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Development of sweet potato (*Ipomoea batatas* Lamk.) as excipient in tablet formulation

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Abstract

Background: Sweet potato has a potential to be used as a raw material for tablets. However, it needs chemical modifications to produce derivatives with excellent pharmaceutical characteristics. The primary purpose of this research was to use sweet potato starch (*Ipomoea batatas* Lamk.) as a tablet excipient modified through a chemical process.

Design and Methods: This study is experimental and is divided into three stages. The first stage is the extraction process to obtain sweet potato starch. The second stage is the chemical modification of sweet potato starch using pentanol-1 and glacial acetic acid. The third step is the analysis of the pharmaceutical properties of the mutated lab model compared to the control sample and Amprotab.

Results: The descriptive-comparative analysis showed sweet potato starch modified with panthenol-1 had a higher hardness value (=2.55±0.34) compared to native starch (1.00±0.08). The particle size distribution of the modified sample with acetate acid (=15.20±1.79) was higher than the others.

Conclusions: In conclusion, modified sweet potato starch has better pharmaceutical properties than native starch. Further research needs to be conducted on the magnitude of the potential of sweet potato starch as an excipient, both as filler, a binder, and a crushing agent on tablet preparations.

Introduction

The majority of the pharmaceutical industry in Indonesia is limited in the industrial manufacture of finished drugs. This causes the rise in demand for imported raw materials for medicines, where almost 90% is imported, with a large bulk originating from China, India, and Europe.[1] The high dependence on imported raw materials makes the Indonesian pharmaceutical industry very vulnerable, especially with the weakening of the rupiah, which increases production cost.[1] The industry needs to transform, not only as a formulation but also in the future, being able to be based on research, development, and manufacturing, producing raw materials independently.[1] Physical and chemical modified starch is a medicinal ingredient still imported in Indonesia. In various countries such as India, China, and New Zealand, the starch modification effort has been excellent to produce various derivatives with diverse characteristics suiting their functions in pharmacy.[2-4] Several studies examined the potential of various tropical starch from local Indonesian bulbs, especially sweet potato. Excipients and other active components are usually added to tablet formulations. [5-7] There are non active ingredients that can be directly compressed into tablets without excipients.[8]

Starch from local sweet potato needs a chemical modification process to produce derivatives with better specific pharmaceutical characteristics. The modification include the use of sodium tri polyphosphate[8] and sodium acetate.[9] Therefore, this research aims to utilize local Indonesian plants, such as sweet potatoes, to develop raw pharmaceutical materials. Sweet potato was chemically modified using pentanol-1 and glacial acetic acid to improve its pharmaceutical properties for the production of tablets.

Design and Methods

This research is experimental. It is divided into three stages. The sweet potato varieties at hand were determined in biology laboratories. The stages then involved the extraction process to obtain sweet potato starch and the chemical modification of the starch using pentanol-1 and glacial acetic acid. The alteration was obtained by mixing 125 ml of pentanol-1 into 125 g of unmodified starch, then blending for 30 minutes at room temperature. The blend is further mixed with 375 ml of aquadest and dissolved. Thereafter, 8 ml of glacial acetic acid is added to the solution and heated to 45˚C for 60 minutes stirring. The residue after filtration was washed with aquadest four times. The precipitate was dried in the oven and mashed using a sieve. The third and final step is the analysis of the pharmaceutical properties of mutated and unmodified sweet potato starch and amprotab using a comparative descriptive method. It included: organoleptic, microscopic, solubility, iodine identification, particle size, powder flow properties, tapping test, and compactibility.

Significance for public health

Sweet potatoes are Indonesia native plants that have potential for use as pharmaceutical raw materials. Starch from sweet potatoes needs a modification process to produce derivatives with better and specific pharmaceutical characteristics. We describes the development of sweet potato as excipient in tablet formulation can provide better level security for human than synthetic excipients, so it could avoid more serious side effects caused by the use of synthetic excipients.

Results and Discussions

Based on the particle size test on the three types of sweet potato starch and Amprotab, the average result was set out in Table 1. Flow time tests on chemically modified and control starch shows lack of flow time. Based on the tapping test on three types, the average index obtained is shown in Table 2. Table 3 shows the average values obtained based on the compatibility test. The organoleptic examination shows chemically modified sweet potato starch is a fine powder with white color and no taste or smell. Furthermore, there was no significant difference between the modified sample, the remaining unmodified sample and Amprotab. Microscopic examination showed a single-grained and spherical chemically modified sweet potato starch with a hilus in the middle of the particle. Dissolution in aquadest was meant to test the solubility of the sample, and the results showed it did not dissolve in water. Sweet potato starch and Amprotab produce purple and dark blue colors in Iodine with a similarity in the particles analysis.

Organoleptic examination

This test was carried out to determine the shape, color, smell, and taste. The results show the two types of chemical modified sweet potato starch are in form of fine powders and white color. The same was observed for Amprotab and the unmodified sample.[10]

Microscopic examination

A x40 magnification showed the chemically modified sweet potato starch was spherical shape, and appeared as a single grain with a hilus in the middle of the particle. The results remained constant when the same test was carried out to compare with unmodified starch and Amprotab.[10]

Solubility examination

Chemical modified sweet potato starch was dissolved in aquadest. The results show no solubility in water. The same test findings were reached with the remaining sample materials. According to Rowe *et al.*, starch is insoluble in water[11,12] since it contains large amounts of amylopectin, which is insoluble.[13]

Iodine identification

The sweet potato starch produce purple color while Amprotab showed dark blue pigments. This is attributed to the larger amounts of amylopectin than amylose in its composition. However, Amprotab's composition shows contrary results with more amylose.[13] The formation of a purplish-blue color is due to the reaction of amylose and iodine forming a complex substance, while the amylopectin from starch turns a bluish or violet color.[14]

Particle size analysis

The results indicated similar sizes for the test sample material. According to Indonesian Pharmacopoeia, the microscopic examination results of starch diameter is 5-10µm and 20-35µm for small and large grains, respectively.[10] The size of particles affects the physical and chemical properties of the drug, including the rate of dissolution, texture, and homogeneity.[15] Sweet potato starch and Amprotab have a small and excellent particle size, which causes variations in the weight of the tablet. Starches with particle sizes that are too small affect the uniformity of the tablet contents.[16]

Powder flow properties test

This test is based on flow time and stationary angle.[14] Good flow speed requirements are >10 g/sec (free-flowing) and 4-10 g/sec (easy flowing).[15] The test showed that all the sample material do not have flow time, which means they have poor movement properties. This condition is attributed to their small and fine particle size, which increases their cohesion power and slow down the powder flow. Good fixed angle value of starch is 20°-40°, and above 50°, the flow presents difficulties, and might even be impossible.[15] Several factors influence the stationary angle, including the tensile and frictional forces between particles. The angle is narrowed if the magnitude of the factors is reduced.[17] Without the flow time, the stationary angle cannot be measured; hence the starches were declared not to meet the requirements of good flow properties.

Tapping test

The test shows a decrease in the volume of granules due to pounding and vibration. Generally, a smaller tapping index (%) makes the flow properties better. A small compressibility value

Table 1. Particle size test on the three types of sweet potato starch and Amprotab.

No.	Type of starch	Particle size average (µm)
1.	Unmodified starch	15.80
2.	Modified starch using pentanol-1	12.90
3.	Modified starch using glacial acetic acid	15.20
4.	Amprotab	18.25

Table 2. Tapping test on the three types of sweet potato starch and Amprotab.

No.	Type of starch	Average tapping index (%)
1.	Unmodified starch	20.6
2.	Modified starch using pentanol-1	24.6
3.	Modified starch using glacial acetic acid	28.0
4.	Amprotab	15.4

Table 3. Compatibility test on the three types of sweet potato starch and Amprotab.

No.	Type of starch	Hardness scale		
		5 Average of compactibility	6 Average of compactibility	7 Average of compactibility
1.	Unmodified starch	-	0.56	1.00
2.	Modified starch using pentanol-1	0.62	1.04	2.55
3.	Modified starch using glacial acetic acid	0.59	0.84	2.01
4.	Amprotab	0.72	1.53	4.52

shows the granules organize themselves for tapping, leading to volume reduction.[18,19] Essentially, powders with a tapping index lower than 20% have good flow properties.[20] The results in Table 2 show the average tapping index of all sweet potato starch is more than 20%. And, is in contrast from Amprotab's with an index of less than 20%. This shows that sweet potato starch has poor compressibility.

Compatibility test

This test was meant to determine the ability of the powder to form a compact mass. In general, the size of particles affects the compactness of the tablet when printing. Small-sized and fine powder fills the printing space well.[16,21,22] In this experiment, sweet potato starch was modified using pentanol-1, glacial acetic acid, and Amprotab to form tablets on a hardness scale of 5, 6, and 7. Unmodified starch only forms tablets on a hardness scale of 6 and 7, showing that modified starch is more compact.

Conclusions

The physio-chemical characteristics of laboratory modified sweet potato starch show the same features of Amprotabs. However, mutated sweet potato and Amprotab have equal compatibility strengths. Overall, modified sweet potato starch has better pharmaceutical properties. Further research needs to be conducted on the magnitude of the potential of sweet potato starch as an excipient, both as a filler, a binder, and a crushing agent on tablet preparations.

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