

## Research Article

# Optimization of Tablet Formulations Containing Green Robusta Coffee Beans (*Coffea canephora*) Extract with Various Concentrations of Sodium Starch Glycolate As a Disintegrant

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Chlorogenic acid, found in robusta green coffee beans, is an antidiabetic agent. It is made into robusta green coffee bean extract tablets which are varied with 3 concentrations of sodium starch glycolate (SSG) as a disintegrant. This paper aimed to determine the effect of variations in the concentration of sodium starch glycolate (4%, 6%, 8%) on the physical characteristics of the granules (particle size distribution, flow properties, angle of repose and compressibility) and tablet dosage characteristics, which include, hardness, friability, and disintegration time of robusta green coffee extract tablets. Robusta green coffee bean extract tablets were made with varying concentrations of sodium starch glycolate (4%, 6%, 8%) using the dry granulation method. The granule test parameters: flow properties test, compressibility test and particle size distribution test, were carried along with the tablet test parameters: hardness test, friability test and disintegration time test. Data were analyzed using the one Way-Anova. From the results of the study, it was found that the concentration of SSG did affect granule properties and tablet hardness. There was a significant difference in the friability test and disintegration time test.

**Keywords:** sodium starch glycolate, disintegrant, robusta green coffee bean extract, tablet

## 1. INTRODUCTION

Diabetes mellitus (DM) is a metabolic disease resulting from defects in insulin secretion, or due to the action of insulin or both. DM is commonly referred to as a clinical syndrome characterized by hyperglycemia due to either absolute or relative insulin deficiency, or a combination of resistance and insufficient insulin secretion to compensate (1,2).

Chlorogenic acid is a chemical compound that has the potential to be used as a therapeutic option in patients with type II diabetes mellitus. A study showed that

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Published 8 March 2023

Publishing services provided by Knowledge E

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Selection and Peer-review under the responsibility of the ICMEDH Conference Committee.

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chlorogenic acid inhibits the release of glucose into the bloodstream which can lower blood pressure and has no negative side effects (3). The pharmacological effect of chlorogenic acid as an antidiabetic through an in vivo study using the AMPK (Adenosine Monophosphate-Activated Protein Kinase) method found that chlorogenic acid regulates fat and glucose metabolism through AMPK activation. Chlorogenic acid can also inhibit G6Pase expression, improve fasting glucose, glucose tolerance and insulin sensitivity.

Chlorogenic acid is one of the many compounds contained in robusta green coffee beans. Many benefits can be obtained from chlorogenic acid for health, including chlorogenic acid is an antioxidant that is useful for reducing the effects of cell damage due to free radicals and a metabolic booster that minimizes the release of excessive glucose from the liver into the blood (4).

Extraction of the chromogenic acid compounds in coffee beans can be carried out. The extraction method used is meseration. The extraction results obtained were dried using freeze-drying. The removal of water content in this technology occurs at low temperatures, through a sublimation mechanism, directly from the solid phase of water (ice) to the gaseous form (5)

In this research, a tablet formulation with green coffee extract will be made, and appropriate additives will be used, each formula will be distinguished from the concentration of disintegrant. In this formula, sodium starch glycolate (SSG) will be used as a disintegrant.

The purpose of this study was to determine how the effect of variations in disintegrant concentration on the physical characteristics of the granules including (test flow properties, angle of repose, particle size distribution and percent compressibility), and in the second stage, namely evaluation of tablet preparations which include (hardness test, friability test, and disintegration time test).

## 2. METHOD

Research materials used for the manufacture of tablets are robusta coffee beans as active ingredient, aquadest pro analysis, SDL (SuperTab® 11SD, DFE Pharma), Avicel® 102 (Microcrystalline Cellulose, FMC CORPORATION), SSG (sodium starch glycolate, Gujarat Overseas INC. ), Mg Stearate (Magnesium Stearate pure, Applichem), talcum (Talc, Fagron). In this study there were 3 tablet formulas containing SSG concentrations of 4%, 6% and 8% which can be seen in table 1.

TABLE 1: Robusta Green Coffee Bean Extract Tablet Formula.

| Ingredient                    | K(-) % | Formula |       |       |
|-------------------------------|--------|---------|-------|-------|
|                               |        | F1 %    | F2%   | F3%   |
| Green Coffee Bean Extract     | 15.38  | 15.38   | 15.38 | 15.38 |
| SSG (sodium starch glycolate) | -      | 4       | 6     | 8     |
| SDL (spray dried lactose)     | 58.62  | 54.6    | 52.6  | 50.6  |
| Avicel 102                    | 20     | 20      | 20    | 20    |
| Mg stearate                   | 2      | 2       | 2     | 2     |
| Talk                          | 4      | 4       | 4     | 4     |

## 2.1. Tablet Manufacturing Method

The process of making tablet preparations uses the dry granulation method, namely by mixing the active ingredients and additives (only half of the disintegrants and lubricants will be used) in a mortar, then compressed into large, coarse tablets (slugs). Then crushed into larger particles, sieved with an 80 mesh sieve and then added the rest of the crushing material and lubricant. Then a flow test was carried out, then compressed again to get tablets that meet the requirements.

## 2.2. Evaluation of the Physical Quality of Granules and Tablet Preparations

In this study, an evaluation of the physical quality of the granules was carried out to determine the effect of different disintegrants on the distribution of granule size, flow properties, angle of repose, and granule compressibility. Examination of the physical characteristics of the granule preparation was carried out in accordance with the procedures in the Indonesian Pharmacopoeia VI edition. The tablet characteristics were then tested which included testing for hardness, friability, and disintegration in accordance with the procedures in the USP (6)

## 2.3. Tablet Hardness

A tablet is placed in the center and perpendicular to the hardness tester, initially at the zero position (7). The tool is rotated slowly until the tablet breaks. The scale reached on the tablet when it breaks or crumbles is read (6)

## 2.4. Friability Tablets

Amount 20 tablet dust-free and weighed on an analytical balance expressed as M1. Then the tablet is inserted into the friabilator. The tool is run for 4 minutes at a speed of 25 revolutions per minute. After 4 minutes or 100 rounds, the tablets were removed from the apparatus, freed from dust again and weighed which was then expressed as M2. The fragility of the tablet which is the difference between the weight of the tablet before and after being tested should not decrease by more than 1% of the initial weight of the initial tablet of the test (6)

## 2.5. Disintegration Tablets

The disintegration time of the tablet is the time required for the tablet to disintegrate in the appropriate time, so that no part is left on the gauze (USP, 2018). The disintegration time for uncoated tablets is less than 15 minutes. (8) The disintegration time test apparatus consisted of a basket rack having six holes located vertically above a number 10 mesh sieve. During the experiment a tablet was placed in each hole of the basket. The basket moves up and down in the transparent solution at a speed of 29-32 revolutions per minute. The disintegration time interval is 5-30 minutes (USP, 2018). Complete disintegration occurs when no tablet particles (except the coating) are still left on the sieve (6)

## 3. RESEARCH RESULTS AND DISCUSSION

The flow time test is carried out to determine the flow properties of a mixed powder. Powder or granules are said to flow well if 100 g of granules are less than 10 seconds or > 10 g/second (9)

TABLE 2: Granule Physical Quality Evaluation Results.

| Physical Characteristics of Granules |                      |                     |                    |                     |
|--------------------------------------|----------------------|---------------------|--------------------|---------------------|
| Granule                              | Flowability (g/sec.) | Angle of Repose (°) | Particle size (µm) | Compressibility (%) |
| K(-)                                 | 20.98±1.39           | 26.26 ± 0.54        | 270.48 ± 8.70      | 13.00±1.00          |
| F1                                   | 17.07 ± 2.19         | 27.17 ± 0.52        | 267.91 ± 8.99      | 14.00 ± 0.00        |
| F2                                   | 18.25 ± 1.52         | 28.35±1.77          | 253.57 ± 8.14      | 14.67±0.58          |
| F3                                   | 18.22±0.67           | 26.25 ± 1.41        | 265.35 ± 6.79      | 14.33±0.58          |

The four formulations showed results that were in accordance with the requirements and there was no significant difference between each formulation (p>0.05). The angle

of repose is the angle formed in the process of testing the flow time. Angle of repose is said to be good when its value is less than  $30^{\circ}$  (10). The four formulations showed good results and there was no significant difference between the formulations. The granules formed have sizes that do not differ between each formulation, as well as their compressibility. A good compressibility value is 5-20%

TABLE 3: Tablet Evaluation Results.

| Physical Characteristics of Tablets |               |                |                            |
|-------------------------------------|---------------|----------------|----------------------------|
| Granule                             | Hardness (Kg) | Friability (%) | Disintegration time (sec.) |
| K(-)                                | 6.50±0.5      | 0.41 ± 0.07    | 210±17.27                  |
| F1                                  | 6.00±0.5      | 0.58±0.05      | 154±11.58                  |
| F2                                  | 6.00±0.5      | 0.72±0.04      | 120±8.06                   |
| F3                                  | 5.83±0.29     | 0.87 ± 0.03    | 91±6.09                    |

The tablet hardness requirement of about 4-8 kg is the minimum requirement for a good tablet (11). In the statistical analysis for the tablet hardness test, the P value was  $0.370 > 0.05$ , so it can be said that there was no significant difference.

The maximum mean weight loss requirement of the three samples is not more than 1.0% (USP, 2018). Based on statistical analysis, it can be seen that the P value of  $0.00 > 0.05$ , it can be said that there is a significant difference in the fragility test. The higher the disintegrant content, the more brittle the tablet will be, but it still meets the compendial requirements. While the requirement for tablet disintegration is within the time specified in the monograph, there should not be more than 1-2 undissolved tablets (6). Based on statistical analysis, the results of the P value of  $0.00 < 0.05$ , it can be said that there is a significant difference between the four money formulations tested. The higher the concentration of SSG disintegrant, the faster the tablet disintegrates.

Sodium starch glycolate is a disintegrant with a swelling mechanism which means the polymer will expand when in contact with water. The swelling mechanism from within the tablet mass will cause the tablet to be pushed and eventually disintegrate. Conventional tablets that have a disintegration time of less than 15 minutes can facilitate the dissolution process and ultimately increase the absorption of the active ingredient.

## 4. CONCLUSION

Based on the results of the research that has been carried out, it can be concluded that the difference in the concentration of sodium starch glycolate 4%, 6% and 8% does not have a significant effect on the granule test, namely (flow properties test, compressibility

test and particle size distribution test), and also does not provide significant effect on tablet hardness, but also has a significant effect on other tablet tests, namely friability and disintegration time

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