FJIF Vol.15, No.1, June 2025, Page: 11-18, pISSN: 2549-9068, eISSN: 2622-755X

FITOFARMAKA: Jurnal Ilmiah Farmasi

(FJIF)

https://fitofarmaka-fmipa.unpak.ac.id

Research Article

Formulation and Evaluation of Effervescent Tablets from Guava Leaf Extract with Variations of Polyvinylpyrrolidone Concentration

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https://doi.org/10.33751/jf.v15i1.36

Article info:

Submitted : 06-11-2025

Accepted : 06-28-2025

Published : 06-30-2025

Published by:
Universitas Pakuan

ABSTRACT

This study aimed to formulate and evaluate effervescent tablets of guava leaf extract with varying concentrations of polyvinylpyrrolidone (PVP) as a binder, specifically at 0%, 1%, 2%, 3%, and 4%. The research was conducted as a laboratory-based experimental study using a Completely Randomized Design (CRD). Evaluation included granule characterization (moisture content, flow time, and angle of repose) and tablet assessment (weight uniformity, hardness, dissolution time, moisture content, pH, and organoleptic properties). The results showed that increasing PVP concentration significantly improved granule flow properties and overall tablet quality, particularly in terms of hardness and dissolution time ($p < 0.05$). Formulations F3 and F4 met the requirements for tablet hardness and weight uniformity, while all formulations except F4 dissolved in less than 5 minutes. Moisture content remained within the acceptable range (<10%), but pH values did not reach the ideal range (6–7). Organoleptic characteristics such as aroma, taste, and color were relatively consistent across all formulations; however, only F2 exhibited a nearly perfect physical shape. Overall, variations in PVP concentration had a significant effect on the physical characteristics of both granules and effervescent tablets, though further optimization is needed for pH and shape uniformity.

Keywords: Completely Randomized Design; Effervescent Tablet; Granules; Guava Leaf Extract; Polyvinylpyrrolidone (PVP)

INTRODUCTION

For thousands of years before the advent of modern medicine, plants have served as the primary source of remedies for various illnesses (Atik et al., 2018). Among these medicinal plants, guava (*Psidium guajava* L.) stands out as one of the most popular traditional medicinal plants among the Indonesian population (Simbolon et al., 2021). Traditionally, various parts of the guava plant have been utilized for medicinal purposes, with the leaves being the most commonly used (Handarni et al., 2020).

Guava leaves are known to improve vision, treat constipation, act as an antidiarrheal, anti-inflammatory, anti-stomatitis, antioxidant, and are used for treating ulcers, vaginal discharge, diabetes, bacterial infections, and cancer. They are also believed to increase platelet levels, lower cholesterol, and reduce blood sugar levels (Simbolon et al., 2021). These bioactivities are attributed to the plant's secondary metabolite compounds. According to Handayani et al. (2017) and Safitri et al. (2023), guava leaves contain secondary metabolites such as including steroids, saponins, flavonoids, phenols, and tannins. Among the many medicinal properties, their antidiarrheal effect is one of the most widely utilized (Fratiwi, 2015). Flavonoids, especially quercetin, along with tannins, essential oils, and alkaloids, are the active compounds in guava leaves responsible for their antidiarrheal activity (Rambe et al., 2022).

Indonesian communities commonly process guava leaves using a simple method—by boiling them in hot water and drinking the decoction as a traditional herbal remedy. However, this method is considered impractical, and the taste is often unpleasant, making it

less acceptable for regular use. Therefore, there is a need for more user-friendly dosage forms such as tablets, capsules, syrups, and effervescent preparations. Effervescent tablets are among the most convenient forms of medication. They are particularly suitable for individuals who have difficulty swallowing pills or taking liquid medications directly from a bottle, as they dissolve easily in water and offer a palatable, fizzy taste similar to carbonated beverages (Dewi et al., 2014). Effervescent tablet formulations offer provide several advantages, including rapid dissolution, accurateprecise dosage, and the ability to mask the unpleasant taste, odour, and colour of guava leaf extract. To bind the ingredients into small granules, the production of effervescent tablets requires a strong binder. One of the commonly used binders is polyvinylpyrrolidone (PVP). Granules prepared with PVP as a binder exhibit good flow properties, a low angle of repose, produce fewer fines, and have better compressibility (Aprilia et al., 2021).

According to research by Devi et al. (2018), the use of PVP as a binder results in yields tablets that are not too hard and disintegrate rapidly. As a result, the tablets dissolve quickly in bodily fluids, are absorbed efficiently, and are distributed throughout the body to exert therapeutic effects. PVP serves as an effective binder in direct compression, wet granulation, and dry granulation, making it superior to many other binding agents (Rahmatullah et al., 2023). Several researchers have demonstrated that PVP can be used as a binder in various concentrations. For instance, PVP at 2% concentration was used in the formulation of effervescent granules of pineapple extract (Egeten, 2016), while a 3% concentration was applied in the formulation of taro leaf effervescent tablets (Dewangga et al., 2018). Previous studies have explored the formulation of tablet preparations using guava leaf extract. Andini et al. (2022) investigated the formulation of floating tablets containing guava leaf extract, Pratama (2014) conducted a study on the formulation of guava leaf extract tablets as an antidiarrheal using different concentrations of PVP as a binder, and Rachmawati et al. (2015) optimized a dispersible tablet formula of guava leaf extract using a combination of disintegrants.

A review of the literature indicates that no prior studies have been conducted on the formulation of effervescent tablets using guava leaf extract with varying concentrations of PVP as a binder. Therefore, the researcher is interested in conducting a study on the formulation and evaluation of effervescent tablets containing guava leaf extract with different concentrations of PVP binder. The objective of this research is to develop effervescent tablets made from guava leaf extract and to obtain a physically stable effervescent dosage form.

METHODS

Type of Research

This study is a laboratory based experimental research using a Completely Randomized Design (CRD). The concentrations of PVP binder used in the effervescent tablets of guava leaf extract are 1%, 2%, 3%, and 4%. The negative control in this study is the effervescent tablet of guava leaf extract formulated without PVP binder (0 %).

Population and Sample

The population in this study consists of guava leaves (*Psidium guajava* L.) collected from guava trees in Bogor Regency, West Java. The sample used in this study comprisesconsists of guava leaves (*Psidium guajava* L.) obtainedcollected from guava trees located in Tajurhalang District, Bogor Regency, West Java. The selected leaves were fresh, healthy, green in colour (neither too young nor too mature), and free from pests.

Tools and Materials

The tools used in this study include an analytical balance (Osuka, Japan), a mortar and pestle, a blender (Cosmos, Indonesia), an oven (IKA Oven 125 basic-dry, Staufen, Germany), trays, sieves no. 44, 40, 16, and 14, a maceration apparatus, a rotary evaporator (Heidolph, Schwabach, Germany), a water bath (B-ONE, China), a Buchner funnel (Rocker 300, New Taipei City, Taiwan), test tubes, dropper pipettes, measuring cylinders (Pyrex, New York, USA), beaker glasses (Approx, Japan), porcelain crucibles, filter paper, aluminium foil, funnels (Pyrex, New York, USA), storage containers, a calliper (Kinemaster, South Korea), a pH meter (Hanna Instruments, Woonsocket, USA), a hot plate (Maspion, Indonesia), a granule flow tester (Copley Scientific, Nottingham, UK), a hardness tester (YD-I, Shanghai Tianhe Pharmaceutical Machinery, China), and a single punch tablet press machine (Maksipack, Indonesia).

The materials used in this study include guava leaves (*Psidium guajava* L.), 96% ethanol (Brataco), 70% ethanol (Brataco), polyvinylpyrrolidone (PVP K30, Sigma-Aldrich), tartaric acid (Merck), citric acid (Merck), sodium bicarbonate (Merck), sucrose (Brataco), magnesium stearate (Merck), lactose monohydrate (DMV-Fonterra), magnesium powder (Mg, Merck), hydrochloric acid (HCl, Merck), Dragendorff's reagent (Sigma-Aldrich), Mayer's

reagent (Sigma-Aldrich), 10% ferric chloride ($FeCl_3$, Merck), sulfuric acid (H_2SO_4, Merck), acetic acid (Merck), and distilled water (aquadest, laboratory grade).

Preparation of Guava Leaf Extract (*Psidium guajava* L.)

A total of 3 liters of 96% ethanol solvent was used to macerate 1 kg of guava leaf simplicia powder for 24 hours, with occasional stirring during the first 6 hours. The maceration mixture was then filtered using a Buchner funnel and filter paper to obtainseparate the ethanol extract andfrom residue. The residue was subsequently remacerated once more using the same method (Andini et al., 2022). To obtain a concentrated extract, the ethanol extracts were combined and evaporated using a rotary evaporator at 45°C, followed by further concentration in a water bath at 70 °C. The resulting thick extract was weighed to determine the yield and was then subjected to Phytochemical Screening and ethanol-free testing.

Phytochemical Screening

Phytochemical analysis is used to qualitatively identify the presence of secondary metabolites in plants, which as flavonoids, alkaloids, saponins, and tannins. This method is conducted by observing color changes that occur after the addition of specific reagents. A total of 0.5 grams of thick guava leaf (*Psidium guajava* L.) extract is weighed and diluted with 50 mL of 70% ethanol in a glass beaker. Ethanol is added gradually while stirring until a homogeneous mixture is formed (Handarni et al., 2020).

Flavonoid Test

One milliliter of the diluted guava leaf extract is placed into a test tube along with 0.5 grams of magnesium (Mg) powder. The mixture is allowed to stand until the magnesium is fully dissolved and mixed with the extract. Then, 2 to 3 drops of concentrated hydrochloric acid (HCl) are added gradually. The appearance of a red or yellow color within three minutes indicates a positive result for flavonoids (Handarni et al., 2020).

Alkaloid Test

Mayer's Reagent

Ten drops of the extract are added to a test tube, followed by 2 to 3 drops of Mayer's reagent. The formation of a yellowish-white precipitate indicates a positive result for alkaloids (Syamsul et al., 2020).

Dragendorff's Reagent

Ten drops of the extract are placed in a test tube, and 2 to 3 drops of Dragendorff's reagent are added. The formation of an orange to reddish-brown precipitate indicates a positive presence of alkaloids (Syamsul et al., 2020).

Saponin Test

A volume of 0.5 mL of the diluted extract is added to a test tube. Separately, 5 mL of distilled water is boiled for 2 to 3 minutes and then added to the same test tube containing the extract. The tube is then shaken vigorously for 60 seconds. The formation of stable foam or persistent froth indicates a positive result for saponins (Handarni et al., 2020).

Tannin Test

One mL of the diluted guava leaf extract is transferred into a test tube, followed by the addition of 2 to 3 drops of 10% ferric chloride ($FeCl_3$) solution. A blue-black or green coloration indicates a positive result for tannins (Handarni et al., 2020).

Ethanol-Free Test

The ethanol-free test is conducted to determine whether any ethanol remains in the extract. This test is based on the principle of esterification. In this method, 1 mL of the concentrated extract is placed into a test tube, followed by the addition of 2 drops of sulfuric acid (H_2SO_4) and 2 drops of acetic acid, and then the mixture is heated. The extract is considered ethanol-free if there is no it does not exhibit a distinctive ester odour characteristic of ethanol (Tivani et al., 2021).

Effervescent Tablet Formulation

A separate granulation process for the acid and base components was used to prepare the effervescent granules. As shown in table 1, four formulations were developed using different concentrations of PVP binder: 1%, 2%, 3%, and 4%. A formulation without PVP served as the negative control (K). The effervescent granules were prepared as follows: citric acid, tartaric acid, sucrose, guava leaf ethanol extract, and part of the PVP binder were mixed thoroughly in a single container. The mixture was then passed through a 14-mesh sieve to produce wet granules. These wet granules were dried in an oven at 40° C for three hours and then sieved again using a 16-mesh sieve. The resulting granules constituted the acid component. For the base component, sodium bicarbonate, lactose, and the remaining PVP binder were mixed evenly and sieved through a 14-mesh sieve to obtain wet granules. These were also dried in an oven at 40° C for three hours and re-sieved using a 16-mesh sieve.

Table 1. Formulation of Effervescent Tablets of Guava Leaf Extract (*Psidium guajava* L.)

Ingredients	Function	K (%/mg)	F1 (%/mg)	F2 (%/mg)	F3 (%/mg)	F4 (%/mg)
Extract	Active substance	10 / 50	10 / 50	10 / 50	10 / 50	10 / 50
PVP	Binder	0 / 0	1 / 5	2 / 10	3 / 15	4 / 20
Citric Acid	Acid source	7 / 35	7 / 35	7 / 35	7 / 35	7 / 35
Tartaric Acid	Acid source	23 / 115	23 / 115	23 / 115	23 / 115	23 / 115
Sucrose	Sweetener	9 / 45	8 / 40	7 / 35	6 / 30	5 / 25
Lactose	Filler	20 / 100	20 / 100	20 / 100	20 / 100	20 / 100
Sodium Bicarbonate	Effervescent agent	30 / 150	30 / 150	30 / 150	30 / 150	30 / 150
Magnesium Stearate	Lubricant	1 / 5	1 / 5	1 / 5	1 / 5	1 / 5
Total		**100 / 500**	**100 / 500**	**100 / 500**	**100 / 500**	**100 / 500**

The resulting granules formed the base component. To produce guava leaf extract effervescent granules, the acid and base granules were mixed until homogeneous. These final effervescent granules were then subjected to evaluation prior to tableting. The effervescent granules were compressed into tablets using a tablet press machine. A specific amount of granules was fed into the die cavity through the hopper. The applied pressure, generated by the meeting of the upper and lower punches, compressed the granules into tablets. The upper and lower punch settings had to remain consistent across all formulations to ensure uniform tablet hardness and weight. Subsequently, evaluation tests were conducted on the resulting effervescent tablets using standard effervescent tablet quality parameters. Each formulation produced 100 effervescent tablets, resulting in a total of 500 tablets across five formulations, the weight of each tablet is 500 mg.

Evaluation of Effervescent Tablets Containing Guava Leaf Extract

*Organoleptic test, t*he physical characteristics of the effervescent tablets, including appearance, taste, aroma, and color, were evaluated for organoleptic properties (Kusumawati et al., 2014). *Tablet Weight Uniformity Test,* the tablet weight was determined as follows: each of the twenty tablets was accurately weighed using an analytical balance. The tablets were considered to meet optimal criteria if no more than two tablets deviated by more than 5% from the average weight and none deviated by more than 10% (BPOM RI, 2014). *Uniformity of Size Test***,** using a calliper, the diameter and thickness of the twenty tablets were measured to ensure size consistency in size. According to Tanjung and Puspita (2019), the diameter of a tablet must not be less than at least one-third of its thickness and no more than three times its thickness. *Tablet Hardness Test***,** each of the ten tablets was individually placed into a hardness tester. The tablet was positioned on the plunger area, and the device was turned until the hardness value was recorded. Effervescent tablets with a hardness between 2 – 4 kg are considered acceptable (Sari et al., 2018). *Disintegration Time Test,* a beaker containing 200 mL of distilled water was used to test one effervescent tablet. A stopwatch was started immediately after the tablet was immersed, and timing was stopped once the tablet completely dissolved in the water.

The tablet is considered acceptable if it dissolves within ≤ 5 minutes (BPOM RI, 2014). *Moisture Content Test***,** the effervescent tablets were crushed and placed in a porcelain dish of known weight. The sample was then heated in an oven at 105°C for three hours. This procedure was repeated until a constant weight was achieved. Effervescent tablets made from herbal materials should have a maximum moisture content of 10% (Yulianti & Sutoyo, 2021). *pH Test,* the pH of the solution was measured using a pH meter after the effervescent tablet was dissolved in 200 mL of distilled water. According to Yuliani and Sutoyo (2021), effervescent tablets should have a neutral pH value of 6–7.

Data Analysis

The data processing and analysis techniques used in this study are as follows: organoleptic tests, including shape, odour, taste, and colour, were analyzed descriptively. The procedures outlined in the Indonesian Pharmacopoeia were used to analyse weight and size uniformity, while SPSS was employed to analyse tablet hardness, moisture content, disintegration time, and pH. The Shapiro–Wilk test was applied to determine whether the data followed a normal distribution. For normally distributed data, Analysis of Variance (ANOVA) with a 95% confidence level was used. At the same time, the Kruskal–Wallis test was applied to data that did not follow a normal distribution (Sutomo et al., 2019).

Table 2. Evaluation of Granule Characteristics

Test Parameter	K	F1	F2	F3	F4	p-value	Requirement
Moisture Content (%)	1.60 ± 0.05	1.47 ± 0.04	1.44 ± 0.06	1.83 ± 0.07	1.75 ± 0.03	0.021	< 5% *
Flow Time (seconds)	2.45 ± 0.08	2.09 ± 0.05	2.19 ± 0.06	2.11 ± 0.07	1.90 ± 0.04	0.034	< 10 seconds **
Angle of Repose (°)	6.00 ± 0.12	5.07 ± 0.10	6.52 ± 0.09	5.96 ± 0.11	7.54 ± 0.08	0.048	< 40° **

RESULTS AND DISCUSSION

Results Evaluation of Granule Characteristics

Granule characterization of the effervescent was conducted to obtain granule mass with good characteristics that meet the requirements of the literature. This assessment helps determine the quality of the granules before compression, ensuring that the resulting tablets meet acceptable quality standards. In this study, the granule evaluation included tests for moisture content, flow time, and angle of repose. The test results are presented in Table 2. Granule characterization, including tests for moisture content, flow time, and angle of repose, was conducted to assess the initial physical quality of the formulation prior to tablet compression.

The test results are shown in Table 2, indicating variations among the formulas (F1–F4) and the control (K). The moisture content of all formulas was within the acceptable range, remaining below the maximum limit of 5% as stated in the literature. The lowest moisture content was observed in F2 (1.44 ± 0.06%), while the highest was found in F3 (1.83 ± 0.07%). Excessive moisture can increase the risk of particle aggregation or chemical reactions between components, especially in effervescent formulations that are sensitive to humidity. Statistical analysis revealed a significant difference between formulas ($p = 0.021$), suggesting that the composition of ingredients or drying techniques influenced the residual moisture.

In the flow time test, all formulas exhibited excellent flowability, with values under 10 seconds. Formula F4 had the fastest flow time (1.90 ± 0.04 seconds), likely due to more uniform particle size and smoother surface texture. The control formula (K) showed the slowest flow time (2.45 ± 0.08 seconds). These results confirm that all formulas possess good flowability according to pharmacopeial standards. Statistical analysis showed a significant difference ($p = 0.034$) between the formula groups.

The angle of repose, which serves as an indicator of flow properties, was well below the maximum limit of 40° for all formulations, indicating very good flow behavior. The angle ranged from 5.07 ± 0.10° (F1) to 7.54 ± 0.08° (F4). Although the differences were relatively small, statistical analysis still showed significant variation ($p = 0.048$), possibly due to a combination of particle shape and surface characteristics. Overall, all formulas met the required physical quality standards for granules. The significant p-values suggest that formulation modifications had a real impact on granule characteristics, which may further influence the tablet compression process and the quality of the final dosage form.

Based on the results obtained, the higher the concentration of PVP, the faster the flow time of the granules. This can be attributed to the cohesive properties and interparticle friction of PVP. At higher concentrations, PVP acts as an effective binder, enhancing granule formation and uniformity while reducing interparticle friction. In addition, increased cohesiveness allows the granules to pack more efficiently and reduces resistance during flow, thereby accelerating the flow time.

Evaluation Results of Guava Leaf Extract Effervescent Tablets

The evaluation of the effervescent tablet characteristics included both physical and organoleptic parameters (Table 3). The effervescent tablet containing guava leaf extract presents a distinct physical form, the results showed that tablet weights ranged from 289.85 ± 4.12 mg (control) to 357.65 ± 5.32 mg (F1), with only F3 and F4 meeting the weight uniformity requirement as outlined by BPOM RI (2014). This difference was statistically significant ($p = 0.019$) and may be attributed to variations in binder composition or granulation technique.

The tablet diameters were relatively consistent across all formulations and met the proportional thickness requirements, with a significant difference observed ($p = 0.044$), indicating good control over the compression process. In terms of hardness, only F3 and F4 complied with the standard range of 2–4 kg, while the control and other formulas fell below the minimum limit. The difference was statistically significant ($p = 0.012$), suggesting that binder concentration had a notable effect on tablet hardness.

Table 3. Evaluation Results of Guava Leaf Extract Effervescent Tablets

Parameter	Control	F1	F2	F3	F4	p-value	Requirement
Weight (mg)	289.85 ± 4.12	357.65 ± 5.32	355.85 ± 6.01	342.05 ± 3.85	344.60 ± 4.10	0.019	±5% max for 2 tablets or ±10% for 1 tablet (BPOM RI, 2014)
Diameter (mm)	7.81 ± 0.02	7.89 ± 0.03	7.96 ± 0.02	7.81 ± 0.02	7.81 ± 0.01	0.044	Diameter must not exceed 3× or be less than ⅓× thickness
Hardness (kg)	1.62 ± 0.06	1.80 ± 0.08	1.90 ± 0.07	2.06 ± 0.05	2.31 ± 0.06	0.012	2–4 kg (Sari et al., 2018)
Dissolution (minutes)	2.13 ± 0.12	3.02 ± 0.18	3.08 ± 0.20	4.15 ± 0.22	6.55 ± 0.25	0.008	< 5 minutes (BPOM RI, 2014)
Moisture Content (%)	2.40 ± 0.11	3.01 ± 0.09	1.61 ± 0.07	1.49 ± 0.08	1.91 ± 0.06	0.027	≤ 10% (Yulianti & Sutoyo, 2021)
pH	5.44 ± 0.03	4.75 ± 0.04	5.31 ± 0.06	5.83 ± 0.05	4.97 ± 0.04	0.016	pH 6–7 (Yulianti & Sutoyo, 2021)
Shape	Round, broken on both top and bottom	Round, broken on top	Round, almost perfect	Round, some tablets imperfect	Round, top and bottom parts imperfect	—	Should be uniform and intact (BPOM RI)
Taste	Sour, sweet, salty, slightly bitter	Same	Same	Same	Same	—	Palatable, typical of ingredients
Smell	Characteristic guava leaf	Same	Same	Same	Same	—	Consistent with composition
Color	Dark green with white spots	Dark green with white variation	Dark green with white specks	Dark green with white variation	Dark green with white color variation	—	Uniform and representative

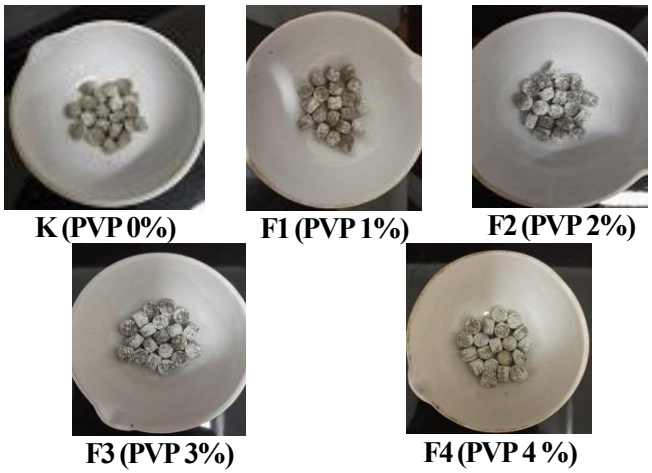

Figure 1. Physical appearance of effervescent tablets all formula

CONCLUSION

The evaluation of effervescent granules and tablets showed that PVP concentration significantly affects physical characteristics. All granules met moisture content standards (<5%) and exhibited good flow properties (flow time <10 seconds, angle of repose <40°). Increasing PVP concentration sped up granule flow due to improved cohesiveness. For tablets, only formulations F3 and F4 met weight uniformity and ideal hardness (2–4 kg). All formulas dissolved quickly except F4, with moisture content within safe limits (<10%) but pH values were not within the ideal range (6–7). Physically, only F2 had near-perfect shape, while others showed defects. Higher PVP concentration improved granule flow and tablet quality, especially hardness and dissolution time, but attention is needed to optimize tablet pH and shape uniformity.

CONFLICT OF INTEREST

There was no conflict of interest in this manuscript.

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