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Characterization of modified sorghum starch and its use as a film-forming in orally dissolving film composition with glycerol as a plasticizer

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ABSTRACT: Film-forming polymers and plasticizers are the components of Orally dissolving film (ODF) compositions that have the most influence on the physical properties of the film preparations. Modification of sorghum starch produces maltodextrin (MDX)-sorghum, which can be used as a film-forming polymer, and glycerol can be used as a plasticizer in ODF compositions. This research aims to determine the optimal concentrations of MDX-sorghum and glycerol for producing ODF compositions using the response surface method (RSM) with a central composite design (CCD). Hydrolysis of sorghum starch yielded MDX-sorghum, characterized by yield value, dextrose equivalent (DE) value, solubility, swelling power, and FTIR analysis. The CCD design included a 2-6% and 3-10% concentration range for MDX-sorghum and glycerol, respectively, as parameters in the optimization process. The test response was evaluated using tensile strength, elongation, and disintegration time tests, so 14 experimental designs were obtained. The modification of sorghum starch yields a light brown MDX-sorghum powder with desirable properties. Optimization of MDX-sorghum and glycerol concentrations yielded an optimal formula with a tensile value of 1.81 MPa with an error percentage of 0.33%, an elongation of 104% with an error percentage of 0.33%, and a disintegration time of 82.95 seconds with an error percentage of 0.06%. By modifying sorghum starch to make MDX-sorghum, the starch's properties can be enhanced and used as a film-forming. The optimal MDX-Sorghum and glycerol concentrations for the production of ODF are 3.56 % and 10 %, respectively.

KEYWORDS: Sorghum starch, modified, film-forming, glycerol, response surface methodology.

1. INTRODUCTION

Sorghum starch is a film-forming polymer with hydrophilic properties used in manufacturing orally dissolving film (ODF) preparations [1]. Sorghum starch is a natural biopolymer that is easily accessible and contains 72-75% carbohydrates, 20-30% amylose, and 70-80% amylopectin, which can be used as film-forming components [2,3]. However, there are several drawbacks to natural sorghum starch: it is sticky, hard, brittle, not transparent, and not resistant to acid treatment. In a study by Putri et al. (3), using single sorghum starch resulted in a less elastic film preparation. This problem can be overcome by modifying sorghum starch through a partial hydrolysis process so that its characteristics resemble those of maltodextrin (MDX) (4). MDX is obtained from starch that has been enzymatically modified by partial hydrolysis. As a result, MDX has a dextrose equivalent (DE) value of less than 20. Moreover, MDX has good film-forming solubility and adhesive characteristics, allowing it to produce elastic films [5,6].

The film-forming polymer influenced the film preparation's elasticity; plasticizers can also increase film's elasticity [7]. Glycerol is one of the plasticizers that can be used in the manufacture of ODF preparations. Glycerol is a plasticizer that is easily soluble in water (hydrophilic), has a low molecular weight so that it can reduce the intermolecular forces along the polymer chain, and has the advantage of increasing the viscosity of the solution, reducing the brittleness and increasing the strength of ODF preparations [8]. Glycerol, as a plasticizer, produced edible films with improved characteristics compared with sorbitol and polyethylene glycol [9]. Research conducted by Walfathiyah et al. (2017) showed that adding of glycerol resulted in a more

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elastic edible film [10]. The optimal concentrations of glycerol and MDX-sorghum can be analyzed using the response surface methodology (RSM).

RSM can be used to design several formulas with varying concentrations of MDX-sorghum and glycerol. The RSM can reduce the number of materials used because it does not require a trial formula stage, which would require considerable research [11]. Furthermore, this method can describe the interaction among variables toward the response [11,12]. Several models can be used in RSM. The experimental design in this study used the central composite design (CCD) model. CCD is a fractional factorial design often used in RSM as it can be set up several experimental designs [13]. The independent variable was the concentration of MDX-sorghum as a film-forming agent and glycerol as a plasticizer, and the dependent variables (response) were the value of tensile strength, percentage elongation, and disintegration time. MDX-sorghum and glycerol as components in the manufacture of films are expected to produce films with characteristics that meet the requirements so that they can be used as alternative pharmaceutical preparations for the cetirizine. Therefore, it is necessary to optimize the concentrations of MDX-sorghum and glycerol to obtain an ODF compositions with the best physical properties so that it can be used as a reference in the development of natural excipients in the pharmaceutical field.

2. RESULTS AND DISCUSSION

2.1. Characteristics of MDX-Sorghum

The characteristics of sorghum starch and MDX-sorghum are shown in Table 1. Based on the results, the DE value of MDX-sorghum met the requirements (i.e., <20). In each sugar chain undergoing hydrolysis, there was one reducing sugar group; as the number of simple sugar groups increased, the number of reducing sugar groups and the value of DE also increased. In the swelling power and solubility studies, the swelling ability and solubility of MDX-sorghum more significant than that of sorghum starch. This was due to the hydrolysis reaction performed by the amylase enzyme on sorghum starch by breaking the glycosidic bond in starch molecules into simple sugars, such as glucose and dextrin, so that the three parameters increased [5,6].

Table 1. Characteristics of sorghum starch and modified sorghum starch

No	Inspection	Sorghum Starch	MDX-Sorghum
1	Organoleptic:		
	Form	Powder	Powder
	Texture	Fine/smooth	Fine/smooth
	Aroma	Typical Sorghum	Brown sugar
	Flavour	Slightly Sweet	Slightly Sweet
	Colour	Light brown	Dark brown
2	Dextrose Equivalent	0.84	6.22
3	Swelling Power	2.44	2.87
4	Solubility	12.52%	52.9%
5	Yield Value	72.58%	86.71%

Sorghum starch and modified sorghum starch were analyzed by evaluating the spectrum's shape, namely the specific peaks indicating the type of functional group by a starch compound. The analysis results using FTIR are shown in Figure 1 and 2. The peak for the O-H group was in the range of 3,400–2,400 cm^{-1} . The results of the sorghum starch group were around 3,270.7 cm^{-1} , while the O-H functional group was obtained at a modified sorghum starch peak of 3,287.0 cm^{-1} , and the C-H functional group was obtained at the peak of 2,924.1 cm^{-1} in the range of 3,850.0–2,850.0 cm^{-1} , indicating no change in peak between the two samples. However, the C-O-C functional group obtained 1,149.9 cm^{-1} of sorghum starch and a peak shift of 1,148.0 cm^{-1} , which indicated a change in the modified starch. This treatment aimed to determine the results of the transfer between the functional groups on the two spectra, whereby the difference between the transmittance in the O-H and C-O-H functional groups could be observed. This was due to the breakdown of 1,4 glycosidic bonds by the amylase enzyme on the inside of the polysaccharide chain so that the starch could be modified into MDX [14].

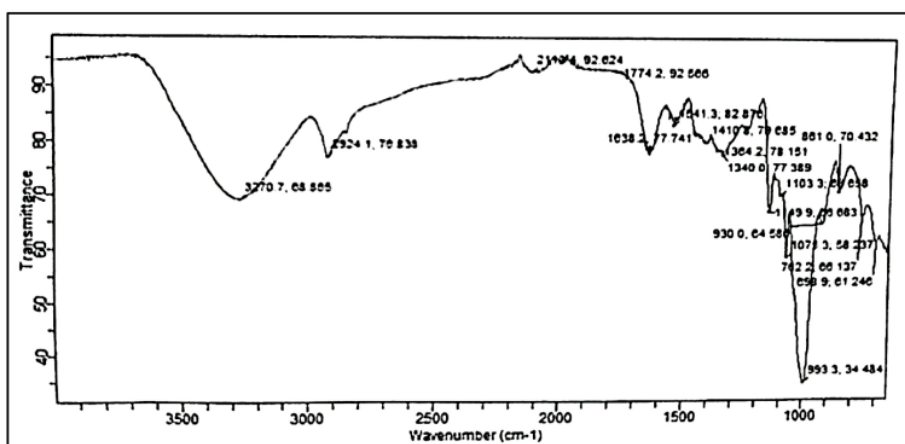


Figure 1. FTIR Spectrum of Sorghum Starch

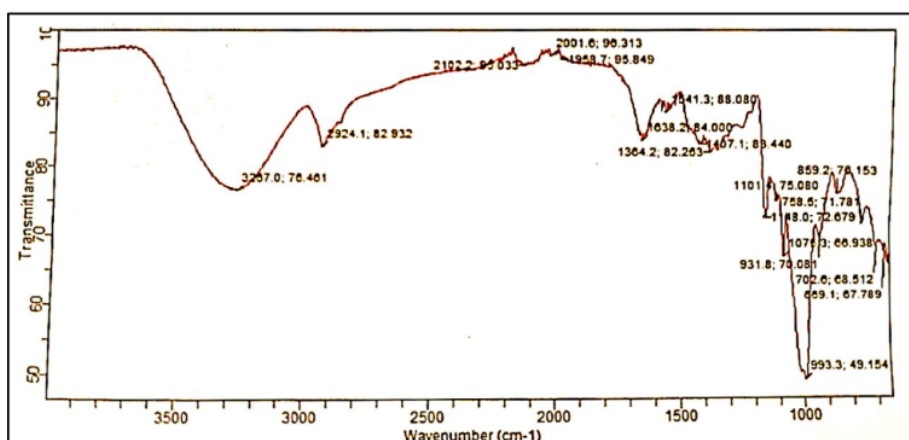


Figure 2. FTIR Spectrum of MDX-Sorghum

2.2. Evaluation of ODF Preparations

The results of the evaluation of ODF preparations are shown in Table 2. Based on the evaluation, all ODF formulas meet the requirements of a 'good' film. The film preparation was considered good if it had a tensile strength value of 1.02 - 10.2 Mpa [15], elongation > 70% [16], and disintegration time < 3 minutes [17].

Table 2. Evaluation of ODF Preparations

Run	Factor		Response		
	A: MDX-Sorghum Concentration (%)	B: Glycerol Concentration (%)	Y ₁ : Tensile Strength (MPa)	Y ₂ : Elongation (%)	Y ₃ : Disintegration Time (sec)
1.	4.00	6.50	1.98	86.26	152
2.	4.00	3.00	2.47	66.74	181
3.	4.00	10.00	1.52	101.68	75
4.	4.00	6.50	1.92	89.44	155
5.	5.41	8.97	1.32	103.96	85
6.	4.00	6.50	1.67	91.94	160
7.	2.59	8.97	1.48	97.72	112
8.	4.00	6.50	1.95	86.58	158
9.	6.00	6.50	1.61	99.16	90
10.	4.00	6.50	1.98	93.18	150

11.	4.00	6.50	1.91	84.84	159
12.	2.59	4.03	1.87	61.41	191
13.	2.00	6.50	2.05	72.41	176
14.	5.41	4.03	1.58	78.56	166

2.3. Data Analysis Using RSM

The combination of MDX-Sorghum as a film-forming agent and glycerol as a plasticizer affects the tensile strength, elongation, and disintegration time, as shown in Figure 3. The color on the graph represents tensile strength (a), elongation percentage (b), and disintegration time (c). The color positioned bottom has the lowest response value, while the above color has the highest response value. The number of color changes along the curve indicates the influence of film-forming and plasticizing concentrations. The combination of factors (A and B) affects the response related to the number of colors on the curve [14,18]. According to the observed results, the disintegration time is the response most affected by factors concentration.

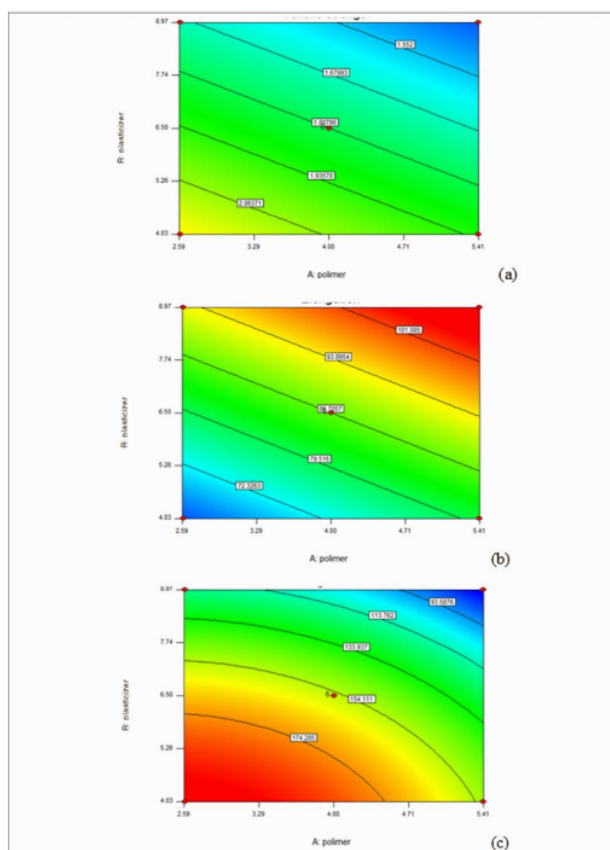


Figure 3. Graph showing the effect of film-forming polymer (MDX-Sorghum) concentration and plasticizer (glycerol) concentration on tensile strength value (a), percentage of elongation (b), and disintegration time (c)

2.3.1. Tensile Strength

The results of the tensile strength data analysis indicated that factors influenced the tensile strength. In the 14 formulas, tensile strength results ranged from of 1.32 to 2.47 MPa. The results met the requirements for good tensile strength, namely 1.02-10.20 MPa [9]. Based on the analysis results (Table 3), the suggested analytical model was a linear model based on the sum of the squares of the tensile strength response model sequence. The linear model with an R-squared value of 0.56 showed that the polymer concentration factor and

the plasticizer concentration influenced the diversity of tensile strength responses. The adjusted R-squared value of 0.5613 served as a generalization of the population's R-Squared due to the existence of the population estimation element (11). Based on the data in Table 3, the model equation for the tensile strength response was: $Y_1 = +1.81 - 0.13 \cdot A - 0.25 \cdot B$.

The equation shows that the polymer value (A) was -0.13 and the plasticizer value (B) was -0.25, indicating an increase in the tensile strength response (Y_1) that was influenced by a decrease in the polymer concentration and a decrease in plasticizer concentration. The higher the concentrations of polymer and plasticizer, the lower the tensile strength. This occurs because plasticizers can reduce the strong intermolecular attraction between the polysaccharide chains in MDX-sorghum and promote hydrogen formation between the plasticizer and polysaccharide molecules, thereby reducing the tensile strength of the film by weakening the hydrogen bonds between the polymers and plasticizers. This reduces film's tensile strength by weakening the hydrogen bonds between polysaccharide chains [19].

2.3.2. Elongation

Elongation percent data indicated the influence of factors on the elongation results. In the 14 formulas, the elongation results were 61.41–10.96%. Therefore, based on the analysis results (Table 3), the suggested analytical model was a linear model based on the sum of the squares of the order of the elongation response model. Furthermore, it was emphasized by the results of the lack-of-fit test, which obtained the correct model and was suggested to be used in the elongation response as a linear model. The linear model had a P value (Prob>F) of 0.2747, which indicated the model's fit to the elongation response. Based on the data in Table 3, the model equation for the elongation response was: $Y_2 = +86.71 + 7.67 \cdot A + 13.90 \cdot B$.

Based on the equation, the polymer value (A) was +7.67, and the plasticizer value (B) was +13.90, indicating an increase in elongation response (Y_2) influenced by an increase in polymer concentration and plasticizer concentration. The higher the concentration of polymer and plasticizer, the more likely the elongation is to increase. This occurs because the glycerol molecules in the polymer matrix disrupt the polymer structure through hydrogen bonds and transform it into an irregular flexible structure, a process that can be considered as restructuring (rearrangement) of the polymer matrix, with increased resistance (resistance) towards received pressures which in turn increase the stretchability (elongation) of the film [19].

Table 3. Analysis of ODF Cetirizin HCl Tensile Strength, Percent Elongation, and Disintegration Time Using CCD

Factors		Y_1	Y_2	Y_3
A	Coefficient	-0.13	7.67	-21.75
	p-value	0.1031	0.0002**	0.0003**
B	Coefficient	-0.25	13.90	-38.78
	p-value	0.0070**	0.0001**	0.0001**
A . B	Coefficient	-	-	-0.50
	p-value	-	-	0.9238
A ²	Coefficient	-	-	-9.37
	p-value	-	-	0.0364*
B ²	Coefficient	-	-	-11.87
	p-value	-	-	0.0130*
Analytical model		Linier	Linier	Quadratic
Intercept		1.81	86.71	155.68
Degree of freedom		2	2	5
Sum of squares		0.64	2012.01	17342.43
Mean of squares		0.32	1006.00	3468.49
F-value		7.04	62.85	33.80
p-value		0.0108	0.0001	0.0001
R-squared		0.5613	0.9195	0.9548

* p-value < 0.05

** p-value < 0.01

2.3.4. Disintegration Time

The results of the disintegration time test indicated that the film could be destroyed within 75–191 seconds. Based on the analysis results in Table 3, the suggested analytical model was a quadratic model grounded on the sum of the squares of the sequence of the disintegration time response models. This was confirmed by the results of the analysis of variance using the suggested model, namely the quadratic model.

Furthermore, the P value (prob>F) of 0.0001 was smaller than 0.05, indicating a significant model to determine the interaction of responses to variables in the disintegration time response. Based on Table 3, the model equations for the disintegration time response were: $Y_3 = +155.68 - 21.75A - 38.78B - 0.50A^2 - 9.37B^2 - 11.87AB$.

Based on the equation, the polymer value (A) was -21.75, and the plasticizer value (B) was -38.78, indicating an increase in the disintegration time response (Y_3) that was influenced by a decrease in polymer concentration and a decrease in plasticizer concentration. The higher the concentrations of polymer and plasticizer, the faster the disintegration time. This occurs due to the increase in polymer concentration. The shorter disintegration time is caused by MDX, which has a high solubility in water, which aids water penetration into the film structure [17]. Therefore, when the concentrations of polymer and plasticizer are high, the disintegration time is low. This result is in line with a study by Sri et al. (2018), which found that increasing the amount of MDX would make the film disintegrate more rapidly [21]. The plasticizer can increase the intermolecular space of the film, and the increased intermolecular space can provide space for water to move in and allow the film to disintegrate faster [9].

2.4. ODF Preparation Optimal Formula

Based on our experiments, the recommended model to observe the effect of the use of MDX-sorghum and glycerol on the tensile strength and elongation responses was a linear model. In contrast, the suggested model for the disintegration time response was a quadratic model. The optimal ODF formula was verified by reproducing the formula by the RSM recommendations, and testing was performed for tensile strength, elongation, and disintegration time. From the results listed in Table 4, the recommended optimal concentrations of MDX-sorghum and glycerol were 3.56% and 10%, respectively, with a predicted tensile strength value of 1.495 MPa, percent elongation of 104%, and disintegration time of 83 seconds. The prediction results were validated by producing an ODF with the optimal formula, which was then evaluated.

Table 4. Results of Optimal Oral Dissolving Film (ODF) Formula on Response

No	Polymer (%)	Plasticizer (%)	Tensile Strength (MPa)	Elongation (%)	Disintegration Time (sec)	Desirability
1.	3.56	10.00	1.495	104.0	83	0.807
2.	3.55	10.00	1.497	103.9	83	0.806
3.	3.53	10.00	1.499	103.8	83	0.804

The validation of the RSM prediction results is presented in Table 5. The results indicated no significant difference (percentage error < 0,05%) between the results obtained and the RSM predictions. Therefore, the ODF preparation met the requirements for good film-forming characteristics. The literature shows that using polymers and plasticizers affects the characteristics of ODF. A high plasticizer concentration would result in low tensile strength, short disintegration time, and a high elongation value [22].

Table 5. Optimal ODF Evaluation Results

No	Response	RSM Prediction	Observation Results	Percentage Error (%)
1	Tensile Strength (MPa)	1.495	1.50	0.33
2	Elongation (%)	104	104.26	0.25
3	Disintegration Time (second)	83	82.95	0.06

3. CONCLUSION

The modified sorghum starch resulted in MDX-sorghum with enhanced solubility and swelling power. At a concentration of 2-6%, MDX-sorghum can be used as a film-forming polymer with the required tensile strength, elongation (%), and disintegration time. Based on the CCD analysis, the optimal concentrations of MDX-sorghum and glycerol were 4.00% and 6.50%, with a tensile strength response of 1.81 MPa, 86.71% elongation, and a disintegration period of 156 seconds. On the foundation of the obtained data, it can be stated that sorghum starch modification can increase sorghum's use as a pharmaceutical excipient.

4. MATERIALS AND METHODS

4.1. MDX-Sorghum Production

In the production of MDX-sorghum, the sorghum was modified by dissolving sorghum starch (Timurasa, Indonesia) using aquadest to a concentration of 24% (w/v), with the pH of the solution adjusted

using HCl (Merck, Germany) and NaOH (Merck, Germany) to pH 6. Then, anhydrous CaCl_2 (Merck, Germany) and 0.5% (v/v) amylase enzymes (Hench Biotechnology, China) were added. The solution was stirred at 87°C for 90 minutes. After the stirring was complete, the inactivation process began by adding HCl until the pH reached 4. The solution was then cooled to a temperature of 60°C and neutralized using 0.1 M NaOH to pH 6. The solution was then placed into an oven at 50°C in a tin in a thin layer. After drying, the powder was removed, mashed with a blender, and sieved. The MDX-sorghum characterization was then performed [2,5].

4.2. MDX-Sorghum Characterisation

4.2.1. Yield value

The resulting MDX-sorghum was weighed entirely, and the yield value was calculated using Equation [23,24]:

$$\text{Yield (\%)} = \frac{\text{MDX - sorghum weight obtained}}{\text{weight of sorghum starch used}} \times 100$$

4.2.2. Dextrose Equivalent Value

The DE value started by finding the Fehling factor value by dissolving 2.5 g of glucose with distilled water up to 1,000 mL, then removing 15 mL and adding 5 mL each of Fehling's solutions A and B. The mixture was boiled and titrated in a boiling state with glucose solution until it became reddish-brown. The amount of titrant required was recorded, and the Fehling factor was calculated using Equation [5,24]:

$$FF = \frac{\text{titrant volume mL} \times \text{glucose weight (g)}}{1,000}$$

The DE value was then determined by making a solution of MDX-sorghum with a concentration of 10 g/200 mL from the results of the previous dextrin manufacture on a dry starch basis; then, a 5 g portion was added. Next, we added 5 mL each of Fehling's solutions A and B and 15 mL of glucose solution to a total of 50 mL of distilled water. The solution was boiled and titrated with MDX-sorghum solution until a reddish-brown colour was obtained. Finally, the required titrant was recorded, and the DE value was calculated using Equation [5,24]:

$$DE = FF \times \frac{100}{\text{starch concentration} \left(\frac{\text{g}}{\text{mL}}\right) \times \text{titrant volume (mL)}}$$

4.2.3. Solubility

A total of 0.5 g of sample was weighed (b) and dissolved with 10 mL of distilled water, then vortexed for 30 seconds. Next, the solution was centrifuged at 3,000 rpm for 15 minutes. Next, we placed 5 mL of the solution in an oven at 105°C for 5 hours to be evaporated. The product was then weighed and recorded as weight a. Finally, the solubility (%) of the sample was calculated using Equation [23,25]:

$$\text{Solubility (\%)} = \frac{a}{b} \times 2 \times 100$$

4.2.4. Swelling Power

A total of 0.1 g of MDX-sorghum (b) was heated in 10 mL of distilled water in a water bath at 60°C for 30 minutes with constant mixing. Samples were centrifuged at 1,600 rpm for 15 minutes. The part that was deposited was weighed (a) and swelling power was calculated using Equation [23,25]:

$$\text{Swelling Power} = \frac{a}{b}$$

4.2.5. Infra-Red Fourier Transform (FTIR) Analysis

MDX-sorghum was ground and 2 g was weighed. The sample was added to 200 g of KBr and mixed until homogeneous. It was then placed into a pellet mold and analyzed for the MDX-sorghum functional

group using FTIR (Agilent Cary 630). The sample was scanned 64 times at 2 cm⁻¹ above the wave number region of 4,000–400 cm⁻¹ [26,27].

4.3. Production of ODF Cetirizine HCl

ODF was produced using the solvent casting method (see Table 6 for composition). First, citric acid and sucrose were dissolved using distilled water to become mass A. MDX-sorghum was then dispersed in hot water and was stirred until it expanded, forming mass B. Hydroxypropyl Methyl Cellulose (HPMC) (Luxchem, Indonesia) was dispersed in hot water and was stirred until it expanded, forming mass C. Mass B and mass C were mixed, and glycerol was added and stirred until homogeneous. Then, cetirizine HCl (Kimia Farma, Indonesia) and mass A were added and stirred until homogeneous. The remaining water was added until a volume of 100 mL was reached and was stirred until homogeneous. The mixture was poured and leveled on the mold, then dried in the oven at 50°C for 24 hours. The formed film was then released from the mold and cut to a size of 2 × 2 cm² [3].

Table 6. ODF cetirizine HCl composition based on CCD

Run	Batch	Composition						
		Cetirizine HCl (mg)	MDX-Sorghum* (%)	Glycerol* (%)	Sucrose (%)	Citric Acid (%)	HPMC (%)	Aquadest ad (mL)
1.	F1	1,500	4.00	6.50	4	4	4	100
2.	F2	1,500	4.00	3.00	4	4	4	100
3.	F3	1,500	4.00	10.00	4	4	4	100
4.	F4	1,500	4.00	6.50	4	4	4	100
5.	F5	1,500	5.41	8.97	4	4	4	100
6.	F6	1,500	4.00	6.50	4	4	4	100
7.	F7	1,500	2.59	8.97	4	4	4	100
8.	F8	1,500	4.00	6.50	4	4	4	100
9.	F9	1,500	6.00	6.50	4	4	4	100
10.	F10	1,500	4.00	6.50	4	4	4	100
11.	F11	1,500	4.00	6.50	4	4	4	100
12.	F12	1,500	2.59	4.03	4	4	4	100
13.	F13	1,500	2.00	6.50	4	4	4	100
14.	F14	1,500	5.41	4.03	4	4	4	100

*CCD-RSM Concentration Design Results

4.4. Evaluation of ODF Preparation and Cetirizine HCl

4.4.1. Tensile Strength and Elongation Test

Tensile strength and elongation percentage tests were performed using the universal testing machine located at the Centre for Advanced Materials Science and Technology (Pusat Sains dan Teknologi Bahan Maju-PSTBM), Batan, Serpong, South Tangerang.

4.4.2. Disintegration Time Test

A film was placed in a petri dish containing 2 mL of distilled water. The time required for the film to completely disintegrate is recorded as the disintegration time [28].

4.5. Data Analysis

Response data in the form of tensile strength test results, elongation, and disintegration times were entered into the CCD-RSM (Design Expert 7.1.5, trial version) response column and were analyzed to obtain the optimal concentration of MDX-sorghum and glycerol for producing ODF preparations that best met the requirements. The level and limits of the response variables in data analysis using CCD are within range, where the requirements for a good ODF include tensile strength values between 1.02-10.2 MPa [15], elongation more than 70 % [16], and disintegration time less than 3 minutes [17].

4.6. Production and Evaluation of the Optimal ODF Formula

The optimal formula obtained from CCD-RSM analysis was produced and evaluated. The results of the tensile strength, percentage elongation, and disintegration time tests were then compared with the predicted RSM data.

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