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Co-Processed Corn Starch (*Zea mays* L.) as a Novel Pharmaceutical Excipient: Development and Physicochemical Characterization

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Abstract: Corn starch (*Zea mays* L.) is widely used as a pharmaceutical excipient because of its biocompatibility, biodegradability, and non-toxicity. However, its application is limited by poor flow properties, low water solubility, and a tendency toward retrogradation, which may reduce its effectiveness in solid dosage formulations. Although pregelatinization has been used to improve starch functionality, studies on the combined application of pregelatinization and co-processing with sodium starch glycolate (SSG) remain limited. Therefore, this study aimed to develop and characterize co-processed pregelatinized corn starch as a novel pharmaceutical excipient. Pregelatinized corn starch (PCS) was prepared and co-processed with SSG at ratios of 1:1, 1:2, and 1:3 (g/g). The resulting powders were characterized using X-ray diffraction (XRD), differential scanning calorimetry (DSC), Fourier-transform infrared spectroscopy (FTIR), scanning electron microscopy (SEM), and particle size analysis (PSA). Powder properties, including flow rate, angle of repose, moisture content, and bulk density, were also evaluated. The co-processed formulations exhibited diffraction peaks at approximately 23°, indicating structural modification. DSC analysis showed enhanced thermal stability, with transition temperatures ranging from 63.78 °C to 96.50 °C. FTIR confirmed physical interactions without the formation of new chemical bonds. The flow rate increased from 0.472 g/s in native corn starch to 3.852 g/s in F3, while the angle of repose decreased from 37.38° to 24.1° in F1. Overall, co-processing improved the physicochemical and functional properties of corn starch, demonstrating its potential as a multifunctional pharmaceutical excipient for solid dosage forms.

Introduction

The selection of raw materials (excipients) is a crucial part of the preformulation and formulation process. The chemical and physical properties of excipients significantly influence the quality of the resulting preparation (1). Excipients are derived from natural materials such as minerals, plants, and animals that have undergone complex purification and characterization processes to ensure their safety and non-toxicity (2). Excipients in Indonesia are generally imported from abroad to meet the pharmaceutical industry's needs, including starch, a key excipient in pharmaceutical preparations (3). Starch is readily available at a lower price. Starch is also widely used because it is inert and can be mixed with all drugs without causing chemical reactions (4).

Corn starch (CS) is widely recognized as one of the most commonly used excipients. CS exhibits high biocompatibility, biodegradability, non-toxicity, and bioavailability (5). CS at concentrations of 3-15% w/w plays a role in increasing the bioavailability of drugs in tablets through its ability to swell in water, which is associated with the amylose content of approximately 28% in corn kernels (6). However, the use of corn starch has limitations, such as insolubility in water and a tendency to retrograde (7). These limitations require modification through pregelatinization to produce starch with better properties and capabilities (8). Pregelatinization modifies the physicochemical structure of starch through high pressure, temperature, and friction, resulting in granule rupture and triggering physical swelling (9). This process breaks the strong hydrogen bonds between amylose and amylopectin molecules that form crystalline regions, resulting in starch becoming more amorphous (irregular), thereby increasing starch solubility (10). This reduction in crystallinity is directly correlated with an increase in surface area, as well as the starch's enhanced ability to

absorb water more quickly and in greater quantities. Pregelatinized starch exhibits significantly better solubility and swelling properties in cold water compared to unpregelatinized starch (11).

Efforts to optimize the physical properties and physicochemical characteristics of pregelatinized corn starch (PSC) require modification through co-processing. Co-processing is a method of combining two or more compendial or non-compendial excipients to modify physical properties without changing the chemical composition (12). This co-processing method will combine PCS: SSG. SSG has a high expansion power at a concentration of 2-8% which can expand 7-12 times in <30 s with a swelling power of up to 200-300% in water. The open structure of corn starch granules during the pregelatinization process enables SSG, which has carboxymethyl groups, to enhance water absorption (13). Water can easily enter the PCS matrix and bind to the hydrophilic groups of SSG due to the osmotic pressure exerted by the sodium ions in the glycerol sodium salt (1). The interaction between the amylose and amylopectin starch components occurs through hydrogen bonds due to the presence of hydroxyl groups. Amylopectin and SSG form a complex, three-dimensional branched structure, which has the potential to increase the viscosity of the mixture. This property allows SSG to absorb and physically expand rapidly when exposed to water (14). Pregelatinization partially disrupts the crystalline regions of starch granules, resulting in a more porous structure with increased water accessibility and improved compressibility. However, pregelatinized starch alone may still exhibit limited swelling capacity and suboptimal flowability for direct compression applications. Sodium starch glycolate (SSG), a cross-linked carboxymethyl starch, is widely used as a superdisintegrant because of its exceptional water absorption and swelling capacity. Combining pregelatinized corn starch with SSG through co-processing is expected to integrate the open matrix of pregelatinized starch with the rapid swelling behavior of SSG, thereby enhancing powder flow, water uptake, and overall functionality as a pharmaceutical excipient. Therefore, this study systematically investigated PCS ratios of 1:1, 1:2, and 1:3 (g/g) to evaluate the influence of SSG concentration on the physicochemical properties of the co-processed excipient. Furthermore, the selected ratios were considered sufficiently distinct to reveal compositional effects while maintaining PCS as a major component of the formulation. As this study was exploratory in nature, the ratios were chosen to cover a practical experimental range and to establish a preliminary understanding of the influence of PCS: SSG composition.

Experimental Section

Materials

The materials used in this study were local yellow corn (*Zea mays* L.), Sodium Starch Glycolate (SSG) USP45 (Maize), iodine, aluminum foil (Bagus brand), distilled water, and Toyobo cloth. The tools used in this study were X-Ray Diffractometer (XRD) D8 Advance ECO (Bruker), Differential scanning calorimetry (DSC) (Netzsch 214 Polyma®), Faurier Transform Infrared (FTIR) (Bruker Tensor 27), Oven (Memmert UN55), Homogenizer D160), Blender, Hot plate (Nesco H280 Pro), Analytical balance (*Fujitsu*®), Sieve no. 20, 40, and 80 mesh, stopwatch, mortar, stamfer, and Laboratory glassware (*Pyrex*).

Preparation of Corn Starch

Twenty kg of locally grown yellow corn kernels that had been separated from the cobs were weighed and washed thoroughly under running water. The cleaned kernels were soaked in water for 12 h and subsequently ground using a blender until a homogeneous slurry was obtained. The slurry was diluted with distilled water and filtered through a cloth to separate the fibrous residue. The filtrate was allowed to stand at 37 °C for 12 h to facilitate starch sedimentation. After sedimentation, the supernatant was carefully removed, and the starch sediment was washed three times with distilled water. The purified starch sediment was dried in an oven at 50 °C for 48 h. The dried starch was then sieved through a 40-mesh sieve and stored in an airtight container until further use (15).

Pregelatinization Corn Starch

Five hundred g of pure corn starch were weighed and dispersed in 500 mL of distilled water to obtain a 1: 1 (w/v) suspension. The suspension was heated on a hot plate at 55 °C under continuous stirring for 50 min to induce starch pregelatinization. The resulting pregelatinized starch was dried in a hot-air oven at 60 °C for 48 h. After drying, the material was milled gently, if necessary, and sieved through an 80-mesh sieve to obtain a uniform particle size (16).

Co-process Corn Starch

Pregelatinized corn starch (PCS) and sodium starch glycolate (SSG) were weighed at PCS ratios of 1:1, 1:2, and 1:3 (w/w). Each material was separately dispersed in an appropriate volume of distilled water to obtain homogeneous slurries. The PCS and SSG slurries were heated on a hot plate at 80 °C for 30 min. Subsequently, the SSG slurry was gradually added to the PCS slurry while stirring at 300 rpm for 20 min until a homogeneous mass was obtained. The resulting homogeneous mass was dried in a hot-air oven at 40 °C for 72 h. After drying, the co-processed starch was sieved through a 60-mesh sieve and stored in a screw-capped container until further characterization.

Co-process Corn Starch Characterization

X-Ray Diffractometer (XRD)

A 10 mg sample was weighed and placed into a glass sample holder. The sample surface was carefully leveled to ensure uniform packing before analysis. The sample holder was then positioned in the X-ray diffractometer, and diffraction patterns were recorded at room temperature over a 2θ range of 5°–50° using an operating voltage of 40 kV and a tube current of 40 mA (17).

Differential Scanning Calorimeter (DSC)

A 5 mg sample was weighed and placed into an aluminum crucible, which was subsequently positioned in the differential scanning calorimeter (DSC). Thermal analysis was performed at a heating rate of 10 °C/min over a temperature range of 25 – 500 °C to accurately determine phase transitions and melting behavior (18).

Table 1. Corn starch yield result.

Type of starch	Weight of corn	Starch weight	Yield (%)
Natural corn starch	50 kg	7.5 kg	15

Fourier Transform Infrared (FTIR)

A 1 mg sample was analyzed using the potassium bromide (KBr) pellet method. A 1% (w/w) sample–KBr mixture was prepared by thoroughly grinding the sample with spectroscopic-grade KBr in an agate mortar until a homogeneous powder was obtained. The mixture was then compressed using a hydraulic press under vacuum to form a transparent pellet. The pellet was placed in the sample holder of the Fourier transform infrared (FTIR) spectrometer, and the infrared spectrum was recorded over the wavenumber range of 4000–400 cm^{-1} (19).

Scanning Electron Microscopy (SEM)

The samples were dispersed in ethanol and allowed to dry after being deposited onto aluminum stubs using double-sided conductive adhesive tape. The mounted samples were sputter-coated with a thin layer of gold prior to observation. The surface morphology of the starch granules was examined using a scanning electron microscope (SEM) at magnifications of 100×, 200×, 400×, and 1000×. The dimensions of the starch granules were measured using ImageJ software (Version 1.5.2) based on the calibration scale provided in the SEM micrographs. For each sample, three of the smallest granules and three of the largest granules were selected, and their lengths were measured. The average granule length was then calculated (20).

Particle size analysis (PSA)

Particle size analysis (PSA) was performed to determine the particle size distribution of the co-processed starch. Measurements were carried out using a Shimadzu SALD-2300 particle size analyzer (WingSALD II, Version 3.4.4) equipped with a High Concentration Cell. The samples were analyzed using the wet dispersion method, in which the co-processed starch powder was dispersed in an appropriate liquid medium to minimize particle agglomeration and ensure that individual particles were measured (21).

Powder Evaluation

Organoleptic

Organoleptic tests include shape, color, taste, and smell (22).

Angle of Repose and Flow Rate

For the angle of repose determination, 100 g of the sample was placed into the funnel of a powder flow tester with the outlet initially closed. The outlet was then opened, allowing the powder to flow freely onto a flat surface covered with graph paper and form a conical pile. The height and radius of the powder cone were measured, and the angle of repose was calculated. The flowability of the powder was considered acceptable when the angle of repose was within the range of 25° - 40° (22). For the flow rate determination, 100 g of the sample was placed into the funnel of the powder flow tester until approximately two-thirds of the funnel volume was filled. The outlet was then opened, allowing the powder to flow freely through the funnel orifice. The time required for the entire sample to pass through the funnel was recorded using a stopwatch. The powder was considered to exhibit acceptable flow properties when the flow time did not exceed 10 s (23).

Specific Gravity

A 40 g sample of powder was placed into a 250 mL graduated cylinder, and the initial bulk volume (V_0) was recorded (23).

Water Content

A 5 g sample was placed in a moisture analyzer. The sample was analyzed at a drying temperature of 110 °C for 15 min, and the moisture content was recorded automatically by the instrument. The moisture content was considered acceptable when it was within the range of < 1 - 5% (23).

Statistical Analysis

All experiments were conducted in triplicate, and the results were expressed as mean ± standard deviation (SD). Statistical analysis was performed to evaluate differences among native corn starch (CS), pregelatinized corn starch (PCS), and co-processed formulations (F1, F2, and F3). Data were analyzed using one-way analysis of variance (ANOVA), followed by Tukey's *post hoc* test for multiple comparisons when significant differences were observed. Statistical significance was established at a confidence level of 95% ($p < 0.05$). All statistical analyses were carried out using IBM SPSS Statistics version 26.0.

Results and Discussion

Corn Starch Yield

Corn starch yield was obtained using a wet extraction method from natural materials, which measured the weight of the raw material before and after the process. The resulting data showed that CS from 50 kg of corn yielded a yield of 15%. The yield results can be seen in **Table 1**.

Screening was carried out to identify the presence of starch in CSsamples with an iodine test that showed a color change from cloudy white to purplish blue, which means that the CS sample contains starch. The iodine test was performed to confirm the presence of starch and evaluate whether the pregelatinization and co-processing treatments altered its fundamental molecular structure. The characteristic blue coloration observed after the addition of iodine solution is attributed to the formation of an inclusion complex between amylose and polyiodide ions rather than a chemical reaction. In aqueous potassium iodide solution, iodine forms polyiodide species (I_3^- and I_5^-), which are accommodated within the hydrophobic cavity of the amylose single-helix structure through non-covalent interactions. The resulting amylose–iodine inclusion complex is responsible for the characteristic blue color of starch. The persistence of the blue coloration in all

Table 2. Co-process comparison PCS:SSG.

Formulas	Starch	Polymer	Comparison
F1	PCS	SSG	1: 1
F2	PCS	SSG	1: 2
F3	PCS	SSG	1: 3

formulations indicates that the helical structure of amylose was largely preserved following pregelatinization and co-processing with sodium starch glycolate (SSG). This finding suggests that the modification process predominantly involved physical changes, including granule swelling, partial disruption of intermolecular hydrogen bonds, and molecular rearrangement, without altering the fundamental chemical structure of starch. These results are consistent with the FTIR analysis, which showed no evidence of new covalent bond formation after co-processing, confirming that the interaction between pregelatinized corn starch and SSG was primarily physical in nature.

This is because the amylose content in corn starch is a component that has a straight chain structure that can form inclusions with iodine molecules (I2) and iodide ions (I-) in iodine solution. In the evaluation of CS powder, it has a flow rate of 0.472 (g/s), an angle of repose of 32.45, a water content of 0.66%, and a specific gravity of 0.53 (g/mL).

Pregelatination

Pregelatinized CS, heated and in the presence of water during the pregelatinization process, was then observed under a microscope to produce larger granules than native corn starch. Microscopic observations revealed a more stable shape, better flow properties, and acceptable water content for drug formulations (16).

The results of modification with pregelatinization by mixing corn starch (CS) with distilled water 1: 1 ratio (g/g) produced pregelatinized corn starch (PCS) in the form of a fine, odorless, and white powder. In the pregelatinization process, the granule structure in corn starch is exposed and damaged due to the heating temperature. In the manufacture of pregelatinized corn starch, the higher the temperature and the greater the stirring rpm, the greater the effect on the flow properties of the pregelatinized starch that will be produced. This is based on research on cassava starch with a ratio of 1: 1 (g/g). The results of the study showed that increasing temperature and rpm have a significant effect on the starch produced (4). Flow rate testing showed that PCS (0.472 g/s) has a better flow rate compared to CS (0.418 g/s). At an angle of repose with an average value of 33.7°, it shows that the angle of repose of PCS is better than the angle of repose in CS with an average of 37.38°. The smaller the angle of repose, the easier it is for the powder to flow because the cohesive forces between the particles are weaker. Powders with fast-flowing properties tend to have a smaller angle of repose (26). PCS moisture content testing showed a result of 0.66%, and a specific gravity of 0.56 g/mL.

Co-process

Co-processing is a method of mixing natural CS and SSG, which involves heating the two components in three different ratios, namely 1: 1, 1: 2, and 1: 3 (g/g), resulting in an excellent powder. Co-processing is carried out to see

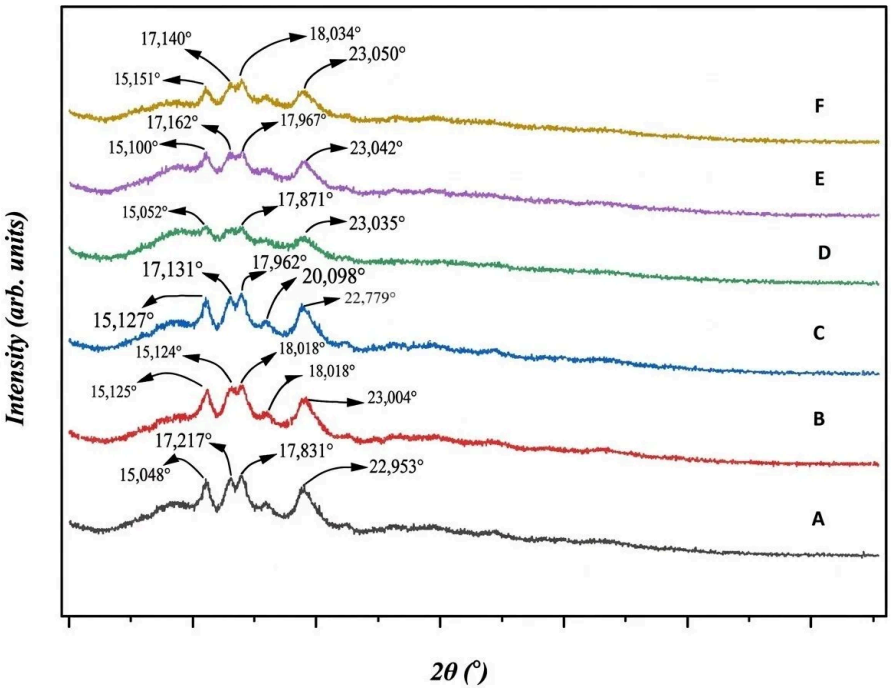


Figure 1. Diffractogram of SSG (A); CS (B); PCS (C); F1 (D); F2 (E); F3 (F).

the effect of the physical combination of the union of the two materials without changing their chemical structure as a disintegrant. The co-process comparison can be seen in **Table 2**.

The modification of the sample between PCS was made by the co-process method using SSG, with a comparison that can be seen in the Table. This solid dispersion is made by involving the co-processing of two or more excipients to achieve better characteristics compared to physical mixtures. In the co-process, PCS and SSG interact physically, involving the formation of a matrix by PCS, which traps SSG particles. The resulting co-processed powder is pale white, which is due to the heating process.

Physicochemical Characterization

X-Ray Diffraction (XRD)

The X-Ray Diffraction (XRD) method is used to find out information about polymorphism and crystallinity index in samples. The findings can be seen in **Figure 1**.

Based on the data results, SSG has a peak that is not too high and wide at an angle of 22.953°. This peak shape indicates that the main structure in SSG tends to be amorphous, meaning that the atoms in it are not arranged regularly over long distances and do not have a well-organized crystal structure. This indicates a structure that does not have good crystal regularity. In contrast, CS and PCS show a higher level of crystallization, although the visible peak is still somewhat wide. The presence of several peaks indicates the presence of crystalline parts, but the peak width is not too sharp, indicating an imperfection in the crystal structure. When comparing CS and PCS, the peak patterns that appear look similar. However, there are differences in peak intensity. This difference in intensity is caused by several things after the pregelatinization modification process in PCS, where the crystalline part changes to become more amorphous (26).

Analysis of F1 (23.035º), F2 (23.042º), and F3 (23.050º) showed that all three formulas exhibited high levels of crystallinity, characterized by sharp and distinct diffraction peaks. Similar major peak positions indicate the same dominant crystalline phase in all three formulas. Small differences in peak intensity are likely due to small variations in the degree of crystallinity or crystallite size. Despite the differences in composition, all three formulas maintained high levels of crystallinity. This high level of crystallinity could potentially facilitate water absorption into the tablet matrix, which could further accelerate tablet disintegration (27).

Differential Scanning Calorimetry (DSC)

Differential Scanning Calorimeter (DSC) was carried out in the range of 20 - 500 °C with a heating rate of 10 °C per min to observe the melting point. It can be seen in **Figure 2.**

Based on the results of the thermogram test, there is a clear difference in the thermal temperature between the samples. The curve shows the heat flow against temperature with an endothermic peak point (T_m) indicating the temperature at which significant structural changes occur in the sample. CS shows an endothermic peak at 59.54 °C, indicating gelatinization, which is the process of damage to the crystal structure of starch granules due to heating and water absorption (28). CS shows an endothermic peak at 59.54 °C, indicating the gelatinization process, which is when the crystal structure of starch granules begins to break down due to water absorption and heating. SSG has a peak at 60.10 °C, almost similar to CS, but because SSG is a chemically modified starch, the type of structural change can be different. PCS shows an increase in peak temperature to

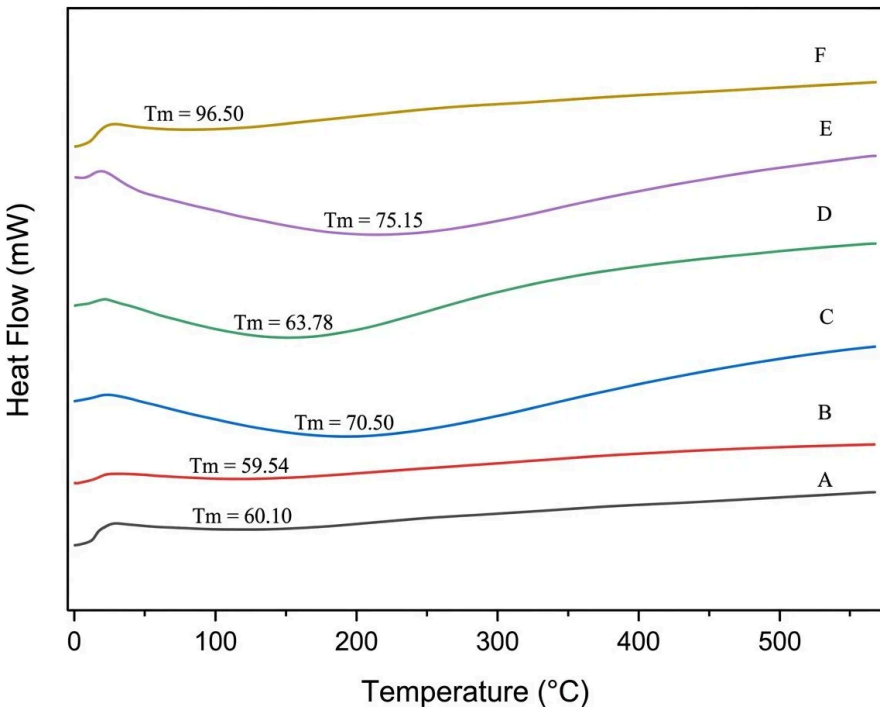


Figure 2. Thermogram of SSG (A); CS (B); PCS (C); F1 (D); F2 (E); F3 (F).

Table 3. The waves of fungtional.

Number of waves (cm-1)						Functional clusters
SSG	CS	PCS	F1	F2	F3	
3200-3600	3300	3700-3000	3700-3000	3700-3000	3700-3000	O-H elongation vibration
1500-1400	1550-1400	1550-1400	Vibration C-C			
2920	2920	3000-2800	3000-2800	3000-2800	3000-2800	C-H elongated vibration
1200-1000	1200-1000	1700-1600	1200-1000	1700-1600	1700-1600	C-O elongation vibration

70.50 °C. This indicates that the previous pregelatinization process has altered the initial crystal structure of CS, such that the temperature required to trigger structural changes is higher.

Formulas F1, F2, and F3 each exhibited peak temperatures at 75.15 °C, 63.78 °C, and 96.50 °C, respectively. All three had higher peak temperatures than their ingredients, indicating interactions between the components within the formula. This increase could be due to the formation of a more stable structure, for example, through hydrogen bonding, Van der Waals forces, or even the formation of new physical complexes (29). F3 showed the greatest increase, indicating that the combination of ingredients in this formula produced the most thermally stable system compared to the other formulas. The difference in peak temperatures between the formulations indicates that each combination of ingredients produces a different internal structure, which affects heat resistance. The higher the peak temperature, the more stable it is to temperature changes (30).

Fourier Transform Infrared (FTIR)

FTIR is a method that uses infrared spectroscopy. In infrared spectroscopy, infrared radiation is passed through a sample. Some of the radiation is absorbed by the sample, while the rest is transmitted. Functional group analysis using FTIR aims to determine the physical or chemical processes that occur during mixing. However, FTIR spectroscopy also has a weakness: the analytes in the sample are not separated, so the absorption spectra of the compounds in the sample can overlap (31). The FTIR spectra of SSG, CS, PCS, and the co-processed formulations (F1, F2, and F3) are shown in **Figure 3**.

Based on the results of functional group identification in the form of a spectrum, SSG shows a broad and strong absorption band at 3200–3600 cm^{-1}, which indicates the stretching of the –OH (hydroxyl) group, reflecting the hydrophilic nature of the modified starch. The band at 2920 cm^{-1} indicates aliphatic C–H stretching, while the band in the range of 1000–1200 cm^{-1} comes from the C–O stretching, typical of polysaccharide structures. There is no significant peak at 1700 cm^{-1}, indicating the lack of carbonyl groups. In corn starch (CS), the –OH band also appears strongly at around 3300 cm^{-1}, indicating the high hydroxyl content in natural starch. The C–H (2920 cm^{-1}) and C–O (1000–1200 cm^{-1}) bands appear clearly with sharper intensity than SSG, indicating a structure that is still intact and unmodified. In (PCS), a change in intensity and a small shift in the –OH band are observed, indicating modification due to pregelatinization. The C–O band also shows a change, indicating a conformational change in the structure, without the formation of new functional groups

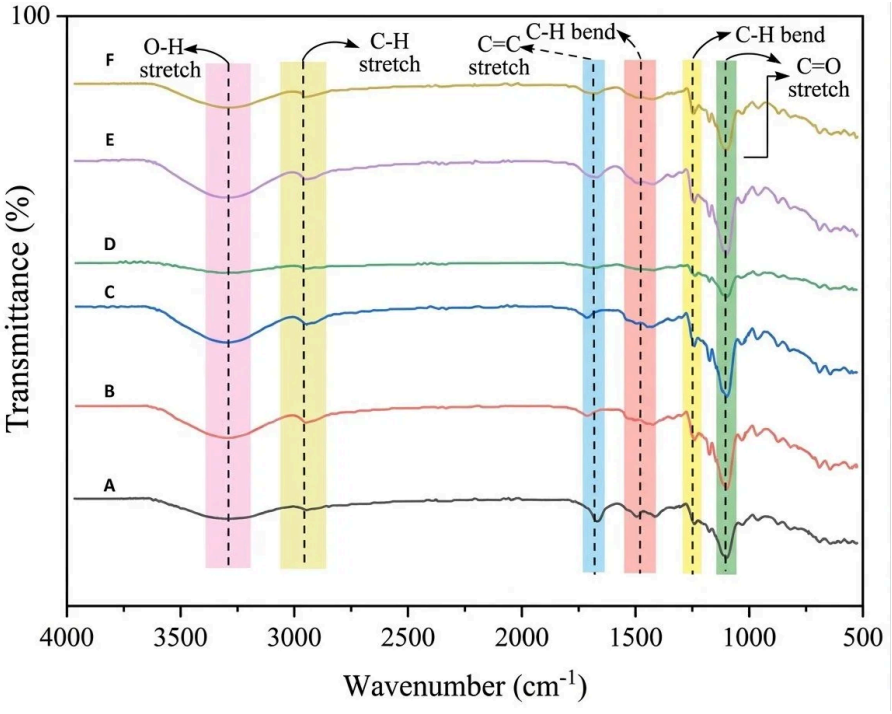


Figure 3. Spectrum of SSG (A); CS (B); PCS (C); F1 (D); F2 (E); F3 (F).

Table 4. Particle size analysis test result.

Formulation	Particle size (nm)	Polydispersity index (PDI)
SSG	3326.3	0.616
CS	4770.4	0.418
PCS	5250.1	0.203
F1	5708.9	0.233
F2	6332.5	0.51
F3	4505.0	0.288

(32).

F1 shows a combination of SSG and PCS characters where the –OH band appears wider due to the union, indicating physical interactions in the form of hydrogen bonds. The intensity of the C–O and C–H bands remains similar to the starting material without the appearance of new groups. In F2, the –OH band is more intense than in F1, reflecting the dominance of PCS. The C–O and C–H bands also increase in intensity. There is no significant change in peak position, indicating no chemical reaction, only physical interactions. F3 shows the dominance of the PCS spectrum with the –OH band appearing the sharpest and strongest, indicating the abundance of hydroxyl groups and the formation of stronger hydrogen bonds. The C–O band becomes more prominent as the proportion of PCS increases but still does not indicate the formation of new functional groups. The waves of the existing compounds can be seen in **Table 3**.

Based on the spectral data in the table, functional group analysis shows the presence of absorption peaks for OH stretching vibrations in the range of 3200–3700 cm^{-1} in all samples, indicating the presence of hydroxyl groups, which are commonly found in alcohols. In addition, C-H stretching vibrations were also detected in the range of 2920–3000 cm^{-1}, confirming that all samples are organic compounds. The main difference is seen in the C-O stretching vibrations. Samples SSG and CS show peaks at 1000–1200 cm^{-1}, which are usually associated with C-O single bonds, while samples PCS, F2, and F3 display peaks at 1700–1600 cm−1. Sample F1 shows both types of peaks, both at 1500–1400 cm^{-1} and 1500–1400 cm^{-1} for C-C stretching vibrations. This variation indicates significant chemical structural differences between the sample groups, with PCS, F2, and F3 likely possessing carbonyl groups that are absent in SSG and CS.

Scanning Electron Microscope (SEM)

SEM is a method that is widely used for observing surface morphology, structure, and mapping the content of various types of samples ranging from natural materials, organic, inorganic, polymers, metals, to biological samples (33). The results of the scanning electron microscope instrument test can be seen in **Figure 4**.

Observer based on the analysis of the Scanning Electron Microscope (SEM) test results, it can be seen that there are morphological changes in CS and its interaction with SSG. In image (a), pure corn starch shows intact starch granules, round and polygonal in shape, with a smooth surface and uniform size. This reflects the structure of starch that has not undergone modification. After the pregelatinization process, as seen in image (b), the structure of CS granules is damaged. These granules appear broken, bulged, and some stick together, which are characteristics of starch that have undergone gelatinization due to heating and drying. Meanwhile, image (c) shows that SSG granules have a different morphology, namely round, and oval in shape, with a rougher or more porous surface than pure starch. When PCS is mixed with SSG, as shown in images (d), (e), and (f), a physical interaction is seen between the two components. At a 1:1 ratio (d), the two types of particles appear to mix and begin to stick together. This interaction becomes stronger and more visible as the proportion of SSG increases. At ratios of 1:2 (e) and 1:3 (f), SSG granules appear more dominant and form agglomerations or clumps with the damaged PCS granules. This indicates that increasing the SSG concentration affects the morphology

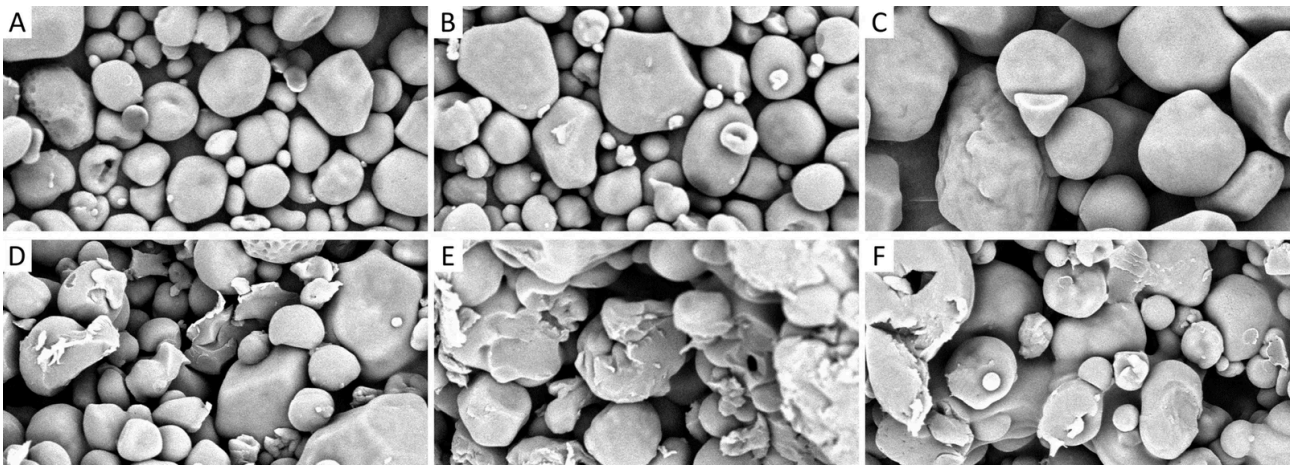


Figure 4. Morphology of SSG (A); CS (B); PCS (C); F1 (D); F2 (E); F3 (F).

Table 5. Organoleptic test result.

Sample	Colour	Smell	Taste	Shape
CS	White	Odorless	No taste	Powder
PCS	White	Odorless	No taste	Powder
CCS	White	Odorless	No taste	Powder
F1	White	Odorless	No taste	Powder
F2	White	Odorless	No taste	Powder
F3	White	Odorless	No taste	Powder

Table 6. Data from the flow rate and angle of repose.

Formulation	Flow rate (g/s)	Requirements	Angle of repose (°)	Requirements
SSG	0.476	Very Poor	32.45	Passable
PCS	0.472	Very Poor	33.7	Passable
CS	0.418	Very Poor	37.38	Passable
F1	1.605	Poor	28.61	Good
F2	2.106	Poor	24.53	Good
F3	3.852	Poor	24.1	Good

of the mixture, where these granules bind together, creating a less uniform and denser structure.

Particle Size Analyzer (PSA)

Based on the results of the particle size analysis, it can be concluded that there are changes in morphology and complex interactions between components. The data from the particle size analysis test results can be seen in **Table 4**.

In the results of the particle size analysis test, it can be seen that the particle size (CS), which was initially 4770.4 nm, increased to 5250.1 nm after undergoing the pregelatinization process. This increase in size can be caused by the gelatinization process, where starch granules expand and experience agglomeration (34). Meanwhile, (SSG) has a smaller particle size, namely 3326.3 nm, and shows a very non-uniform size distribution with the highest PDI (0.616), which reflects the variation in particle size (35).

When PCS is mixed with SSG, interactions occur that affect particle size and distribution. At a ratio of 1: 1 (F1), the particle size of the mixture increases to 5708.9 nm, indicating initial agglomeration between PCS and SSG. This increase in agglomeration peaks at a ratio of 1: 2 (F2), where the particle size reaches its largest value, namely 6332.5 nm. This large particle size is accompanied by the highest PDI (0.51), indicating that in this composition, strong interactions occur that produce particle clumps with a very non-uniform size distribution (36). At a ratio of 1: 3 (F3), the particle size decreases to 4505 nm, and the PDI also decreases to 0.288. This can be interpreted as meaning that at higher SSG concentrations, SSG no longer only interacts and agglomerates, but also acts as an agent that can prevent excessive agglomeration, resulting in a smaller particle population and a more uniform distribution compared to F2.

Powder Evaluation

Organoleptic

Organoleptic observations involve examining the shape, odor, taste, and color of a preparation (22). Based on the results of the co-processing between PCS and SSG, it was found that the resulting powder had a whiter color than the CS powder or PCS without co-processing, was odorless, and tasteless (or bland). The organoleptic test results can be seen in **Table 5**.

The organoleptic test results on co-process powders, including CS, PCS, SSG, F1, F2, and F3, showed homogeneous organoleptic characteristics. Visually, all co-process powder formulations showed a crystal white color. From the olfactory aspect, no specific odor was detected in all formulations, indicating that the powders were odorless. Furthermore, in terms of gustatory, all co-process powder formulations were tasteless, indicating a bland nature. Finally, the physical morphology of all co-process powders was powder. The consistency of these organoleptic characteristics is crucial in evaluating the quality and standardization of co-process powder products.

Flow Rate and Angle of Repose

Flow rate testing is an evaluation of the time required for a powder to flow when transferred or poured into a container. The flow rate can be seen in **Table 6**.

Based on the results of the flow rate test, F3 with a ratio of (1: 3) showed the best performance with an average value of 3.852 g/s, although this value is still below the standard for a good flow rate of more than 10 g/s (23). A good flow rate is generally influenced by a uniform particle size, which facilitates smooth powder flow (35). In this study, all powder formulas were sieved using a mesh sieve no. 40 to increase particle size uniformity and improve the resulting flow rate. The flow rate test was carried out by observing the time and speed of flow of the powder. A good flow rate makes the powder flow easily so that the resulting formula will have good uniformity (36).

The results of the repose angle evaluation showed that F3 (24.1°) had good flow properties (the smallest repose angle < 25°), followed by F2 (24.53°) with good flow properties, and F1 (28.61°) also good (< 42°) small repose angle indicates low cohesivity and good flow, where large particle size generally increases flow (37). Although F3 had the highest flow rate, it was not the smallest repose angle that was affected by particle size uniformity; on the contrary, F1 with a very good repose angle did not have a flow rate as high as F3, possibly due

Table 7. Water content result.

Formulation	Water content	Requirements
SSG	0.51	Satisfies the required criteria
PCS	0.66	Satisfies the required criteria
CS	0.71	Satisfies the required criteria
F1	0.98	Satisfies the required criteria
F2	0.91	Satisfies the required criteria
F3	0.87	Satisfies the required criteria

Table 8. Specific gravity tests result.

Formulation	Water content	Requirements
SSG	0.58	Good
PCS	0.56	Good
CS	0.55	Good
F1	0.57	Good
F2	0.59	Good
F3	0.67	Above the reported range

to differences in particle distribution and shape, so it was concluded that both particle size and uniformity are important in determining powder flow properties, with F3 superior in flow rate and F1 showing excellent flow potential based on its repose angle.

Water Content

Moisture content testing is the process of measuring and determining the % or amount of water contained in a dry dosage form. The water content can be seen in **Table 7**.

Moisture content is an important parameter in the evaluation of pharmaceutical excipients because it directly influences powder stability, flowability, compressibility, and storage characteristics. The moisture content values obtained for F1, F2, and F3 were 0.98%, 0.91%, and 0.87%, respectively. These low values can be attributed to the drying process applied during pregelatinization and co-processing, which effectively removed free water from the starch matrix. Low moisture content generally contributes to improved physical stability by minimizing the risk of microbial growth, hydrolytic degradation, and moisture-induced physicochemical changes during storage. In addition, reduced moisture levels can decrease interparticle adhesion caused by liquid bridges, thereby improving powder flowability. This observation is consistent with the improved flow properties exhibited by the co-processed formulations compared with native corn starch. However, excessively low moisture content may also influence the functionality of starch-based excipients. Water acts as a natural plasticizer in starch systems, and insufficient moisture can reduce particle plasticity during compression, potentially resulting in brittle tablets with lower mechanical strength. Therefore, although the low moisture content observed in this study may favor storage stability and powder handling, its effect on tablet compaction behavior and mechanical properties should be further investigated. The standard water content of pharmaceutical raw materials usually ranges from < 1 to 5% so that the particles do not bind to each other and the drug remains stable (23). The main cause of the significant difference in moisture content between CS and PCS is the difference in initial moisture content. The heating and drying process after adding water (pregelatinization) removes most of the initial moisture contained in PCS (38). Too low a moisture content can cause brittleness in tablets (39). Overall, the moisture content results indicate that the co-processed starches possess good storage stability and handling characteristics, supporting their potential application as pharmaceutical excipients.

Specific Gravity

Specific gravity measurements are performed to determine the density of a solid without considering the interparticle or intraparticle space. Specific gravity tests are performed to determine the specific gravity of a powder formula. The specific gravity of a preparation is 0.2 - 0.6 g/mL (40). The specific gravity can be seen in **Table 8**.

The specific gravity test above shows the results of F1 (0.57 g/mL), F2 (0.57 g/mL), and F3 (0.67 g/mL). Based on the specific gravity test requirements, only F1 (0.57 g/mL) and F2 (0.57 g/mL) meet the specified specific gravity criteria. Specific gravity that meets the requirements indicates suitable bulk density characteristics for handling and formulation of the preparation. The bulk density of F3 was 0.67 g/mL, which is slightly higher than the commonly reported range of 0.2–0.6 g/mL for pharmaceutical powders. However, bulk density is not an absolute quality criterion, and its acceptability should be interpreted together with other powder properties. Despite the slightly higher bulk density, F3 exhibited excellent flowability, a low angle of repose, an acceptable Hausner ratio and Carr's index, indicating that the co-processed starch possessed satisfactory handling characteristics as a pharmaceutical excipient.

Future Perspective

The incorporation of SSG improved powder performance by enhancing flowability, modifying particle morphology, and increasing thermal stability. Among the investigated formulations, the PCS: SSG systems exhibited superior physicochemical characteristics compared with native and pregelatinized corn starch, indicating a synergistic effect between the two excipients. In particular, the higher proportion of SSG contributed to improved flow properties and thermal resistance, highlighting the potential of co-processing to tailor excipient functionality.

These findings suggest that co-processed PCS: SSG can serve as a promising multifunctional excipient for solid dosage form development, particularly in formulations requiring improved flowability and disintegration performance. Furthermore, this study provides a scientific basis for the utilization of locally sourced corn starch as a value-added pharmaceutical excipient. Future studies should investigate tablet compaction behavior, disintegration efficiency, and compatibility with active pharmaceutical ingredients to further establish its suitability for industrial applications.

Conclusion

The modification of corn starch (*Z. mays* L.) through pregelatinization followed by co-processing with sodium starch glycolate (SSG) successfully improved its physicochemical and functional properties as a pharmaceutical excipient. Characterization by XRD, DSC, FTIR, SEM, and PSA confirmed structural modifications through physical interactions without the formation of new chemical bonds. The co-processed formulations exhibited improved thermal stability, altered particle morphology, and changes in particle size distribution compared with native corn starch. Evaluation of the powder properties demonstrated that co-processing enhanced powder flow characteristics. Among the investigated formulations, F3 (PCS, 1: 3) exhibited the highest flow rate (3.852 g/s), the lowest angle of repose (24.1°), and the highest thermal transition temperature (96.50°C), indicating superior flowability and thermal stability. All formulations showed low moisture content (< 1%), while F1 and F2 met the acceptable bulk density requirements for pharmaceutical excipients. Overall, the results demonstrate that co-processed PCS: SSG has promising potential as a multifunctional pharmaceutical excipient for solid dosage forms. Further studies on tablet compaction, disintegration performance, and compatibility with active pharmaceutical ingredients are required to confirm its applicability in pharmaceutical formulations.

Abbreviations

CS = Corn Starch; PCS = Pregelatinized Corn Starch; SSG = Sodium Starch Glycolate; XRD = X-Ray X-Ray Diffraction; FTIR = Fourier Transform Infrared Spectroscopy; DSC = Differential Scanning Calorimetry; SEM = Scanning Electron Microscope

Declaration

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Conflict of Interest

The authors declare no conflict of interest.

Data Availability

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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Not applicable.

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