

Enhancing Iota Carrageenan Soft Capsules with Modified Starch

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Abstract

Due to the increasing demand for gelatin alternatives, iota carrageenan, a polymer derived from seaweed, is being explored as a potential base material for soft capsule production. However, the rheological properties of iota carrageenan alone are insufficient for commercial manufacturing, necessitating the addition of fillers such as modified starches. This study evaluates the performance of iota carrageenan-based soft capsule shells using modified cassava, potato, and sago starches as fillers. Various mechanical and rheological properties were assessed, including elongation, stickiness, tensile strength, and viscosity. The results demonstrated that modified cassava starch provided the best overall balance of mechanical properties, exhibiting superior moldability (47.56 mm elongation), flexibility, and moderate stickiness (567.45 gf). Scanning Electron Microscopy (SEM) analysis revealed that cassava starch capsules had a more uniform outer surface with smoother internal morphology than other starches. These findings suggest that modified cassava starch is a promising candidate for large-scale production of high-quality soft capsules.

Keywords

Formulation, Iota Carrageenan, Modified Starch, Soft Capsule Shell

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1. INTRODUCTION

Capsule shells are widely utilized as drug delivery systems, with gelatin as the predominant material in their formation (Soraya et al., 2024a). However, the increased demand for capsule shells, particularly in the post-pandemic pharmaceutical industry, has highlighted a need for alternatives beyond gelatin. Gelatin-based capsules, though highly effective, present limitations, such as concerns regarding animal-sourced ingredients and stability in varying environmental conditions (Debnath et al., 2022). Consequently, non-gelatin capsule shell alternatives have become a research focus, primarily for hard capsule formulations, with limited advances in soft capsule production.

In recent studies, kappa carrageenan, derived from seaweed, has been identified as a promising non-gelatin alternative due to its gel strength and viscosity comparable to gelatin (Soraya et al., 2024b). However, the rheological properties required for soft capsule shells differ significantly from those of hard capsules, as soft capsules necessitate a gel material with higher viscosity and gel strength (Naharros-Molinero et al., 2023). As a result, iota carrageenan, another seaweed-derived polymer, has emerged as a potential candidate for soft capsule shell formulation (Djafar et al., 2024).

Unlike kappa carrageenan, iota carrageenan displays a unique viscosity profile, making it suitable for applications requiring enhanced flexibility and mechanical resilience (Hilliou, 2021). Despite this, iota carrageenan has seen limited application due to factors like low cultivation levels of its primary source, *Eucheuma spinosum* algae, and its unique structure that differs from more commonly used polysaccharides (Olatunji, 2020). These factors make iota carrageenan a compelling but underexplored option for developing a gelatin-free soft capsule shell (Rahmawati et al., 2023).

This study investigates the use of modified starches—specifically cassava, potato, and sago starches—as fillers. Modified starches are commonly employed in pharmaceutical applications to enhance mechanical properties and are known to improve film strength and flexibility (Garcia et al., 2020; Nazarudin et al., 2023). Incorporating modified starch with iota carrageenan could yield a capsule shell that meets the mechanical standards for soft capsules and aligns with the industry's shift toward plant-based alternatives.

The novelty of this research lies in the formulation of soft capsules using iota carrageenan and modified starches, specifically chosen for their potential to enhance the shell's physical

properties. While most prior studies have concentrated on non-gelatin hard capsules, this work uniquely addresses the formulation of gelatin-free soft capsules by evaluating the mechanical and rheological effects of different modified starches. This study aims to identify an optimal starch-carrageenan blend, providing insights into a sustainable, high-performance alternative for large-scale soft capsule production. The study is limited to evaluating physical properties and must address pharmaceutical performance, such as dissolution rates or bioavailability. Future research could expand into pharmaceutical assessments, including compatibility with drug formulations and safety testing, to fully establish iota carrageenan as a practical, sustainable gelatin alternative for drug delivery.

2. EXPERIMENTAL SECTION

2.1 Materials

The materials used in this study included various modified starches: modified cassava starch (Erkang), modified potato starch (CLEARGUM® PG80-05), and modified sago starch. Glycerol and sorbitol were used as plasticizers, while iota-carrageenan was sourced from Hangzhou Junfeng Bioengineering Co., Ltd.

2.2 Instruments

The key instrument used in this study was the Scanning Electron Microscope (SEM, Model JEOL JSM-IT500), which examined the morphology of the soft capsule shells. The SEM was operated at an accelerating voltage of 20 kV, and capsule samples were cut, coated with gold using a sputter coater (Q150RES), and observed at magnifications of 200× and 500×. The Universal Testing Machine (UTM GD 1171BL) was used to evaluate the tensile strength and elongation of the soft capsule films. Viscosity measurements were conducted using a Rapid Visco Analyzer (RVA 4500 Perten Instruments). Disintegration tester (ZT 320 series ERWEKA, Germany) for disintegration time measurements.

2.3 Formulation

The iota carrageenan-based soft capsule shells were formulated by incorporating various modified starch fillers. The formulation was developed based on trial-and-error results from preliminary research. The ratios of the materials used are detailed in the Table 1.

Table 1. Formulation of Iota Carrageenan-Based Seaweed Soft Capsule Shells

Materials	Percentage (%)
Modified starch	30
i-Carrageenan	1.5
Glycerol	10
Sorbitol	15
Water	43.5

2.4 Soft Capsule Shell Sheet Production Process

Water, glycerol, sorbitol, and iota carrageenan were mixed and stirred until a homogeneous solution was achieved, followed by heating to 60°C. Modified starch was then added to the mixture and stirred until fully integrated. Once homogeneity was reached, the mixture's temperature was raised to 95°C and maintained for 90 minutes. The cooked mixture was then poured into an acrylic mould and set for 10 minutes. The resulting film sheet was carefully removed and analyzed.

2.5 Response Measurement

2.5.1 RVA Profile Measurement of Starch

The viscosity properties of starch products are readily assessed in the Rapid Visco Analyzer (RVA 4500, Perten instruments). The test was carried out by inserting 3.5 g of starch sample with 14% water content and 25 g of distilled water (1% w/w aqueous solution) into the sample can. Use a non-stick stirrer to dissolve the starch thoroughly in the water before starting the test. Measurement results can be determined by looking at the viscosity value during a decrease in temperature from 95 to 50°C for 13 minutes with 160 rpm rotation so that the viscosity properties obtained are a function of time and temperature (Guelpa et al., 2015).

2.5.2 Tensile Strength and Elongation

Tensile strength (TS) and elongation at break (Eb) were evaluated for each film using a Universal Testing Machine (UTM GD 1171BL). The sheet samples were prepared by cutting them into the required shape using an ASTM dumbbell cutter (ASTM D412 type C). The gauge length and grip distance were 50.0 mm, with a crosshead speed of 200 mm/min. The tip of each sample was clamped onto the machine's grip, and the sample was then pulled at a constant speed until a displacement of 100 mm was achieved. Tensile strength and elongation values were automatically recorded and displayed on the machine's screen.

2.5.3 Scanning Electron Microscope Test

In order to examine the structural characteristics of the capsule shell, a Scanning Electron Microscope (SEM) test was conducted. Soft capsules produced from production are cut and cleaned of their inner and outer surface contents. For imaging purposes, 200× magnification was utilized to capture detailed views of the capsule shell structure.

3. RESULT AND DISCUSSION

3.1 Observation of Starch Properties

Modified starches are produced by altering the hydroxyl groups of native starches through chemical or physical processes (Haq et al., 2019). In soft capsule shell production, viscosity is a crucial parameter due to the limitations of the production machinery (Hoag, 2017). Machines that produce soft capsules require a solution with low viscosity; excessive viscosity can lead to production failures (Gullapalli, 2010). The gelatinization properties of starches, which are crucial for understanding

Table 2. Formulation of Iota Carrageenan-Based Seaweed Soft Capsule Shells

Starch	Swelling Power (g/g)	
	Native	Modified
Potato	8.16 ± 0.01	3.25 ± 0.12
Sago	6.08 ± 0.11	6.62 ± 0.22
Cassava	10.62 ± 1.48	3.19 ± 0.07

their behaviour during capsule shell formation, were evaluated using a Rapid Visco Analyzer (RVA). The results are presented in Figure 1.

As shown in Figure 1, starch modification significantly alters gelatinization properties, resulting in a drastic reduction in viscosity-up to tenfold lower than native starch. Modified starches also display a higher final viscosity than their peak viscosity, indicating the formation of a denser and tighter matrix upon cooling (Włodarczyk-Stasiak et al., 2019). The modification process impacts the gelatinization profiles and viscosity characteristics, as measured by a Rapid Visco Analyzer (RVA). Notably, modified cassava starch forms a particularly dense matrix upon cooling, as indicated by its high final viscosity (Das et al., 2023). This dense matrix structure enhances film formation and stability, creating a cohesive and resilient structure suitable for soft capsule applications.

This change in gelatinization profile impacts how modified starches interact with iota carrageenan during the formation of soft capsule shell solutions. The denser matrix formed by modified starch reduces water retention (Zia-Ud-Din et al., 2017), which influences the drying time of the solution on the drum roller in production machines and affects the final properties of the capsule shell. Furthermore, the lower viscosity of modified starch improves the solution's flowability (Bhatt et al., 2022), facilitating easier processing in soft capsule shell production (Ock et al., 2020).

The swelling power of both native and modified starches significantly impacts the performance of the capsule shells, as it reflects the density of the starch matrix. A decrease in swelling strength indicates a denser matrix (Sringam et al., 2022). Table 2 provides the swelling power values for native and modified starches.

The data in Table 2 shows that starch modification generally reduces swelling power. For example, the swelling power of modified potato starch (3.25 g/g) is significantly lower than that of native potato starch (8.16 g/g). A similar reduction is observed in modified cassava starch (3.19 g/g) compared to its native counterpart (10.62 g/g). However, an exception is seen in sago starch, where the swelling power increases slightly after modification (6.62 g/g) compared to the native form (6.08 g/g). This behaviour in sago starch may be due to its unique structural characteristics (Marta et al., 2022; Jia et al., 2023).

The reduced swelling power and lower viscosity of modified starches, mainly potato and cassava starches, enhance their suitability for soft capsule shell production. This decrease in

Table 3. Final Viscosity of Modified Starches

Modified Starch	Final Viscosity (cP)
Potato	32 ± 0.01
Sago	3967.5 ± 315.08
Cassava	284.5 ± 13.44

swelling power indicates lower water absorption (Gagneten et al., 2023), which contributes to improved film stability and resistance to deformation. Such a matrix structure facilitates effective film formation and ensures overall stability, making it ideal for producing cohesive soft capsule shells essential for industrial applications (Arias et al., 2024). Additionally, the improved flowability of the solution during processing increases production efficiency on industrial equipment, ensuring consistent and effective formation of soft capsule shells (Yusriadi et al., 2022; Naharros-Molinero et al., 2023). The combination of modified starch and iota carrageenan in the formulation holds significant promise for achieving high-quality soft capsule shells with the required characteristics for pharmaceutical applications.

3.2 Seaweed Soft Capsule Shell Sheet Production Process

The production process involved mixing all ingredients, such as modified starch, iota carrageenan, glycerol, sorbitol, and water, in a process tank and casting the mixture in a flat mould to produce measurable sheets. The properties of both the solution and the resulting sheets provided insights into the characteristics of the final soft capsule shell. The results showed that different modified starches had distinct effects on the solution and the resulting capsule shell sheets. Modified potato starch produced a transparent white sheet with a brittle texture, which was easy to remove from the mould but exhibited minimal stickiness. In contrast, modified sago starch resulted in sheets that were challenging to form due to their high stickiness, making them difficult to remove from the mould. These sheets were also very brittle, breaking easily when removed. On the other hand, sheets formed with modified cassava starch demonstrated good printability and consistent formation, with moderate stickiness and ease of removal.

One significant factor influencing the casting process of the capsule shell solution was viscosity (Dash and Singh, 2023). The adhesiveness of the modified starches followed the same trend as their viscosity values (Sun et al., 2018); potato starch had the lowest stickiness, cassava was intermediate, and sago was the highest. This trend is consistent with the final viscosity values measured using a Rapid Visco Analyzer (RVA), as shown in Table 3.

The viscosity values of the modified starches varied significantly, with potato starch exhibiting the lowest value and sago starch the highest. These results indicate that solutions with high viscosity, such as those containing sago starch, are more difficult to process into soft capsule shells due to their thick and sticky nature, which complicates production and lowers

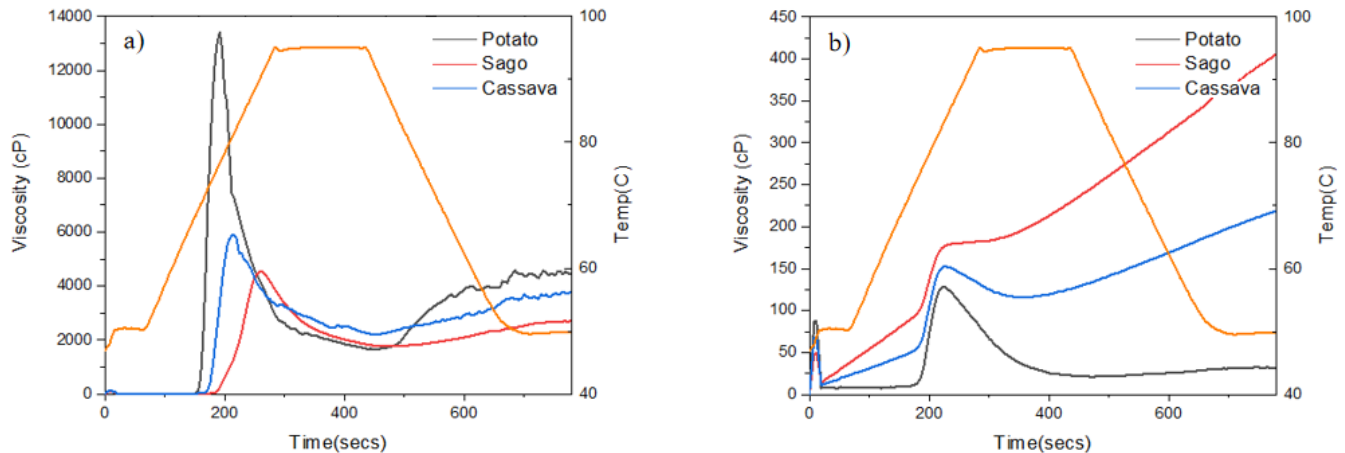


Figure 1. Gelatinization Profile with RVA: a) Modified Starch, b) Native Starch

yield (Harimurti et al., 2023). In contrast, potato and cassava starches, with their lower viscosity values, offer more potential as fillers to enhance the formation of seaweed-based capsule shells from iota carrageenan.

Upon drying, the soft capsule shell film sheets were evaluated for their ease of detachment from the mould and the success of forming lab-scale soft capsule prototypes. Modified potato starch demonstrated excellent ease of detachment, but the formation of soft capsule prototypes could have been more successful, indicating challenges in producing consistent, functional products. Despite its poor mould detachment and brittle texture, modified sago starch exhibited low success in capsule formation. In contrast, modified cassava starch performed well in both categories, detaching easily from the mould and forming lab-scale soft capsule prototypes.

Based on these observations, it is concluded that modified cassava starch is the most promising candidate for scaling up to industrial soft capsule production, compared to modified potato and sago starches. The viscosity of the solution plays a crucial role in the injection moulding process. High-viscosity solutions, as seen with sago starch, are more challenging to process due to their thickness, leading to difficulties in mould filling and lower production yields. In contrast, with low viscosity, modified potato starch facilitates easy mould filling but lacks sufficient cohesion and flexibility, resulting in brittle, inconsistent capsules. Modified cassava starch, with its moderate viscosity, offers an optimal balance that enhances flow and shell cohesion, reducing the likelihood of incomplete formations during processing (Tseng, 2023). The ease of mould detachment and consistent formation of cassava starch prototypes further highlight its suitability for industrial applications, providing a potential gelatin alternative that meets both production efficiency and capsule integrity requirements.

Table 4. Universal Testing Machine Measurement Results

Modified Starch	Stickiness (gf)	Tensile Strength (load max) (gf)	Elongation (mm)
Potato	3.41	200	3.06
Sago	1445.11	207.5	6.57
Cassava	567.45	192.5	47.56

3.3 Physical Observation of Soft Capsule Shell Sheet Results

The mechanical properties of soft capsule shell sheets are critical indicators of the formulation's quality, particularly regarding their suitability for industrial production and consumer use (Fauzi et al., 2021). Several fundamental mechanical properties were measured to assess whether the produced sheets meet acceptable standards. The results of these mechanical tests are presented in Table 4.

As previously discussed, the stickiness values observed in the soft capsule shell sheets align with the viscosity of the modified starches. Potato starch, which had the lowest viscosity, also exhibited the lowest stickiness, while sago starch, with the highest viscosity, showed the highest stickiness. This correlation underscores the dominant role of modified starch in determining the stickiness of the soft capsule shell solution, with iota carrageenan having a lesser influence. Proper stickiness control is essential in preventing capsules from sticking together, which can otherwise lead to production delays and material waste (Tsuji et al., 2019). Modified cassava starch, with a moderate stickiness value (~500 g), demonstrated optimal moldability during production, balancing ease of handling with adhesive properties.

Regarding tensile strength, the values for all three modified starches were similar, indicating that the choice of starch does not significantly affect the tensile strength of the soft capsule shell. This finding suggests that factors other than starch, such as water content, plasticizers, and thickeners, play a more crucial role in determining the tensile strength of the final product.

Proper balance between tensile strength and flexibility ensures capsule integrity, prevents brittleness, and maintains functionality during application (Tindal, 2018). The measured tensile strength values indicate that all three starches provide adequate strength for soft capsule production.

Elongation, a key indicator of flexibility and structural integrity, differed significantly among the starches (Domene-López et al., 2019). Modified cassava starch displayed the highest elongation, contributing to its superior moldability and ease of processing in soft capsule shell production. The ability of cassava starch to form elastic, stretchable sheets enhances the capsule's performance, ensuring structural stability and minimizing the risk of breakage during handling and packaging. In contrast, potato and sago starches showed lower elongation values, which may limit their application where greater flexibility is required. The combined use of modified starch and carrageenan in the formulation enhances elasticity, reducing the potential for oxidative cross-linking and contributing to the stability of the soft capsule shell (Manzoor et al., 2022).

The physical observations and mechanical tests showed that modified cassava starch outperformed modified potato and sago starches. Modified cassava starch provided a balanced level of stickiness, sufficient tensile strength, and notably higher elongation, suggesting it has the most favourable properties for soft capsule shell production. In comparison, modified potato starch exhibited lower stickiness and tensile strength, leading to brittle capsules more prone to breakage. On the other hand, modified sago starch displayed excessive stickiness and minimal elongation, resulting in capsules that were difficult to release from moulds and had limited flexibility. The higher elongation of modified cassava starch ensures improved flexibility and moldability, which is essential for large-scale production.

Furthermore, the optimal stickiness of modified cassava starch reduces the risk of capsules sticking to the equipment, preventing production delays and minimizing waste—a key advantage in commercial manufacturing. In contrast, the stickiness of sago starch caused production challenges due to adhesion, while potato starch's minimal stickiness compromised capsule cohesion. Therefore, modified cassava starch emerges as the most promising candidate for achieving high-quality soft capsule shells that satisfy industrial standards for efficiency, durability, and consistency, meeting both production and consumer expectations.

3.4 Observation of Soft Capsule Shells with Iota Carrageenan and Modified Cassava Starch

Following production trials at an industrial scale, only the formula incorporating modified cassava starch was deemed feasible and passed quality control assessments. In contrast, formulas containing modified potato and sago starch faced significant production challenges, highlighting the unique suitability of cassava starch in this application. The modified potato starch formula failed primarily due to the solution's inability to set, as it remained too fluid to adhere to the drum roller surface, preventing proper capsule shell formation. This issue points

to the low viscosity of modified potato starch, which, while beneficial for initial mixing, lacked the cohesion needed for stable shell formation (Zhang et al., 2019).

Conversely, the modified sago starch formula encountered production failure due to its high viscosity, which led to difficulties in processing; the solution was too thick to be effectively transported via the vacuum pump from the mixing tank to the drum roller (Ningrum et al., 2022). This excessive viscosity contributed to poor flow properties and hindered shell formation, emphasizing that high viscosity can impede large-scale manufacturing by complicating material handling. The successful production of soft capsule shells using iota carrageenan and modified cassava starch is depicted in Figure 2.



Figure 2. Production of Soft Capsule Shells with Iota Carrageenan and Modified Cassava Starch

These results confirm that modified cassava starch, with its intermediate viscosity and balanced flow properties, best meets the production standards for soft capsule shell formation. Its ability to provide both adequate cohesion and manageable flow properties under industrial conditions suggests that it offers an optimal balance between potato starch's low viscosity and sago starch's high viscosity (Das et al., 2023), making cassava starch the most viable option for large-scale manufacturing of iota carrageenan-based capsule shells.

The soft capsule shells produced were subjected to disintegration tests to determine whether they met the established standards for pharmaceutical applications. The disintegration tests were conducted using a disintegration tool, and the results are presented in the following Table 5.

The average disintegration time of the soft capsule shells was 66.44 minutes. According to the Indonesian Pharmacopoeia, the acceptable disintegration time for soft capsule shells is a maximum of 60 minutes, while the United States Pharmacopoeia (USP) requires a disintegration time of no more than 30 minutes for soft capsules (Lodha et al., 2012).

Based on the disintegration test results, the combination of iota carrageenan with modified cassava starch did not achieve the rapid disintegration time required for oral drug delivery applications, as it exceeded both the standards set by the Indone-

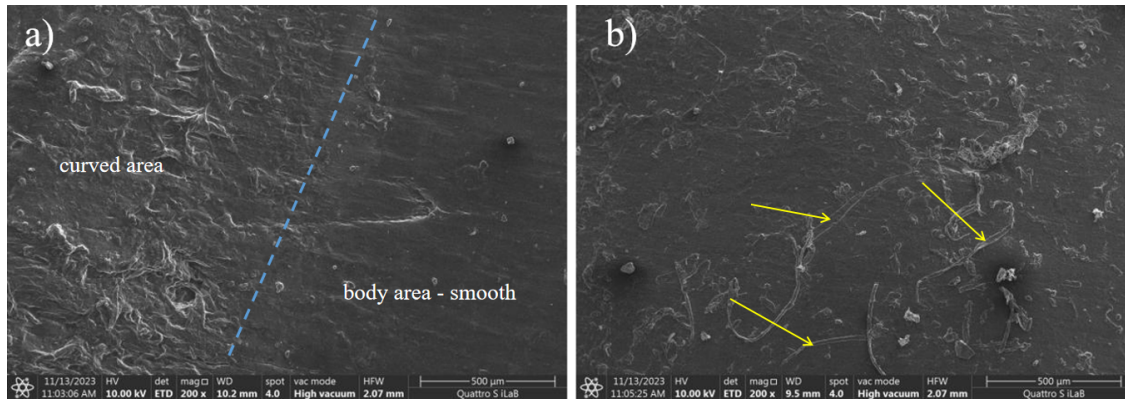


Figure 3. SEM Images of the Soft Capsule Shell Made with Iota Carrageenan and Modified Cassava Starch: a) Inner Surface, b) Outer Surface

Table 5. Disintegration Test Results

n	Length (mm)	Width (mm)	Weight (g)	Leak Time (min)	Disintegration Time (min)
1	13.6	7.15	0.48	20	49.56
2	13.18	7.31	0.52	20	55.07
3	14.09	7.72	0.48	25.56	60
4	13.36	7.50	0.48	25.56	76
5	13.55	7.37	0.49	27.11	76
6	13.58	7.80	0.49	37.11	82
avg	13.56	7.48	0.49	25.89	66.44

sian Pharmacopoeia and the United States Pharmacopoeia. This slower disintegration rate may be attributed to the dense matrix formed by modified cassava starch combined with iota carrageenan, which provides structural integrity and prolongs the breakdown process (Fauzi et al., 2020).

However, the extended disintegration time highlights potential applications beyond oral drug delivery, particularly in non-oral packaging preparations, where a slower breakdown rate may be advantageous. The stability and delayed dissolution observed could be beneficial in applications where prolonged structural integrity is desired, such as controlled-release packaging or encapsulation for non-digestible products. Consequently, while the current formulation may not meet rapid disintegration requirements, it opens avenues for developing iota carrageenan-based soft capsules tailored for specific non-oral applications that can leverage its extended durability.

To further investigate the structural properties of the soft capsule shells, surface images were obtained using Scanning Electron Microscopy (SEM). The surface images of the capsules are shown in Figure 2, illustrating the internal and external surfaces of the shells.

Scanning Electron Microscopy (SEM) was used to analyze the inner and outer surfaces of the soft capsule shells, providing insights into the surface morphology and structural characteristics that influence capsule performance.

The inner surface (Figure 3-a) displays a smoother and

more uniform texture, contrasting areas with rougher features. The smoother section interacts directly with the capsule's contents, typically an oil-based fill, providing a coating effect on the inside surface of the capsule shell, contributing to its refined morphology (Naharros-Molinero et al., 2023). This smoothness is essential for maintaining the integrity of the capsule contents, as it reduces the likelihood of leaks or structural failures and ensures effective encapsulation-critical for the capsule's functional performance. The rough surface is formed at the curved end of the capsule shell, resulting in a contrasting line that delineates the smooth and rough areas. This fold is more pronounced on the inside of the capsule than on the outer surface, as the layers forming the capsule are folded inward (Hülagü et al., 2024).

In contrast, the outer surface of the capsule shell (Figure 3-b) exhibits a fibrous and rough texture, highlighted by the yellow arrow, likely due to direct contact with the heated drum roller during production. This fibrous texture could influence drying, leading to increased rigidity or brittleness in the capsule shell (Moreton and Armstrong, 1998). The rougher outer surface may also impact the capsule's interaction with environmental factors, such as moisture absorption during storage, which is crucial for maintaining capsule stability and extending shelf life (Naharros-Molinero et al., 2023).

The SEM images demonstrate that the modified cassava starch formulation makes apparent differences between the

outer and inner surfaces of the soft capsule shells. The fibrous outer layer contributes structural durability, enhancing the capsule's resilience during handling and storage. At the same time, the smoother inner surface allows for secure encapsulation of the contents, minimizing the risk of leaks (Al-Haddad et al., 2024). These distinct surface properties suggest that the modified cassava starch-based iota carrageenan capsule could meet industrial production standards by balancing stability with effective encapsulation. This surface differentiation could provide an advantage over other formulations by improving the capsule's robustness and ensuring consistent performance under various storage conditions.

4. CONCLUSIONS

This study demonstrates that modified cassava starch offers superior overall performance as a filler for iota carrageenan-based soft capsule shells compared to modified potato and sago starches. The formulation with modified cassava starch showed an optimal combination of mechanical properties, including balanced stickiness, adequate tensile strength, and notably higher elongation, which are crucial for flexibility and scalability in industrial applications. Scanning Electron Microscopy (SEM) analysis confirmed that the modified cassava starch capsules had a distinct surface morphology with a durable outer fibrous layer and a smooth inner layer, enhancing structural stability and encapsulation effectiveness. While the current formulation did not meet the rapid disintegration standards required for oral drug delivery applications, it exhibited potential for non-oral applications, such as controlled-release packaging. These findings establish modified cassava starch as a promising gelatin alternative, providing a viable, sustainable option for high-quality soft capsule production with applications in various pharmaceutical and non-pharmaceutical industries.

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