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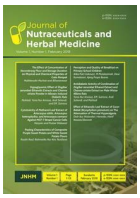

Effervescent Granule Formulation of Bitter Melon Extract (*Momordica charantia* L.) with Gelatin as A Wet Granulation Binder

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Abstract

Bitter melon plants (*Momordica charantia* L.) have a bitter taste and are used as medicinal plant, such as: diabetes, so *effervescent* granule is made because it can be given to people who have difficulty swallowing tablets or capsule. This study is to make *effervescent* granule formulation of bitter melon with variations the concentration of gelatin as a binder. Gelatin will produce granule of uniform size and has a stronger binding power between particles than starch and PVP. The method of making *effervescent* granule was carried out by wet granulation separately. *Effervescent* granule is formulated with gelatin concentrations of 3%, 6% and 9%. The granules obtained were carried out organoleptic evaluation, flow time, tapping test, water content, pH test, dissolution time and taste response. The result of evaluation physical properties obtained brown granule shape, while the result of testing the flow time, tapping test, pH test, dissolved time obtained the results that meet the requirements and moisture content tests did not meet the requirements because the use of hygroscopic acids other than that affected by minimum relative humidity during the manufacture of *effervescent* granule. The taste response test was carried out on 20 respondents; formula with 9% gelatin had a sour taste and was preferred. Based on these results, so the best formula of *effervescent* granules is formula with 9% gelatin because the higher the concentration of gelatin will increase the binding power between particles, so that the friction force between particles becomes smaller and the flow rate gets better, and provide a sour taste so that the bitter taste of the bitter melon can be covered.

Keywords: Carbopol 940; Flavonoid; Gel; Strawberry.

1. INTRODUCTION

Pare fruit plant (*Momordica charantia* L.) is one type of plant in Indonesia that can be used as medicine. In Indonesia, bitter melon is very easy to get, because bitter melon can be found in almost all parts of Indonesia. Bitter melons can also be served in the form of processed foods.

The chemical content of bitter melon which has medicinal properties are siphoning, flavonoids, polyphenols, alkaloids, triterpenoids, momordisin, cucurbitacin glycosides, charantin, butyric acid, palmitic acid, linoleic acid and stearic acid (Subahar, 2004).

According to the research of Tati (2004), in addition to the high nutritional content, bitter melon plants also contain medicinal properties, so it is often used as an ingredient of herbal medicine. In Indonesia for generations bitter melon plants are widely used to several diseases, such as diabetes, wounds and other infectious diseases and can be made *effervescent* granule preparations.

Effervescent granules have the advantage of easier preparation and use, can be given to people who have difficulty swallowing tablets or capsules, these preparations will be dissolved in water so that it will be easier for absorption by the body in addition to the presence of carbonate can improve the bitter taste and can provide refreshing taste (Ansel, 1989).

Effervescent granules require a source of acids and bases and additional ingredients. The source of acid in effervescent usually uses a combination to make it easier to make. The use of citric acid as a single acid makes the mixture sticky and difficult to become granules, while the use of single tartaric acid will make granules easily clot (Anam et al., 2013). Sodium bicarbonate is a salt that is crystalline and soluble in water, when it reacts with an acidic source it will produce froth on the *effervescent* preparations, the addition of sodium bicarbonate in *effervescent* preparations can increase total levels of dissolved solids and can improve taste (Murdianto & Syahrumsyah, 2012).

Additional ingredients are needed in the formulation to improve appearance, improve stability and help release the drug. These include: fillers, binders, crushers, lubricants, dyes and flavor enhancers (Voigt, 1994). Additional ingredients used are gelatin. Gelatin binder is better because it is not easily contaminated such as tragacant and Arabic gum while polyvinyl pyrrolidone is hygroscopic. Another advantage of gelatin is that it can improve taste, odor and color in preparations (Siregar, 2010). According to research conducted by Prambudi (2017) in a journal entitled formulation of bitter melon extract tablets with variations in the concentration of gelatin binder by wet granulation obtained good gelatin concentration as a binder is 5%.

The purpose of this study was to determine the effect of variations in the concentration of gelatin as a binding agent on effervescent granules of bitter melon fruit and determine the best variations of gelatin concentration in the formula of effervescent granule of bitter melon extract.

2. METHODS

1. Research Tools and Materials

   The tools used are analytical balance, glassware, mortar-stammer, blender, basin, spoon, mesh 20 sieve, mesh 40 sieve, rotary evaporator, spatula, pipette, water bath, flannel cloth, oven, thermometer, moisture balance, pH meter, flow rate test equipment, stopwatch.

The ingredients used are ethanol extract of bitter melon fruit, citric acid (Brataco), tartaric acid (Brataco), sodium bicarbonate (Brataco), gelatin, aspartame and lactose. The bitter melon used was obtained from the market in Dawung Village, Bandar dawung, Tawangmangu.

2. Making Simplisia and Powder

Fresh bitter melon is washed and cut thinly with a diameter of 2-3 mm, after that it is placed in a baking dish and dried in the oven at 40^{O}C until dry. Then sieved with 40 mesh sieve according to the degree of fineness of the bitter melon fruit (Department of Health RI, 1995)

3. Making Bitter Melon Extract

450 g of dried bitter melon powder macerated with 70% ethanol in a ratio of 1: 7.5. Maceration is done for 5 days while in the gojok once in a while, then filtered with a flannel cloth to get the juice, the juice is concentrated using a rotary evaporator and evaporated on a water bath to get a thick extract.

4. *Effervescent* Granule Formulation

In this research, three *effervescent* granule formulations of bitter melon extract were made with different concentrations of gelatin binder. The formula can be seen in table 1.

Table 1. *Effervescent* granules of bitter melon extract

Ingredients	Formula I (mg)	Formula II (mg)	Formula III (mg)
Bitter melon extract	500	500	500
Sodium bicarbonate	1000	1000	1000
Tartaric acid	500	500	500
Citric acid	500	500	500
Aspartame	20	20	20
Gelatin	120	240	360
Lactose	1360	1240	1120
Total granules	4000	4000	4000

Information:
Formula 1: Gelatin concentration 3%
Formula 2: Gelatin concentration 6%
Formula 3: Gelatin concentration 9%

5. Making *Effervescent* Granules

Manufacture of effervescent granules of bitter melon extract using the wet granulation method. This method uses a separate wet granulation process between the base component and the acid component. The first step is to mix some of the bitter melon extract with sodium bicarbonate and dry it at a temperature of 35^{o}C - 40^{o}C in the oven to dry, then add a portion of gelatin solution, aspartame and some lactose, then stir until smooth, then granulate with a mesh 20 sieve and dry it in the oven at 50^{o}C for

24 hours. The second step is granulation of the acid component made by mixing citric acid and tartaric acid dried at 35^{o}C - 40^{o}C in the oven to dry, then adding a portion of bitter melon extract, some gelatin solution and some lactose, stirring until smooth and sieved with a mesh 20 sieve, then dry it in the oven at 50^{o}C for 24 hours. After the two components of the granules dried, then mixed and sieved with a mesh sieve 20 then the physical properties of the granules were tested including organoleptic, granule flow time, tapping test, moisture content, pH test, dissolved time, taste response test and Anova test.

3. RESULTS AND DISCUSSION

1. Result of determination

Bitter melon fruit plant was determined to prove the truth of the sample of bitter melon plants to be used. Determination was carried out in the Biology Laboratory of FKIP Muhammadyah University of Surakarta. The results of the determination show that the plants used in the study were true bitter melon with the family Cucurbitaceous, genus Momordica and species *Momordica charantia* L.

2. Results of bitter melon extract fruit

Table 2. Bitter Melon Extraction Results

Fresh bitter melon	Dry simplisia weight	Simplisia powder weight	Thick extract	Rendemen
10 kg	500 gram	450 gram	150.8 gram	33.51%

The extraction process was carried out by maceration and re-maceration with 70% ethanol solvent with a ratio of 1:7,5. Ethanol is a polar solvent that is able to attract flavonoid compounds so that the more the amount of solvent used can produce more extract and obtained a greater rendemen. The rendemen of viscous extract against pare fruit simplisia powder was 33.51%, as in Table 2. Bitter melon extract in the form of thick blackish brown color and bitter taste.

3. Physical Properties Test Results

a. Organoleptic

Table 3. Physical organoleptic *effervescent* granules

Organoleptic	Formula I	Formula II	Formula III
Color	Chocolate	Chocolate	Chocolate
Form	Granules	Granules	Granules
Smell	Distinctive smell	Distinctive smell	Distinctive smell
Taste	A little bitter	Almost tasteless	Very sour

Based on Table 3, organoleptic examination of the three formulas there are differences in the taste of granules which is influenced by gelatin concentration.

From the results of the examination of organoleptic formula III, it was found to be very acidic, this happened because the concentration of gelatin was greater than that of formula I and formula II so that the solvent used would be greater.

b. Flow time

Table 4. *Effervescent* granule flow time test

	Flow time (seconds)		
	Formula I	**Formula II**	**Formula III**
Average V (g/s)	2.77 ± 0.21 9.04 ± 0.68	2.72 ± 0.25 9.24 ± 0.84	4.82 ± 0.64 5.24 ± 0.75

Based on the results of the data on Table 4, it shows that all three formulas have a type of flow that is easy to flow. Granule has good flow properties if 100 g of powder has a flow time of ≤ 10 second or a flow rate of ≥ 10g / sec. The quality of effervescent granule preparations is characterized by good flow rates. The greater the speed of a granule is so the better the granule. Based on the results of the granule flow time velocity of formulas I, II and III obtained granules that are easily flowing and the best flow characteristics are formula II because it has a flow time higher than formula I and formula III, which is 9.24 g / sec. . ANOVA test results obtained significant results of 0.001 with a confidence level of 95% so that there are significant differences.

c. Designation Test

Table 5. *Effervescent* granule test fixing

Formula	%T
1	3.33% ± 1.52
2	3.67% ± 0.57
3	3.67% ± 1.52

Based on the ANOVA test results obtained significant results 0.936 (> 0.05) so that the data obtained do not have a significant difference between the concentrations of gelatin used in each formula. This is because gelatin is a good binding material because it has a high binding strength, so as resulting in uniform granules with good compressibility (Rowe, 2006). Of the three forms meet the requirements of good test that is less than 10%.

d. Water content

Table 6. Test the *effervescent* granule moisture content

Water content		
Formula I	**Formula II**	**Formula III**
2.23% ± 0.21	1.936% ± 0.22	1.78% ± 0.38

Evaluation of the effervescent granule moisture content of bitter melon extract was carried out using a Moisture balance tool. Table VI. shows that the higher the concentration of gelatin, the water content decreases. Moisture content requirements of effervescent granules are 0.4% - 0.7% (Elfiyani et al, 2014). The results show that none of the three formulas met the water content requirements.

Anova test results obtained significance of 0.222 (> 0.05) so that it can be concluded that the data did not have a significant difference between the concentrations of gelatin used in each formula. This is due to the gelatin binding agent has the ability to bind water so that the amount of water trapped in the structure of gelatin molecules in line with the addition of a higher concentration of gelatin. The higher the concentration of gelatin, the more water is trapped in the gelatin gel micelles (Fennema, 1996 in Prihardhani et al., 2016).

Non-fulfillment of effervescent granule water content is caused by citric acid and tartrate acid which have hygroscopic properties. Also influenced by the process of making effervescent granules carried out in a room that has minimal relative humidity, even though it should be done in a room with a maximum relative humidity of 25%, so that even though it has been dried in an oven, the effervescent granules produced cannot reach the humid content 0.4% - 0 .7%

e. pH test

Table 7. *Effervescent* granule pH test

pH test		
Formula I	**Formula II**	**Formula III**
6.3 ± 0.17	6.4 ± 0.10	6.3 ± 0.57

Based on the Anova test results obtained a significance value of 0.609 (> 0.05) so it can be concluded that the pH test does not have a significant difference, so it can be seen that the concentration of gelatin binder does not affect the pH

A pH test needs to be done because if the effervescent solution that is formed is too acidic it can irritate the stomach while if it is too alkaline it causes a bitter and unpleasant taste. The measurement results are said to be good when the pH of the effervescent solution is near neutral (Rahmah in Juita, 2008).

f. Soluble Time Test

Table 8. Soluble *effervescent* granule test

Soluble time (minute)								
Formula I			**Formula II**			**Formula III**		
10°	**27°**	**60°**	**10°**	**27°**	**60°**	**10°**	**27°**	**60°**
2,17 ± 0,04	1,27 ± 0,03	1,12 ± 0,06	2,92 ± 0,40	2,30 ± 0,06	1,29 ± 0,11	3,88 ± 0,58	2,80 ± 0,61	2,15 ± 0,05

Granule dissolution time evaluation was carried out on three temperatures. Soluble time indicates the time it takes for the granule to dissolve. Based on the table, it can be concluded that the three formulas meet the soluble time test because it has a dissolution time of less than 5 minutes (Elfiyani et al, 2014).

Based on the Anova test, granule solubility temperature of 10^{o}C obtained a significant value of 0.007 (<0.05) which means that it has a significant difference in each formula. Soluble time at temperature 27^{o}C obtained a significant value of 0.005 (<0.05) means that there was a significant difference in each formula, and solubility time at temperature 60^{o}C obtained a significant value of 0,000 (<0.05) which means that there are significant differences in each formula. From the Anova test results it can be said that differences in the concentration of gelatin in each formula affect the dissolution time test, this is due to an increase in gelatin concentration will increase hardness, disintegration time and dissolution (Banker and Anderson, 1986). The temperature in the soluble time test, the higher the temperature used, the time needed to dissolve faster. This is due to the increase in temperature which can increase the solubility of solids which absorb heat (endothermic process) when dissolved.

g. Responsive taste

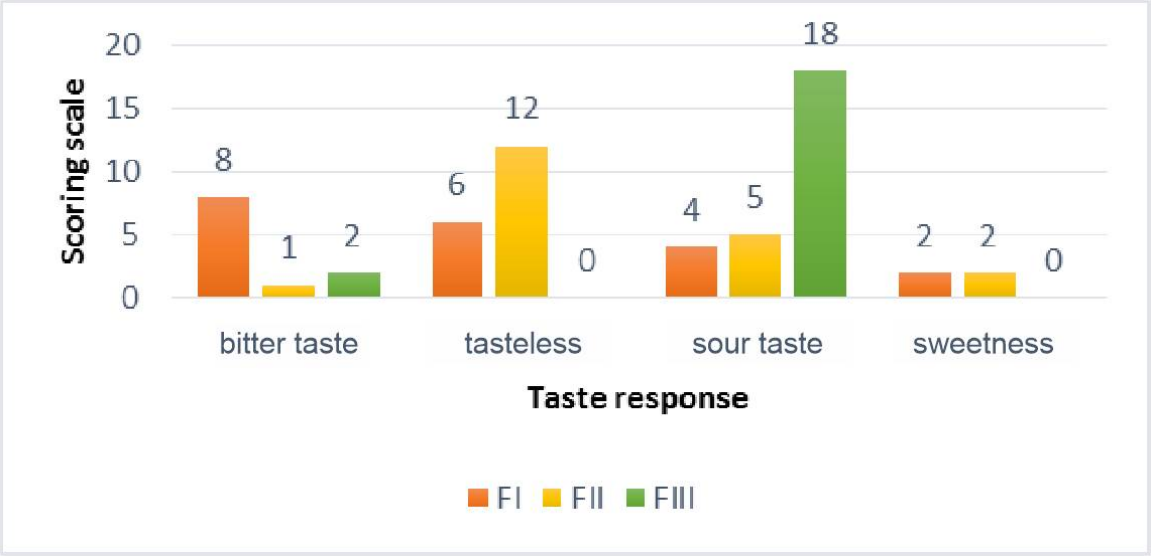

Figure 1. Graph of *effervescent* granule taste response test results

Figure 2. Graph of *effervescent* granule test results

From the taste response test results can be seen in Figure 1 and 2. It is known that formula I has more bitter taste than formula II and formula III so that respondents do not like the effervescent granules in formula I. The bitter taste of formula I can be caused because respondents feel the foam that is still left around the solution has not been lost and the taste of the granules which still has a slightly acidic taste that eventually becomes bitter. The foam is formed due to the acid-base reaction as the main component of effervescent granules.

Formula II is more dominant without taste and tends to be tasteless, this is because in the organoleptic test results on taste, Formula II is almost tasteless so that when dissolved in water also produces the same taste. Formula III has an acidic taste because it is influenced by the large concentration of the gelatin binding agent. In organoleptic test on taste, formula III has a very acidic taste so that when dissolved in water the taste will remain the same.

4. CONCLUSION

Based on the results and discussion, it can be concluded that:

1. The higher the concentration of gelatin affects the physical properties of the granule test. The higher the concentration of gelatin the lower the water content and the longer the soluble time.
2. 9% gelatin concentration is the best formula of effervescent granules of bitter melon extract. This can be seen from the results of the 1.783% water content test because the higher the concentration of gelatin, the smaller the water content, pH 6.3 test because the pH measurement results are said to be good when approaching a neutral value, not too acidic and not too alkaline.

5. SUGGESTION

1. In further research, it is necessary test the stability of effervescent granules to determine effervescent granules during storage.

2. In future studies, it is expected to be able to make effervescent granules using additives which are soluble in water so as to produce clear solutions.

6. ACKNOWLEDGEMENTS

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