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Research Article

Formulation and Evaluation of *Ipomoea batatas* L. Capsules: The Role of Magnesium Stearate in Enhancing Flowability and Quality Standards for Traditional Medicine

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ABSTRACT

Ipomoea batatas L (IBL) has the potential to be developed as a herbal medicine to treat DM. Capsules were chosen for the formulation of IBL due to their compatibility with its characteristic. During the manufacturing process, issues related to the flowability and compressibility of granules may arise. Mg stearate, as a lubricant, can be used to improve the flow properties of granules. The finished products must then undergo a series of test to ensure compliance with the standards and regulations. The aims of this study are to evaluate the impact of Mg stearate addition on the characteristic of granules within capsule formulations. Two formulations were made, F1 consisted of granules containing IBL leaf extract mixed with avicel and F2 used similar granules but included the addition of magnesium stearate. In this research, evaluation of both granule and capsule were conducted. The outcomes obtained shows that the F1 and F2 capsule have met the quality and safety requirements set for traditional medicine preparations according to the quality and safety requirements of traditional medicine. Compared to F1, the formula with magnesium stearate (F2) had a better compressibility index, which improved flowability, more uniformity of weight, and a longer disintegration time. However, there was no significant difference between the two formulas.

Keywords: Capsule; diabetes mellitus; formulation; *Ipomoea batatas*; red sweet potato

INTRODUCTION

Ipomoea batatas L. (IBL), commonly known as red sweet potatoes, is a plant recognized for its antidiabetic properties. The bioactive compounds present in IBL including anthocyanins, flavonols, flavanols, flavones, phenolic acids have been reported to effectively reduce blood glucose levels. Furthermore, the concentration of these compounds demonstrates a linear correlation with decreases in blood glucose and malondialdehyde levels (Yustiantara et al., 2021). The primary component of IBL, particularly in its leaves, is anthocyanins, which exhibit significant pharmacological activities, including antioxidant and antidiabetic properties (Lukitsari et al., 2017; Mahmudatussa'adah et al., 2014). IBL holds significant potential for development as a herbal medicine for managing diabetes mellitus through its mechanism of action and target organs.

The IBL is reported to be able to lower blood sugar levels through the Glucagon-like Peptide-1 (GLP-1) mechanism. The flavonoid content in IBL stimulates the secretion of GLP-1 in L cells of the

digestive tract, leading to an increase in intracellular calcium ion (Ca^{2+}) concentration. This interaction enhances the release of GLP-1 into the systemic circulation, where it binds to its receptors (GLP-1R) in various organs including the pancreas and the digestive tract. Binding of GLP-1 to its receptor in the pancreas promotes increased insulin secretion, while binding in the digestive tract reduces intestinal motility and contributes to weight loss. The bioactive components contained in IBL leaves can improve the function of pancreatic beta cells, liver, skeletal muscle, and adipose tissue, thereby increasing insulin secretion in pancreatic beta cells and increasing glucose transport into cells (Arisanti et al., 2023; Dewi et al., 2024).

These statements are in line with the study conducted by Yustiantara et al. (2021). According to this research, TLC fingerprints were employed to identify biomarker compounds in ethanol extracts of IBL leaves. The results of this study showed that the main flavonoid derivatives identified were anthocyanins and their acylated forms. The ethanol extract of IBL leaves containing the identified biomarkers given to rats at a dose of 250 mg/kg BW, 500 mg/kg BW, 750 mg/kg BW successfully exhibited antihyperglycemic effects in streptozotocin-induced rats. This pharmacological activity is attributed to flavonoids as antioxidant agents. Another study conducted by Jiang et al. (2020), shows anthocyanin antidiabetic effect. The in vivo study was conducted using protein-bound anthocyanin compounds (500 mg/kg BW) and free anthocyanin compounds (200 mg/kg BW) with total anthocyanins of 40.74 ± 2.88 mgC3G/g providing antidiabetic activity by reducing oxidative stress, reducing liver damage in diabetic mice, and inducing the expression of AMP-activated protein kinase. Based on this, it is known that IBL has pharmacological activity as an antidiabetic. This pharmacological activity of IBL makes the reason for the importance of developing IBL as an alternative to antidiabetic drugs. The optimal dosage of IBL for antidiabetic therapy varies depending on the preparation and formulation, emphasizing the importance of developing a standardized delivery method.

Capsules were selected as the delivery system for IBL extract due to their specific advantages that align with the characteristics of the extract. While anthocyanins possess significant potential as antidiabetic agents, their efficacy limited by their stability. The anthocyanin content in IBL exhibits significant instability when exposed to several factors such as pH, temperature, light, and oxygen (Enaru et al., 2021). In this study, capsules were chosen for the formulation of traditional medicine because of that reasons, which were capsules dosage form can mask unpleasant taste and odor form IBL extract, are easy to consume as they are easy to swallow, easy to prepare, and has the advantage of protecting the contents from external factor such as pH, temperature, light, oxygen, and humidity (Dewi & Farida, 2021). Also, capsules dosage form has a simpler formulation compared to other dosage form, such as tablets (Wulandari et al., 2020). To facilitate the use of IBL leaf extract in treatment of DM, it should be formulated into a pharmaceutical dosage form. Formulating medicinal plants into capsule form makes the extract easier to use because it is easy to swallow, dissolves or disintegrates quickly in the stomach, allowing the medicine to be absorbed quickly, and can mask the unpleasant taste and smell of the medicine (Syamsuni, 2006).

The quality determination of traditional medication capsule dosage form is a primary requirement in herbal products. Following the regulation regarding the quality and safety requirements of traditional medicines by BPOM (2023), the quality and safety of traditional medicine in capsules dosage form need to be ensured through a several parameters, including organoleptic test, moisture content, contamination of microbial, total aflatoxin, disintegration time, pH, contamination of heavy metal, deliverable volume, and/or alcohol content. In this study, the safety and quality evaluation were conducted using several parameters. For the granules, tests were conducted using moisture content and flowability (flow time and Hausner Ratio) parameters. As for the capsules, the tests were conducted using compressibility, disintegration time and weight uniformity. To achieve the quality and safety requirements of traditional medicines, efforts are needed to obtain an optimal capsule formula that ensures quality and safety. Therefore, excipients are used in capsule formulations to produce high-quality capsules.

In the manufacturing of capsule preparations, common issues are often encountered. One such problem is that capsules may contain materials that can damage the capsule shell. An example is a powder with a low bulk density (voluminous) (Syamsuni, 2006). Thus, apart from the additions of the active ingredient, excipients are required in the capsule formula. This

related because excipients are added to maintain the stability of the capsule and improve its flow properties. One such excipient is magnesium stearate. Magnesium (Mg) stearate functions as a lubricant in capsules. The selection of appropriate excipients to achieve specific functions in capsule formulation, such as lubrication, is crucial for producing a product that meets standards. During the manufacturing process several problems are encountered relating to the flowability and compressibility of granules. Poor powder flow can create problems in the manufacturing process and cause tool and capsule damage (Shah et al., 2023). Therefore, these problems must be corrected by improving and enhancing the flowability of the powder. One way is the addition of lubricants or glidants such as magnesium stearate. The addition of mg stearate reduces friction between the capsule shells (Wulandari et al., 2020). Mg stearate is a commonly used lubricant in capsule formulations. Its use can affect the physical properties of the dosage form, particularly in terms of physical appearance, weight uniformity, and flow properties of solid dosage form (Susanthi et al., 2017). The reasons for using mg stearate as a lubricant in capsules include its availability, inert nature, relatively low cost, and compatibility with other ingredients used in the capsule formula (Moreton, 2024).

Based on this background, this study aimed to evaluate the impact of magnesium stearate addition on characteristic of the granule within capsule formulations. The objective was to produce granules with optimal flowability and compressibility, enabling the development of a capsule formulation of IBL leaf extract that is both effective and suitable as an alternative treatment for diabetes.

METHODS

Material

The material used in this study included IBL leaves harvested from trees in Aan Village, Klungkung Regency, Bali Province, Indonesia. The leaves were then cut into smaller pieces and dried using a dessicator. Additional ingredients used in the study were avicel (Pharma Grade), magnesium stearate (Merck®), distilled water, ethanol p.a (Merck®), glacial acetic acid p.a (RCI Labscan®), and size 0 capsule shells.

Equipment

The tools used in this study included extractor machines (e&e Verfahrenstechnik GmbH®), Evaporator (e&e Verfahrenstechnik GmbH®), Rotavor R-220 (Buchi®), Fitz Mill machine, granule flow testers (Erweka®), tapped density tester (Erweka®), measuring cylinders (Pyrex®), stirring rods, glass funnels (Pyrex®), analytical scales (Mettler Toledo®), disintegration tester (Erweka®), moisture balance analyzers (Mettler Toledo®), parchment paper, manual capsule filling machine, 40-mesh sieve, and oven (Memmert®).

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Methods

Plant Determintation

The determination of red sweet potato (Ipomoea batatas L.) plant sample including its roots, leaves, stems, tubers, was conducted at the UPT Balai Konservasi Tumbuhan Kebun Raya Eka Karya, Bali-LIPI, Tabanan, Bali.

Preparation of Ethanol Extract from Ipomoea batatas L. (IBL) Leaves

Dried IBL leaf simplicia was extracted using 50% ethanol acidified with 0,5% acetic acid, at a simplicia-to-solvent ratio of 1:13, to achieve a pH of 4,5. The extraction process was conducted with an extractor machine for both batch 1 and 2. The simplicia was circulated with the solvent for 30 minutes at a 40o C via a heat changer, followed by 30 minutes of soaking. This cycle was repeated and the liquid extract was filtered and transferred to an evaporator, where it was concentrated at 40 °C for 15-20 minutes. The distillate was reused to re-macerate the residue for 30 minutes, then evaporated again for 15 minutes. The final extract was concentrated using a vacuum rotary evaporator for 40 °C and 40 mbar.

Preparation of Granule

The thick extract of IBL leaves was mixed with an absorbent, which was Avicel pH 101, at a extract-to-absorbent ratio of 1:1. The mixture was dried in an oven at 40° C until the moisture content was reduced to a less than 5%. The dried granule was than sieved using a Fitz Mill machine equipped with 40-mesh sieve. In this study, two batches of granule, batch 1 and batch 2, were prepared with identical preparation methods.

Formulation of IBL Capsule

The preparation methods for granules in batches 1 and 2 were identical, and statistical analysis confirmed no significant differences between the two batches. Therefore, batch 1 granules were selected for the capsule formulation, ensuring consistency and reliability in the final product. For capsule formulation, two formulations were prepared. The first formulation (F1) consisted of granules containing IBL leaf extract mixed with avicel. The second formulation (F2) used similar granules but included the addition of magnesium stearate. Each formulation was used to produce 250 capsules. The formulation on the content of the capsules can be found in Table 1. For F2, the granule contained the mixture of IBL leaf extract and avicel was blended with lubricating agents (magnesium stearate) until homogeneous, while F1 uses only the granule consisted the mixture of IBL leaf extract and avicel without additional lubricants. The mixture was sieved using a 40-mesh sieve and dried in an oven at 40 °C until the moisture content is below 5%. After drying, the granules were removed from the oven and filled into size 0 capsule shells using manual capsule filling machine.

The extract content in each capsule formulation of F1 is 50% (w/w), while the extract content in each capsule formulation of F2 is 49,5% (w/w). The extract content in each capsule formulation differs due to variations in composition. In F1, the total weight is 500 mg, consisting of 250 mg each of IBL leaf extract and avicel, resulting in an extract concentration of 50% (w/w) per mg of granule. While in F2, the total weight is 505 mg due to the addition of magnesium stearate, reducing the extract concentration to 49,5% per mg of granule.

Table 1. Formulation of Red Sweet Potato Leaf Extract Capsules

Formula	Material	
	Granule [Extract : Avicel (1:1)] (mg)	Mg stearate (mg)
F1	500	-
F2	500	5
Capsule Shell	Size 0 Green Transparent Capsule Shells	

Batch 1 and Batch 2 Granule Evaluation

Moisture Content Test

Sample of 1 gram and 5 grams of granules were weighed and analysed using moisture balance analyzer set at 105 °C. The granule weight was measured until it reached a constant value. The moisture content of the granule was determined using the analyzer, with results expressed as percent moisture content (%MC). The required moisture content for granules is ≤10% (BPOM, 2023).

Flow Time Test

Granule flow time was tested using a flow tester. First, 100 grams of granules were weighed. Then, they were placed into a funnel. The funnel's bottom cover was then slowly opened, allowing the granules to flow. The flow time was measured using a stopwatch. In this study, the flow tester was equipped with a built-in timer for precise measurement. After that, the granule flow time was recorded and the test was repeated three times to ensure accuracy and minimize errors.

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Hausner Ratio

The Hausner ratio is determined by measuring two key parameters. First, the initial apparent volume (V_o) of the powder in its loose state. Second, the final tapped volume (V_f), achieved after repeatedly tapping the material until the volume stabilizes. The hausner ratio are calculated as follows (USP, 2020):

$$\text{Hausner Ratio} = \frac{V_o}{V_f}$$

Capsules Evaluation

Compressibility Test

The compressibility and Hausner ratio were carried out by comparing the bulk density and tapped density using tapped density tester. Initialy, 100 grams of capsule content (powder) were weighed and placed into a 250 mL measuring cylinder. The initial volume without tapping (V0) was recorded. The cylinder was then tapped 500 times, and the compressed volume (Vu) was measured. Subsequently, 750 taps were applied, and the volume (Vb) was recorded. If the volume difference between 500 and 750 taps was less than 2%, Vb was used as the tapped volume (Vf). Tapping continued up to 1250 taps until the volume difference between measurements was consistently below 2% (USP, 2020).

Bulk density testing was also carried out using the same tapped density tester. A dry 250 mL measuring cylinder was filled with 100 grams of capsule content without tapping. The capsule content (powder) were added gradually, using a funnel if necessary, to avoid compaction. The surface of the powder was leveled gently with a stirring rod and the bulk The volume of the powder in the glass measuring cylinder was read accurately, with eye observations made parallel to the surface of the granules (Vu) was measured by reading the scale at eye level parallel to the powder surface (USP, 2014).

Weight Uniformity Test

A total of 20 empty capsules were each weighed, and after filling, the capsules were weighed again. For capsules containing dry traditional medicines, the specified requirements are as follows: out of the 20 capsules, the maximum number of capsules that may deviate by more than 10% from the average weight is 2 capsules, and no capsule should deviate from the average content weight ≥25% (BPOM, 2023).

Disintegration Test

The disintegration test was performed using a machine called Disintegration Tester with distilled water as the medium at 37±0.5 ºC. Six capsules were inserted into each tube, then the device was turned on. The device was stopped after all the capsules in each tube were completely disintegrated, and the disintegration time was recorded.

Data Analysis

The disintegration test was performed using a machine called Disintegration Tester with distilled water as the medium at 37±0.5 ºC. Six capsules were inserted into each tube, then the device was turned on. The device was stopped after all the capsules in each tube were completely disintegrated, and the disintegration time was recorded.

RESULTS AND DISCUSSION

Plant Determination

The determination results confirmed that the plant used in this study belongs to the family Convolvulaceae, genus Ipomoea, and species Ipomoea batatas L. The determination results indicate that the plant used is correct.

Capsule Formulation

The development of capsule formulations was made using commercial hard capsule shells size 0. The "0" size capsule shells used in the preparation are a manufacturer's product, which has a length of 22 mm and a capacity of 500 mg. In this study, granule from batches 1 and batch 2 were prepared using identical methods. A homogeneity test fo yielded a significance value of >0.05, confirming consistency variance between the data groups. Statistical analysis using one way ANOVA also produced significance value of >0.05, indicating no significant differences between the two batches. Consequently, only granules from batch 1 were utilized for the capsule formulation. The process of making granules involves using an adsorbent which was avicel at a extract-to-absorbent ratio of 1:1. Avicel possesses the ability to bind up 50% of active substances, exhibits excellent binding properties, and offers strong dilution potential and plastic deformation, ensuring optimal compressibility even under low pressure. Furthermore, it can function as a lubricant, enhancing the compatibility of the formulation (Said et al., 2014; Supomo et al., 2015). The capsule formulation in this study utilizes Avicel as a binder, filler, and disintegrant. Applications Avicel or Microcrystalline Cellulose in pharmaceutical formulation and technology, mainly use as a binder or diluent in capsule formulation with wet granulation and direct compression methods. In addition Avicel also has other functions as a lubricant and disintegrant agent (Chaerunissa et al., 2020). Avicel is advisable for active ingredients that are sensitive to hygroscopic substances or moisture (Sa'adah et al., 2016).

In this research, evaluation of both granule and capsule were conducted. The first formulation (F1) consisted of granules containing IBL leaf extract mixed with avicel. The second formulation (F2) used similar granules but included the addition of magnesium stearate. Mg stearate is used as a lubricant to improve flowability, affects the uniformity of weight, increase disintegration time, and improve capsule or tablet physical properties (Veronica et al., 2024; Parezanović et al., 2019; Blanco et al., 2023). This study utilizes two formulations to evaluate the impact of magnesium stearate addition on the granule characteristics in capsule formulations.

According to the Handbook of Pharmaceutical Excipients, the magnesium stearate concentration used in formulations ranges from 0.25% to 5.0% w/w. The

concentration of magnesium stearate used affects the hydrophobic properties of a powder. Mg stearate is hydrophobic, forming a film layer on solid particles, which reduces friction between particles and facilitates their flow. Additionally, its hydrophobic nature can inhibit water penetration by forming a film layer, thereby affecting disintegration time (Ansel, 2017). According to Liu et al (2008), it was known that adding 0.5% mg stearate affect increased cohesive flowability of ibuprofen. In this study, the Hausner ratio and shear cell measurements were used to determine the flowability. One study conducted by Puspadina et al. (2021) demonstrated the impact of variety of magnesium stearate concentrations as a lubricant (1%, 2%, and 3%) on the physical quality of a solid dosage form. The optimal physical quality test results were shown at a magnesium stearate concentration of 2%. The study found that adding a lubricant to the formulation could improve the flow properties of granules, as evidenced by flow time and compressibility. The higher the concentration of magnesium stearate, the better it was at reducing particle adhesion, thus reducing friction between particles and resulting in good granule flow rates. In this study, the capsule formula uses magnesium stearate at a concentration of 0.99% (1%) w/w. Based on this, it can be known that mg stearate as a lubricant can be used to improve the flow properties of granules so that further research is needed to determine the influence of mg stearate in the formulation of traditional medicine capsules. Mg stearate increases the hydrophobic properties of the capsule, causing the formation of a stronger layer on the surface of the excipient or other active ingredients (Parezanović et al., 2019; Blanco et al., 2023).

Evaluation Results of Batch 1 and Batch 2 Granule

Moisture Content Test

Moisture content was also conducted to evaluate the physical properties of the granule. The moisture content test was conducted using a moisture balance device with the temperature set at 105 °C. The intends of the test is to identify the water content present in the granule. High moisture can render the preparation unstable and accelerate the growth of microorganisms (Suprapti, 2003). Results of the moisture test, conducted extract at 105 °C, met the requirements as the moisture content of the granules was <10% (Table 2) (BPOM, 2019). During the formulation stage, the capsule formula utilized granules that had been sifted using a sieve with number 40 to achieved a fine powder with reduced particle size, maximizing the filling of the powder into the capsule shell. From the statistical test using one-way method ANOVA, a significant p-value of 0.079 was obtained, which indicated that between the two batches there was no significant difference because the p-value obtained in this test was greater than 0.05.

Flowability Test

The flowability test uses flow time to determine flow properties of the granule. Flow time refers to the duration needed for draining a quantity of granules on a device. This parameter is crucial in granule manufacturing as it ensures uniform weight. For 100 grams of granules, an optimal flow time should be ≤ 10 seconds or a flow rate of 10 g/second (USP, 2023). The flow time test results are displayed in Table 2. Conducting flow time tests is imperative as it directly influences the flow properties of the powder mixture, which, in turn, impacts the filling process. According to the results of the flow time test, it can be concluded that the granules (batch 1 and 2) have met the requirements. From the statistical test using one-way method ANOVA, a significant p-value of 0.435 was obtained, which indicated that between the two batches there was no significant difference because the p-value obtained in this test was greater than 0.05.

Hausner Ratio

According to the 20th United States Pharmacopeia, there are several methods for evaluating granule flowability, including compressibility and Hausner ratio tests (United States Pharmacopeia Convention, 2020). The Hausner ratio is used to predict the flow characteristics of granules. The Hausner ratio values presented in Table 2 indicate that the flow properties of both batches fall into the passable category. From the statistical test using one-way method ANOVA, a significant p-value of 0.152 was obtained, which indicated that between the IBL leaf extract capsule formulas there was no significant difference because the p-value obtained in this test was greater than 0.05.

Table 2. Test Results of Granule Batch 1 and Batch 2

Granule	Test Parameters		
	Moisture Content (%)	Flow Time (minutes)	Hausner Ratio
Batch 1	2.01±0.18	3.4±0.17	1.28±0.02
Batch 2	2.36±0.18	3.5±0.1	1.25±0.02

Table 3. Test Results of IBL Capsules Formulation

Formula	Test Parameters		
	Compressibility Index (%)	Weight Uniformity (mg)	Disintegration Time (minutes)
F_1	23.67±0.28	510.7±17.07	9.01 ± 2.34
F_2	21.17± 2.06	500.4±18.37	10.17 ± 2.17

Capsule Evaluation

Compressibility Index Test

Flowability is one of the most critical physical characteristics of granules. It pertains to their ability to flow during the filling process, which significantly impacts distribution. Poor flowability may lead to blockages during filling, resulting in uneven distribution of granules (Lebang et al., 2020). According to the United States Pharmacopeia (2020), there are several methods for evaluating granule flowability, including compressibility and Hausner ratio tests (United States Pharmacopeia Convention, 2020). The compressibility index in formulas are influenced by the size of the granule and the shape of the granules, the smaller the bulk density obtained, the better the flow properties. The compressibility and compactibility of powders is affected by the size of particle. The improvement in compactibility was linked to a reduction in particle size, resulting froam a increased number of bonds within the cross sectional area of the pharmaceutical dosage form (Wünch et al., 2021). The research conducted by Hlosta et al. (2016) revealed that the distribution of particle size and shape are properties that affect compressibility. The bulk properties of powders are influenced by air, because the voids between the particles are filled with air volume. The amount of air influences the interactions between particles and, thus, influences the flow properties of the powder. The conclusion that can be drawn from this study is that particle size affects compressibility. While the flow properties depend on the particle shape.

In all formulas, the granules used has been sifted using a 40 mesh sieve. Compressibility and flow properties are related to the size distribution of powder particles. Powders sifted using a number 40 mesh sieve are categorized as "moderately coarse powder", meaning all powder particles can pass through the number 40 sieve. Sieve size is a key factor affecting the compressibility powder in capsule formulations. The sieve size affects the distribution of particles in the powder: the smaller the sieve size, the finer the particles that pass through it (Allen & Ansel, 2014). The lower the compressibility value, the higher the density of the granules after undergoing compression, resulting in a more compact granule mass (Winarti et al., 2016). The granule compressibility test intends to identify the ability of powdery material or granules to form a compact mass after being subjected to a certain pressure.

According to the results of the compressibility index test (Table 3), the compressibility index value is 23,5% for F1 and 19,5% for F2. The F2 formulation has a better compressibility index compared to F1 because the lower the compressibility index, the better the flowability of the granules. The difference between F1 and F2 is the addition of excipients, which is magnesium stearate, as a lubricant in F2. This addition causes F2 to have better compressibility than the formula that only uses IBL leaf extract. According to the research carried out by Veronica et al (2024), The variability of magnesium stearate has an effect on powder flow. Research shows that the use of magnesium stearate in the formulation will help to achieve good flowability. Additionally, magnesium stearate can fill the surface voids of the granules which causes a significant increase in their flowability. The addition of magnesium stearate affects the compressibility of the granules because magnesium stearate accelerates granule's flow time. The smaller the compressibility value, the better the flowability of the granules will be (Puspadina et al., 2021). From the statistical test using one-way method ANOVA, a significant p-value of 0.108 was obtained, which indicated that between the IBL leaf extract capsule formulas there was no significant difference because the p-value obtained in this test was greater than 0.05.

Weight Uniformity Test

According to BPOM (2023) and Indonesian Pharmacopoeia (Kemenkes RI, 2020), the weight uniformity for capsule containing dry traditional medicine is assessed by weighing 20 capsule. Of these, no more than two capsule may have a fill weight deviating by more than 10% from the average, and none may deviate by more than 25% from average fill weight. The results of weight uniformity indicate that none of the capsules exceeded the 10% deviation limit, and none exceeded the 25% deviation limit. A good

weight uniformity value suggests that the active substances are evenly distributed throughout the formula, thereby influencing the drug's effectiveness and efficacy when consumed (Farida et al., 2019). From the one-way ANOVA statistical test, a significant p value of 0.073 (p> 0.05) was obtained. This result indicated that there was no significant difference between the IBL leaf extract capsule formulas. Weight uniformity is greatly influenced by the quality of flow properties. Good flow properties ensure that the volume of material entering the compression chamber is consistent, resulting in minimal variation in the weight of the produced capsules (Susanthi et al., 2017).

However, the average weight uniformity shows that there is a difference between the two formula. As a lubricant, mg stearate can affect the physical properties of the solid dosage forms produced, particularly in terms of physical appearance and weight uniformity (Susanthi et al., 2017). The variation in weight uniformity among the formulas can be attributed to factors such as filler characteristics, flow properties, and the mixing process. The method used to determine the weight uniformity of the capsules two formula. As a lubricant has several problems associated with completely clearing the capsule. Each formulation has a different weight of content due to how the weight of the empty capsule was calculated. There consistently remained material inside the capsules after they were emptied. Also, a loss of content cannot be avoided because the pharmacopoeia mandates that the capsules must be emptied to determine the weight of their contents (Tichy et al., 2008).

In the formulation of IBL leaf capsule, avicel was used not only as an absorbent but also as an filler. The type and properties of the filler can affect the weight uniformity. Filler, which are inert substances added in the formulation to provide bulk and aid in the manufacturing process. It can impact the distribution and homogeneity of the active ingredients within the formulation. The flow characteristics impact the consistency of capsule contents, which in turn influences the accuracy of the dosage (Sutiswa & Rahman, 2020).

Disintegration Test

The data displayed in Table 3 it can be seen that all formulations F1 and F2 exhibit a crushing disintegration time indicates that the capsule can disintegrate and dissolve quickly after ingestion, thereby facilitating the desired pharmacological effect within a short period. The results of the statistical analysis using the ANOVA test indicate no significant difference in capsule disintegration time among the formulations, as evidenced by a non-significant p-value of 0.485 (p>0.05). Additionally, it is observed that F1 exhibit faster disintegration times compared to the F2 which contain granule with the addition of magnesium stearate. This happens because mg stearate is hydrophobic. It forms a film layer on solid particles, which reduces friction between particles and facilitates their flow. Additionally, its hydrophobic nature can inhibit water penetration by forming a film layer, thereby affecting disintegration time (Ansel, 2017). The higher the concentration of mg stearate, the longer the disintegration time of the capsule. The high concentration of mg stearate will affect the hydrophobic properties of the capsule which will then inhibit water penetration by forming a film layer so that it can extend the capsule disintegration time (Sheth et al., 2016; Puspadina et al., 2021).

CONCLUSION

The quality evaluation of granules and capsule preparations, including tests for moisture content, flow time, compressibility, weight uniformity, and disintegration time, showed that formulations F1 and F2 met the Perka BPOM (2019) standards for traditional medicine. Therefore, red sweet potato (Ipomoea batatas L.) capsules has the potential to be used as an alternative treatment for diabetes. The addition of magnesium stearate in F2 improved compressibility, flowability, weight uniformity, and extended disintegration time compared to F1. However, the differences between the formulas were not statistically significant.

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CONFLICT OF INTEREST

All authors declared that there was no conflict of interest.

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