

FORMULATION CHEWABLE TABLETS ETHANOL EXTRACT OF ALOE VERA (*Aloe vera* L.) WITH THE COMBINATION OF EXCIPIENT AVICEL PH 102- MALTODEXTRIN

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Abstract

Background Aloe leaves (*Aloe vera* L) is one of plant that can use as laxative agent, thus the tablet formulation of this plant will give beneficial effect. The tablet production from extract requires combination of excipient to obtain the standard tablet considerin the physical characteristics. This study was aimed to explore the physical characteristic of tablet which was content of the combination of excipient Avicel PH 102 and Maltodextrin.

Method. Aloe leaves extract was gotten with maseration using 96% ethanol as solvent. The orientation was performed with 5 formula mix of powder based on various excipient, that was formula I (100% Maltodextrin), formula II (75% Maltodextrin and 25% Avicel PH 102), formula III (50% Maltodextrin and 50% Avicel PH 102), formula IV (25% Maltodextrin and 75% Avicel PH 101), and formula V (100% Avicel PH 102). Mix of powder was tested by the physical characteristics including tapping index, compactibility, and mass density of powder. The direct compress was used in tableting process . The tablet was tested for the physical characteristics including weight uniformity, hardness, friability, and taste test. The content of antraquinon in the extract was tested with TLC. The difference of tableting testing were testing using T test.

Result. The study found that the formulation of mix powder with higher prosentage of Avicel PH 102 had tapping effect index bigger, mass density of powder smaller, but compactibility test cause variation hardness of each formula. Character of chewable tablet with higher prosentase Avicel PH 102 have an effect weight uniformity more better, tablet hardness go down, friability more higher, and have not an effect significancy with taste comments test. From these research getting result that formula four is formula obtain up to standard tablet seen from the physical character of powder and chewable tablet. Result show that extract having glikosida antraquinon.

Conclusion. Variations of the excipient of Avicel PH 102- maltodextrins will effect the physical properties of powder mixtures and chewable tablet aloe vera extracts as well ethanol does not affect acceptance by consumers. Formula qualified physical properties of granules, and chewable tablets are a combination of formula four.

Keyword : Aloe Leaves (*Aloe vera* L.), direct compress, formulation

INTRODUCTION

Aloe vera (Aloe vera L.) is one of the single traditional medicinal plants used empirically as diabetes mellitus medicine (Wijayakusuma , 1994) . Aloe vera can also be used as a purgative , on upset stomach , eczema drugs , hair fertilizer (syamsuhidayat & Hutapea , 1991) , headaches , seizures in children , whooping cough (perfuses) , hemorrhoids , and menstrual pleura (Wijayakusuma , 1994) . In fact, some previous studies have found the effects of anthraquinone glycosides in aloe vera leaves on the gastrointestinal efficacious as a laxative (Kemper and Chiou , 1999) .

Maceration is used as method which could the isolate the active substance, glycoside, from the plant material. However, this extract, in general is difficult to mix and active ingredients in drug dosage is not stable because of the high-water content . Thus a more practical preparation to should be explored to overcome to this problem. In this study , selected a particular solid dosage tablet that is chewable .

Tablet is one of the pharmaceutical dosage forms of the most widely used with the advantage of measuring precisely, low cost of manufacture, easily packed and distributed (Lachman et al, 1986) . The chewable tablet is a preparation intended disintegrate slowly in the mouth with a reasonable speed with or without chewing. This formulation cab give a delicious residue in your mouth, easy to swallow, increas the practicality of use and do not require the consumption of water to workers, tourists in carrying out their daily activities. With a steadily crushed chewable tablet , it is expected that the active ingredient in the chewable tablet can be rapidly adsorbed by the gut so laxative effect in patients who consume.

To support the manufacture of chewable tablets, the excipients used to include a combination of Avicel PH 102- maltodextrins using the direct felts method. The use of a combination of excipients Avicel PH 102 and maltodextrins is aimed to improve the flow properties. Avicel PH 102 has the form of

granules and costly, while maltodextrins addition to the price cheap is also often used for chewable tablet formulations.

The purpose is to prevent the use of felt directly damage the active substance (glycosides) which is caused by heating. This study aims to determine the effect on the combination of Avicel PH 102 - maltodextrins as the excipient to the granules and the physical properties of aloe vera extract chewable tablet that can be used as a laxative.

METHOD

Materials

The materials are derived from the Aloe vera plant which is obtained from the Purworejo, Jawa Tengah. Ethanol 96 % , Avicel PH 102, maltodextrins , Mg Stearate, talc.

Method of Preparation

1. The fine powder making ethanol extracts of Aloe Vera

Fresh was washed with water, then the kernel of aloe vera was cut into small pieces and dried on the cupboard with a temperature of 50oC for two days. The simplicia was dried blended and then immediately sieved in order to get a homogeneous powder of subtlety. The simplicia dried powder to was extracted with 96 % ethanol and stirred using a maceration method with an electric stirrer so that the maceration process can be shortened to 6-24 hours, after this process the pulp was soaked again with 96 % ethanol and then collected as macerat. Subsequently, ethanol was evaporated by heating at 70°C waterbath until a thick extract. To ensure anthraquinone glycosides in the extracts tested TLC. Thick aloe vera extract made into dried Aerosil 102 PH to obtain a dry powder and then sieved with 60 mesh sieve to obtain a uniform mass.

2. Preparation of Ethanol Extracts of Aloe chews Tablet

improved physical properties of powders and tablets aloe vera extracted.

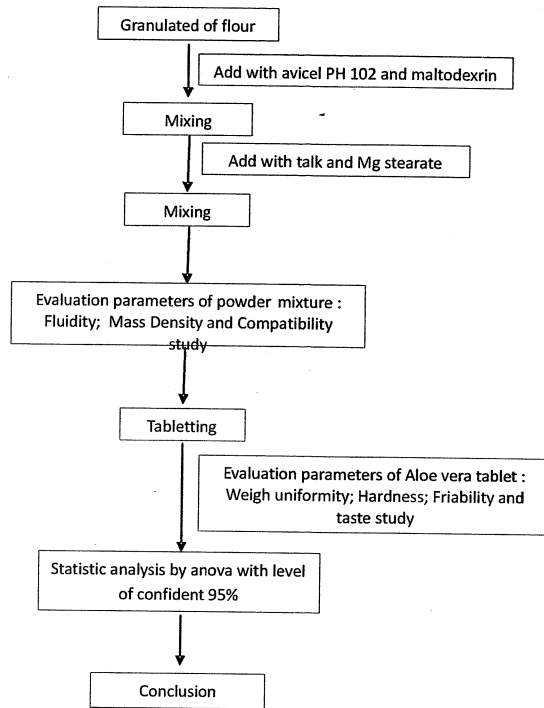


Figure 1. Scheme chewable tablet of ethanol extract of aloe vera and physical properties test of powder mixtures and tablets

3. Formula Tablets

Table I. Formula chewable tablet's ethanol extracts of aloe vera

Materials	Formula				
	I	II	III	IV	V
Etanol of extract	50 mg	50 mg	50 mg	50mg	50 mg
Maltodextrin	235 mg	176.25 mg	117.5 mg	58.75 mg	-
Avicel PH 102	-	58.75 mg	117.5 mg	176.25 mg	235 mg
sugar Stevia	5 mg	5 mg	5 mg	5 mg	5 mg
Mg-stearat : Talk (1 : 9)	10 mg	10 mg	10 mg	10 mg	10 mg

RESULTS AND DISCUSSION

A. Result of powder mixture study

These results prove that the aloe vera extracted dosage tablet can be prepared by the method of direct felts. The selection of additional material Aerosil 102 PH and maltodextrins

Table II. The physical properties of five formulas of powder mixtures of ethanol extract of aloe vera.

Physical properties	FORMULA				
	I	II	III	IV	V
Fluidity (% tap) ± SD	7,99±1,63	5,19±3,05	9,49±1,15	14,16±0,57	18,78 ±0,78
Mass Density (gr/ml) ± SD	0,94±0,04	0,91±0,00	0,60±0,01	0,51±0,00	0,53±0,05
Compatibility (kg) ± SD	5,56±0,47	4,49±0,51	5,68±2,92	4,78±3,27	4,19±3,16

1. Evaluation of the Flow properties of powder mixtures

The Flow property of materials is very significant to travel through the hopper into the die, so that the granular flow properties associated with the uniformity of weights. In this study, the flow rate of granule to be one consequential parameter

maltodextrins and 25 % Avicel PH 102) differ significantly.

2. The mixture mass density of the powder study

Measurement of the mass density of the powder mixture is done by pouring the powder mixture into a 100 ml measuring cup to the brim without any jerk and then calculated the weight of the powder compared to the volume.

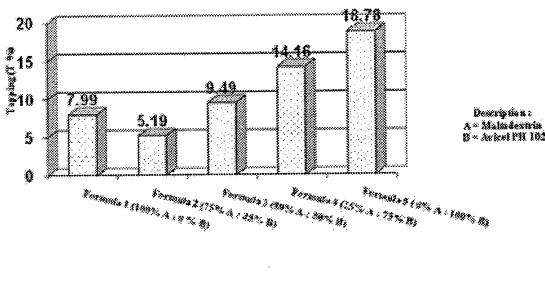


Figure 2. Histogram of the flow properties of powder mixtures of ethanol extracts of aloe vera (Aloe vera L.)

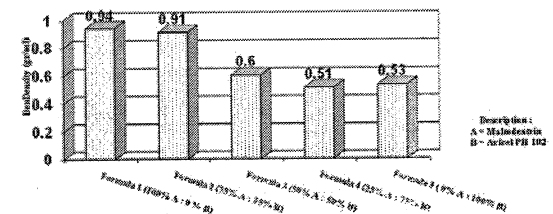


Figure 3. Histogram of the mass density of the powder mixture of ethanol extracts of aloe vera (Aloe vera, L.)

The histogram 2 shows that the highest percentage of tap indexes obtained through the formula 5 for 18.78 % while the lowest was 5.19 % of formula 2. However, according to an index, Fassihi and after at him less than 20% of the fine powder flow properties. The results of t test (LSD) showed that only the formula 1 (100 % maltodextrins) and the formula 2 (75 %

Ignore once the mass density profile of the powder mixture is contained in figure 3 can be seen that the value of the mass density of the mixture of maltodextrin's powder mixed Avicel PH - 102 decreases with increasing ratio of maltodextrins and Avicel PH 102 to the ratio of

25 % maltodextrins and 75 % Avicel PH 102, after was ascending again with increasing proportions of Avicel PH 102. High density on the proportion of 100 % maltodextrins cause better flow properties.

The results of t test (LSD) showed that the formula one (100 % maltodextrins) with the formula two (75 % maltodextrins and 25 % Avicel PH102) there is no significant , because the value of testing the density is not much different. In addition, the formula four (75 % Avicel PH 102 and 25 % maltodextrins) with the formula five (100 % Avicel PH 102) is also not a significant.

3. Compatibility Study

The study was conducted to determine easily whether or not the granules compressed into tablets with each other to do the bonds between the particles, forming a compact mass. Treatment compatibilities test performed on a single punch tablet machine with a punch on a scale between 7 mm and 11 mm below the punch.

The Histogram 4 shows that the violence decreased in the formula two tablets (25 % maltodextrins and 75 % Avicel PH 102) and then

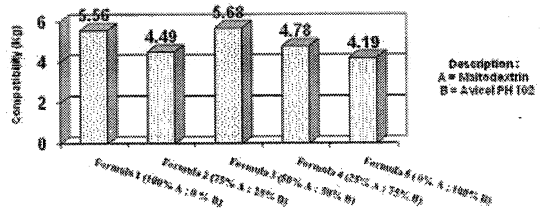


Figure 4. Histogram study of compatibilities powder mixture of ethanol extract of aloe vera.

shows the conclusion that all formulas are not a significant difference.

B. Tablet physical properties study results.

The determine the effect of additives on the quality of the ethanol extract aloe vera tablet then study the physical properties of tablets . Tablet physical properties study results can be seen in table III.

Table III . The physical properties of test chewable tablets ethanol extract of aloe vera

Tablet physical properties	FORMULA				
	I	II	III	IV	V
Average weight (mg) $\bar{X} \pm SD$	549,49± 27,84	507,68± 35,69	363,97 ± 20,72	383,66 ± 21,52	323,31 ± 6,45
uniformity of weight CV (%)	0,05	0,07	0,06	0,06	0,02
Hardness(kg) $\bar{X} \pm SD$	5,37± 1,11	7,95± 0,74	2,81 ± 0,24	5,97 ± 2,09	2,52 ± 1,10
Friability(%) $\bar{X} \pm SD$	0,34± 0,15	0,37± 0,36	0,84 ± 1,59	0,26 ± 0,24	2,76 ± 0,81

reaches the highest tablet hardness on the formula 3 (50 % maltodextrins and 50 % Avicel PH 102) , results from a show that compatibility is still appropriate with the standard tablet hardness 4-8 kg. The results of t test (LSD)

1. The uniformity Test Weights

The uniformity of tablet weight is determined based on the deviation average tablet weight is still permissible under the specified

requirements. One requirement of uniformity of weight is the value of CV (coefficient of variation) . A result is said to satisfy the requirements if it fulfills the CV values < 5 %. The weight uniformity results obtained can be seen in figure 5

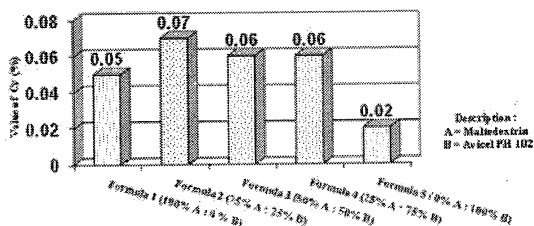


Figure 5. Histogram chewable tablet weight uniformity of the ethanol extract of aloe vera

The histogram 5 shows the results of tablet weight uniformity that obtained the highest CV formula 2, while the lowest in the formula 5. However, of all the formula shows CV of less than 5 %, meaning the five formulas have the same uniformity of tablet weight.

The results of t test (LSD) showed that every formula, there is a significant difference to the weight of the resulting uniformity. This suggests that the addition of Aerosil 102 PH and maltodextrins did not affect the uniformity of tablet weight.

2. Tablet Hardness study

The tablet hardness is affected by pressure at tableting, felted material properties, the amount and type of binder used. If the granules have a low compatibilities it takes considerable pressure to produce a tablet with the desired hardness (Rawlins, 1977) .

The histogram 6 shows that the formula 3 and formula 5 does not meet the standards desired tablet hardness, which is 2.81 kg and 2.52 kg. It is possible influenced by the amount

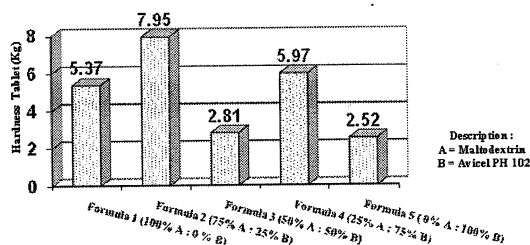


Figure 6. Histogram chewable tablet hardness study of ethanol extract of aloe vera.

of Aerosil 102 PH in the formula. Aerosil 102 PH has a better water absorbing properties so that when in contact with air for months, it resulted in the moist powder. The powder is too damp can cause poor structuring of powder in the die so that the effect of tablet hardness.

The results of t test (LSD) showed the conclusion that there are significant differences in almost all formulas, except for between one and four formula and the formula of three and five.

3. Friability Test Tablets

Friability is a parameter that describes the resistance (force) that acts to resist physical

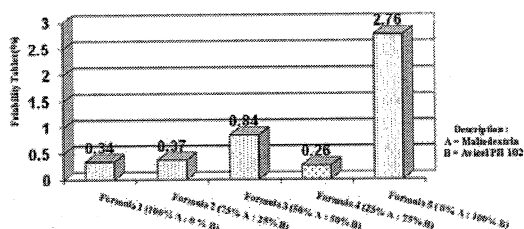


Figure 6 . Histogram friability test chewable tablets ethanol extract of aloe vera

stress and mechanical vibration. According to the friability tablet, Fonner and Parrot who are good if not better than 0.5-1%.

Figure 7 shows that the four formulas had the friability of less than 1 % of its original weight, which is a tablet good condition so that it can be concluded that the four formula meets the requirements of the friability of the tablet. Formula except five who have a friability value of more than 1 % is 2.76 %. This is because the amount of air voids in the tablet and the arrangement of particles in the compression chamber and the bonds between the constituent particles on the surface. T test results showed no significant different friability among formula, although formula one through four have friability > 1 %.

4. Response to taste study

The taste study was conducted to examine the responses obtained from the flavor chewable tablet ethanol extracted of Aloe vera leaves after filler powder is formulated as a combination of maltodextrins - Avicel PH 102 is acceptable. Tablets taste tests conducted with the adult target and uses 50 respondents.

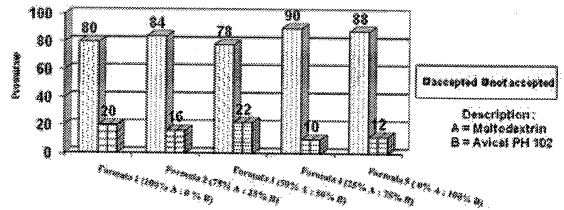


Figure 9 . Histogram responses flavor chewable tablet ethanol extract of aloe vera

is more suitable for consumption as a Chewable tablet.

The results of t test (LSD) showed that all the formulas do not have significant differences. So it can be concluded that variation's fillers maltodextrins, and Avicel PH 102 did not significantly affect the taste response.

C. Evaluation of Thin Layer Chromatography Results (TLC)

Table IV. Value Rf glycoside's anthraquinone ethanol extracted of aloe vera is done UV at 254, 366, and the visible

No.	Sample	Rf	UV 254	UV 366	Visible	Antraqinon
1.	Standart	0,48	tawny	flaxen	yellow	+
2.	Extract	0,30	blue	light blue	yellow	-
		0,50	tawny	flaxen	yellow	+
		0,70	tawny	flaxen	young brown	-
		0,80	tawny	flaxen	yellow	-

Based on the taste test responses of 50 respondents who tried to taste the tablet is seen almost all formulas taste good, but who has the percentage of bad taste is the least amount of formula four in which only 10 %. Based on these results it can be concluded that the formula four

Table IV, show that the value of the standard Rf and extracts almost contiguous, but the color appearance of the UV 254, 366, and a different visible. In addition, plant drug analysis in the book mentioned that the glycoside fluoresced anthraquinone tawny with Rf 0.50. So that from the data mentioned above can be

concluded that the extract of aloe vera is still an active substance contained anthraquinone glycosides that have the potential as a laxative, the main one is aloin A and B.

D. Limitation of study

The purpose of study is to get the best formula with aloe vera extract tablet combination of excipient Avicel PH 102 and maltodextrins based on tests on physical properties of powders and tablets.

E. The idea about the further study

This research is necessary to continue study anthraquinone content in each tablet and needs to be done clinical trial's dosage tablet pre ethanol extracted of aloe vera to the mice against the effects of laxative.

CONCLUSION

Variations of the excipient of Avicel PH 102- maltodextrins will effect the physical properties of powder mixtures and chewable tablet aloe vera extracts as well ethanol does not affect acceptance by consumers.

Formula which was qualified physical properties of granules, and chewable tablets are a combination of formula 4 with a excipient material 25 % maltodextrins and 75 % Avicel PH 102

REFERENCES

- Anonim, 2005, *1001 Tentang Diabetes*, hal 5, Penerbit Nexx Media, Bandung
- Fassihi, A.R., and Kanfer, 1986, Effect of Compressibility and powder Flow

Properties on Tablet Weight Variation in Drug Development and Industrial Pharmacy 12 th Edition, Hal 1947-1948, Marel Dekker, Afrika.

- Kemper, K.J. and Chiou, V. (1999). A. vera. The Longwood Herbal Task Force (www.mcp.edu/herbal/default.htm) and The Center for Holistic Pediatric Education and Research (www.childrenhospital.org/holistic). Revised July 29, 1999.

- Lachman, L., Lieberman, H.A., and Kanig J.L., 1986, Teori dan Praktek Farmasi Industri II, diterjemahkan oleh Siti Suyatmi, Edisi III, 644-646, 655-656, 698, 712, Penerbit Universitas Indonesia, Jakarta.

- Parrott, E. L., 1971, Pharmaceutical technology Fundamental Pharmaceutics, 3rd edition, hal 86-173, Burgess publishing company, Mineapolis.

- Rawlins, E. A., 1977, Textbook of Pharmaceutics, 8 th edition, Hal 269-289, BailliereTindal, London.

- Syamsuhidayat, S. S. dan Johnny Ria Hutapea, 1991, Inventaris Tanaman Obat Indonesia, Jilid I, 30 - 31, Badan Penelitian dan Pengembangan Kesehatan, Departemen Kesehatan Republik Indonesia, Jakarta.

- Wijayakusuma, H., 1992, Tanaman Berkhasiat Obat Indonesia Jilid 3, Pustaka Kartini, Jakarta