Journal of
Food and Pharmaceutical Sciences

Original Article

Optimization of Oral Disentegrating Film (ODF) Matrix from Alginate and Pectin/Gum Acacia/Carrageenan Polymer Using PEG/Glycerol as Plasticizer

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Received: 15 December 2025; Revised: 04 April 2026; Accepted: 10 April 2026; Published: 13 June 2026

Abstract: Oral dispersible film (ODF) is an innovative oral drug dosage form that is easy to consume, especially by pediatric, geriatric, and low-compliance patients. This preparation quickly disintegrates in the mouth without the need for water, providing a rapid onset of action, high bioavailability, and comfort of use. Hydrophilic polymers such as alginate are often used because they form strong films and dissolve readily in saliva. One important component in ODF formulations is a plasticizer, which increases flexibility and reduces film fragility. Two common plasticizers used are polyethylene glycol (PEG) and glycerol, each with different characteristics. This research method uses solvent casting. The polymers used are combinations of alginate:pectin, alginate:gum acacia, and alginate: carrageenan, with ratios of 3:0, 3:1, 3:2, 2:2, 2:1, and 0:3. Each polymer formulation was given additional PEG400 or glycerol at three concentration levels: 1%, 2.5%, and 5%. All formulas were tested for organoleptic, physical characteristics, disintegration time, strength, elongation, Scanning Electron Microscopy (SEM), and FTIR. The selection of glycerol and PEG400 plasticizers can affect disintegration time, tensile strength, elongation percentage, and SEM. Polymers also affect film characteristics, including the type of polymer and the concentration of the combined polymers.

Keywords: alginate, film, glycerol, ODF, PEG, plasticizer, polymer

1. INTRODUCTION

The oral route of drug administration is a highly preferred route due to its ease of administration, non-invasiveness, adaptability, and good patient compliance and acceptance. Many oral dosage forms can serve as alternatives for pediatric, geriatric, and non-compliant patients. Oral drug dosage forms have been widely developed, including the use of polymer films for buccal drug delivery, among them the Oral Disintegrating Film (ODF) preparation [1]. Oral Disintegrating Film (ODF) is a thin-layer preparation that is placed on the tongue and will quickly hydrate due to the presence of saliva, followed by disintegration and/or release of the active drug substance from the preparation [2]. ODF has many advantages, including good delivery, easy administration in geriatrics and pediatrics, comfortable use, accurate dosing, no water required for administration, and fast onset and high bioavailability because it can bypass first-pass effects and has good stability [3]. The active ingredient in Oral Disintegrating Film (ODF) preparations can be drugs, nutrients, vitamins, or food supplements, which must be easily released quickly and then produce a smooth suspension or solution in saliva [4]. ODF preparations are a breakthrough in the pharmaceutical industry because they have unique characteristics and disintegrate rapidly, from seconds to 1 minute. The disadvantages of ODF include packaging requirements that demand materials that can withstand temperature and humidity and that do not contain high doses [5].

Polymer selection is essential in ODF formulation [6]. Natural polymers have been widely used in drug formulations, such as alginate, pectin, and carrageenan. [7], [8]. In previous research,

researchers have studied the synergy of alginate-pectin, alginate-gum acacia, and alginate-carrageenan mixtures. The combination of alginate with pectin/ gum acacia/carrageenan has the advantage of improving the mechanical properties of an alginate preparation [8]. In previous research, researchers have also succeeded in creating a drug preparation from this polymer combination, namely ketoconazole beads, to increase its solubility [9] and inhibit supersaturation, thereby increasing ketoconazole bioavailability in the blood [10]. Alginate is a natural polymer derived from brown seaweed. Alginate has potential for producing biopolymer films because it can form strong, hydrophilic films.

One of the components critical to film formation is the plasticizer, a material added to increase flexibility and reduce film fragility [11]. Among various types of plasticizers, Polyethylene Glycol (PEG) and glycerol are the two most common ingredients because of their safety, ease of use, and compatibility with various polymer films [12], [13]. Although PEG and glycerol have different physicochemical properties, which can influence mechanical properties, durability, dissolution time, and overall film stability. The PEGs, especially those with low molecular weight (such as PEG 400), are known to produce stronger, smoother films but may have a higher potential for higher dissolution rates due to their hydrophilic nature. While that, glycerol is known to be more effective in guard film moisture and increase elasticity; however, excessive use can cause the film to become too soft or even sticky.

The difference in characteristics shows that the election type and concentration of plasticizer have a significant influence on the quality of film supplies. However, to date, no systematic research has been conducted to compare the influence of PEG400 and glycerol on the physical, mechanical, and dissolution characteristics of film-forming materials, especially in the context of applications on specific polymers and different active materials. Therefore, research is essential to gain a greater understanding of the advantages and disadvantages of each plasticizer, so that it can serve as a basis for more rational and optimal formulation development in the fields of pharmaceutical and cosmetic industries. In this study, the optimization of the use of PEG400 and glycerol in combinations with alginate:pectin, alginate: gum acacia, and alginate:carrageenan polymers in the form of ODF preparations was carried out. Evaluation of the s organoleptic , weight , film thickness , tensile strength, percentage of elongation, disintegration time and the profiles of SEM and FTIR.

2. MATERIALS AND METHODS

2.1. Materials

Sodium alginate (derived from brown seaweed, 1% viscosity of 150 mPa, pH 7.3) produced by Shandong Jiejing Group Corporation, pectin manufactured by Danisco USA Inc (USA), gum acacia manufactured by Spectrum Chemical MFG Corporation (California), carrageenan produced by Top P&P Co (China), glycerol, PEG400, distilled water.

2.2. Preparation of Polymer Matrix Film with Plasticizer

The solvent-casting method was used to prepare natural polymer matrix films. The compositions of the various formulations are described in Table 1. Film preparation began by dissolving each polymer, namely sodium alginate/pectin/ gum acacia/carrageenan, in 75 mL of water with a stirring speed of 400 rpm for 50 minutes using *a Hotplate Magnetic Stirrer* (Heidolph). The plasticizer was dissolved in 25 mL of distilled water and added to the alginate solution. The mixture was slowly poured into another polymer solution and stirred at 200 rpm for 20 minutes using a Rotary Homogenizer (IKA RW 20) until homogeneous. After the formulation solution was thoroughly mixed, the solution was left at room temperature for 24 hours to remove air bubbles. The bubble-free solution was then poured into a petri dish and dried in an oven at 40°C overnight. The dried film was then carefully peeled from the dish for further testing.

Table 1. Formulation of alginate/pectin/gum acacia/carrageenan using PEG400 and Glycerol

ALGINAT-PECTIN					ALGINATE–GUM ACACIA					ALGINATE-CARRAGEENAN				
CODE	**A**	**P**	**GLY**	**PEG**	**CODE**	**A**	**G**	**GLY**	**PEG**	**CODE**	**A**	**K**	**GLY**	**PEG**
A3P1	3	1	1	-	A3G1	3	1	1	-	A3K1	3	1	1	-
A3P2	3	2	1	-	A3G2	3	2	1	-	A3K0.5	3	2	1	-
A2P1	2	1	1	-	A2G1	2	1	1	-	A2K1	2	1	1	-
A2P2	2	2	1	-	A2G2	2	2	1	-	A2K0.5	2	2	1	-
A3	3	0	1	-	A3	3	0	1	-	A3	3	0	1	-
P3	0	3	1	-	G3	0	3	1	-	K1	0	3	1	-
A3P1	3	1	2.5	-	A3G1	3	1	2.5	-	A3K1	3	1	2.5	-
A3P2	3	2	2.5	-	A3G2	3	2	2.5	-	A3K0.5	3	2	2.5	-
A2P1	2	1	2.5	-	A2G1	2	1	2.5	-	A2K1	2	1	2.5	-
A2P2	2	2	2.5	-	A2G2	2	2	2.5	-	A2K0.5	2	2	2.5	-
A3	3	0	2.5	-	A3	3	0	2.5	-	A3	3	0	2.5	-
P3	0	3	2.5	-	G3	0	3	2.5	-	K1	0	3	2.5	-
A3P1	3	1	5	-	A3G1	3	1	5	-	A3K1	3	1	5	-
A3P2	3	2	5	-	A3G2	3	2	5	-	A3K0.5	3	2	5	-
A2P1	2	1	5	-	A2G1	2	1	5	-	A2K1	2	1	5	-
A2P2	2	2	5	-	A2G2	2	2	5	-	A2K0.5	2	2	5	-
A3	3	0	5	-	A3	3	0	5	-	A3	3	0	5	-
P3	0	3	5	-	G3	0	3	5	-	K1	0	3	5	-
A3P1	3	1	-	1	A3G1	3	1	-	1	A3K1	3	1	-	1
A3P2	3	2	-	1	A3G2	3	2	-	1	A3K0.5	3	2	-	1
A2P1	2	1	-	1	A2G1	2	1	-	1	A2K1	2	1	-	1
A2P2	2	2	-	1	A2G2	2	2	-	1	A2K0.5	2	2	-	1
A3	3	0	-	1	A3	3	0	-	1	A3	3	0	-	1
P3	0	3	-	1	G3	0	3	-	1	K1	0	3	-	1
A3P1	3	1	-	2.5	A3G1	3	1	-	2.5	A3K1	3	1	-	2.5
A3P2	3	2	-	2.5	A3G2	3	2	-	2.5	A3K0.5	3	2	-	2.5
A2P1	2	1	-	2.5	A2G1	2	1	-	2.5	A2K1	2	1	-	2.5
A2P2	2	2	-	2.5	A2G2	2	2	-	2.5	A2K0.5	2	2	-	2.5
A3	3	0	-	2.5	A3	3	0	-	2.5	A3	3	0	-	2.5
P3	0	3	-	2.5	G3	0	3	-	2.5	K1	0	3	-	2.5
A3P1	3	1	-	5	A3G1	3	1	-	5	A3K1	3	1	-	5
A3P2	3	2	-	5	A3G2	3	2	-	5	A3K0.5	3	2	-	5
A2P1	2	1	-	5	A2G1	2	1	-	5	A2K1	2	1	-	5
A2P2	2	2	-	5	A2G2	2	2	-	5	A2K0.5	2	2	-	5
A3	3	0	-	5	A3	3	0	-	5	A3	3	0	-	5
P3	0	3	-	5	G3	0	3	-	5	K1	0	3	-	5

Note: A=alginate, P=pectin, G=gum acacia, K= carrageenan

2.3. Weight and thickness measurements

Film weight measurements were performed using an analytical balance (Mettler Toledo, USA). All measurements were replicated three times. To measure thickness, the film was first cut into 2 × 1.5 cm sections. The thickness was measured on three cut sections using a digital micrometer (Tricel Micrometer 0-25 x 0.01 mm).

2.4. Disintegration time

The films that had been cut into 2x1.5 cm sizes were placed in a well-plate, and 2 mL of distilled water at room temperature (25°C ± 2°C) was added. The films were stirred manually every 10 seconds to simulate oral conditions using a waterbath (Memmert). The time required for the film to disintegrate was observed visually and recorded as the disintegration time (n=3).

2.5. Tensile strength and elongation test

Tensile strength and elongation were measured on intact round films without cutting using a tensile tester from MESDAN LAB. Spa (Italy), Model Tenso.300, Type 168 E, Serial Number 397.

The testing parameters applied were an initial separation distance (gauge length) of 60 mm with a testing speed of 296.16 mm/minute.

2.6. Scanning electron microscopy (SEM)

SEM testing was performed to determine the surface morphology of the samples. The samples were first crushed until smooth. SEM analysis was performed using a Phenom Desktop ProXL SEM-EDX instrument for bead imaging with a resolution of 1-10 nm. The samples were then placed in a metal tub and photographed at magnifications of 500x, 1000x, and 10000x.

2.7. Fourier transform infrared (FT-IR)

The samples were first finely ground. Analysis was performed using a Perkin Elmer Spectrum Two L160000A system equipped with an ATR accessory. Spectral measurements were performed by scanning over the wavenumber range 400–4000 cm^{-1}.

2.8. Data analysis

The quantitative data were analysed and presented as mean ± standard deviation. Statistical analysis was performed using the One-way ANOVA, descriptive analysis, and box-plot diagram test using IBM SPSS Statistics software version 20. Data visualization was presented using GraphPad software.

3. RESULTS AND DISCUSSION

3.1. Physical and Organoleptic Tests

The physical characteristics of the formulated [insert your product type, e.g., thin films/gels/membranes] were comprehensively evaluated based on several qualitative parameters, including transparency, appearance, flexibility, ease of peeling, and pourability. The results of these observations are summarized using a standardized scoring system, where (+++) indicates very good/very easy, (++) indicates good/easy, and (+) indicates not good/difficult. The samples exhibited a Oral Disintegrating Film (ODF) **transparency**, suggesting a high degree of structural homogeneity and proper integration of the components within the matrix. Regarding the **appearance**, the best appearance (+++), characterized by a smooth surface, uniform color, and the absence of air bubbles. The mechanical integrity, observed qualitatively, showed good **flexibility** (+++), which is essential for maintaining structural durability during handling. Furthermore, the samples were found to be **very easy to peel** (+++), indicating an optimal balance between adhesion to the substrate and cohesive strength. The rheological behavior during preparation also facilitated a **very easy to pour** (+++) consistency, ensuring uniform distribution during the casting process and minimal loss of material.

The visualization of alginate and pectin film using PEG or glycerol can be shown at (Supp. 1). Evaluation of physical film based on transparency parameters of the resulting film, easy to peel off from the Petri dish after drying, appearance with a smooth surface, flexibility or convenience folded, and convenience poured into the petri dish at the moment it entered the oven.

In the combination alginate-pectin polymer (Table 2), all formulas successfully formed films, including the single pectin formula (P3). In general, the results of physical evaluation between glycerol and PEG400 plasticizers show differences in flexibility. With PEG plasticizer, the film appears stiffer and thicker than with glycerol.

The visualization of alginate and gum acacia film using PEG or glycerol can be shown at Supp. 2. In the making of the combination alginate-gum acacia polymer (Table 3), films with the composition alginate:gum acacia in the ratios 2:1 and 2:2 do not form because the films break and are too attached to the dish. For single gum acacia, no good film forms because it is too sticky, making it difficult to peel to peel from the dish.

Table 2. Results of Physical Evaluation of Alginate (A) and Pectin (P) Polymer Matrix Films using Glycerol (GLY) plasticizer

Formula	Plasticizer	Physical Evaluation				
		Transparency	Easy to Peel	Appearance	Flexibility	Easy to Pour
A3P1	GLY 5	Transparent	(+++)	(++)	(++)	(++)
A3P2		Transparent	(+++)	(++)	(++)	(++)
A2P1		Transparent	(++)	(++)	(+++)	(++)
A2P2		Transparent	(+++)	(++)	(+++)	(++)
A3		Transparent	(++)	(+++)	(++)	(+++)
P3		Transparent	(+++)	(+++)	(+++)	(+++)
A3P1	PEG 5	Transparent	(+++)	(++)	(+)	(++)
A3P2		Transparent	(+++)	(++)	(+)	(++)
A2P1		Transparent	(+++)	(++)	(+)	(++)
A2P2		Transparent	(+++)	(++)	(+)	(++)
A3		Semi	(+++)	(++)	(+)	(+++)
P3		Transparent	(++)	(++)	(++)	(+++)
A3P1	GLY 2.5	Transparent	(++)	(++)	(+++)	(++)
A3P2		Semi	(++)	(+++)	(++)	(++)
A2P1		Transparent	(++)	(++)	(++)	(++)
A2P2		Semi	(++)	(+++)	(+++)	(++)
A3		Transparent	(++)	(+++)	(+++)	(+++)
P3		Transparent	(+)	(++)	(+)	(+++)
A3P1	PEG 2.5	semiTransparent	(+++)	(++)	(++)	(++)
A3P2		semiTransparent	(+++)	(++)	(++)	(++)
A2P1		Transparent	(+++)	(++)	(++)	(+++)
A2P2		Transparent	(+++)	(++)	(++)	(+++)
A3		Semi	(+++)	(++)	(+)	(+++)
P3		Transparent	(++)	(++)	(++)	(+++)
A3P1	GLY 1	Transparent	(++)	(+++)	(++)	(++)
A3P2		Transparent	(++)	(++)	(++)	(++)
A2P1		Transparent	(++)	(++)	(++)	(+++)
A2P2		Transparent	(++)	(++)	(++)	(+++)
A3		Transparent	(++)	(+++)	(+)	(+++)
P3		Transparent	(+++)	(++)	(++)	(+++)
A3P1	PEG 1	Semi	(+++)	(+++)	(++)	(+++)
A3P2		Semi	(+++)	(+)	(+)	(+++)
A2P1		Semi	(+++)	(++)	(+)	(+++)
A2P2		Transparent	(+++)	(++)	(+)	(+++)
A3		Semi	(+++)	(++)	(+)	(+++)
P3		Transparent	(++)	(++)	(++)	(+++)

Table 3. Organoleptic Results of Alginate (A) and Gum Acacia (G) Polymer Matrix Films using Glycerol (GLY) Plasticizer

Formula	Plasticizer	Organoleptic				
		Transparency	Easy to Peel	Appearance	Flexibility	Easy to Pour
A3G1	GLY 5	Transparent	(++)	(++)	(++)	(+++)
A3G2		Semi	(++)	(++)	(+++)	(++)
A2G1		Semi	(++)	(++)	(+++)	(+++)
A2G2		Semi	(++)	(++)	(+++)	(+++)
A3		Transparent	(++)	(+++)	(++)	(+++)
G3		NA	NA	NA	NA	NA
A3G1	PEG 5	Semi	(+++)	(++)	(++)	(++)
A3G2		Semi	(+++)	(++)	(++)	(++)
A2G1		Tidak	(++)	(++)	(++)	(+++)

A2G2		Tidak	(+++)	(++)	(++)	(+++)
A3		Transparent	(++)	(+++)	(++)	(+++)
G3		NA	NA	NA	NA	NA
A3G1		Transparent	(++)	(+)	(++)	(+++)
A3G2		Transparent	(++)	(+++)	(++)	(+++)
A2G1	**GLY 2.5**	Transparent	(++)	(++)	(++)	(+++)
A2G2		Transparent	(++)	(++)	(++)	(+++)
A3		Transparent	(++)	(+++)	(+++)	(+++)
G3		NA	NA	NA	NA	NA
A3G1		No	(+++)	(+)	(+)	(++)
A3G2		No	(+++)	(+)	(+)	(++)
A2G1	**PEG 2.5**	No	(+++)	(+)	(+)	(++)
A2G2		No	(+++)	(+)	(+)	(++)
A3		Transparent	(++)	(+++)	(+++)	(+++)
G3		NA	NA	NA	NA	NA
A3G1		Semi	(+++)	(++)	(++)	(+++)
A3G2		Semi	(+++)	(+++)	(++)	(+++)
A2G1	**GLY 1**	Transparent	(+)	(+)	(+)	(+++)
A2G2		Transparent	(+)	(+)	(+)	(+++)
A3		Semi	(+++)	(++)	(+)	(+++)
G3		NA	NA	NA	NA	NA
A3G1		No	(+++)	(+)	(++)	(++)
A3G2		Semi	(+++)	(++)	(++)	(++)
A2G1	**PEG 1**	No	(+++)	(+)	(++)	(+++)
A2G2		Semi	(+++)	(+++)	(++)	(+++)
A3		Semi	(+++)	(++)	(+)	(+++)
G3		NA	NA	NA	NA	NA

Note: NA does not form a film

The visualization of alginate and carrageenan film using PEG or glycerol can be shown at Supp. 3. In the manufacture of alginate-carrageenan polymer combinations (Table 4), a lengthy process is required to dissolve the carrageenan, and warm water is also needed. Films with a single carrageenan composition do not form because the mixture settles, making it impossible to proceed to the pouring process. Films with 1% PEG plasticizer appear white, faded, or non-transparent.

Table 4. Organoleptic Results of Alginate (A) and Carrageenan (K) Polymer Matrix Films using Glycerol (GLY) Plasticizer

Formula	**Plasticizer**	**Organoleptic**				
		Transparency	**Easy to Peel**	**Appearance**	**Flexibility**	**Easy to Pour**
A3K1		Semi	(+++)	(+++)	(+++)	(+++)
A3K2		Semi	(++++)	(++++)	(+++)	(+++)
A2K1	**GLY 5**	Semi	(++++)	(+++)	(+++)	(+++)
A2K2		Semi	(++++)	(++)	(+++)	(+++)
A3		Transparent	(++)	(+++)	(++)	(+++)
K3		NA	NA	NA	NA	NA
A3K1		Semi	(+++)	(+++)	(++)	(++)
A3K2		Semi	(+++)	(++)	(++)	(++)
A2K1	**PEG 5**	Semi	(+++)	(++)	(+++)	(++)
A2K2		Semi	(+++)	(++)	(+++)	(+++)
A3		Transparent	(++)	(+++)	(++)	(+++)
K3		NA	NA	NA	NA	NA
A3K1		Semi	(+++)	(+++)	(+++)	(++)
A3K2	**GLY 2.5**	Semi	(+++)	(+++)	(++)	(++)
A2K1		Semi	(+++)	(++++)	(+++)	(++)
A2K2		Semi	(+++)	(++++)	(+++)	(+++)

A3	**PEG 2.5**	Transparent	(++)	(+++)	(+++)	(+++)
K3		NA	NA	NA	NA	NA
A3K1		Semi	(+++)	(+)	(++)	(+)
A3K2		Semi	(+++)	(+)	(++)	(+)
A2K1		Semi	(+++)	(+)	(++)	(+)
A2K2		Semi	(+++)	(+)	(++)	(+)
A3	**GLY 1**	Transparent	(++)	(+++)	(+++)	(+++)
K3		NA	NA	NA	NA	NA
A3K1		Transparasi	(++)	(++++)	(++)	(++)
A3K2		Semi	(++++)	(++++)	(++)	(++)
A2K1		Semi	(+++)	(++)	(+++)	(+++)
A2K2		Semi	(++++)	(++)	(+++)	(+++)
A3	**PEG 1**	Semi	(+++)	(++)	(+)	(+++)
K3		NA	NA	NA	NA	NA
A3K1		No	(+++)	(++)	(++)	(+)
A3K2		No	(+++)	(++)	(+++)	(++)
A2K1		No	(+++)	(++)	(+++)	(++)
A2K2		No	(++)	(++)	(+++)	(++)
A3		Semi	(+++)	(++)	(+)	(+++)
K3		NA	NA	NA	NA	NA

Note: NA does not form a film

3.2. Tensile and Elongation Test

The ideal film characteristics are strong enough to resist tearing or cracking during distribution or application, yet flexible enough to conform to surfaces. Tensile strength is related to film hardness, while Young's modulus is related to its brittleness. In general, the mechanical properties of polymer-based films are highly dependent on their chemical composition. Alginates with a higher proportion of G (glucuronic acid) units tend to form brittle, stiff, but more stable gels. Conversely, alginates with a high proportion of M (mannuronic acid) blocks produce softer and more flexible gels. The results of film-strength tests on combinations of all polymers that use PEG show that the relative strength is higher than with glycerol. In the combination of alginate-pectin and alginate-gum acacia (Figures 1A and 1B), it can be seen that the improvement ratio of glycerol or PEG is higher than that of the improvement in film strength. In combination with alginate and pectin/gum acacia/carrageenan, glycerol shows the highest power at 1% glycerol. There is a correlation between adding glycerol to film strength. In the alginate-pectin combination with PEG, the highest power was obtained with the addition of 1% PEG in the alginate-carrageenan combination. A correlation is observed between the improvement in PEG ratio and the power of the film, so that the highest power is at 5% PEG. Liew et al. stated that increasing the plasticizer not only impacts elongation but also tensile strength. The higher the plasticizer, the lower the tensile strength [14]. It is consistent with this study, in which the lowest tensile strength for both glycerol and PEG were at the highest concentration (5%), while the highest tensile strength was at the lowest concentration (1%) (Figure 1).

Research conducted by Gohil et al. found that alginate-pectin films and single alginate films have higher tensile strength values than single pectin films [15]. This fact may be related to their lower thickness and molecular structure. Makaremi et al. also observed that alginate-pectin films exhibit lower elongation [16]. The interaction between alginate and pectin, especially between the polyguluronate block and the methyl ester region, causes the formation of a dense and rigid structure. Higher tensile strength indicates good strength. The higher the tensile strength, the lower the elongation value. The tensile strength values for both glycerol and PEG were higher at the maximum polymer concentration than for alginate and pectin (Figure 1A). It means that the two polymers work synergistically to increase the film's tensile strength.

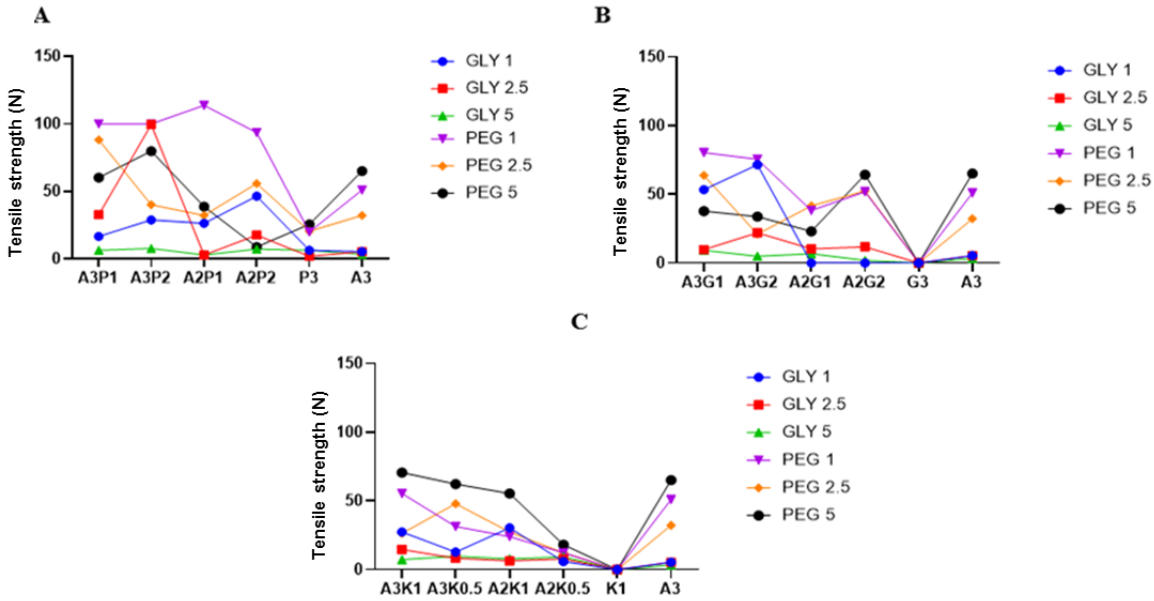

Figure 1. Strength Test Results of Alginate (A)/Gum Acacia (G)/Pectin (P)/Carrageenan (K) Polymer Matrix Films using PEG/Glycerol (GLY) plasticizer. A) Alginate-pectin (AP), B) Alginate-gum acacia (AG), and C) Alginate-carrageenan (AK)

Percent elongation is related to flexibility; the higher the % elongation, the more flexible the film. In Figure 2, the highest % elongation is observed for the plasticizer glycerol. It is in line with the observation of the physical properties of the resulting film (Table 1-3). However, the percentage of glycerol did not influence elongation. It can be seen that 1% glycerol yields greater elongation than 2.5% and 5% glycerol. The main factor affecting elongation results is the plasticizer. Woertz et al. reported significantly higher elongation values in films containing 0.3% glycerol as a plasticizer. Glycerol is relatively sticky and stretches easily [17].

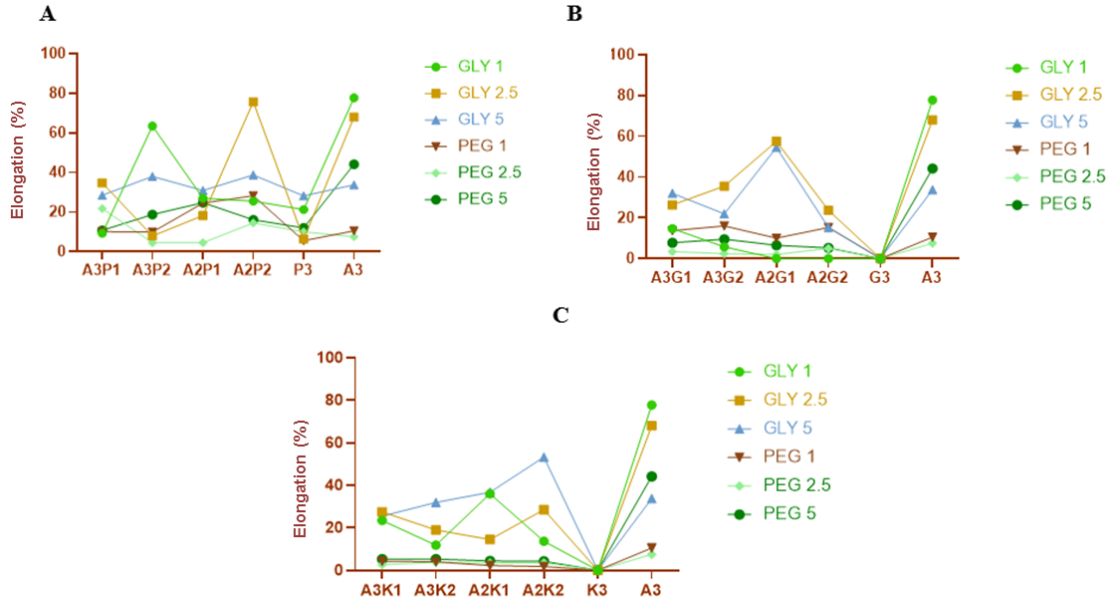

Figure 2. Elongation Test Results of Alginate (A)/Gum Acacia (G)/Pectin (P)/Carrageenan (K) Polymer Matrix Films using PEG/Glycerol (GLY) plasticizer. A) Alginate-pectin (AP), B) Alginate-gum acacia (AG), and C) Alginate-carrageenan (AK)

3.3. Disintegration time

The time test method replaced the Petri dish method, with a film containing the liquid medium (2 mL of water) placed in the form. The container used is a 6-well plate. Stirring is

performed during testing to simulate washing conditions on the surface of the film in the mouth [18].

In the alginate-pectin combination, the time for destruction obtained 5% glycerol is 60-150 seconds, 2.5% glycerol is 97-234 seconds, 1% glycerol is 52-420 seconds, PEG 5% is 264-371 seconds, PEG 2.5% is 116-280 seconds, and PEG 1% is 104-240 seconds (Figure 3A). From the results, the combination polymers that affect 2-3 times the duration time destroyed are present in all glycerol concentrations; the presence of additional maximum pectin (2%) increases the time destroyed film. Time destroyed polymer single: both alginate and pectin use glycerol more quickly than the combination, namely 33-70 seconds and 27-91 seconds consecutively. There is a combination polymer because the destruction time becomes longer. The gel character formed depends on the degree of esterification of pectin and alginate guluronic acid [9]. Bond between pectin and alginate formed in the methyl ester region of pectin and guluronic acid block from alginate [19].

In contrast to PEG400, the influence of the combination polymer is not significant on disintegration time. It can be seen that disintegration time of alginate and pectin, single and in combination, namely, in PEG, 120-150 seconds and 221-274 seconds, respectively. It is caused by PEG influence on time, which is more dominant than with the combination polymer. The term' time 'ruined a good film, according to BPOM (Indonesian Food and Drug Authority) regulations: it must be no more than 5 minutes or 300 seconds. In the alginate-pectin matrix (Figure 3A), the time required to disintegrate the obtained matrix was the same for all combinations, except in A2P2 with 1% glycerol and A3P2 with 5% PEG. According to the strength test results (Figure 1A), the formula combination has more strength than other combinations at the same concentration of glycerol/PEG plasticizer. Therefore, we can say that the strength showed correlation with the disintegration time. The greater the film strength, the longer the time required for disintegration. It is correlated with weight and thickness data, and those with higher results are, in general, more similar to others (Supp. 4).

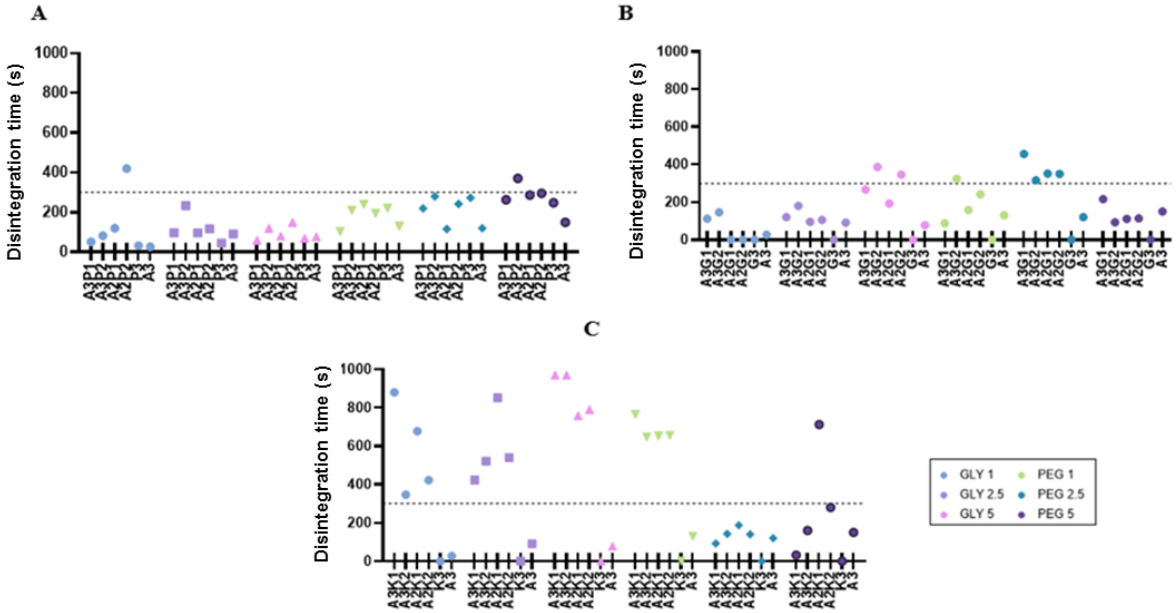

Figure 3. Results of the Disintegration Time Test of Alginate (A)/Gum Acacia (G)/Pectin (P)/Carrageenan (K) Polymer Matrix Film using PEG/Glycerol (GLY) plasticizer. A) Alginate-pectin (AP), B) Alginate-gum acacia (AG), and C) Alginate-carrageenan (AK). The caption (----) is the disintegration time standard

In the alginate-gum acacia combination, the disintegration time obtained 5% glycerol is 193-387 seconds, 2.5% glycerol is 95-180 seconds, 1% glycerol is 112 and 146 seconds, PEG 5% is 93-216 seconds, PEG 2.5% is 316-456 seconds, and PEG 1% is 88-324 seconds (Figure 3B). At 1% glycerol, the film breaks and sticks too much on the dish surface, making it hard to peel off. Combining the alginate-gum acacia affects the time required for disintegration in glycerol plasticizer and PEG. In glycerol, the 3:2 alginate:gum acacia ratio has longest disintegration time of all glycerol concentrations. It is said that the higher the percentage of the second polymer, the longer the time to disintegrate. The disintegration time of alginate single with glycerol (33-72 seconds) and PEG (120-150 seconds) is faster than with the combination of alginate and gum acacia. A combination polymer causes the disintegration time to become longer. The single composition of gum acacia cannot form a film because the gum has a negative charge, which indicates declining stability. *Cross-linking* with alginate can improve the mechanical properties of the gum, so a combination of alginate and gum can form a film [8].

At PEG 2.5%, the time required to disintegrate is not different in the combination polymer. It is caused by the role of PEG in influencing time, which is more dominant than with the combination polymer. In the alginate-gum acacia matrix (Figure 3B), the results over time show that the mixture with 5% glycerol and 2.5% PEG plasticizer was disintegrated over 5 minutes. It is correlated with weight and thickness data, and those with higher results are, in general, more similar to others (Supp. 5). However, there is a correlation with strength data (Figure 3B).

In the alginate- carrageenan combination, the disintegration time obtained 5% glycerol is 759-970 seconds, 2.5% glycerol is 423-852 seconds, 1% glycerol is 347-880 seconds, PEG 5% is 32-713 seconds, PEG 2.5% is 93-188 seconds, and PEG 1% is 648-765 seconds (Figure 3C). Disintegration time of alginate with single glycerol is 33-70 seconds, whereas with PEG it is 120-150 seconds. If carrageenan is added, the observed disintegration time reach 10 times longer. The presence of carrageenan has a significant influence on the duration of the destroyed film. The disintegration of single matrix of carrageenan was unknown because no form was formed. In the alginate-carrageenan matrix (Figure 3C), the film meets the condition only in combination with 2.5% PEG plasticizer, whereas the others do so in a general way above 5 minutes. The disintegration time of the alginate-carrageenan combination reached up to 900 seconds. The result was taller than with time-destroyed combination polymers, and others only reached a maximum of 400 seconds. It is correlated with weight and thickness data, and those with higher results are, in general, more similar to others (Supp. 6). The effect of the type of carrageenan used in this study was kappa carrageenan, which carries a negative charge from the sulphate group [8]. Kappa carrageenan has good gel- and film-forming ability and the highest tensile strength among other types of carrageenan. [20]. It can also be seen that the alginate-carrageenan film strength is much higher than that of the alginate-pectin or alginate-gum acacia combination.

A combination of alginate with anionic polymers can form intermolecular associations through hydrogen bonds and with calcium ions through ionic bonds [10]. Synergy effects from combinations of alginate with gum acacia, pectin, or carrageenan can be seen in characterization viscosity results from multicomponent gels, as well as in gel strength data, which implies the synergy effect [21].

3.4. Fourier transform infrared (FT-IR)

Fourier transform infrared (FT-IR) spectra determine the intermolecular interactions and specific vibrations of each functional group in alginate and other polymer samples using PEG (Figure 4) or Glycerol (Figure 5) plasticizers.

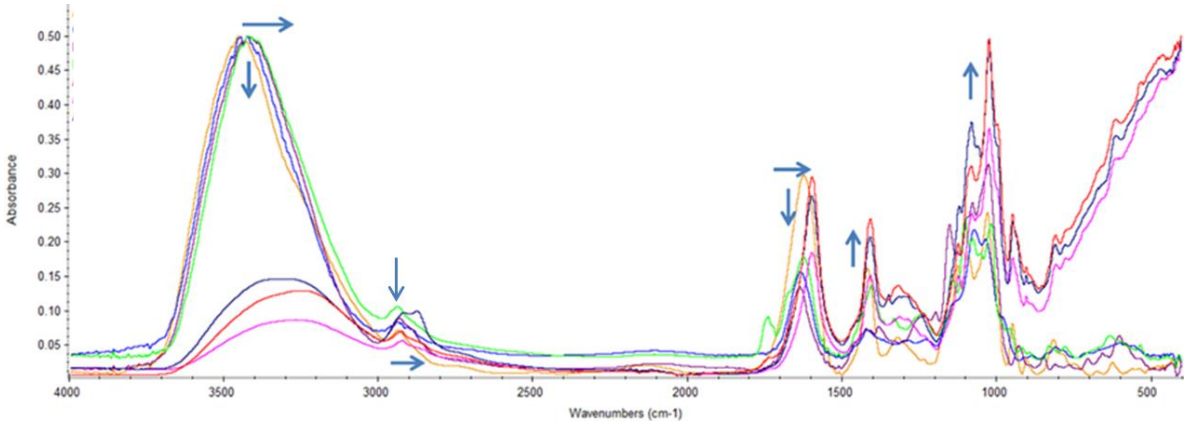

Figure 4. Comparison of infrared absorption profiles of single natural polymers alginate (---), gum acacia (---), pectin (---), carrageenan (---) against a matrix formed from a combination of polymers and plasticizer alginate-pectin-PEG (---), alginate-gum acacia-PEG (---), alginate-carrageenan-PEG (---). Up and down arrow indicates the increase/decrease in intensity while rightward arrow indicates the shift to lower wavenumber.

The FTIR spectra of alginate and gum acacia show similar bands. In the mixed solution, a sharp peak appears at 1420 cm^{-1} as the alginate ratio increases. The OH absorption band has shifted to a lower wavenumber. This change may result from intermolecular hydrogen bonding between alginate and gum acacia. The specific peak in the 1035-1072 cm^{-1} region shows differences across all combinations of alginate and gum acacia ratios, depending on the ratio of each polymer, which can help distinguish the ratios. The intensity of the absorption band at 1635 cm^{-1} decreases as the alginate ratio decreases. The spectrum of alginate shows bands at 1622 cm^{-1} and 1417 cm^{-1}, which correspond to the asymmetric and symmetric C=O stretching vibrations of the carboxylic group, respectively. The results of the alginate spectrum show bands at 1622 cm^{-1} and 1417 cm^{-1}, which correspond to the asymmetric and symmetric C=O stretching vibrations of the carboxylic group, respectively.

The spectra of alginate and pectin show specific absorption bands in the range of 1000-1200 cm^{-1}, corresponding to ring vibrations that overlap with the stretching vibrations of the C-OH side groups and the vibrations of the C-O-C glycosidic bonds. The spectrum at 1738 cm^{-1} increases with increasing pectin ratio due to the presence of methyl esterified carboxyl groups.

The FTIR spectra of alginate and carrageenan show similar bands. The specific peaks of carrageenan are observed at 1381 cm^{-1} and 1234 cm^{-1}, corresponding to stretching vibration bands associated with sulfate (SO_4^{2-}). Single carrageenan shows a sharper peak at 1149 cm^{-1}, which corresponds to the glycosidic bond. In the alginate/carrageenan mixture solution, there are two spectra similar to the bands with single alginate. The absorption band intensity of single carrageenan at 1421 cm^{-1} decreases with increasing alginate ratio because alginate has more carboxylic groups than carrageenan. Its intensity will increase with increasing alginate ratio.

In Figure 5, the addition of glycerol causes a reduction in OH stretching, so that the film containing glycerol forms stronger hydrogen bonds with water. The peak at 3298 cm^{-1} shifts to 3300 cm^{-1} for the film containing glycerol. This shift indicates that the addition of glycerol promotes hydrogen bonding interactions between glycerol and the polymer. Combination of polymers with the glycerol plasticizer shows a broader spectrum at 3000-3500 cm^{-1} than PEG. This wavelength indicates the presence of -OH groups on glycerol, which contribute to the broadening of the spectrum in that region. The results of these spectra are the impact of interactions and hydrogen bonds between the plasticizer and the polymer [22], [23]. In the spectra of glycerol and PEG (Figure 5), differences are observed at ~2900 cm^{-1}, indicating the presence of CH groups with symmetric and asymmetric CH_3 sp^3 vibrations [11]. The spectra of all polymer combinations in Figure 5 are similar to those of combinations without plasticizers. The difference between the two plasticizers is observed at ~3500 cm^{-1}, which indicates the OH group. The intensity of the band in the carbonyl group of a single polymer experiences a reduction in the band associated with stretching vibrations in the CO band in the OH group and COC in the glycosidic bond. However, most of the bands

associated with chemical groups, including hydrogen bonds, such as those at 1650, 1550, and 1410 cm $^{-1}$, are slightly shifted. Thus, it can be said that the addition of glycerol and PEG can form new hydrogen bonds [24].

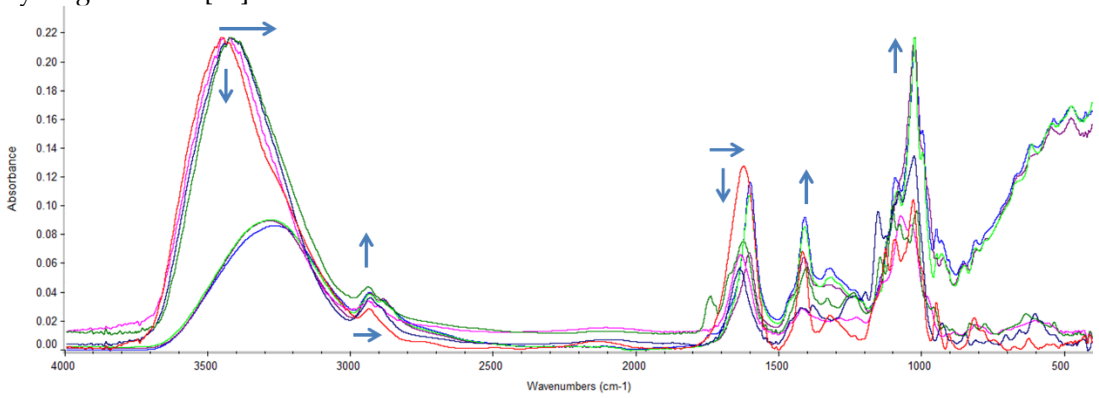

Figure 5. Comparison of infrared absorption profiles of single natural polymers alginate (---), gum acacia (---), pectin (---), carrageenan (---) against a matrix formed from a combination of polymers and plasticizer alginate-pectin-glycerol (---), alginate-gum acacia-glycerol (---), alginate-carrageenan-glycerol (---). Up and down arrow indicates the increase/decrease in intensity while rightward arrow indicates the shift to lower wavenumber.

3.8. Scanning electron microscopy (SEM)

Scanning electron microscopy (SEM) testing was carried out to determine the characteristics of the morphology, matrix, film surface, and polymer with plasticizer. The film is considered good if it has no pores and a uniform, good surface [18].

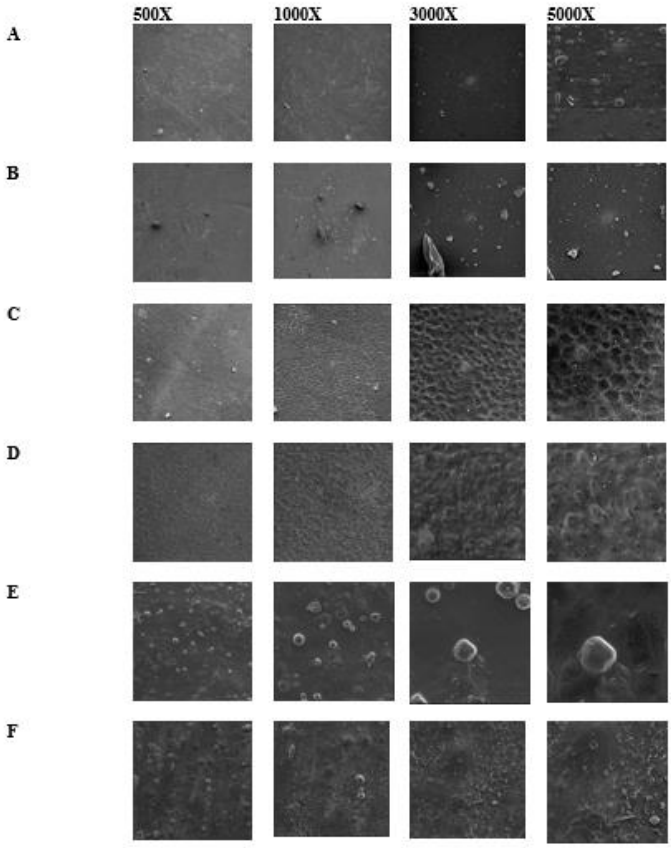

Figure 6. SEM Visualization of Alginate-pectin (AP), Alginate-gum acacia (AG), and Alginate-carrageenan (AK) Polymer Matrix Film using PEG/Glycerol (GLY) plasticizer. A) AP-GLY, B) AP-PEG, C) AG-GLY, D) AG-PEG, E) AK-GLY, and F) AK-PEG with magnifications of 500x, 1000x, 3000x and 5000x

Morphology of alginate-pectin film surfaces with glycerol and PEG shows a smooth surface (Figure 6A, 6B). It indicated the distribution of particles and their solubility in the alginate-pectin film, which is already good. In the research conducted by Palezi et al., a combination film of alginate and glycerol was produced, with a uniform, smooth surface, indicating that alginate and glycerol were effective as a conol [25]. According to Walkenstrom *et al.,* the microstructure of single pectin shows that pectin cross-linking has smaller pores than the cross-linking obtained from the combination [19].

This matter differs from the combination alginate-gum acacia (Figure 6C, 6D), which appears like a network or a bee hive. The structure can increase the surface area of the film, thereby increasing dissolution [26]. In the alginate-carrageenan combination (Figure 6E, 6F), uneven surfaces, especially with the PEG combination, are visible on the surface. Surface roughness is caused by carrageenan that is not distributed evenly in the mixture because it is too thick and gel textured. On the surface, film morphology with glycerol (Figure 6A, 6C, 6E) shows a cohesive, compatible coarse fracture phase, whereas with PEG, the surface appears rougher and harder. It is in line with results: film strength on PEG is higher than with glycerol. We can say that a rough surface correlates with the film strength.

The combination of alginate with other polymers shows results with a non-porous surface, such as a single film, in the research conducted by Rani et al. It means that an additional polymer, namely alginate, provides benefits, namely the ability to produce a smooth film surface [27].

3.9. Statistical Data Analysis

Statistical Data Analysis can be seen in Supp. 7. Given plastic content test data based on three different types of plastic films, the effect of plastic type will be tested based on five response variable indicators: strength, elongation, disintegration time, weight, and thickness. The following is the data analysis algorithm. a) Data Cleaning: From the test data obtained from observations, some data will be cleaned. For example, the treatment with the carrageenan formulation will be removed due to a failure to meet the quality test criteria. b) Descriptive: The following is a summary of the descriptive analysis performed on the plastic content test data based on three different types of plastic films.

The descriptive analysis results show that all test variables exhibit a large range and standard deviation, indicating that the quality of the plastic film is greatly influenced by the composition and type of plastic. There are indications that the distribution of variables is not normal, especially for disintegration time and elongation, indicated by the large difference in the mean and median. Based on the descriptive analysis, it was found that each type of plastic has distinct advantages. Alginate-pectin film is good in strength and elongation, but variations indicate that Alginate-pectin film is less stable. Alginate-carrageenan film is good in disintegration time and thickness. Meanwhile, Alginate-gum acacia tends to be superior in terms of weight and strength stability.

Next, a description of each plastic test indicator will be created using a boxplot. The result of strength shows that Alginate-gum acacia and Alginate-pectin film are stronger than Alginate-carrageenan film, based on their strength. Furthermore, the IQR and total distribution graphs show the greatest variation in strength for Alginate-pectin, indicating unstable Alginate-pectin film production. However, Alginate-carrageenan plastic exhibits the lowest but most consistent strength. The result of elongation showed that all three film types have similar elongation distribution patterns, with significant variance within each group. The data shows that the presence of numerous outliers across all film types indicates that elongation is more influenced by other factors.

Next, an ANOVA test was conducted on three types of plastic films to identify the comparative effects of the three film types. A one-way ANOVA hypothesis test was conducted to compare the average values of the three types of plastic films (Table 6).

Table 6. The ANOVA Result

Parameter	p-values
Strength	0.195
Elongation	0.598
Disintegration time	2.2×10^{-07}
Weight	0.0474
Thickness	0.258

The results were as follows:

a. Film type had the greatest influence on disintegration time, indicating that the chemical formulations have significantly different water degradation characteristics.
b. Strength, elongation, and thickness were not affected by film type, so these mechanical attributes were more influenced by other variables (e.g., plasticizer, concentration, manufacturing process).
c. Weight was affected by film type, but the effect was weak, with only alginate-gum acacia vs. alginate-carrageenan showing a significant difference.
d. Alginate-carrageenan was the most durable film, while the other polymer combination is readily dissolved.

Thus, the general hypothesis that film type influences all mechanical and physical properties was not fully supported. Significant effects were observed only for disintegration time and weight, while the other three variables were not affected by film type.

4. CONCLUSION

The choice of glycerol and PEG400 plasticizers can affect disintegration time, tensile strength, percent elongation, and SEM. Polymers also affect film characteristics, including the type of polymer and the concentration of the combined polymers. The addition of carrageenan to alginate results in a disintegration time that is too long, exceeding the maximum required disintegration time limit. Therefore, it is recommended not to use it as an oral film but rather as thin-layer packaging.

Funding: This research was funded by the Faculty of Mathematics and Natural Sciences, Universitas Islam Indonesia (UII) through research grant with Contract Number: 601/Dek-FMIPA/70/MIPA/VIII/2025.

Acknowledgments: This research was funded by the Faculty of Mathematics and Natural Sciences, Universitas Islam Indonesia (UII). We would also like to thank the UII Pharmacy Biopolymed Research Group (Shafana, Malika, Amel, Nurul, and Muis) team for their assistance in conducting this research.

Conflicts of interest: The authors declare no conflict of interest.

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