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FORMULATION OF HERB PILLS OF *STENOCHLAENA PALUSTRIS*: AN OVERVIEW OF FINENESS VARIATIONS OF POWDERS, CONCENTRATION OF DISSINTEGRANT, AND DRYING TIME

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Abstract : This study aims to determine the influence of fine degrees of variation powders, the concentration of dissinegrant and drying time of the test uniformity of weight and disintegration time in order to produce a good supply of pills. Herb powder formulation pills kelakai using variation of the degree of fine powder with the sieve numbers 60, 80 and 100, starch concentration Manihot 3%, 4%, 5% as a dissintegrant, Mucilago amili with 10% concentration as a binder, 5% distilled water and glycerin as a wetting materials, as well as lactose as filler. Dried at a temperature of 45°C with time drying four, five and six hours. The test results were analyzed statistically with kolmogorov-smirnov to know the data distribution ($P < 0.05$) means that no normal and normality ($P > 0.05$) means homogeneous, followed by non-analyzing using parametric Kruskal Wallis test and Mann whitney. Formula. The best is the formula A1 with a type of fine powder of 60 degrees, Manihot amyllum with 3% concentration with time as dissintegrant 4 hours of drying, where the uniformity of the test results showed an average weight there are no two pills that deviate 10% from the average weight and none of the pills deviates 20% from the average weight. The average disintegration time of drying hours to 4, 5, and to six or less more than 60 minutes.

Keywords : formulation pills, kelakai (*Stenochlaena palustris*), disintegration time.

INTRODUCTION

Herb kelakai (*Stenochlaena palustris*) are the types of plants-ferns spread nails used as medicine by the people of Indonesia. Efficacy of this plant is treating diarrhea in a dose of 500 mg/kg (Sutomo et al, 2008). In addition, kelakai can also treat anemia, fever reducer, ageless (antioxidants), and for the periods become irregular [Boon, 1999; Krisdianto, 2007]. Kelakai dosage forms that circulate in today's society is still shaped traditional preparations such as vegetables and steeping bulbs. To increase the practicality of its use is necessary to develop other dosage forms such better pill form.

Pill is one of the solid dosage forms of traditional medicine and a small circular containing ingredients and are used for consumption by mouth (orally). Preparation and use of the pill no less than other finished drug dosage in terms of quality and efficacy and the price is relatively cheaper (Ansel, 1989). The quality of a pill is determined from some physical parameters such as degree of fine powders, the uniformity of weight and disintegration time pill. The degree of fine powder is one factor in determining the quality of a preparation of a drug because the degree of fine powders will affect drug absorption in the gastrointestinal tract.

This study aims to formulate herb pill Kelakai which focused on the influence of variations in the degree of fine powders, the influence of the concentration of dissintegrant and the effect of drying time on the uniformity of weight and disintegration time of the pill so it can be a good dosage pill.

MATERIAL AND METHODS

Materials

Materials used for the herb kelakai, *Amylum Manihot*, *mucilago amili*, lactose, talc, glycerin, distilled water.

Procedure

Picking and collecting herbs kelakai

Picking and collecting herbs kelakai were done in the area Gambut, Banjarbaru, South Kalimantan. The selected herbs are herbs that are still fresh and which are directly quoted, also herbs that are not too young and not too old.

Processing materials

Herbs kelakai processed by washing and then sliced thinly and dried with aerated. Samples are dried and sorted is separated from foreign particles like dirt. Haksel considered dry when crushed be crushed. Haksel made into powder using a blender a blender, then sieved with the numbers 60, 80 and 100.

Formula Pills

Table 1. Formula A Pill Herb Kelakai

FORM A	A1 (Sieve 60)	A2 (Sieve 80)	A3 (Sieve 100)
Kelakai	0.125 g	0.125 g	0.125 g
<i>Amylum manihot</i>	3 %	3 %	3 %
<i>Mucilago amili</i>	10 %	10 %	10 %
Glycerin	5 %	5 %	5 %
Lactose	2.34 g	2.34 g	2.34 g
Aquadest	qs	qs	qs
Talc	qs	qs	qs
Drying time (hour)	4 5 6	4 5 6	4 5 6
Weight of pill	200 mg	200 mg	200 mg
Total pill	180 pills	180 pills	180 pills

Table 2. Formula B Pil Herb Kelakai

FORM A	A1 (Sieve 60)	A2 (Sieve 80)	A3 (Sieve 100)
Kelakai	0.125 g	0.125 g	0.125 g
<i>Amylum manihot</i>	4 %	4 %	4 %
<i>Mucilago amili</i>	10 %	10 %	10 %
Glycerin	5 %	5 %	5 %
Lactose	2.22 g	2.22 g	2.22 g
Aquadest	qs	qs	qs
Talc	qs	qs	qs
Drying time (hour)	4 5 6	4 5 6	4 5 6
Weight of pill	200 mg	200 mg	200 mg
Total pill	180 pills	180 pills	180 pills

Tabel 3. Formula C Pil Herb Kelakai

FORM A	A1 (Sieve 60)	A2 (Sieve 80)	A3 (Sieve 100)
Kelakai	0.125 g	0.125 g	0.125 g
<i>Amylum manihot</i>	5 %	5 %	5 %
<i>Mucilago amili</i>	10 %	10 %	10 %
Glycerin	5 %	5 %	5 %
Lactose	2.10 g	2.10 g	2.10 g
Aquadest	qs	qs	qs
Talc	qs	qs	qs
Drying time (hour)	4 5 6	4 5 6	4 5 6
Weight of pill	200 mg	200 mg	200 mg
Total pill	180 pills	180 pills	180 pills

Procedure of making the pill includes:

1. Created pill mass by mixing powdered herb kelakai, *Amylum Manihot*, lactose, distilled water and glycerin and mucilago amili, shear zones all ingredients until smooth and form the appropriate pill mass.
2. After the pill mass is formed, the cylindrical shape made by rolled-Roll with a flat wooden board on board tools pill with the number 180 pill, then roll the pill long-stem cut to the same pill.
3. The mass of a cylindrical pill that has been rolled-Roll cut with a cutter knife on the mold tool pills. then rolled on a board so that the masses become pill round board. To prevent the pill mass attached to the appliance, then the board is paved with material that is talkum sower which is a thin coating for pills no spots.
4. Pill that has been rounded then roll on a board with coated talkum round pill.
5. Pill that has been so included in the oven at a temperature of 45°C with different drying times of 4, 5, and 6 hours.

Pill Testing

Weight uniformity

Weighed as much as 20 pills by weighing 20 pills at once and weigh pills one by one. After that calculated weighted average. Results weighing 20 pills compared to the table, which should not be more than 2 pills a weight deviates 10% from the average weight and weight pills that none deviated 20% of average weight.

Disintegration time

Pill is said to meet the test of time were disintegration by SK Menkes number 661/MENKES/SK/VII/1994, for pills that are not covered should be disintegration in no more than 60 minutes (Menkes, 1994). To determine the disintegration time desintegration pill use tool tester. A total of 5 pills included in the tool. Each tube filled with 1 pill. Equipment included a vessel of water temperature of 36oC-38oC, the water level of not less than 15 cm, so the tool can go up as much as 30 times per minute in the medium regularly. At the top notch plate netting right on the water surface and at the lowest position of the mouth of the tube just above the water surface. Pil otherwise destroyed completely when the remaining inventory left on the screen test device is the software that does not have a clear core. Determination carried out 3 times and calculated the average.

RESULTS AND DISCUSSION

Kelakai pill herb formulations made with reasonable consideration of economic value, making it more efficient in use by the public. With consideration of the pill has the advantage that is easy to use. Making additional substances such as pills necessary to enlarge the volume of filler, binder, material spreader, material destruction and the materials and if necessary added wetting coating materials (Anief, 2006). Basically, additional material should not toxic, available in sufficient quantities, the price is quite cheap, do not have the opposite properties (odor), an inert or neutral, physically and chemically stable in combination with other components, free of microbes, does not interfere with color active substance (Syamsuni, 2006). The additional materials used are *Amylum Manihot*, mucilago amili, talkum, glycerine, lactose and distilled water.

The degree of fine powder is one factor in determining the quality of a drug dosage. Where the degree of fine powder used for the measurement of particle size range which aims to improve drug absorption in the gastrointestinal tract. (Health Department, 1995). The variations in the degree of fine powder used in the powder 60, 80 and 100. Where powder 60 is roughly half of powder, powder 80 is half fine powder and powder 100 is a fine powder.

Amylum Manihot 5-15% is a destructive material added to facilitate rupture or collapse of the pill into small particles so that the surface area in contact with digestive

fluids enlarged and cause more rapid absorption (Kibbe, 2000). Mucilago amili 50-10% is a binder that serves to enlarge the power of cohesion and adhesion power pill for pill masses attached to each other into a compact mass (Anief, 2006). Talkum powder is a material that serves to minimize friction between the molecules are similar or not similar, so the mass of pills to be not stick to each other. Sticky in question is a sticky on the pill maker or sticky between one pill with another pill (Anief, 2006).

Table 4. Weight Uniformity Measurement and Time Crushed Pills

Form	Drying time (hour)	Weight uniformity \pm SD (g)	Disintegration time (s)
A1	4	0.2066 \pm 0.00319	25.04
	5	0.2073 \pm 0.00308	27.35
	6	0.2047 \pm 0.00245	29.74
A2	4	0.2080 \pm 0.00196	28.37
	5	0.2083 \pm 0.00195	31.15
	6	0.2049 \pm 0.00205	36.17
A3	4	0.2101 \pm 0.00225	35.07
	5	0.2079 \pm 0.00192	32.87
	6	0.2020 \pm 0.00307	35.37
B1	4	0.2082 \pm 0.00193	29.48
	5	0.2078 \pm 0.00158	32.93
	6	0.2026 \pm 0.00185	36.03
B2	4	0.2086 \pm 0.00188	37.76
	5	0.2070 \pm 0.00136	36.16
	6	0.2046 \pm 0.00150	44.30
B3	4	0.2091 \pm 0.00186	45.26
	5	0.2079 \pm 0.00132	47.87
	6	0.2014 \pm 0.00333	48.33
C1	4	0.2091 \pm 0.00165	52.97
	5	0.2071 \pm 0.00118	51.06
	6	0.2024 \pm 0.00280	64.10
C2	4	0.2100 \pm 0.00170	59.27
	5	0.2079 \pm 0.00118	59.32
	6	0.2034 \pm 0.00244	64.83
C3	4	0.2102 \pm 0.00185	54.99
	5	0.2077 \pm 0.00118	58.00
	6	0.2017 \pm 0.00385	65.24

Glycerine and distilled water is the wetting material that serves to minimize the contact angle ($<90^\circ$) between molecules so that the masses become wet and soft and easy to set up [Depkes RI, 1995]. Lactose is a filler that is added to enlarge the volume of the pill mass to be easily made. The charger is needed if the drug dose is not sufficient to achieve the ideal weight (Anief, 2006).

Weight uniformity

Based on the weight of an average table weight uniformity by varying degrees of fine powder and drying on the formula, there is more weight reduction increased with drying time. The average weight uniformity in the formula A3, B1, B2, B3, C1, C2 and C3 indicate the longer the drying time is less and less weight. This is due to the homogeneity at the time of making the pill and the decrease of water content along with the length of drying time. While the average weight uniformity in the formula A1 and A2 with drying time 4, 5 and 6 hours showed an average weight uniformity formula A1 with a drying time 5 hours greater weight than the drying time of 4 hours and the formula A2 with drying time 5 hours is also greater weight than the drying time of 4 hours. This may be due to different pills that are used at the time of testing uniformity of weight and the pill is not homogeneous when making a pill because of the limitations pill maker can not

make a lot of pills to the scale. How to overcome these problems either before the pill should be made at the time of the mass distribution of the pill were measured for equal distribution to the pill so that the resulting weight is also equally.

Pill formulation was varied, this is due to the influence of variations in the degree of fine powders and length of drying time. Judging from the average weight uniformity of weight, weight pills tend to decrease with the use of subtle variations in the degree of powder and the addition of drying time, the biggest drop occurred on the formula C3 to 6 hours drying time. While the largest average decline occurred in all the formulas that the type of powder 100 (formula A3, B3 and C3), this is because the powder used is too subtle and thus affects the weight reduction pills after drying.

In the weight uniformity test, if the formula pills are made with a weighting of 100 mg to 250 mg 2 pills should not be there that deviate 10% from the weighted average and not a single pill that deviate 20% from the average weight (Depkes RI, 1995). The results show that pill weight uniformity requirements that have been determined.

Disintegration time.

The test results were destroyed when the pill can be seen in Figure 1. Disintegration time is closely related to the ability to crushed pills in the body after consumption of the patient. Under the optimum formula is attempted still meet the requirements of the disintegration time is less than 60 minutes, although there are some pills that do not meet the requirements.

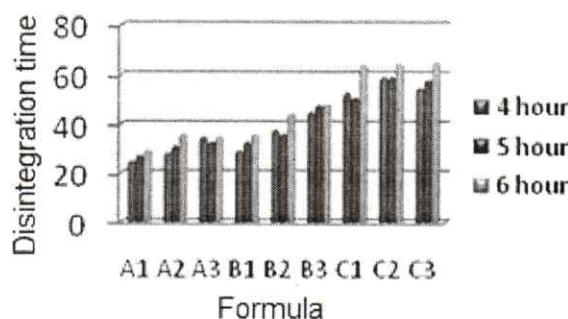


Figure 1. Bar chart average disintegration time with the variation of drying

This test is intended to find out how long does it take pills to destroyed after exposure to water or gastric fluid. Test time was damaged beyond stating that its active ingredient preparations or dissolved completely. Preparations otherwise destroyed completely when the remaining inventory left on the screen test device is the software that does not have a clear core, but part of the coating or capsule shell that is insoluble (Ansel, 1989).

When viewed from the variations in the degree of fine powder is used, then the degree of fine powder type 100 (formula A3, B3 and C3) in all formulas have the power tie stronger and harder to destroy than to the type of degree of fine powder 60 (formulas A1, B1 and C1) and 80 (formula A2, B2, C2). This is due to the fine powder used to make pills that formed the more solid and stronger binding power, causing the destruction of growing old.

Addition Amylum Manihot with concentration of 3%, 4% and 5% can not be functioning optimally as a destroyer. This may be due to the concentration of material destruction on the formula C1, C2 and C3 are used is still not big enough to offset a very fine powder and binder used. But the formula A1, A2, A3, B1, B2 and B3, the binder concentration variation and destruction can still be tolerated by the disintegration time of not more than 60 minutes. The results obtained in testing the disintegration time showed that the disintegration time of the pill still meet the established requirements.

Data Analysis

Disintegration time formula analyzed using non parametric Kruskal Wallis test because it does not meet the requirements for parametric analysis. This is due to data not normally distributed in all formulas ($P < 0.05$), but can be homogeneous in all formulas ($P > 0.05$). While non-parametric analysis results between formulations using Kruskal Wallis test on each formulation is obtained that all formulas disintegration time was significantly different ($P < 0.05$). Mann Whitney test results for the formula A1 at 4.5 and 6 hours of drying can be seen in Table 3. As for the other formulas have the same results.

Table 3. Mann Whitney test results for the time crushed pill formula A1 with drying time 4, 5 and 6 hours

Drying time (hour)	4	5	6
4	-	B	B
5	B	-	B
6	B	B	-

Based on the results of Mann Whitney test for disintegration time in the various formulas are derived any significant differences between the disintegration time formula with drying time of 4 and 5 hours, where in all formulas showed significant differences ($P < 0.05$). At the time destroyed the formula with drying time 4 and 6 hours and with a drying time of 5 and 6 hours showed significant differences in all formulas ($P < 0.05$). This is due to the longer drying time is used the greater the power of binding and the reduced weight and water content so that when crushed between the formula with drying time of 4 and 6 hours with 5 and 6 h show all formulas significantly different.

While based on the results of the analysis Mann Whitney test on drying time 4, 5 and 6 hours to various formulas show formula A1 to A2, the formula B1 to B2, C1 with C2 formula was not significantly different, this is because the formula A1, B1 and C1 using powder 60 and the formula A2, B2 and C2 using the powder 80, in which the two powders is still a rough and half coarse powder. In the formula A1 to A3, B1 to B3 and the formula for formula C1 with C3 showed significant differences, this is because the formula A1, B1 and C1 using a powder 60 that is a coarse powder and the formula A3, B3 and C3 using the powder 100 is an fine powder. This suggests differences in the degree of fine powder will cause the difference in disintegration time of the pill.

Table 4. Results of Mann Whitney tests were destroyed in the drying time of 4 hours

Form	A1	A2	A3	B1	B2	B3	C1	C2	C3
A1	-	TB	B	B	B	B	B	B	B
A2	-	-	B	B	B	B	B	B	B
A3	-	-	-	B	B	B	TB	B	B
B1	-	-	-	-	TB	B	B	B	B
B2	-	-	-	-	-	TB	TB	TB	B
B3	-	-	-	-	-	-	TB	TB	TB
C1	-	-	-	-	-	-	-	TB	B
C2	-	-	-	-	-	-	-	-	TB
C3	-	-	-	-	-	-	-	-	-

Table 5. Mann Whitney test results were destroyed in the drying time of 5 hours

Form	A1	A2	A3	B1	B2	B3	C1	C2	C3
A1	-	TB	B	B	B	B	B	B	B
A2	-	-	B	B	B	B	B	B	B
A3	-	-	-	B	B	TB	B	B	TB
B1	-	-	-	-	TB	B	B	B	B
B2	-	-	-	-	-	B	B	TB	B
B3	-	-	-	-	-	-	TB	TB	TB
C1	-	-	-	-	-	-	-	TB	B
C2	-	-	-	-	-	-	-	-	TB
C3	-	-	-	-	-	-	-	-	-

Table 6. Mann Whitney test results were destroyed in the drying time of 6 hours

Form	A1	A2	A3	B1	B2	B3	C1	C2	C3
A1	-	TB	B	B	B	B	B	B	B
A2	-	-	B	B	B	B	B	B	B
A3	-	-	-	TB	B	B	B	B	B
B1	-	-	-	-	TB	B	B	B	B
B2	-	-	-	-	-	B	B	B	B
B3	-	-	-	-	-	-	TB	TB	TB
C1	-	-	-	-	-	-	-	TB	B
C2	-	-	-	-	-	-	-	-	B
C3	-	-	-	-	-	-	-	-	-

Description:

B: Different meaning

TB: Not significantly different

In the formula A1 are significant differences with the formula B1 and C1, this is because the formula A1, B1 and C1 using the same type of powder that is powder 60, but using a concentration of destroyer (Amylum Manihot) different. Where the formula A1 uses material concentration destroyer 3%, using the formula B1 and C1 concentration of 4% using a concentration of 5%. This shows that the difference in the concentration of material destruction caused disintegration time difference resulting from the pill.

Formula pill is best formula A1 with a type of degree that is fine powder 60, Amylum Manihot with a concentration of 3% as a destroyer with a drying time of 4 hours of testing showed an average weight uniformity and the average disintegration time requirements in terms of physical quality with test weight uniformity and disintegration time. Where is the drying time of 4 hours showed the fastest disintegration time so that the pill is expected to provide the desired therapeutic effect.

CONCLUSION

The conclusion that can be gained from this research that the best formula pill is a pill that is herbal formula A1 with a type of degree kelakai fine powder 60, Amylum Manihot 3% as a destroyer with a drying time of 4 hours.

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