

THE EFFECTS OF INCREASING PVP K-30 CONCENTRATIONS TO THE PHYSICAL QUALITY OF *Mangifera indica* L. And *Syzygium polyanthum* LEAF EXTRACT TABLET

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ABSTRACT

Diabetes mellitus (DM) is a chronic disease caused by decreased effectiveness of insulin resulting in abnormalities in carbohydrate, protein, and fat metabolism, potentially triggering increased triglyceride formation in the liver due to increased production and decreased VLDL catabolism. Treatment of diabetes and hypertriglyceridemia still using chemical drugs in the long term cannot be separated from unwanted side effects so a combination of *Mangifera indica* L. and *Syzygium polyanthum* leaf extracts is needed which can be used as antidiabetes and antihyperlipidemia which can reduce triglyceride levels in the body. This study aims to determine an impact of the binders concentration of PVP K-30 1,5%, 2%, and 2,5% to the physical qualities that fulfill the range of requirement. The extract was made by using maseration method with ethanol 96% as solvent. The tablet was produced by using wet granulation method utilizing PVP K-30 as the binding agent. The physical quality tests that cover the hardness, friability and disintegration time of the tablet. After that, the obtained data were statistically analyzed. The result of the study indicated that the increase of PVP K-30 concentrations 1,5, 2% dan 2,5% in physical tests was able to decrease the friability of the tablets, disintegration time and increase the hardness. The statistical analysis result showed that there was significant difference in terms of the hardness and disintegration time of the tablets among the formulas. While, it was significantly difference in terms of friability in the formulas with the concentration of 2% (F2) and 2,5% (F3). Formula 2 with 2% concentrations is the optimum formula with physical qualities which is fulfill the requirements.

Keywords: mangifera indica L. and syzygium polyanthum leaf extract; PVP K-30; tablet; wet granulation

BACKGROUND

Diabetes mellitus (DM) is a chronic disease caused by decreased effectiveness of insulin resulting in abnormalities in carbohydrate, protein, and fat metabolism, potentially triggering increased triglyceride formation in the liver due to increased production and decreased VLDL catabolism. Treatment of diabetes and hypertriglyceridemia still using chemical drugs in the long term cannot be separated from unwanted side effects so a combination of *Mangifera indica* L. and *Syzygium polyanthum* leaf extracts is needed which can be used as antidiabetes and antihyperlipidemia which can reduce triglyceride levels in the body. To make a combination of *Mangifera indica* L. and *Syzygium polyanthum* leaf extracts easily used by people, the existed products of *Mangifera indica* L. and *Syzygium polyanthum* that have been circulated in the market are necessarily developed into new products.

METHODS

The extract was made by using maseration method with ethanol 96% as solvent. The tablet was produced by using wet granulation method utilizing PVP K-30 as the binding agent. The physical quality tests that cover the hardness, friability and disintegration time of the tablet. After that, the obtained data were statistically analyzed.

RESULTS

Tablet Formulation of *Mangifera indica L.* and *Syzygium polyanthum*

1. Extract tablets of *Mangifera indica L.* and *Syzygium polyanthum* containing *Mangifera indica L.* and *Syzygium polyanthum* extracts made in 3 formulations with a concentration of binding ingredients different PVP K-30, namely 1.5, 2% and 2.5%.

2. Evaluation of Physical Properties of Tablets

a. Organoleptic

The ethanol extract of *Mangifera indica L.* and *Syzygium polyanthum* leaves was obtained through a soaking maceration process, 500g each and soaked in 96% ethanol solvent.

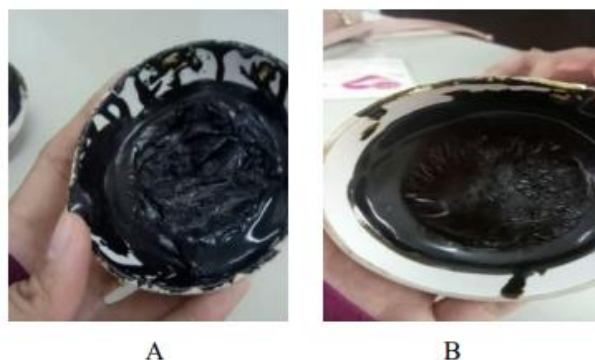


Figure 1. Thick extract resulting from extraction,
A). Ethanol extract of *Mangifera indica L* leaves, B) Ethanol extract of *Syzygium polyanthum* leaves

Results of qualitative examination of extracts *Mangifera indica L.* and *Syzygium polyanthum* can be seen in Table 1:

Table 1. Extract Qualitative Examination Results *Mangifera indica L.* and *Syzygium polyanthum*

Pemeriksaan	Pengamatan
Organoleptis	Organoleptis
Form	
Color	Sticky Solid
Smell	Black
Flavor	Typical
	Bitter

B. Extract Tablet Specifications *Mangifera indica L.* and *Syzygium polyanthum*

Tablet specifications *Mangifera indica L* and *Syzygium polyanthum* can be seen in Table 2:

Table 2. Extract Tablet Specifications *Mangifera indica L.* and *Syzygium polyanthum*

Tablet Specifications	Observation
Extract dosage	100 mg/tab
Collor	Black
Smell	Typical
Flavor	Bitter
Thick	3 mm
Diameter	13 mm
Weigh	650 mg
Therapy	Diabetes Millitus

b. Physical Quality Examination of Extract Tablets *Mangifera indica L.* and *Syzygium polyanthum*

Results of the physical quality inspection of extract tablets *Mangifera indica L.* and *Syzygium polyanthum*, including hardness, friability and tablet disintegration time, can be seen in Table 3:

Table 3. Results of Physical Quality Examination of Extract Tablets *Mangifera indica L.* and *Syzygium polyanthum*

Examination	F1	F2	F3	F4
Hardness (Kg) ^a	2.75±0.37	4.75±0.47	5.20±0.26	6.15±0.15
Fragility (%) ^b	0.83±0.04	0.75±0.01	0.66±0.08	0.53±0.05
Disintegration Time (minutes) ^b	4.00±0.10	9.80±0.60	11.01±0.23	13.10 ± 0.87

a) average data of 10 measurements and standard deviation; b) average data of 3 measurements and standard deviation

Information:

- F1 : Tablet formula without binding agent
 F2 : Tablet formula with binder PVP K-30 1.2%
 F3 : Tablet formula with PVP K-30 2% binder
 F4 : Tablet formula with binder PVP K-30 2.5%

c. Physical Quality Analysis of Tablets

To determine the effect of PVP K-30 levels on the hardness, Fragility and disintegration time of tablets, an analysis of the physical quality of the tablets was conducted.

Tablet Hardness Analysis

The effect of PVP K-30 content on extract tablet hardness *Mangifera indica L.* and *Syzygium polyanthum* can be seen in Figure 3.

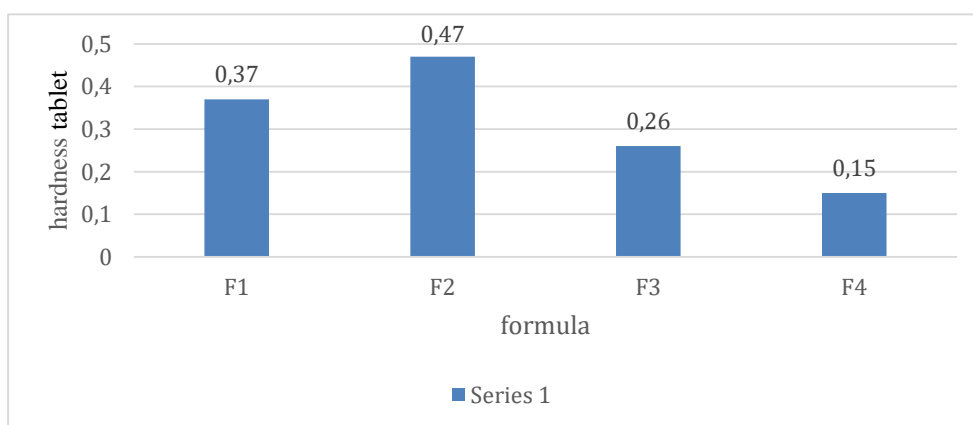


Figure 3. Hardness Histogram of Extract Tablet *Mangifera indica* L. and *Syzygium polyanthum*

The histogram of tablet hardness (Figure 2) shows that increasing the levels of PVP K-30 increases the hardness of *Strobilanthes Crispa* leaf extract tablets. In F1, the tablet hardness does not meet the requirements, while in F2 and F3, the tablet hardness meets the requirements. Statistical analysis shows that the calculated F-value is (231.604) with a confidence level of 95% ($\alpha=0.05$). It can be said that there is a significant difference between the formulas.

Tablet Fragility Analysis

The effect of PVP K-30 content on extract tablet Fragility *Mangifera indica* L. and *Syzygium polyanthum* can be seen in Figure 4

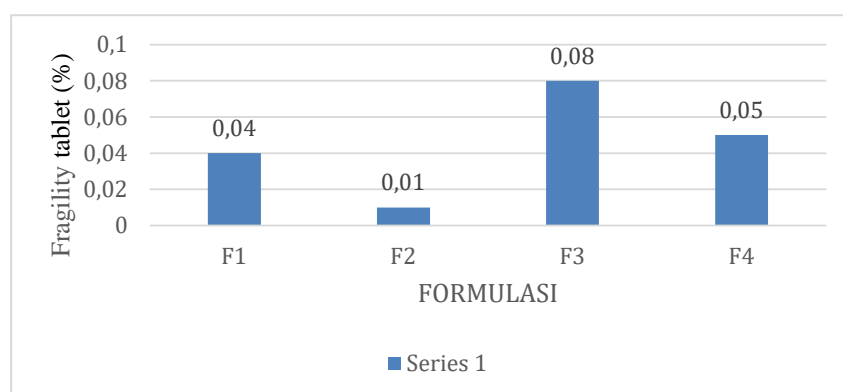


Figure 4. Fragility Histogram of Extract Tablets *Mangifera indica* L. and *Syzygium polyanthum*

The tablet Fragility histogram (Figure 3) shows that increasing levels of PVP K-30 causes the fragility of *Strobilanthes Crispa* leaf extract tablets to decrease. All formulas show tablet fragility that meets the requirements, namely $<1\%$. The statistical analysis results show that the calculated F-value is (12.512) with a confidence level of 95% ($\alpha=0.05$). It can be said that there is a significant difference between the formulas.

DISCUSSION

One of the plants believed to reduce triglyceride levels and blood glucose levels is the *Mangifera indica* L and *Syzygium polyanthum* plants, especially the leaves. The levels of PVP K-30 binder used in this research were 1.5%, 2%, and 2.5%, and without binder as a control, which was made using the wet granulation method by making *Mangifera indica* L and *Syzygium polyanthum* extracts using immersion maceration and remaceration three times. Simplicia powder was macerated using 96% ethanol solvent and soaked for 24 hours.

From the pre-formulation conducted, the results were selected with ingredients, namely *Mangifera indica* L and *Syzygium polyanthum* extract 1.5%, 2%, 2.5%, lactose 80%, avicel pH 101 20%, PVP K-30, primogel 3% and Mg stearate 1% for the tablet manufacturing process. Then, for tablet-making and granule-making, replication was conducted to increase the validity of the data for 100mg, 80% lactose, 20% avicel pH 101, PVP K-30, 3% primogel and 1% Mg stearate for the tablet-making process. Then, replication is conducted to increase the validity of the data for making tablets and granules.

CONCLUSION

From the overall results of the physical quality inspection of the extract tablets *Mangifera indica* L. and *Syzygium polyanthum*, it can be concluded that increasing PVP K-30 levels of 1.5%, 2%, and 2.5% shows an increase in tablet hardness and disintegration time, while tablet

fragility decreases. Formula 3 extract tablets *Mangifera indica* L. and *Syzygium polyanthum* with a PVP K-30 binder content of 2% is the optimum formula because the tablets produced meet the requirements with the physical quality test results of the tablets, namely hardness 5.12 ± 0.21 kg, fragility 0.66 ± 0.08 and tablet disintegration time 11.56 ± 0.37 minutes.

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