

Formulation and Physical Evaluation of Antihypertensive Sustained-release Tablet from Matoa Leaf Ethanolic Extract (*Pometia pinnata* J.R & G.Forst)

Arifuddin Yunus*, Siti Qurrataayun, Lutfiah

Pharmacy Study Programme, STIKes Salewangang Maros, Jl. Poros Maros-Makassar Km.3, 90516, Indonesia

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***Corresponding author:**

Arifuddin Yunus

email:

arifuddin.yunus54@gmail.com

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ABSTRACT

Matoa leaf extract (*Pometia pinnata* J.R & G.Forst), known for its antihypertensive compound quercetin-3-O-rhamnoside, was developed into sustained-release tablets to improve its bioavailability. This study used the direct compression method with xanthan gum as the polymer matrix. The resulting tablets were then rigorously evaluated. A series of physical tests were conducted, including organoleptic assessment, uniformity of weight and size, hardness, friability, and moisture content. The biopharmaceutical properties were analyzed through *in vitro* disintegration and dissolution tests using UV-Vis spectrophotometry. The findings demonstrated that formulation F3 was the most optimal. It successfully passed all physical stability standards, confirming its excellent mechanical properties. In the dissolution test, F3 achieved the highest absorbance value of 0.29, indicating a consistent and controlled release of the active ingredient. This optimal release was sustained over 6 to 10 hours, with an active substance content of 12%. Therefore, the F3 formulation is confirmed as a successful and effective sustained-release tablet, offering a promising approach for drug delivery.

INTRODUCTION

Hypertension is a global health issue that ranks among the top causes of death, increased disease, and high expenditures on healthcare services, including in Indonesia. Hypertension is defined as systolic blood pressure values ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg (Suling, 2018). In Indonesia, the 2023 Indonesian Health Survey (SKI) reported that 59.1% of disabilities experienced by individuals aged 15 years and above were caused by disease, with 53.5% originating from non-communicable diseases, primarily hypertension, which represented 22.2% (Ministry of Health of the Republic of Indonesia, 2018).

The increasing prevalence of hypertension in Indonesia has led people to self-medicate. This includes the use of herbal plants as an alternative therapy for hypertension, which has been

increasing annually (Ministry of Health of the Republic of Indonesia, 2018). The use of natural ingredients as medicine is currently on the rise, particularly with the emerging trend of "Back to Nature". People widely use traditional medicine for preventive, promotive, curative, and rehabilitative purposes. Furthermore, many believe that using herbal remedies is a safer option than chemically produced drugs (BPOM RI, 2023).

Based on the results of previous research conducted by Malikii *et al.*, in 2019, matoa leaves contain secondary metabolites such as alkaloids, saponins, tannins, terpenoids, and flavonoids. Flavonoids are compounds with potential antihypertensive properties. Flavonoids have derivative compounds, one of which is flavonol. Flavonol, one of six groups of flavonoid compounds, has antihypertensive activity.

Flavonols are aglycones, or compounds that do not bind to sugar groups. This compound has potential antihypertensive properties because it contains Quercetin-3-O-rhamnoside and Kaempferol 3-O-rhamnoside (Maaliki *et al.*, 2019).

Furthermore, in the research conducted by Lepakari *et al.*, (2023) titled, *Antihypertensive Activity Test of Ethanol Extract of Matoa Leaves (Pometia pinnata J.R. & G.Forst) in Male Rats Induced by Angiotensin II with Blood Flow Parameters*, the results showed that the ethanol extract of matoa leaves with a dose of 300 mg/kgBB was the extract with the best percentage (67.35%). This was effective as an antihypertensive with a mechanism of reduction using blood flow parameters or blood flow circulation in rats that were made hypertensive by angiotensin II induction (Lepakari *et al.*, 2023).

Sustained-release dosage forms are gaining popularity due to their ability to release drugs gradually over a longer period of time, thus prolonging their effectiveness in the body. The matrix system approach is a popular choice due to its ease of application and the matrix's ability to regulate the rate of drug diffusion (Santosa & Pertiwi, 2020). Based on the above background, we conducted research by formulating ethanol extract of matoa leaves (*Pometia pinnata* J.R & G.Forst) into a sustained-release tablet preparation.

METHODS

Research Design

This experimental research was conducted with samples in the form of ethanol extract of matoa leaves (*Pometia pinnata* J.R & G.Forst) obtained from the Sanrangan Environment, Pangkajene Regency and the Islands, South Sulawesi Province. It was then formulated into a sustained-release tablet preparation and subjected to physical stability and biopharmaceutical tests.

Tools and Materials

The tools used included Pyrex glass[®], Shimadzu ATX 224[®] analytical balance, mortar and stamper, horn spoon, digital caliper[®], Friability Tester TFT-2-D[®], Dissolution Tester RC-6[®], Top Density Tester TDT-2-H[®], Above Memmert[®], Disintegration Tester BJ2[®], stopwatch[®], mesh sieve, ICL single punch tablet

press[®], UV-Vis spectrophotometry (thermos scientific[®]), dissolution tester SOTAX-AT70[®], Vial AGIENT[®], and Purshee Cuvette[®].

The material used was simple matoa leaves (*Pometia pinnata* J.R & G.Forst), aluminium foil (Heavyl Duty[®]), 96% alcohol (Onemed[®]), Polivinyll Pyrolidon (MERCK 5295-100GMCN[®]) Xanthan Gum (Ziboxan[®]), Aerosil (Wacker HDK[®]), Magnesium Stearat (Unicarb[®]), Lactose Monohydrate (FlowLac[®]), NaCl (EMSURE[®]), and Concentrated HCl (EMSURE[®]).

Making Ethanol Extract of Matoa Leaves (*Pometia pinnata* J.R. & G.Forst)

Matoa leaves (*Pometia pinnata* J.R & G.Forst) were obtained from the Sanrangan Environment, Pangkajene and Kepulauan Regency, South Sulawesi Province. Sample collection was done at 06.00-07.00 WITA, with the criteria for picked leaves being bright green, not brown. Next, wet sorting was done to remove damaged stems and leaves and remove foreign impurities. The leaves were then rinsed with running water to wash away any adhering dirt, then chopped and weighed the wet simplicia. Next, the samples were air-dried at room temperature 30°C until dry, then weighed until the water content of the medicinal plant is ≤10%. After drying, the medicinal plant is dry sorted to remove foreign matter such as unwanted plant components and various contaminants that may still be present in the dried medicinal plant. It is then stored in a dry, tightly closed container (Syahrina and Noval, 2021).

The simplicia was then extracted using the maceration method with 96% ethanol as a solvent. The maceration was carried out in a glass container at room temperature for 2x24 hours. The filtrate was then filtered and collected, and the process was repeated twice. The maceration filtrate was concentrated using a rotary evaporator until a thick extract was obtained, then evaporated using a water bath until a thick extract is obtained (Latifah, 2022).

Preparation of Slow Release Tablet Preparations from Matoa Leaf Extract (*Pometia pinnata* J.R. & G.Forst)

Matoa leaf extract (*Pometia pinnata* J.R & G.Forst) was then crushed in a hot mortar and two drops of alcohol were added until the extract dissolved, then xanthan gum (Polymer) was added and crushed until homogeneous, then lactose and PVP were added and crushed until smooth and

Table 1. Formulation of sustained-release tablets from matoa leaves (*Pometia pinnata* J.R. & G.Forst)

No.	Material	Formula				
		K(+)	K(-)	1	2	3
1.	Matoa Leaf Extract			300 mg	300mg	300mg
2.	PVP		5%	5%	5%	5%
3.	Xanthan gum	Glucophage 500 mg	5%	5%	10%	15%
4.	Aerosil		1%	1%	1%	1%
5.	Mg. Stearat		2%	2%	2%	2%
6.	Lactose monohydrate		ad 100%	ad 100%	ad 100%	ad 100%
	Total tablet weight	800 mg	800 mg	1000 mg	1000 mg	1000 mg

even. Next, aerosil and magnesium stearate were added, then the powder mixture was evaluated (Azizah *et al.*, 2023). The sustained-release tablets were printed using the direct compression method referring to the formulation listed in Table 1, the process includes homogeneous mixing of the active ingredient (extract) with the required excipients, then the mixture was directly compressed using a single punch tablet machine, after which a physical stability test and a dissolution test were conducted.

Physical Stability Test of Preparations Compressibility Test

This test is performed using a 100 mL measuring cylinder to measure the change in volume of the powder after it is added. The powder is first weighed, then the measuring cylinder is shaken 100 times (Wulandari, 2021). The compressibility index is expressed as a percentage and is considered satisfactory if the result is less than 20% (USP, 2023).

Humidity Test

This test is performed by measuring the moisture content of the powder using an oven. A total of 4 grams of powder from each formula is weighed before being placed in the oven. The cup is heated in the oven at 105°C for 15 minutes to test the moisture content. The oven is then reheated at 105°C for 2 hours for the drying process. After the drying process is complete, the cup containing the granules is reweighed (Indonesian Pharmacopoeia VI, 2020).

Weight Uniformity Test

In this test, we measured 20 tablets using an analytical balance and determined the average weight for each tablet. In column A, the percentage variation should not exceed two deviant tablets, and there should be no deviant

tablets in column B (Indonesian Pharmacopoeia VI, 2020).

Uniformity of size test

The instrument used to assess tablet dimensional consistency is a Vernier caliper. Unless otherwise stated, the tablet diameter should not exceed 3 times its thickness and should not be less than 1½ times its thickness (Indonesian Pharmacopoeia VI, 2020).

Hardness Test

This test is conducted by applying pressure to the diameter of the tablet. The tool used to measure tablet hardness is a hardness tester (Wulandari, 2021). In this test, three tablets were prepared for testing. A quality sustained-release tablet should have a hardness in the range of 10-20 kilograms (Azizah *et al.*, 2023).

Brittleness Test

Tablet friability testing is done using a friability tester. For tablets with a unit weight greater than 600 mg, a sample of 10 intact tablets is used. In a step-wise manner, accurately weigh the tablet sample and place the tablets in the drum. Rotate the drum 100 times at 24 to 26 rpm (USP, 2023), then remove the tablets and weigh them accurately (Table 2). Tablet friability is considered acceptable if the value is not more than 1.0% (USP, 2023).

Disintegration Time & Dissolution Test of Preparations

Making stock solution

Ethanol extract of matoa leaves (*Pometia pinnata* J.R & G.Forst) was weighed as much as 10 mg, then put into a 100 mL measuring flask and then filled with distilled water (Noval & Rosyifa, 2021).

Table 2. Data from compressibility tests, humidity tests, hardness tests, and brittleness tests

		K (-)	K (+)	F1	F2	F3
Compressibility Test Results	Initial volume of granules (ml)	31	30	49	30	9
	Final volume of granules (ml)	27	26	35	27	7.3
	Compressibility (%)	12	13	28	10	18
Humidity Test Results	Initial weight of granules (g)	4	4	4	4	4
	Final weight of granules (g)	3.86	3.9	3.83	3.86	3.87
	MC (%)	3.5	2.5	4.25	3.5	3.25
Hardness Test Results	Formula 1	11 kg	10 kg	4 kg	11 kg	11 kg
	Formula 2	9 kg	11 kg	5 kg	8 kg	9 kg
	Formula 3	6 kg	10 kg	4 kg	8 kg	9 kg
	Rate-rate	8.7 kg	10.3 kg	4.3 kg	9 kg	9.7 kg
Test Results Fragility	Weight before testing (g)	10.58	11.25	8.66	11.34	10.39
	Weight after testing (g)	10.04	11.24	8.62	11.25	10.38
	% Brittleness	5.1	0.08	0.46	0.79	0.09

Preparation of Standard Solution

The standard solution was prepared by taking 0.2 mL, 0.4 mL, 0.6 mL, 0.8 mL, and 1 mL of the stock solution. These were then placed in a calibrated test tube and 10 mL of distilled water was added (Noval & Rosyifa, 2021).

Blank solution

The blank solution in this study used distilled water and HCl solution with a pH of around 1.2 as a negative control solvent.

Making gastric juice without enzymes

Artificial gastric fluid without enzymes is made by mixing 2 grams of sodium chloride, dissolving it in 7 ml of hydrochloric acid, and making up to 1000 ml with distilled water. The resulting solution has a pH of approximately 1.2 (Ministry of Health of the Republic of Indonesia, 2020).

Dissolution testing

This test uses a dissolution tester. As much as 900 ml of artificial gastric fluid without enzymes is placed into the dissolution tester flask, then the device is turned on until the liquid temperature reaches $37^{\circ} \pm 0.5^{\circ}\text{C}$. The tablet is placed into the dissolution tester tube. Ensure there are no air bubbles on the surface of the test preparation. The device is set at a speed of 50 rpm, in 60-minute intervals (BPOM, 2023). A 1 mL sample of liquid is taken at time intervals of 1, 2, 4, 6, and 10, carried out in the middle area, not too close to the surface or the bottom of the dissolution tube at a distance of 1 cm from the flask. The liquid is taken using a syringe and

placed in a sample container (vial) and then diluted with aquadest to 10 mL. Then, the absorbance is measured using UV-Vis spectrophotometry at a wavelength of 255 nm-260 nm.

Determination of maximum wavelength

The tool used to measure the maximum wavelength (λ_{max}) is carried out using a UV-Vis spectrophotometer (Noval & Rosyifa, 2021). Based on research by Damayanti *et al.* (2023), the ethanol extract of matoa leaves (*Pometia pinnata* J.R & G.Forst) shows maximum absorbance at a wavelength of 430 nm. Determination of Content and Preparation of Result Curves The concentration of dissolved active substances was analyzed quantitatively by interpolating the absorbance value obtained into a linear regression equation ($y = ax + b$). Next, a dissolution profile was created by plotting the relationship between the percentage of dissolved drug and the sampling time (Azizah *et al.*, 2023).

RESULTS AND DISCUSSION

Organoleptic Test

Based on the results, in the test of the control tablets (-) and (+), the tablets obtained were evenly white in color, and did not have a distinctive odor because they did not contain ethanol extract of matoa leaves (*Pometia pinnata* J.R & G.Forst), while in F1, F2 and F3, green tablets were obtained and had the distinctive smell of matoa leaf extract (*Pometia pinnata* J.R & G.Forst). While the overall shape of the tablet is round and flat, following the shape and size of the tablet using a punch tablet printing machine.

Compressibility Test

In the compressibility test, tablets K (-), K (+), F2 and F3 have a good compressibility index because they meet the standard requirements, namely a compressibility index of less than 20%. whereas tablet F1 obtained a yield of 28%. This formula does not meet the standard requirements because its value exceeds the required value (Indonesian Pharmacopoeia VI, 2020). The compressibility value in tablet formulation is related to the flow properties of the powder. The higher the compressibility value, the lower the resulting flow rate. This condition impacts the uniformity of tablet weight produced during the compression process, as it is determined by the flow rate of the powder exiting the hopper on the tablet press. Because the active ingredient used in this preparation is ethanol extract from matoa leaves (*Pometia pinnata* J.R & G.Forst) where the physical properties of the extract are hygroscopic, so that in the manufacturing process the extract is absorbed into the cellulose matrix (xanthan gum). As can be seen in Table 1, the amount of cellulose xanthan gum matrix composition used in Tablet F1 is less than F2 and F3. This causes the granules to become moist and affects the compressibility of the preparation. It is known that the higher the compressibility value, the less good the flow rate. So, if the granules are moister, the flow rate capability from the granules to the punch will decrease (Azizah *et al.*, 2023).

Humidity Test

The results of the compressibility test on formulations K(+), K(-), F2, and F3 met the required criteria for good moisture content according to the Indonesian pharmacopoeia, which is between 2-4%, while F1 did not meet the requirements because it had a moisture content exceeding the standard, which was 4.25%. This was due to the presence of the main raw material which is hygroscopic, namely matoa leaf extract (*Pometia pinnata* J.R & G.Forst), thus affecting the flow of the powder so that it tends to stick. F2 and F3 are the best formulas with water content values (*moisture content*) of 3.5% and 3.25%. Increasing the water content in the powder can reduce its flow properties, because the water-absorbing layer will thicken, thereby strengthening the capillary forces between the powder particles. In addition, high moisture content in the powder can increase the risk of powder adhesion to the surface of the tablet press (Azizah *et al.*, 2023).

Uniformity of Size

Test This test is conducted to determine the overall tablet size, including thickness and diameter measurements. Uniformity of tablet size is one of the parameters used to assess tablet quality and aesthetics. Unless otherwise stated, the tablet diameter should not exceed three times its thickness and should not be less than one-third of its thickness (Indonesian Pharmacopoeia VI, 2020). Observations showed that the molded tablets had consistent diameters, ensuring that all formulations met the standards set forth in the Indonesian Pharmacopoeia. Consistency in tablet size can be influenced by various factors. In terms of tablet thickness, the primary influencing factors include the pressure applied during compression and the amount of active component enclosed in the mold area. Meanwhile, for tablet diameter, the primary factor is the dimensions of the mold chamber used (Aziza *et al.*, 2023).

Weight Uniformity Test

This test is an initial parameter that the resulting tablets have a uniform content (Wulandari, 2021). Based on the test results, formulas K(+), F1, and F3 meet the requirements, while K(-) and F2 do not meet the requirements because in tablet weighing, the requirements that must be met are in column A, the percentage of variation must not exceed two deviating tablets, and there must be no deviating tablets in column B. Based on the test results, tablets with formulas K(-), K(+), F1, F2, and F3 have an average weight above 300 mg. Therefore, the deviation limits set are a maximum of 5% in column A and a maximum of 10% in column B of the average weight. Tablets with uniform weight are expected to have uniform active ingredient content. The consistency of tablet weight is influenced by the composition and number of components used, which in turn impacts the flow characteristics of the powder (Table 3). Optimal flow characteristics will result in better uniformity in tablet weight (Azizah *et al.*, 2023).

Hardness Test

This test is conducted to evaluate the tablet's ability to withstand shocks or impacts that may occur during the manufacturing and distribution process. A good sustained-release tablet meets a hardness value in the range of 10-20 kg (Azizah *et al.*, 2023).

Based on the observation results, each formulation of K(-), F1, F2, and F3 sustained-release tablets did not meet the requirements,

Table 3. Data from the results of the uniformity test for size (diameter), thickness, and weight of the tablets

Tablet	Diameter (mm)					Thickness (mm)					Weight (g)				
	K(-)	K(+)	F1	F2	F3	K(-)	K(+)	F1	F2	F3	K- (g)	K+ (g)	F1 (g)	F2 (g)	F3 (g)
1	14	12	14	14	14	4.31	7.25	4.13	4.09	6.24	1.41	0.71	0.84	1.13	1.22
2	14	12	14	14	14	4.21	7.25	4.21	4.12	5.45	1.11	0.72	0.83	1.15	0.98
3	14	12	14	14	14	4.49	7.25	4.09	4.22	5.18	0.83	0.73	0.84	0.94	1.10
4	14	12	14	14	14	4.08	7.25	4.16	4.05	5.01	0.85	0.72	0.86	1.03	1.00
5	14	12	14	14	14	4.06	7.25	4.16	4.03	5.46	0.85	0.72	0.84	1.04	0.98
6	14	12	14	14	14	4.25	7.25	4.17	4.46	5.02	1.13	0.72	0.85	1.08	1.00
7	14	12	14	14	14	4.30	7.25	4.15	4.48	5.42	1.00	0.72	0.83	1.21	1.01
8	14	12	14	14	14	4.09	7.25	4.18	4.08	5.05	0.86	0.72	0.86	1.01	1.01
9	14	12	14	14	14	4.48	7.25	4.12	4.17	5.00	0.82	0.72	0.87	1.22	0.99
10	14	12	14	14	14	4.06	7.25	4.13	4.05	5.24	0.85	0.72	0.85	1.21	0.85
11	14	12	14	14	14	4.07	7.25	4.16	4.05	5.40	0.87	0.73	0.86	1.17	1.01
12	14	12	14	14	14	4.39	7.25	4.06	4.04	5.47	0.78	0.72	0.84	1.19	0.99
13	14	12	14	14	14	4.12	7.25	4.20	4.06	5.49	0.87	0.72	0.92	1.17	1.00
14	14	12	14	14	14	4.09	7.25	4.17	4.01	5.49	0.87	0.71	0.85	1.17	0.99
15	14	12	14	14	14	4.38	7.25	4.22	4.08	5.49	1.21	0.72	0.85	1.05	0.99
16	14	12	14	14	14	4.34	7.25	4.13	4.42	5.48	0.96	0.72	0.82	1.16	0.99
17	14	12	14	14	14	4.36	7.25	4.13	4.00	5.00	1.10	0.72	0.86	1.09	0.99
18	14	12	14	14	14	4.27	7.25	4.18	4.04	5.49	1.08	0.71	0.80	1.15	1.04
19	14	12	14	14	14	4.46	7.25	4.11	4.00	5.41	0.80	0.72	0.83	1.17	0.97
20	14	12	14	14	14	4.44	7.25	4.14	4.17	5.37	0.81	0.72	0.83	1.15	1.00
Mean	14	12	14	14	14	4.26	7.25	4.15	4.13	5.36	0.95	0.72	0.85	1.12	1.01
SD	0	0	0	0	0	0.15	0	0.04	0.15	0.28	0.168	0.005	0.024	0.077	0.067

Table 4. Table of results of dissolution profile testing of Matoa leaf extract (255 nm)

Formula	Release time				
	1 hour	2 hours	4 Hours	6 Hours	10 Hours
F1	0.12	0.28	0.00	0.00	0.00
F2	0.12	0.12	0.13	0.17	0.00
F3	0.05	0.05	0.05	0.29	0.28

but F3 was the formula that approached a good hardness value with a volume of 9.7 kg. Formula K(+) showed the best results with a hardness value of 10.3 kg. Tablet hardness is influenced by two main factors, namely compression pressure and binder concentration. In the tablet printing process that was conducted, there was no difference between the pressure compression with a formula. However, the equipment used is

still a simple tablet press, which is very different from industrial-scale equipment.

Brittleness Test

Tablet friability parameters measure the resistance of the tablet surface to abrasion forces due to friction or mechanical shock (Wulandari, 2021). Tablet friability is defined as the

percentage of tablet mass loss due to exposure to mechanical forces during testing. This value is calculated by comparing the difference in tablet mass before and after the test to the initial tablet mass. The test results showed that formulations K(+), F1, F2, and F3 met the friability requirements according to the USP with a value of no more than 1.0%. Meanwhile, formulation K(-) showed results that did not meet the requirements.

Disintegration Time Test and Dissolution Test

The disintegration and dissolution test measures the time it takes for a tablet to break down into smaller particles in body fluids or simulated media, the initial step in drug release and absorption by the body. The disintegration time test showed that all formulas (F1, F2, and F3) met the requirements for sustained-release tablets, with a disintegration time ranging from 60 minutes to 10 hours (Santosa and Pertiwi, 2020).

In formula 1 (Table 4), the release of active substances is relatively faster with the highest absorbance value of 0.28 with the level of active substances released of 0.82% which is achieved within 2 hours, then formula 2 peak absorbance value of 0.17 with the level of active substances released of 10.5% which is achieved within 6 hours, while formula 3 highest absorbance value of 0.29 which is achieved within 6-10 hours with the level of active substances of 12%.

CONCLUSIONS

Based on the discussion above, it can be concluded that matoa leaf extract (*Pometia pinnata* J.R & G.Forst) can be made into a slow-release tablet preparation with the results of physical stability and dissolution profile tests showing the best results for F3 tablets with a xanthan gum polymer concentration of 15%.

CONFLICT OF INTEREST

The authors stated that there is no conflict of interest.

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