

NASKAH PUBLIKASI

**UJI STABILITAS FORMULASI TABLET EFFERVESCENT DARI BEE
POLLEN LEBAH KELULUT (*TRIGONA SP*) DENGAN ASAM SITRAT
DAN NATRIUM BIKARBONAT**

***FORMULATION AND EVALUATION OF EFFERVESCENT TABLET
FROM KELULUT BEE POLLEN (*TRIGONA SP*) WITH CITRIC ACID
AND SODIUM BICARBONATE***

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**Uji Stabilitas Formulasi Tablet Effervescent dari Bee Pollen Lebah Kelulut
(Trigona Sp) dengan Asam Sitrat dan Natrium Bikarbonat**

***Formulation and Evaluation of Effervescent Tablet from Kelulut Bee Pollen
(Trigona Sp) with Citric Acid and Sodium Bicarbonate***

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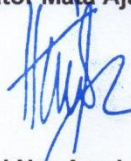
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Formulation And Evaluation Of Effervescent Tablet From Kelulut Bee Pollen (*Trigona Sp*) With Citric Acid And Sodium Bicarbonate

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ABSTRACT:**(Times New Roman front 11 Bold Capital)****Content (Times New Roman front 10)**

Since the beginning of human history, bee honey has been used by humans. However, there are also other products such as bee pollen (BP), royal jelly, propolis, and beeswax. Previous research has identified pollen as consisting of amino acids, lipids, flavinoids, micronutrients and contains many fat-soluble vitamins such as vitamins A, E and D, as well as water-soluble vitamins such as vitamins B1, B2, B6 and C4. The method in this study uses alkaline granulation which requires an oven process for 24 hours. the use of a combination of sodium bicarbonate with citric acid as an effervescent. Formulation 3 has an average moisture content of $0.5696 \pm 0.6154\%$, formulation 3 had an average flow rate of 0.67 ± 0.02054 g/sec, the average compressibility in formulation 1 is $0.046 \pm 0.0452\%$. Overall it is also known that formulation 2 has the smallest dissolution time compared to other formulations. The effect of the combination of citric acid and sodium bicarbonate used in the formulation of effervescent tablets from bee pollen on the physical quality of the tablets, namely friability, hardness, and dissolving time, the higher levels of citric acid and sodium bicarbonate used do not have a significant effect on friability, hardness, and time dissolving effervescent tablets from bee pollen from kelulut bees (*trigona sp*)

KEYWORDS: Kelulut bee (*trigona sp*), Bee polen, Cefdinir, Effervescent , combination of citric acid and sodium bicarbonate.

(Times New Roman front 11 Bold Capital)**Content (Times New Roman front 10 [at least 5 key words])**

INTRODUCTION :

Apart from the disadvantages of delayed absorption and prolonged onset caused by slow dissolution, solid oral pharmacological molecular formulations have their own significance. Additionally, the lack of stability of the drug in liquid oral form limits its delivery¹. The dissolution of oral formulations has been improved with the application of so many changing methods. Among these, effervescent pills are a viable alternative dosage type².

Since the beginning of human history, bee honey³ has been used by humans⁴. However, there are also other products such as bee pollen (BP), royal jelly, propolis, and beeswax⁵. The most common type of bee that produces honey but does not sting is the kelulut bee. In Indonesia, there are several types of kelulut bees, including klanceng, tewetul, Lilin, galo-galo, and ketap⁶. *Trigona sp* is a type of kelulut bee. Kelulut bees have very significant differences compared to body shape and their products with other strap-producing honey⁷.

Kelulut Bees Produce More Honey About 5,8 kilograms each year, with a more sour taste and increased propolis. Larger than similar bees⁸. Bee pollen is one of the results of flower pollen agglutination; it is made by worker honey bees with nectar and salivary substances and stored at the entrance to the hive as well as pouches and leets on the bees' feet^{8,5}. Previous research has identified pollen as consisting of amino acids⁹, lipids, flavinoids, micronutrients and contains many fat-soluble vitamins such as vitamins A¹⁰, E¹¹ and D, as well as water-soluble vitamins such as vitamins B1, B2, B6¹² and C¹³. Due to the presence of phenolic substances with anti-oxidant activity¹⁴, the effect is beneficial to health¹⁵.

Bee pollen is also still considered as a bee product that has utility. The low one. Matter this is also proven by the absence pharmaceutical preparations or formulations for bee pollen. Based on p this, it is necessary to do the formulation on bee pollen of kelulut bees (*Trigona sp*) for take advantage of its antioxidant¹⁶ properties has. Nowadays, drug formulation materials Nature is only limited to simple forms and less fun like shape conventional capsules, syrups and tablets. Form pharmaceutical preparations such as these would make someone feel like taking drugs and giving birth deep saturation tendency consume it¹⁷. On this basis, development of the potential of local natural materials like bee pollen bees kelulut into something standardized¹⁸ pharmaceutical preparations as well interesting to use ease in marketing One pleasant pharmaceutical preparations is an effervescent tablet preparation. Effervescent tablets¹⁹ have advantages, including a pleasant taste fun, refreshing effect, can mask the bitter taste of the active ingredients and easy to use²⁰. Effervescent preparations, in contrast to other conventional preparations, not only have the potential to maintain the stability of the active ingredients for a longer period of time because they are in dry form, but they can also hasten the body's assimilation of the active ingredients²¹. Therefore, in this study optimization of the formulation of Effervescent bee pollen from bee kelulut (*Trigona sp*) was carried out, then physical tests of the granules were carried out including tests of moisture content, flow properties and angle of repose, tests of real incompressible specific gravity and comparability. As well as tablet physical tests including organoleptic tests, friability tests, hardness tests, and tablet dissolving time tests.

MATERIALS AND METHODS:

Materials

Tools used Analytical balance (CHQ), moisture analyzer (ohaus), oven (memmert), mortar and stamper, stopwatch, hardness tester, funnel flowability tester, tapped density tester (linux), friabilator tester (guoming), baking sheet, mesh sieve 12 and 16, glassware (iwaki), tablet printer (wipro).

The ingredients used are citric acid, sodium bicarbonate, PVP (Polyvinylpyrrolidone), sucrose, PEG (Polyethylene glycol) 6000, lactose, Airosyl, and 96% ethanol.

Method

Table 1. The Effervescent Tablet Formulation Of Bee Pollen Bee Kelulut *Tigona Sp*

Materials	FI (%)	FII (%)	FIII (%)
Bee Polen	12,5	12,5	12,5
Citric Acid	12,5	15	17,5
Sodium Bicarbonate	25,5	30,6	35,7
Airosyl	12,5	12,5	12,5
Pvp	1	1	1
Sucrose	7,5	7,5	7,5

PEG 6000	10	10	10
Lactose	Ad 100	Ad 100	Ad 100

Effervescent tablets were prepared under special conditions of 25% relative humidity at 20-25°C by wet granulation method. Granules are made separately between acid granules and alkaline granules. First, prepare the tools and materials and weigh all the materials to be used. Then for the sour component, add the bee pollen (which has been in the oven for 2 hours at 50°C) as an active substance mixed with citric acid as a source of acid, sucrose as a sweetener, some lactose as a filler and some PVP as a binder. dripped with 96% ethanol to form banana breaking. Then sieved with sieve mesh no. 12 and dried in an oven at $\pm 50^{\circ}\text{C}$ for ± 18 hours. The dried granules were sifted again using a mesh sieve no. 16. As for the basic component, add sodium bicarbonate as a base source mixed with the remaining lactose as a filler and the remaining PVP as a binder, then drip with 96% ethanol until the banana breaks. Then sieved with a mesh sieve no.12 and dried in an oven at $\pm 50^{\circ}\text{C}$ for ± 18 hours. The dried granules were sifted again using a mesh sieve no. 16²².

Effervescent Granule Moisture Content Test

Granule moisture test was carried out to see the water content in the granule. Air content that is too high in the granules can cause the granules to not flow properly when the tablets are printed because they can stick to the punch and die. Meanwhile, if the moisture content of the granule is too low, it will cause the tablet to become brittle, because the bonding power between the particles in the tablet is low²³. The good moisture content for effervescent granule preparations according to BPOM is $\leq 10\%$ ²⁴.

Test The Properties Of Flow And Rest Angle Of Effervescent Granules

In a good flow rate test, the requirements are $> 10\text{g}/\text{sec}$ ²⁵. The angle of repose is the maximum angle that the granule surface forms with the horizontal surface during rotation. When the angle of repose is less than or equal to 30° it usually indicates that the material can flow freely. If the angle is greater or equal to 40° it usually has poor flow. A granule has good flow properties if it has a repose angle of $25-45^{\circ}$ ²².

Test Real Density, Density and Compressibility (Tap Density)

The compressibility index test has the objective of knowing the flow properties and density of the granules as well as the decrease in each volume due to impact. A good compressibility test is if it meets the requirements $< 20\%$ ²⁵.

Organoleptic Effervescent Tablets

Organoleptic is a test carried out by looking directly at the appearance of the effervescent tablet. Observations made include shape, smell, and color²⁶. The shape and color obtained are the same as one another²⁷.

Tablet Friability Test

This friability test aims to determine the tablet's ability to withstand shocks without collapsing during manufacturing, packaging, shipping and use to consumers²⁸. A good tablet has a standard friability value of no more than 1%. The use of binder also affects the fragility of tablets, generally solid and thick tablets are stronger than thin tablets²⁹.

Tablet Hardness Test

The hardness of effervescent tablets reflects the strength of the tablets as a whole³⁰. Hardness is used as a measure of compressing pressure, the greater the pressure exerted when printing effervescent tablets, the harder the tablet will be. Hard tablets generally have a longer disintegration time (more difficult to crush)³¹. Generally the requirements for tablet hardness range from 4-8 kg, this weight has been considered as the limit for producing satisfactory tablets³². The mechanical strength tablets from each formulation was determined using the Hardness Continuous tablet hardness tester¹⁹.

Effervescent Tablet Dissolving Time Test

The key factor in an effervescent system is the visual effect during melting and the appearance of the effervescent tablet carbonation process in the solution, hence the dissolving time of effervescent tablets is the most crucial parameter³³. The dissolving time of effervescent tablets ranges from 60-120 seconds²⁶

RESULT:

Physical Examination Of Granules For Moisture Content

Table 2. Granule Moisture Content

Formulation	(X±SD)	Information
1	0,4923 ± 0,3749	Qualify
2	0,779 ± 0,8180	Qualify
3	0,5696 ± 0,6154	Qualify

Granule moisture test was carried out to see the water content in the granule. Water content that is too high in the granules can cause the granules to not flow properly when the tablets are printed because they can stick to the punch and die³⁴. Based on table 2, the average moisture content of formulation 1 is $0.4923 \pm 0.3749\%$, formulation 2 averages $0.779 \pm 0.8180\%$, formulation 3 has an average moisture content of $0.5696 \pm 0.6154\%$. These results indicate that the three formulas have met the requirements for the moisture content test, namely $\leq 10^{24}$.

Flow Properties Test

Table 3. Flow Properties

Formulation	(X±SD)	Information
1	0,913 ± 0,08806	not eligible
2	0,68 ± 0,024944	not eligible
3	0,67 ± 0,02054	not eligible

Based on table 3, the average flow properties in formulation 1 were 0.913 ± 0.08806 g/second, formulation 2 had an average flow rate of 0.68 ± 0.024944 g/second, formulation 3 had an average flow rate of 0.67 ± 0.02054 g/sec. These results indicate that the three formulas do not meet the flow properties test requirements of >10 g/second²⁵.

Compressibility Test

Table 4. Compressibility Test

Formulation	(X±SD)	Information
1	0,046 ± 0,0452	Qualify
2	1,43 ± 0,0825	Qualify
3	2,05 ± 0,3852	Qualify

The compressibility index measures the tendency of a powder to compact. Drug packaging capacity is assessed based on volume changes resulting from rearrangement of packaging during tapping³⁵. Good compressibility percent test that is if it meets the requirements $<20\%$ ²⁵. This experiment was carried out with the compressibility index, the granules were put in a volume measuring cup (V1). The measuring cup containing the granules is placed on the tapping tool, tapped 300 times and the volume is measured (V2) then the granules are weighed. The experiment was carried out three times for each formulation. Based on table 4, the average compressibility in formulation 1 is $0.046 \pm 0.0452\%$, formulation 2 has an average of $1.43 \pm 0.0825\%$, formulation 3 has an average compressibility of $2.05 \pm 0.3852\%$. These results indicate that the three formulas have met the compressibility test requirements.

Organoleptic Effervescent Tablets

Evaluation of unique attributes such as touch and texture, as well as color, smell, shape and taste is called organoleptic assessment. These observations can be used to deduce most material identification, purity, and quality³⁵.

Table 5. Organoleptic Effervescent Tablets

Organoleptic	Observation		
	F1	F2	F3
Form	Round	Round	Round
Color	Yellowish White	Yellowish White	Yellowish White
Smell	Special Honey	Special Honey	Special Honey



(F1)



(F2)



(F3)

Tablet Dissolving Time Test

Table 6. Tablet Dissolving Time Test

Formulation	(X±SD)	Information
1	2,62 ± 0,3309	Qualify
2	1,43 ± 0,0825	Qualify
3	2,05 ± 0,3852	Qualify

Based on table 5, it is obtained that the average dissolving time in formulation 1 is 2.62 ± 0.3309 minutes, formulation 2 has an average of 1.43 ± 0.0825 minutes, formulation 3 has an average dissolving time of 2.05 ± 0.3852 minutes. These results indicate that the three formulas have fulfilled the dissolution time test requirements, which range from 60-120 seconds³⁶. Overall it is also known that formulation 2 has the smallest dissolution time compared to other formulations.

Tablet Hardness Test

Table 7. Tablet Dissolving Time Test

Formulation	(X±SD)	Information
1	2,56 ± 0,6086	Qualify
2	3,228 ± 0,3872	Qualify
3	4,344 ± 0,4460	Qualify

Hardness is used as a measure of compressing pressure, the greater the pressure exerted when printing effervescent tablets, the harder the tablet will be. Generally the requirements for tablet hardness range from 4-8 kg, this weight has been considered as the limit for producing satisfactory tablets³². The experiment was carried out by measuring the hardness scale of each tablet formulation using a hardness tester for 5 repetitions. Based on table 7, it was obtained that the average tablet hardness in formulation 1 was 2.56 ± 0.6086 kg, formulation 2 had an average of 3.228 ± 0.3872 kg, formulation 3 had an average tablet hardness of 4.344 ± 0.4460 kg, which was formula 2 and formula 3. These results indicate that of the three formulas that have met the requirements for the tablet hardness test, which ranges from 4-8 kg, this weight has been considered as the limit for producing satisfactory tablets³².

Tablet Friability Test

Table 8. Tablet Dissolving Time Test

Formulation	(X±SD)	Information
1	0,327 ± 0,1593	Qualify
2	0,506 ± 0,2465	Qualify
3	0,385 ± 0,2027	Qualify

This friability test aims to determine the tablet's ability to withstand shocks without collapsing during manufacturing, packaging, shipping and use to consumers. Good tablets have a standard friability value of no more than 1%, generally solid and thick tablets are stronger than thin tablets²⁹. Based on table 8, the average friability of tablets in formulation 1 is $0.327 \pm 0.1593\%$, formulation 2 has an average of $0.506 \pm 0.2465\%$, formulation 3 has an average fragility of tablets of $0.385 \pm 0.2027\%$. These results indicate that the three formulas have fulfilled the tablet friability test requirements.

CONCLUSION:

The effect of the combination of citric acid and sodium bicarbonate used in the formulation of effervescent tablets from bee pollen on the physical quality of the tablets, namely friability, hardness, and dissolving time, the higher levels of citric acid and sodium bicarbonate used do not have a significant effect on friability, hardness, and time dissolving effervescent tablets from bee pollen from *kelulut* bees (*trigona sp*)

CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this investigation.

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Demikian surat keterangan ini dibuat untuk dapat dipergunakan sebagai mana mestinya.

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