn, is a traditional herb prominently featured in Batak cuisine. Renowned for its ability to enhance the flavor, aroma, and color of food, andaliman is not only a culinary spice but also a component in traditional medicine. This spice harbors various bioactive compounds, including alkaloids, flavonoids, tannins, saponins, and terpenoids, which are known for their analgesic properties [1]. Specifically, flavonoid and alkaloid constituents are recognized for their ability to inhibit prostaglandin biosynthesis, thereby offering analgesic effects [3,4]. Moreover, tannins have been identified as inhibitors of COX-1 [5].

Previous study highlight the analgesic activity of andaliman fruit extract, administered at dosages of 100 mg/kgBW, 200 mg/kgBW, and 400 mg/kgBW. These dosages have demonstrated higher analgesic effectiveness compared to a standard dose of 65 mg/kgBW of mefenamic acid, evidenced by a reduction in writhing by more than 50% relative to the negative control [1]. The development of herbal analgesics

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Table 1. Tablet preparation formulation of andaliman fruit extract

Materials	Function	Requirements*	F1	F2	F3
Andaliman extract	Active ingredients	-	100 mg	100 mg	100 mg
PVP K-30	Binder	0.5-5%	1%	3%	5%
Crospovidon	Disintegrant	2-5%	3%	3%	3%
Mg stearat	Lubricant	0.25-5%	1%	1%	1%
Talc	Glidan	1-10%	1%	1%	1%
Lactose monohidrate	Filler	-	74%	72%	70%
Aquadest	Binder solvent	-	qs	qs	qs

*based on Handbook of Pharmaceutical Excipients.

involves formulating this extract into tablet form, offering advantages such as ease of consumption, precise dosages, low variability, and good weight uniformity [6]. Tablet formulations require additional ingredients, such as binders, to ensure particles bond effectively and form a quality tablet [7].

Tablets formulated with polyvinylpyrrolidone (PVP) K-30 as a binder have shown superior results compared to those using Na-CMC and gelatin binders [8]. The optimal concentration of PVP in the tablet formula, yielding the best formulation, ranges from 0.5% to 5% [9]. Consequently, we have formulated sndaliman fruit tablets using PVP as a binder at concentrations of 1%, 3%, and 5%, aiming to produce tablets that meet the necessary requirements.

Methods

Plant

Andaliman fruits were sourced from North Sumatra, Indonesia, and subsequently identified at the Environmental Laboratory, Jenderal Soedirman University, Purwokerto, Indonesia. The identification confirmed the fruits as *Zanthoxylum acanthopodium* DC, evidenced by certificate number B/49/UN23.6.10/TA.00.01/2022.

Preparation of simplicia

Approximately 7 kg of andaliman fruits were washed, oven-dried at 50^{0}C for 6 hours, and then ground using a Philips blender to a fine powder, ready for extraction. The moisture content of the powder was measured using a moisture balance tool and results recorded as a percentage [10].

Extraction

From 5 kg of dried simplicia, 1.5 kg of dry powder was obtained and subjected to maceration using 96% ethanol solvent in a glass jar, sealed with plastic wrap. The mixture was stirred once and allowed to stand for 24 hours before filtration. The process, including the soaking of the filtered dregs in 96% ethanol, was repeated three times. The final extract, after evaporation using a rotary evaporator at 50°C, yielded a thick extract of 157.5 grams, corresponding to a 10.5% yield.

Tablet manufacturing

The initial phase involved weighing the ingredients as per Table 1. The andaliman extract, lactose monohydrate, and half the amount of crospovidone were blended until homogeneous. A solution of PVP K-30 in distilled water was then prepared, sprayed into the mixture until it formed a mass, followed by wet sieving. The granules, after drying, were mixed with the remaining crospovidone, magnesium stearate, and talc until homogeneous. Evaluations of flow time, angle of repose, compressibility index, and Hausner ratio were conducted on the granules. Tablets were formed using a 500 mg mold and evaluated for physical properties including size and weight uniformity, friability, hardness, and disintegration time.

Data analysis

Normality (Shapiro-Wilk) and homogeneity (Levene test) tests were applied to the data. Depending on the results—normal distribution and homogeneity—a one-way analysis of variance (ANOVA) was conducted. For non-normally distributed data, a Kruskal-Wallis analysis was performed [11].

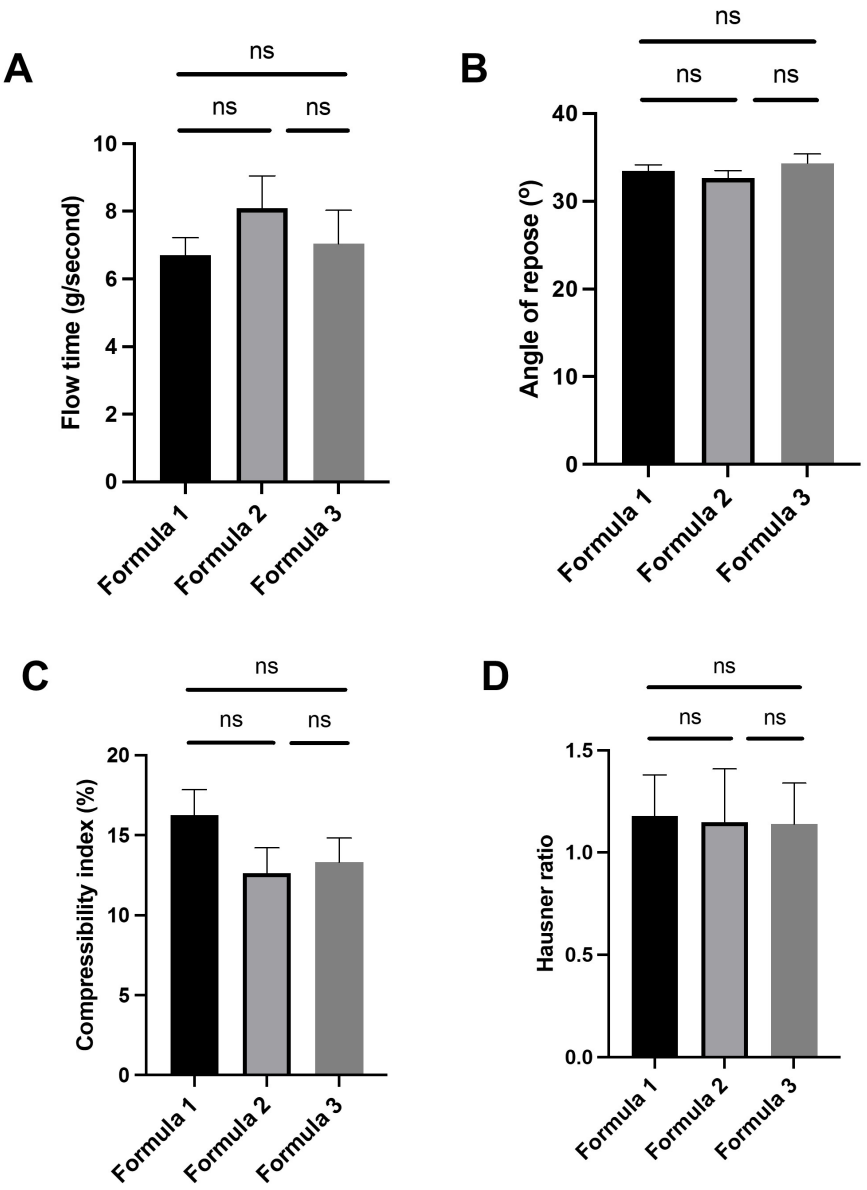

Figure 1. Evaluation of physical properties of andaliman fruit extract granules. (A) Flow time, (B) Angle repose, (C) Compressibility index, (D) Hausner ratio. ns: not significant

Results

Evaluation of physical properties of andaliman fruit extract granules

The evaluation of the granules' physical properties was conducted across three formulations (Figure 1). The flow time for all three formulations was within the acceptable range of 4-10 grams/second, as established by previous research [12], with Formula 2 demonstrating the optimum flow time of 8.10 grams/second. Statistical analysis via one-way ANOVA indicated no significant difference in flow time across the formulations ($p > 0.05$), with a significance value of 0.192.

The angle of repose for all formulations fell within the good category, ranging from 30-35 degrees [13], with specific values of 33.46°, 32.67°, and 34.3° for Formulas 1, 2, and 3, respectively. Kruskal-Wallis test results also revealed no significant difference among the formulations in terms of angle of repose ($p > 0.05$), with a significance value of 0.148.

Compressibility index values were 16.28%, 12.66%, and 13.32% for Formulas 1, 2, and 3, respectively, all of which satisfy the requirement of being less than 20% [14]. According to one-way ANOVA analysis, these differences were not statistically significant ($p > 0.05$), with a significance value of 0.61.

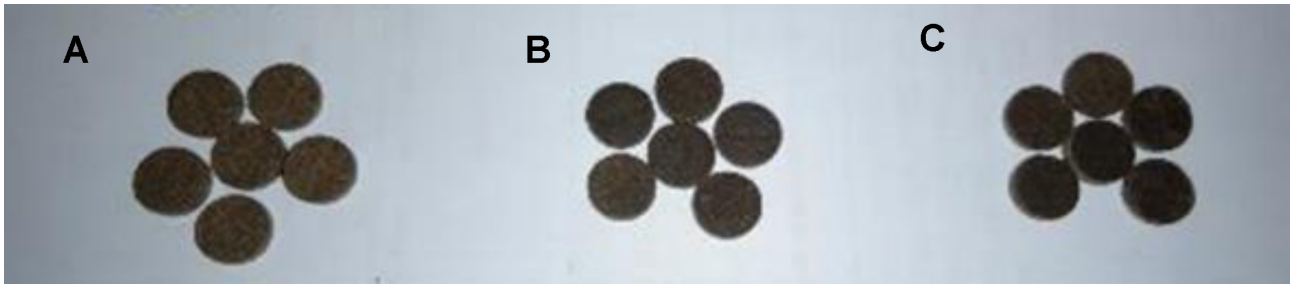

Figure 2. Tablets of andaliman fruit extract. (A) Formula 1, (B) Formula 2, (C) Formula 3

Hausner ratio measurements, used to assess flow properties of the granules by comparing tapped density to bulk density [15], were within the optimal range of 1.12 ± 1.18 [16], recording values of 1.18, 1.15, and 1.14 for Formulas 1, 2, and 3, respectively. Formula 3 exhibited superior flowability. This is consistent with literature stating that a Hausner ratio below 1.25 indicates better flow [17]. The one-way ANOVA test showed no significant difference in Hausner ratios across formulations ($p > 0.05$), with a significance value of 0.136.

Evaluation of physical properties of andaliman fruit extract tablets

The organoleptic properties of the tablets, encompassing shape, color, and odor, were evaluated through observational analysis. Tablets from all three formulations exhibited a consistent round shape and a characteristic odor indicative of the extract. Their color was noted as blackish-green, as depicted in Figure 2.

A total of 20 tablets from each formula were assessed for size uniformity, adhering to established criteria that dictate the tablet's diameter should not exceed three times nor be less than 1 1/3 times the tablet's thickness [18]. All formulas yielded a consistent diameter of 1.22, indicating uniformity achieved through the use of identical molds. Statistical analysis via one-way ANOVA indicated no significant variance among the formulas ($p > 0.05$).

The friability of the tablets for each formula remained within the acceptable limit of less than 1% total mass loss [19]. One-way ANOVA analysis further confirmed the absence of significant differences across the formulas ($p > 0.05$), with a significance value of 0.272.

Tablet hardness for the three formulas fell within the acceptable range of 4-8 kg [18], with recorded values of 6.4, 6.93, and 7.30. The variance in hardness is attributable to the differing concentrations of PVP K-30 binder used; a higher concentration results in increased tablet hardness. The Kruskal-Wallis test yielded a significance value of 0.030 ($p < 0.05$), indicating a statistically significant difference in hardness across the formulas, thereby underscoring the impact of binder concentration on tablet integrity.

The disintegration times for the tablets were within the required timeframe of less than 15 minutes for uncoated tablets, registering at 9.42, 10.93, and 12.09 minutes for the respective formulas. One-way ANOVA analysis revealed a significance value of 0.009 ($p < 0.05$), suggesting a significant difference in disintegration times among the formulas.

Discussion

Tablets formulated from andaliman extract with differing concentrations of PVP K-30 (1%, 3%, and 5%) successfully meet the established criteria for physical property evaluations. These criteria include size and weight uniformity, friability, hardness, and disintegration time. The moisture content of the simplisia powder, recorded at 1.90%, aligns with quality standards, necessitating a maximum moisture content of 10% [20]. Such moisture levels are crucial, as they impact the yield and concentration of bioactive components, with an increase in yield correlating with enhanced bioactivity [21].

The weight uniformity of the tablets adheres to the standards set forth in the Indonesian Pharmacopoeia, which specifies acceptable deviations based on tablet weight. For tablets exceeding 300 mg, deviations beyond 5% for no more than two tablets and none beyond 10% are permissible, ensuring none deviate beyond Column A (7.5%) or Column B (15%) limits. Observed weights—518.53 mg (Formula 1), 515.43 mg (Formula 2), and 509.80 mg (Formula 3)—reflect the influence of granule flow properties on filling precision and uniformity [22].

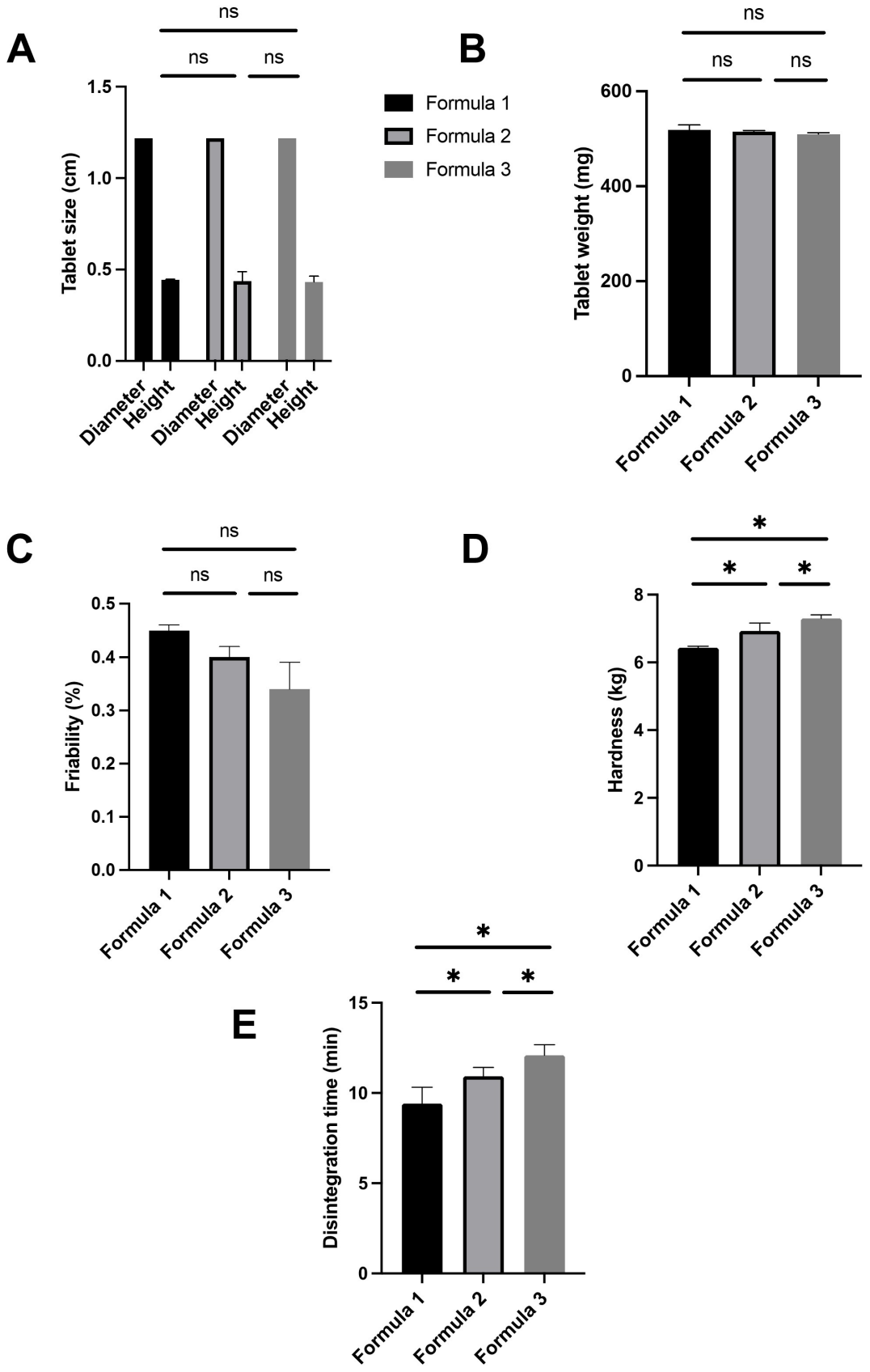

Figure 3. Evaluation of physical properties of andaliman fruit extract tablets. (A) Size uniformity, (B) Weight uniformity, (C) Friability, (D Hardness, (E) Disintegration time

Friability testing, critical for assessing tablet durability during distribution and storage, indicated that all three formulas remained within the acceptable loss threshold of less than 1% of total tablet mass [19]. The observed friability values—0.45% (Formula 1), 0.40% (Formula 2), and 0.34% (Formula 3)—demonstrate the relationship between binder concentration and tablet friability; higher binder concentrations result in less friability. This aligns with literature indicating that tablets with greater hardness typically exhibit lower friability values [23].

The hardness of the tablets, within the 4-8 kg range, signifies compliance with the required standards [18]. The measured hardness—6.4, 6.93, and 7.30 for Formulas 1, 2, and 3, respectively—highlights the role of binder in enhancing tablet cohesion and strength.

Regarding disintegration times, tablets with higher PVP K-30 concentrations exhibited prolonged disintegration. This phenomenon is attributed to the binder's water-gel formation capability, which creates a more compact and less porous tablet structure, thereby reducing water penetration and extending tablet disintegration time. The implication is that increased binder concentrations not only affect tablet hardness but also influence disintegration times, with higher concentrations leading to longer durations [24].

Conclusion

Tablets derived from andaliman fruit, formulated with varying concentrations of PVP K-30 (1%, 3%, 5%), successfully meet established standards for physical property evaluations. These evaluations include assessments of size and weight uniformity, friability, hardness, and disintegration time of the tablets. The consistency across these physical properties demonstrates the effectiveness of the formulations in adhering to pharmaceutical quality requirements.

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Conflict of interest

The authors declare no conflict of interest, ensuring the integrity and impartiality of this research.

Author contributions

MMT was instrumental in the collection and interpretation of data, as well as in the initial drafting of the manuscript. SS and DN provided guidance throughout the research process. All authors have actively contributed to the research and have given their approval for the final version of the manuscript to be published.

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