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Preparation and Characterization of Pregelatinized Sago Starch (PSS) from Native Sago Starch (NSS) (*Metroxylon* sp.) and its Evaluation as Tablet Disintegrant and Filler-Binder on Direct Compression Tablet

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ABSTRACT

Starches are biodegradable and relatively inexpensive natural biopolymers which are widely used in the food and pharmaceutical industries. Sago starch is one of the starches which can be potentially used as the excipient in pharmaceutical formulation. The purpose of this study was to modify and to characterize the physical and chemical properties of native sago starch (*Metroxylon* sp) (NSS) and pregelatinized sago starch (PSS). NSS was evaluated to be confirmed with the requirement, including microscopic analyses, amylum identification, ash content, amylum acidity, loss on drying, solubility in water, solubility in ethanol, and chemical content of Pb, Cd, Hg. Physically evaluated for both types of sago starch were particle size, moisture content, flow rate, angle of repose, tapped density, compactibility, water absorption rate, and water absorption capacity. Fourier transform infrared spectroscopy (FT-IR) was used to characterize and evaluate PSS and NSS's chemical properties. Chemical content (Pb, Cd, Hg) and microbial content (yeast mold figures, number of bacteria, Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella sp., Shigella sp.) of PSS are also identified. The results of this study showed that PSS exhibited different values of those determined parameters compared to that of NSS on particle size, moisture content, flow rate, the angle of repose, tapped density, water absorption rate, and water absorption capacity. In conclusion, PSS has better flow properties because it has a larger particle size than the NSS. PSS also has a larger water absorption rate and water absorption capacity than the NSS because PSS can interact with water easier than NSS. There is no bacterial content in PSS which means PSS follows the regulatory requirement. PSS had a good effect on weight uniformity, hardness, and disintegration time of the tablets. It makes PSS can be potentially used as the excipient in solid dosage form formulation.

Keywords: pregelatinized sago starch, native sago starch, physicochemical properties, tablet.

INTRODUCTION

Starches are natural biopolymers that are biodegradable and relatively affordable. They are frequently employed in the pharmaceutical and food industries. (Hoover *et al*., 2010). Starch is one of the excipients, which is inert and widely used in the pharmaceutical industry as the filler, disintegration agent, and binder of the solid dosage form formulation. Starches that have been frequently used in the pharmaceutical industry are starches from cassava (Manihot starch) and cornstarch. On the other side, sago starch is also potentially used because many sago plants abundantly grow in Indonesia and are relatively easy and cheap to obtain. According to Wong *et al*., (2007), sago starch contains 24.9% amylose and 75.1% amylopectin. It is almost the same as other starches, which is commonly used in pharmaceutical industry, such as corn starch, wheat starch, and sorghum starch, which contains 28% amylose and 72% amylopectin, while potato starch contains 79% amylopectin and 21% amylose.

However, like starch in general, sago starch also has several limitations. It has a poor flow rate and is uncompressible. Sago starch also has a low

water solubility and, in some cases, unacceptable retrogradation following gelatinization. (Fu *et al*., 2012). To overcome such drawbacks, physical, chemical, and/or enzymatic modifications of starch are necessarily needed (Zia-ud-Din *et al*., 2017). One of the methods to modify starch properties is pregelatinization. Pregelatinized starch is a kind of physically modified starch with cold-water-swelling capacity and desirable pasting and texturizing properties (Miyazaki *et al*., 2006). This method might modify starches to be directly compressible by exhibiting a lower amount of plastic deformation occurred during the compression process (Convention, 2021; Alebiowu & Itiola, 2002). Thus, the pregelatinization method was employed in this study to improve the characterization of native starch.

Pregelatinized starch can be produced through many physical processes such as spray drying, high hydrostatic pressure, drum drying, thermomechanical processing, and extrusion cooking, followed by drying (Hoover *et al*., 2010). Conventional extrusion is a continuous high-temperature, short-time process that uses a unique mix of high temperature, pressure, and shear forces to physically modify the wet expansible starchy and proteinaceous material and cause it to swell (Camire, *et al*., 1990). Of these technologies, extrusion cooking is recommended as a faster and more flexible method than other procedures, and it has been widely used in the manufacturing of cereal-based snack-like goods. (Sacchetti *et al*., 2004). The treatment of a suitable amount of water and heating at the proper temperature was used to modify pregelatinized starch. This approach yields starch with a bigger particle size and a higher density of particles (Putra *et al*., 2018). In various immediate-release formulations, pre-gelatinized starches are widely utilized as a binder and disintegrant agent (Kankate *et al*., 2020).

In this study, we reported the preparation of Pregelatinized Sago Starch (PSS) and characterized its physicochemical properties. We compared the physicochemical properties between Native Sago Starch (NSS) and Pregelatinized Sago Starch (PSS), including particle size, moisture content, flow rate, the angle of repose, tapped density, compactibility, water absorption rate, and water absorption capacity. Fourier transform infrared spectroscopy (FT-IR) was used to characterize and evaluate the chemical properties of the PSS and NSS. We also evaluated the performance of PSS as a potential disintegrating agent and filler-binder applied in direct compression tablets.

MATERIALS AND METHODS

The sago starch of *Metroxylon* sp. was collected from Boyolali, Village in Central Java, Indonesia. Chemicals used were potassium hydroxide, hydrochloric acid, potassium iodide, iodine, ethanol 70% v/v, sodium hydroxide, acetic acid, acetosal, Starch 1500®, gelatin, magnesium stearate, talc, and distilled water.

Sample preparation

The native sago starch was produced by peeling the sago trees and then it washed with distilled water until clean to make the native sago starch. The sago was then cut into small pieces and mashed in a blender, followed by the addition of distilled water (2:1 [w/v]). With a flannelette, the mixture was squeezed and filtered. After 48 h of precipitation, the supernatant was removed. The starch precipitate was rinsed in distilled water until being clean. After drying for 24 h at 40°C, the precipitate was crushed and sieved using a 100-mesh sieve. (Bhardwaj *et al*., 2000; Siswanto & Soebagyo, 2006).

The pregelatinized sago starch was created by combining starch and distilled water in a 1:1 (b/v) ratio. The mixture was then agitated until it produced a homogeneous suspension. The suspension was heated with water vapor in a drum at 85°C for 1h, stirring at 125 rpm until gelatinization occurred. The pregelatinized starch was then dried for 24h in a 50°C oven. After drying, it was sieved through a number 80 sieve. (Putra *et al*., 2018).

Physical and chemical properties of the native and pregelatinized sago starch

The starch granule morphologies were viewed and photographed with an optical microscope (CX 31, Olympus®) and stratified sieves with meshes of 20, 40, 60, and 80 (Nafchi *et al*., 2011; Putra *et al*., 2018). Starch solubility was measured with semi micro balances, 0.01mg of starch was added to 1L of cold water and stirred. Subsequently, the sample's solubility was determined. This process was repeated, but this time the water was replaced with 95 percent alcohol. (Qazi *et al*., 2014; Parwiyanti *et al*., 2015). Starch content identity was measured by boiling one gram of starch in 50 mL of water until a transparent starch solution was formed, almost odorless, and did not change the color of litmus paper. The solution was added to a 0.05 mL iodine reagent solution of 0.005 M, which then turned into blue. The blue solution would disappear when

heated and would appear when cooled (Pharmacopeia, 2020).

Starch acidity was measured by mixing ten grams of starch with 100 mL of ethanol 70%, which had been neutralized with phenolphthalein, and shaken well for 1h. After it, the solution was filtered, and 50 mL of filtrate was neutralized with sodium hydroxide 0.1 N. Phenolphthalein was used as an indicator (Pharmacopeia, 2020). Then**,** loss on drying was measured by shrink drying method by adding some of the starch to the moisture balance set at 105°C for an automated time, and the weight was precisely weighed until being constant. (Eckelman, 1998; Piotrowski *et al*., 2014; Krisyanella *et al*., 2013; Pharmacopeia, 2020). Furthermore, the ash content was determined using a furnace technique at a temperature of 550°C (Horwitz, Latimer, 2006). Approximately 1 gram of starch, which had been carefully crushed and weighed, was put into a platinum crucible or silicate crucible that had been annealed at 600^{o} ±50°C for 30 min and tarred. The starch was moistened with 1 mL of sulfuric acid, and then heated slowly until it was composed completely. The residue was moistened with 1 mL of sulfuric acid and heated carefully until no white acid was formed and annealed at 600°±50°C until the residue was burned out. The crush was cooled in a desiccator, and weighed carefully, and then the percentage was calculated (Pharmacopeia, 2020).

Assay for toxic chemical content was analyzed using an experimental method, namely atomic absorption spectrometry (AAS) (Badea, 2015; Bj *et al*., 2020). Also, the microbial limit was analyzed including the total aerobic microbial count (TAMC), the total combined molds and yeasts (TYMC), and the absence of *E. coli*, *P.aeruginosa, S. aureus*, *Salmonella sp.,* and *Shigella sp.* (Karanam, *et al*., 2008*;* Convention, 2021).

Besides that, measurement using scanning electron microscopy (SEM) are applied using SEM (JEOL, JSM-6360, Tokyo, Japan) at X70, X1000, and X2000 magnifications was utilized to examine the surface morphology of native and pregelatinized sago starch. (Gaikwad *et al*., 2010; Halim, *et al*., 2012). To determine the flow rate and angle of repose, the flow time test and the silent angle test were employed. The funnel method was used for calculating flow time. (Dreu *et al*., 2016). Also, bulk density and tapped density for the granules were analyzed by applying 10 g powder of sample was put in a 50mL clean, dry measuring cylinder, and the volume, Vo, occupied by the sample without tapping was calculated. The occupied volume was V500 after 500 manual taps. The bulk and tapped densities were determined by dividing the sample's weight and volume by the sample's weight and volume. (Vo and V500, respectively) (Carstensen & Chan, 1977; Achor *et al*., 2015).

The granules were compressed using single-punch tablet press at 7mm and 10 mm scale pressure for upper punch and lower punch consecutively. The granules compactibility was determined using the hardness level of the resulting tablet (Fudholi & Bestari, 2019). Also, for water absorption analysis, water absorption equipment was connected to an electrical balance where an ampoule was placed. The ampoule was filled with water until its surface had the same level as the water surface on the water absorption apparatus tube. Starch samples were placed in a filter paper with a holder in the tube apparatus. A 0.5 g samples were analyzed and the water loss on ampoules after 8 min were determined (Fudholi *et al*., 2021). Then, to determine the infrared spectra of the native and pregelatinized sago starch samples, Fourier transform infrared (FT-IR) spectrophotometer (JASCO FT-IR-4200 type A model) was utilized by using the potassium bromide pellets format mid-infrared region of 400-4000 cm^{-1} (Fanani *et al*., 2010).

Preparation of tablet

The wet granulation method of massing and screening utilized 300 mg of formulation mixtures of active ingredients and excipient. Asetosal was used as the active ingredient. The excipient included lactose, gelatin 10% w/v, magnesium stearate, talcum, and disintegrant agent. Formula 1 contained PSS as a disintegrant agent, compared with Manihot starch and Starch 1500 in Formula 2 and 3. Acetosal, lactose, and disintegration agent mixed in cube mixer were then moistened with gelatin binder solution 10% w/v. The wet masses were granulated by manually passing them through a 10-mesh sieve, dried in a fluidized bed drier, and then sieved again using a 16-mesh sieve. Having been lubricated with magnesium stearate and talcum, the dried granules were crushed using a single punch compression tablet machine (Table I).

The direct compression method of massing and screening used 300 mg of formulation mixtures of active ingredient and excipient. Acetosal was used as the active ingredient and the excipient included magnesium stearate, talcum, and filler-binder. Formula 1 contained PSS as filler-binder, Starch 1500 in Formula 2.

Table I. The formula of direct compression tablet

The formulation using PSS as disintegrant (compared with Manihot starch and starch 1500)				
Formula 1	**Formula 2**	**Formula 3**	**Function**	**Weight/tab (300 mg)**
Acetosal	Acetosal	Acetosal	Active Ingredient	80 mg
Lactose	Lactose	Lactose	Filler	187 mg
PSS	Manihot starch	Starch 1500 (Pregelatinized corn starch)	Disintegrant	30 mg
Gelatin 10%	Gelatin 10%	Gelatin 10%	Binder	*q.s.*
Magnesium stearate	Magnesium stearate	Magnesium stearate	Lubricant dan anti-adherent	0.3 mg
Talcum	Talcum	Talcum	Glidant dan anti-adherent	2.7 mg
The formulation using PSS as filler-binder (compared with starch 1500)				
Formula 1	**Formula 2**		**Function**	**Weight/tab (300 mg)**
Acetosal	Acetosal		Active Ingredient	80 mg
PSS	Starch 1500 (Pregelatinized corn starch)		Filler-Binder	217 mg
Magnesium stearate	Magnesium stearate		Lubricant and anti-adherent	0.3 mg
Talcum	Talcum		Glidant and anti-adherent	2.7 mg

All materials were mixed in a cube mixer, and then they were compressed with a single punch compression tablet machine (Table I). Visual appearance analysis was performed by sampling at least 20 tablets that should be smooth, undamaged, and have a uniform color. Any physical instabilities such as excessive powder, crack or capping, chipping, swelling, discoloration, mottling, crystals appearance on the tablet or container walls were determined (World Health Organization, 2011). Besides that, uniformity of weight was also performed by individually weighing 20 tablets randomly selected and by determining their individual weight compared with the average weight. The deviation standard was then determined (Convention, 2021). The hardness of four tablets was also measured using Monsanto hardness. Each tablet was placed between two anvils and the force that caused each tablet to break was recorded. The mean hardness and standard deviation were calculated (Assefa *et al*., 2020). Friability test also was performed by rotating the tablets at a motor speed of 25 rpm for 4 min. The tablets were dedusted and reweighed (Assefa *et al*., 2020). Then, the disintegration tests of the six tablets were evaluated using the disintegration apparatus (ERWEKA, Germany). Each tablet was placed in the tubes of basket-rack, which were immersed in a beaker containing distilled water maintained at 37±2°C. The time taken for each tablet to disintegrate was recorded. Disintegration time was determined by the latest tablet, which disintegrated (Assefa *et al*., 2020).

Data analysis

Test results have been analyzed compared with requirements defined by certain references including pharmacopeia and other guidelines issued by the authorized body defined in this article. In addition, data analysis for some statistical data has been calculated using a simple statistical calculation such as the calculation of mean and coefficient of variation (CV).

RESULT AND DISCUSSION

Physical and chemical properties of the native sago starch

The requirement analysis of sago starch in this study referred to cassava starch determination on Pharmacopeia (2020) as the sago starch determination is still not listed in this compendial.

The physical and chemical characteristics of native sago starch met the limit requirements (Table II). It is figured out that the microscopic criteria and its identification of NSS samples met the required specifications. The value for ash content, starch acidity, and loss on drying tests was quantified under the limit specifications. The NSS sample also detected insoluble in water and in ethanol as required.

Table II. Physical and chemical characteristics of native sago starch

Type of Assay	Results	Limit Requirements
Microscopic	oval, present individually, circular hilum	oval, present individually, circular hilum
Identification of starch	Blue color after getting Iodium reagent	Blue color after getting Iodium reagent
Ash content (%)	0.187	< 0.6
Starch acidity (mL)	0.51	< 2.0
Loss on drying (%)	12.64	< 15
Solubility in water	Undissolved	undissolved
Solubility in ethanol	Undissolved	undissolved
Pb (lead)	<0.03 mg/kg	≤ 10 mg/kg
Cd (cadmium)	<0.002 mg/kg	≤ 0.3 mg/kg
Hg (mercury)	35.30 µg/kg	≤ 0.5 mg/kg

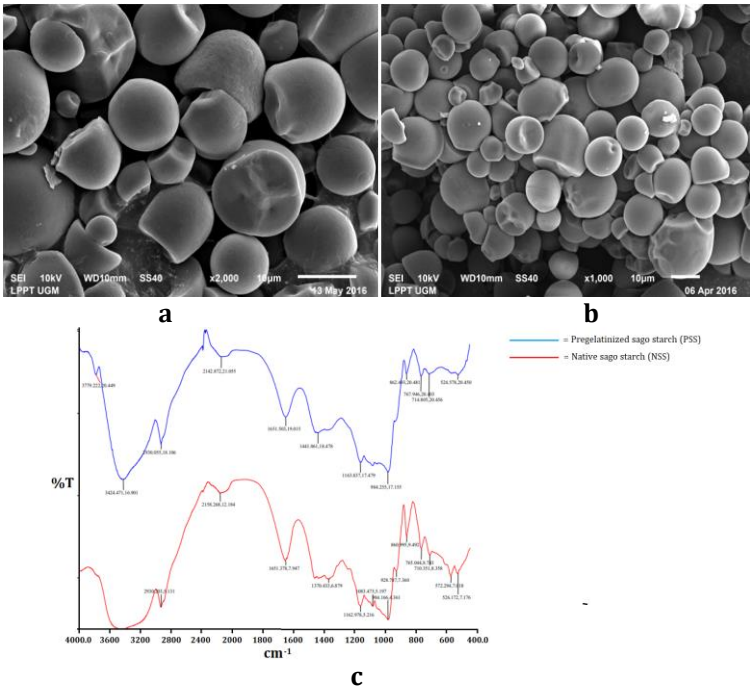

Figure 1. (a) SEM result for native sago starch (NSS) sample on 2000x magnification; (b) SEM result for Pregelatinized sago starch (PSS) on 1000x magnification; (c) Determination result for Pregelatinized Sago Starch as a disintegrant, compared with Cassava Starch and Starch 1500

The quantification of heavy metals (Pb, Cd, and Hg) was carried out using Atomic Absorption Spectrophotometer (AAS) and was detected below the required limit. The NSS sample as oval, truncated, present individually on its circular hilum using 2000x microscope magnification (Figure 1).

The solubility of sago starch in water was tested by mixing one part of sago starch with 10000 parts of water and it resulted in insoluble starch after stirring. Sago starch was shown as compact particles with hydrogen bonds that will not dissolve and break in cold water. Even though sago starch has a hydrophilic carbohydrate chain, it is still difficult to penetrate as starch forms solid and compact particles. A higher temperature and stirring that weaken the hydrogen bonds are required to enable water penetration to starch particles. Also, the solubility of sago starch in ethanol was tested by mixing one part of sago starch with 10000 parts of ethanol and it resulted in insoluble starch after stirring. Similar to its solubility in water, sago starch was also difficult to dissolve in ethanol because of its compact particle and requiring stirring and higher temperature to form a gel-like form.

Table III. Microbiological and heavy metal determination result for pregelatinized sago starch

Type of Assay	Results	Limit Requirements
Pb (Lead)	<0.03 mg/kg	≤ 10 mg/kg
Cd (Dadmium)	<0.002 mg/kg	≤ 0.3 mg/kg
Hg (Mercury)	20.20 µg/kg	≤ 0.5 mg/kg
Total Yeast/Mould Count	<10 cfu/gram	$\leq 10^3$ cfu/gram
Total Aerobic Microbial Count	2x10 cfu/gram	$\leq 10^4$ cfu/gram
E. coli	Negative	Negative
P. aeruginosa	Negative	Negative
S. aureus	Negative	Negative
Salmonella sp.	Negative	Negative
Shigella sp.	Negative	Negative

Iodine reaction was implemented to identify starch content in this study by dispersing sago starch until gelatinization occurred and an opaque solution was formed. The solution was then cooled and added with an iodine reagent resulting in a blue solution. The blue color disappeared when it was reheated, and the dark blue color arose because of the reaction between amylose (a straight-chain compound) with iodine. This reaction was reversible with heating because iodine may be reduced by another reductor due to heating that might cause iodine evaporation. The starch acidity of sago starch samples also met the requirement. Based on Pharmacopeia (2020), not more than 2.0 mL of NaOH 0.1 N is required for a 50.0 mL sample. The sago starch sample in this study required 0.51 mL of titrant, which is under the specification limit.

Loss on drying result shows that the sample met the criteria. Based on Pharmacopeia (2020), not more than 15% is required for loss on drying criteria. While a water content determination test is sufficient to predict water-containing material, loss on drying can be used to determine volatile materials in certain conditions (temperature 105^{o}C). In this study, sago starch had a 12.64% value for this determination. Besides that, starch contains a small number of inorganic substances that can be determined from the residue after stabbing. Starch ash may contain sodium, potassium, magnesium, and metal from calcium. Ash content analysis for this study resulted in 0.187%, which met the requirement in Indonesian Pharmacopeia VI (not more than 0.6%).

In addition, heavy metal requirements from the Indonesian National Agency of Drug and Food Control were fulfilled on PSS samples with the value of the heavy metal being under the required limits for lead, cadmium, and mercury. The negative results for microbial contamination consisting of *E. coli, S. aureus, P. aeruginosa, Salmonella sp., and Shigella sp*. were also detected on pregelatinized sago starch (PSS) samples (Table III).

Physical and chemical properties comparison of the native and pregelatinized sago starch

Pregelatinized sago starch (PSS) particles were stacked together and formed an agglomerate (Figure 1(b)). It can be shown that there is particle size enlargement on pregelatinized sago starch compared with on native sago starch (NSS).

Pregelatinized sago starch particles were found to have a greater diameter compared to native sago starch. It may show that the pregelatinized process increased its particle diameter by enabling water absorption during the heating process to the small spheres and improves the forms to irregular and larger particles. However, extended heating on above gelatinization temperature may expand the starch particle to its maximum dimension and may cause cracking. Also, flowability characterization showed that pregelatinized sago starch provided a larger particle size than native sago starch, which possessed better flowability with 16.67 g/s, angle of repose 32.7^0, and Carr index 24 %. The native sago starch relatively had lower flowability in view of its small particles. The fines produced also may result in electrostatic force between the particles and inhibit particle movement. Based on Šantl *et al*. (2012), fines possessed greater surface area, which may increase the binding rate and may result in a lower flowability rate on more fines.

Table IV. Characterization of Native Sago Starch (NSS) and Pregelatinized Sago Starch (PSS)

Parameter	Native Sago Starch	Pregelatinized Sago Starch
Diameter	10 µm	50-100 µm
Flowability		
Flow rate	No flow	16.67 g/s
Angle of repose	-	32.7^0
Carr's Index	15%	24%
Compactibility	3.56 kg	3.42 kg
Water absorption		
Water absorption rate	3.04 mg/min	172 mg/min
Absorption capacity	1.003 mg/mg	26.56 mg/mg

In this study, compactibility was measured using a hardness level approach. PSS exhibited a lower hardness level than NSS when it was compressed to a tablet (Table IV). Even though it showed that pregelatinized sago starch had a lower value, compatibility analysis for pregelatinized sago starch and native sago starch did not express any significant differentiation from each other. This condition may be described as particle size may impact on compactibility where larger size fraction showed higher compactibility than tablet made of finer size fraction (Šantl *et al*., 2012). Furthermore, pregelatinized sago starch has a greater water absorption ability than native sago starch. It can be shown with its absorption rate of 172 mg/min and water absorption capacity of 6.56 mg/mg. This can be described as starch absorbing the water until its crystal structure is broken and the water then may interact with the starch molecule.

FT-IR study revealed that the starch modification method had no effect on the chemical characteristics of starch. To discover functional groups, the infrared spectra of starch were examined. Each absorption at a certain wavelength indicated the existence of a distinct functional group. The technique yielded an IR intensity (% T) related to wavelength chromatogram signal (cm^{-1}). There was an O-H functional group discovered on the NSS spectrum at wavenumber 3408.95 cm^{-1}, a C-H functional group at wavenumber 2930.20 cm^{-1}, a C-C functional group at wavenumber 2158.26 cm^{-1}, and a C=O functional group at wavenumber 1651.37 cm^{-1}. While in PSS, the O-H group was found at wave number 3424.47 cm^{-1}, C-H at wave number 2930.05 cm^{-1}, C-C at wave number 2142.87 cm^{-1}, and C=O at wave number 1651.50 cm^{-1}.

Preparation of tablet: Pregelatinized Sago Starch (PSS) as disintegrant agent

Acetosal has been used as an active ingredient in pregelatinized sago starch trials. This trial was performed to check the performance of PSS as disintegrant. The result shows that pregelatinized sago starch had a similar performance with Manihot starch and pregelatinized corn starch (starch 1500) by producing similar compressed tablet, which examined by its appearance, weight uniformity (CV less than 5%), hardness, and friability.

Compressed tablet with pregelatinized sago starch as disintegrant exhibited faster disintegration time than a tablet with corn starch (starch 1500) disintegrant, but slower than acetosal tablet with cassava starch disintegrant. Starch acted as disintegrant by capillary mechanism, deformation, and surface contact development with the water. In the compression process, starch was distributed to all parts of the tablet to form a continuous hydrophilic chain. Water was directly absorbed by the tablet through this chain/gate once the tablet contacts the water. Furthermore, pregelatinized sago starch had the greatest capacity to absorb the water and break inter-particle chains.

Preparation of tablet: Pregelatinized Sago Starch (PSS) as filler binder

The study analyzed the performance of pregelatinized sago starch as filler and binder, using acetosal as the active ingredient. Even though it showed a slightly lower on hardness level, tablets using PSS as filler-binder showed similar results on tablet appearance and weight uniformity with tablets using pregelatinized corn starch (starch 1500) (Table V).

Table V. Determination result for Pregelatinized Sago Starch as a disintegrant, compared with Cassava Starch and Starch 1500 and Determination Result of Pregelatinized Sago Starch as filler-binder, compared with Starch 1500

Determination result for Pregelatinized Sago Starch as disintegrant			
Response	**Pregelatinized Sago Starch**	**Manihot Starch**	**Starch 1500**
Tablet Appearance			
Color	White	White	White
Thickness	3.76 mm	3.72 mm	3.88 mm
Diameter	9.10 mm	9.10 mm	9.10 mm
Weight Uniformity			
Mean	300.3±2.49mg	300.85±2.62mg	301.65±3.03mg
CV	0.83 %	0.87 %	1.00 %
Hardness	6.22 kg	6.24 kg	6.1 kg
Friability	0.55 %	0.72 %	0.61 %
Disintegration Time	8.23 min	5.22 min	25.12 min
Determination Result of Pregelatinized Sago Starch as filler-binder			
Response	**Pregelatinized Starch**	**Starch 1500**	
Tablet Appearance			
Color	White	White	
Thickness	3.79 mm	3.79 mm	
Diameter	9.26 mm	9.23 mm	
Weight Uniformity			
Mean	298.3±2.98 mg	297.8±1.70 mg	
CV	0.99 %	0.57 %	
Hardness	2.68 kg	2.86 kg	
Friability	5.01 %	3.36 %	
Disintegration time	43.63 s	562.2 s	

Statistical analysis on weight uniformity showed that they had similar weight uniformity (CV less than 5%).

The friability study observed that pregelatinized sago starch exhibited a more friable tablet (5.01 %) than the tablet using starch 1500 (3.36%) as filler-binder. It may be explained by its lower hardness level, which may produce a softer compact tablet than the tablet using starch 1500 as filler-binder. A further study is needed to advance PSS performance as filler-binder with improved friability profile and may explore the pregelatinized sago starch usage as filler and binder independently.

From hardness level and friability results, tablets with pregelatinized sago starch as filler-binder exhibited shorter disintegration time than a tablet with corn starch (starch 1500) as filler-binder. This disintegration profile may be useful to be implemented for the fast-disintegrating tablet such as oral disintegrating tablets and effervescent tablets.

CONCLUSION

Pregelatinized sago starch (PSS) produced from native sago starch (NSS) was demonstrated as a potential material for pharmaceutical excipients especially disintegrant and filler binder for direct compression tablets. In comparison to NSS, the properties of PSS including flowability, water absorption rate, and absorption capacity showed a number of increasing profiles. It is likely because PSS in comparison to NSS has a larger particle size and it is easier to interact with water. Furthermore, there was no microbial contamination detected in PSS indicating that PSS has followed regulatory requirements. Although the friability result of the compressed tablet using PSS as filler-binder did not meet the specification, some parameters such as weight uniformity, hardness, and disintegration time of the compressed tablets using PSS as disintegrant showed a satisfactory result. Thus, it comprises that PSS can be potentially utilized as the disintegrant or filler-binder with further improvements in solid dosage form formulation.

To capitalize on PSS for direct compression tablet formulation, it is necessary to resolve the issue surrounding the friability process. Future research should be directed towards PSS opportunities for pharmaceutical excipient on another manufacturing method including wet granulation and dry granulation process.

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