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Assessment of Pregelatinized Corn Starch (Zea mays L.) as an Excipient in Pharmaceutical Preparations

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ABSTRACT

Indonesia has a large potential for corn starch production since corn is one of the most widely grown foodstuffs. In addition to being a food ingredient, corn also has the potential as an excipient in pharmaceutical preparations because of its very high starch content, which is 72-73% of the total weight. In tablet preparations, starch is widely used as a binder, disintegrant, and filler. One of the weaknesses of starch is its poor mechanical properties. Pregelatinization is one of the physical modification methods that can improve the mechanical properties of corn starch. The purpose of this study was to determine the effect of pregelatinized corn starch on the physical, chemical, and mechanical properties. Pregelatinized corn starch was prepared as follows: 250 g of starch was added to 250 mL of distilled water, heated at 70°C for 20 minutes, stirred until thick, dried in a drying cabinet at 60°C for 24 hours, and sieved through a 16/18 mesh sieve. The starch was tested for its physical, chemical, and mechanical properties. The results showed that the pregelatinized corn starch base on physical, microscopic and functional properties better than native corn starch in the formulation composition or process.

***Keywords*:** Corn starch, Pregelatinized, Microscopic properties, Physical properties, FTIR Analysis

INTRODUCTION

Indonesia has a large potential for corn flour production and corn is one of the most widely grown foodstuffs in Indonesia. According to data from the Central Statistics Agency, in 2020, corn production in Indonesia reached 29.52 million tons. Corn is a strategic commodity and has the potential to be developed because of its position as the main source of carbohydrates and protein after rice. Corn starch consists of amylose and amylopectin. Starch is the main component in corn kernels, around 72-76% of the total weight. The amylopectin content in corn is generally 70-75% while the amylose content is around 25-30% and for glutinous

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corn it usually contains up to 100% amylopectin.[1]

Corn starch is generally used in the food sector, whereas corn starch can be used as an excipient in pharmaceutical preparations. Corn starch has advantages over other materials because it is easy to obtain, relatively cheap compared to other types of starch and is inert. In pharmaceutical preparations, the amylose content in corn starch is able to absorb water so that it affects the development process, so it can be used as a disintegrant, in addition the high amylopectin content will cause corn starch to be sticky, so it can be used as a binder because it is able to form aggregates through the binding process between particles.[2]

Starch commonly used in the pharmaceutical industry is divided into 2, namely natural starch and modified starch. Natural starch (native starch) is starch produced from tubers and has not undergone changes in physical and chemical properties or has been processed physicochemically. The disadvantages of native starch used as an excipient in tablets can affect the physical properties of granules, namely having poor flow and compactibility properties. Therefore, modification is necessary. In general, there are several modification methods, namely physical, chemical, and enzymatic. Physical modification of starch is easier to use because it does not require chemicals, enzymes and microorganisms.[3]

One of the physical modifications that can be done is pregelatinization. Starch modification will cause differences in physical and chemical characteristics between natural starch and pregelatinized starch. The starch granules will expand in water, so that the flow and compressibility properties of the starch will improve.[4] The advantages of this pregelatinization modification are that it is more efficient and does not require too many ingredients, because the processing is simple, namely by adding water and heating at the right temperature.

In this study, corn starch was modified using the preglatination method and its characteristics as an additive in pharmaceutical preparations were compared with natural corn starch. Pregelatinized corn starch is expected to have better physical, chemical, and mechanical properties as an excipient, especially as a filler-binder and disintegrant in tablet preparations[5].

METHODS

Materials

Native corn starch (DAESANG) and distilled water.

Equipment

Analytical balance (SHIMADZU), Scanning Electron Microscope (SEM) (Phenom Pro X Desktop SEM with EDX, Netherlands), Frontier FT-IR, pH meter (Methorm), hot plate, mortar and stamper, 16 and 18 mesh sieves, Furnace (Ney Vulcan D-130) and oven (Memmert type UM 400).

Pregelatinization Corn Starch

Two hundred and fifty grams of corn starch plus 250 mL of distilled water, heated to a temperature of 75°C for 20 minutes. The mass is stirred using a magnetic stirrer until thick, then dried using a drying cabinet at a temperature of 60°C for 24 hours. After drying, it is sieved using a 16 and 18 mesh sieve.[6]

Evaluation of Starch Characterization Organoleptic

Organoleptic testing is carried out by observing the physical appearance including shape, color, and odor.

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Microscopic

The starch sample is attached to the specimen holder. Then it is inserted into the SEM tool. The resulting photo capture from the SEM is analyzed at 1500x and 7500x magnifications.[7]

FTIR

The starch sample is added with KBr powder, stirred evenly. The mixture is pressed using a mechanical pressure tool. After the KBr plate is formed, it is analyzed using FTIR.[7]

pH

Starch is weighed 1 g and dispersed into 10 mL of distilled water and measured using a pH meter.

Water Content

Starch was weighed as much as 1 g, then dried in an oven at a temperature of 105°C for 5 hours, the water content was calculated from the weight lost during drying.[7]

Ash Content

Amylum was weighed as much as 1 g and placed in a crucible, heated in a mufel at a temperature of 500-600°C for 4-5 hours until white ash was formed.[7]

Solubility

Amylum was made into a suspension by weighing 2.5 grams of material, put into a 50 mL measuring flask, and adding distilled water. The suspension was taken 10 mL, put into a centrifuge tube and heated at a temperature of 60°C for 30 minutes, then centrifuged at a speed of 4000 rpm for 15 minutes. The supernatant obtained was separated from the sediment, the sediment was weighed. The precipitate was dried at 105°C for 1 hour and weighed.[8]

Swelling Power

Amylum was weighed as much as 2.5 g and added with 10 mL of distilled water. The starch suspension was left for 1 hour and continued with the heating process at a temperature of 65°C for 30 minutes. The precipitate obtained was weighed as the increase in mass during the swelling process.[8]

Flow Properties

The flow properties test was carried out using the flow funnel method. The starch powder was weighed 100 g, then put into the funnel. The funnel cap was opened simultaneously with the calculation of the flow time until all the powder passed through the funnel cap.[9]

Angle of Repose

The angle of repose test uses a fixed cylinder with a support. The powder is put into the cylinder, the cylinder cap is opened, and the powder mixture will come out so that a pile is formed on the support. The angle of repose (α) is determined by calculating the radius (r) and height of the pile of powder mixture (h) with the formula[9]:

$$\mathbf{Tan\ \alpha} = \frac{h}{r}$$

Compressibility

The compressibility test is carried out using a volumenometer. The powder is put into a 100 mL measuring cup. The initial volume (V0) is calculated, then the device is turned on until there is no reduction in volume. The final volume (Vf) is recorded and the percent compressibility (I) is calculated with the following calculation[9]:

$$I = \frac{V0-Vf}{V0} \times 100\%$$

Analytical Data

The physical and chemical properties of starch were analyzed statistically using the t-test at a 95% confidence level using

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SPPS 25 software. The organoleptic, SEM, and FTIR properties of starch were analyzed descriptively according to relevant literature.

RESULTS AND DISCUSSION

Characterization of starch includes organoleptic properties, FT-IR analysis, physical properties, and mechanical properties. The test results are presented in Table 1.

Table 1. Characterization of corn starch

Parameters	Type of Starch	
	Native corn starch	Pregelatinized corn starch
Form	Powder	Granule
Color	White	White
Odor	Special	Special
pH	6.94±0.006	6.65±0.006
Water content (%)	6.68±0.158	8.58±0.047
Ash content (%)	0.26±0.0001	0.43±0.0002
Solubility (%)	1.62±0.001	2.34±0.001
Swelling power (%)	78.90±0.007	93.32±0.021
Flowability (g/s)	0.69 ±0.028	15.32 ±0.466
Ange repose (°)	61.21±0.000	38.65±0.00
Compresibility (%)	21.66±0.577	8.66±0.577

Organoleptic examination aims to ensure the truth of the starch used according to its physical characteristics. The results of the organoleptic test in Figure 1 show that native corn starch and pregelatinized corn starch are white, odorless, and tasteless, this is in accordance with the provisions of the Indonesian Pharmacopoeia edition VI (2020).[10] Pregelatinized corn starch is in the form of granules with a larger particle size than native corn starch.

(a) **(b)**

Figure 1. Native Corn Starch (a) and Pregelatinized Corn Starch (b)

Microscopic properties

Microscopic tests of corn starch were carried out using SEM at 7500x and 1500x magnifications. At 7500x magnification (Figure 2), native corn starch and pregelatinized corn starch both have many square and angular shapes, but pregelatinized starch has more pores. At 1500x magnification (Figure 3), pregelatinized corn starch has particles that are very close together and clustered when compared to native corn starch which still has empty cavities. This is in line with the research of Sulaiman et al. (2022) which states that Pregelatinized starch has a larger particle size.[11] This happens because the starch swelling process is caused by the absorption of water into the starch and heating at the optimum temperature during the gelatinization process, causing the starch granules to break and the shape of the granules no longer looks smooth.[12]

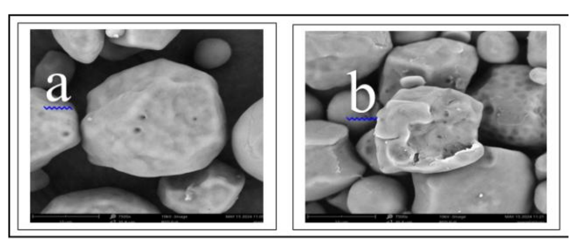


Figure 2. SEM 7500x magnification of native corn starch (a) and pregelatinized corn starch (b)

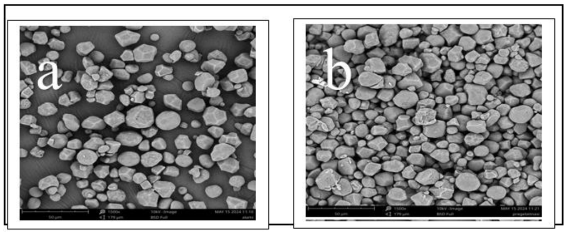
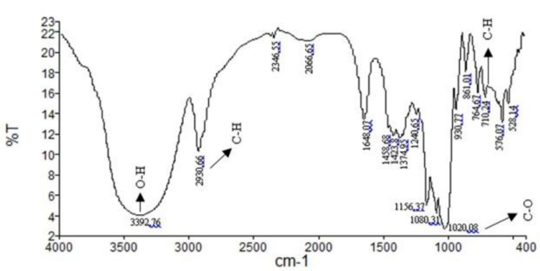


Figure 3. SEM 1500x magnification of native corn starch (a) and pregelatinized corn starch (b)

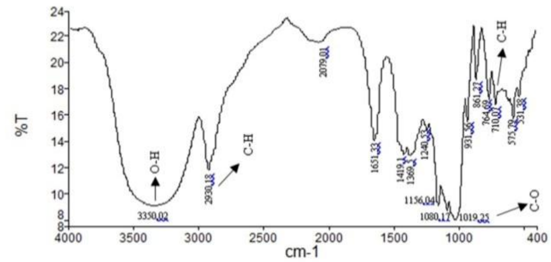
FT-IR analysis

Table 2. FT-IR analysis of corn starch[13]

Wave number (cm^{-1})		Functional group
Native Corn Starch	Pregelatinized Corn Starch	
710.07	710.24	C-H Aromatic
764.67	764.69	C-H Aromatic
861.01	861.27	C-H Aromatic
930.77	931.56	C-H Alkene
1019.25	1020.08	C-O Esther
1080.31	1080.17	C-O Esther
1156.37	1156.04	C-O Esther
1240.65	1240.53	C-O Esther
1374.95	1369.5	C-H Alkanes
1423.8	1419.1	C-H Alkene
1458.68	-	C-H Alkene
1648.07	1651.33	C=H Aromatic
2066.65	2079.01	C=C Alkynes
2346.55	-	C=C Alkynes
2930.18	2930.66	C-H Alkanes
3392.76	3350.02	O-H Alcohol



(a)



(b)

Figure 4. Fourier transform infrared (FT-IR) spectroscopy analysis of Native Corn Starch (a) and Pregelatinized Corn Starch (b)

The results of FT-IR analysis of native corn starch and pregelatinized corn starch consist of several components including amylose and amylopectin which are compounds composed of C-H, C-O, O-H bonds and also aromatic C-H bonds. Based on the data in Figure 4 and Table 2, it shows the difference, namely the loss of the O-H group at wave numbers 2346.55 cm^{-1} and C-H 1458.68 cm^{-1} in pregelatinized corn starch. This is due to the breaking of hydrogen bonds in pregelatinized starch. Although the hydrogen content in pregelatinized starch is higher, pregelatinized starch undergoes a heating process that causes the breaking of hydrogen bonds so that it can affect the intensity of the absorption band.[14]

pH

Measurement of pH on pregelatinized corn starch was carried out to ensure that the starch is safe to use as a pharmaceutical additive and to maintain the stability of the starch during storage. The pH value of native corn starch was obtained at 6.94, while pregelatinized corn starch was 6.65. These values meet the requirements according to the Indonesian National Standard (2018) which is 4.5 - 7.0.[15] Based on the t-test, it shows significantly different results for the pH of native corn starch and pregelatinized corn starch where the T-count value> T-table of 60.881> 2.776 and the resulting sig value is 0.00 where these results indicate good results because they are less than 0.05. Pregelatinized corn starch has a lower pH than natural corn starch due to the heating process of pregelatinization modification.

Water content

The average water content of pregelatinized corn starch is 8.58%, while native corn starch has an average water content of 6.68%. This value meets the water content requirements according to the Indonesian National Standard (2018) which is less than 10%.[15] Products in the form of flour are recommended to have a low water content, because flour is very susceptible to mold growth during the storage process. Based on the t-test, the results showed a significant difference in the water content of natural corn starch and pregelatinized corn starch where the T-count value> T-table of 19.961> 2.776 and the resulting sig value of 0.00 where the results indicate good results because it is less than 0.05. The increase in water content of pregelatinized corn starch due to pregelatinization treatment by boiling will result in water absorption and starch granules becoming swollen.[16] Hydrogen bonds in the granules will weaken due to heating during the gelatinization process, so that the size of the granules becomes large and irreversible. After the gelatinization temperature is reached, the granules break so that water can come out.

Ash content

Ash content test is conducted to show the content of inorganic materials in the material. Inorganic materials can form complex compounds that can cause deposits that have the potential to prevent the reaction in starch modification. The average ash content of natural corn starch is 0.26% while the average pregelatinized corn starch has an ash content of 0.43%. These parameters meet the ash content requirements according to the Indonesian National Standard (2018) which is a maximum of 1.5%.[15] Based on the t-test, it shows significantly different results for the flow properties of native corn starch and pregelatinized corn starch where the T-count value> T-table of 16.152> 2.776 and the resulting sig value is 0.00 where the results indicate good results because it is less than 0.05. The increase in the ash content of pregelatinized corn starch occurs due to the heating treatment in the pregelatinized starch modification process.

Solubility

The average value of the solubility of pregelatinized corn starch is 2.34% while for native corn starch it is 1.62%. Based on the t-test, it shows a significant difference in the solubility of native corn starch and pregelatinized corn starch where the T-count value> T-table of 1081.572> 2.776 and the resulting sig value 0.00 where the results indicate good results because they are less than 0.05. These results show a significant difference because the increase in the solubility of pregelatinized starch is thought to be caused by an increase in temperature which produces heat and as a result the hydrogen bonds will be broken so that shorter chains are produced from the broken starch fraction. This condition produces starch that is easily soluble because it has a smaller molecular size. Starch granules will break with continued heating. This causes the water in the starch granules to easily come out and enter the solution system together with water-soluble starch molecules.[17]

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Swelling power

The average value of the swelling power of pregelatinized corn starch is 93.32%, while native corn starch is 78.90%. The swelling power of this corn starch is higher than that of banana kepok starch (42.55-43.96%) and its modified results, both cross-link (52.24%) and co-process cross-link (69.02%).[18] The results of the t-test showed significantly different results for the swelling power of native corn starch and pregelatinized corn starch where the T-count value> T-table of 1131.462> 2.776 and the resulting sig value of 0.00 where the results indicate good results because they are less than 0.05. These results show a significant difference, because pregelatinized corn starch has a higher swelling power than native starch, because the temperature used will affect the increase in swelling power.

The swelling power is related to the formation of hydrogen bonds so that water is bound by starch molecules.[16] During gelatinization, the crystal structure of starch is disrupted due to the breaking of inter- and intra-molecular hydrogen bonds, resulting in changes in the binding ability of starch to water.[19] The pregelatinization process causes the weakening of intramolecular hydrogen bonds and decreases the interaction between amylose and amylopectin molecules and between amylopectin chains. The weakening of the bond is accompanied by the formation of a smaller stable structure and increased leaching of amylose molecules, which causes an increase in the surface area of the particles and water infiltration.[20] The hydrogen bonds between the starch molecules will be broken after gelatinization, and hydrogen bonds with water are formed instead. This results in increased development of starch granules in the gelatinization process. Ultimately, there is an increase in swelling power because the starch granules expand and more water is absorbed into the starch granules.

Mechanical properties

The results of the mechanical properties test of pregelatinized corn starch showed improvements in the mechanical properties of the material. This is indicated by the increase in the flow and compressibility properties of pregelatinized corn starch. Modification with the pregelatinization method has been proven to be able to improve the mechanical properties of corn starch.

The value of the flow rate test of pregelatinized corn starch showed very good flow properties, namely 15.32 g/s, while for native starch it has poor flow properties, namely 0.70 g/second. Based on these results, pregelatinized corn starch meets good flow properties, namely ≥ 10 g/s (free flowing). Based on the t-test, it shows significantly different results for the flow properties of native corn starch and pregelatinized corn starch where the T-count value> T-table of 54, 401> 2.776 and the resulting sig value is 0.00 where the results indicate good results because it is less than 0.05. The increase in the flow rate of pregelatinized corn starch is due to the pregelatinized corn starch having a larger particle size. The gelatinization process can improve flow properties by changing the shape and size of the starch. The larger the particle size, the faster the flow rate will be. Meanwhile, if the particle size is small, it will affect the density between particles to fill the space, causing the mass to become compressed and the flow rate to decrease.[20]

The flow properties of corn starch are also measured by the angle of repose. The results obtained from testing the angle of repose of native corn starch are 61.210, while pregelatinized corn starch is 38.650. Based on the t-test, it shows significantly different results for the angle of repose of native corn starch and pregelatinized corn starch where the T-count value> T-table of 136.079> 2.776 and the resulting sig value is 0.00 where the results indicate good results because they are less than 0.05. Based on these parameters, pregelatinized corn starch shows good flow properties with an angle of repose of 25-40°.[9] This is because the particle size of pregelatinized native corn starch is larger and has lower cohesive properties, thus forming a smaller angle of repose.[21]

The compressibility index value of native corn starch is 21.66%, while the compressibility index result of pregelatinized corn starch is 8.66%. The requirement for granules that have good flow properties is with a compressibility index of less than 20%.[9] Based on the t-test, it shows significantly different results for the compressibility of natural corn starch and pregelatinized corn starch where the T-count value> T-table of 27.577> 2.776 and the resulting sig value is 0.00 where the results indicate good results because they are less than 0.05. Pregelatinized corn starch has a good compressibility index value. This compressibility index depends on how the starch is able to compress more tightly. This is influenced by the particle size and the number of fines contained in the powder. Pregelatinized corn starch with a larger particle size compresses faster with a higher final volume due to the lower gap between particles, resulting in a lower compressibility index.

CONCLUSION

The results showed that pregelatinated corn starch was granular, white in color, and had a distinctive odor. Compared to native corn starch, pregelatinated corn starch had a lower pH but showed higher water content, ash content, solubility, and swelling power. Pregelatinated modification was able to improve the flow properties and compressibility of corn starch.

Conflict of Interest

The authors declare no conflict of interest.

Authors' Declaration

The authors hereby declare that the work presented in this article is original and that any liability for claims relating to the content of this article.

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