

Stability of Orally Dissolving Film of *Zingiber officinale* Roscoe Extract with HPMC and Maltodextrin as Polymer

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ABSTRACT

The pharmaceutical industry is developing pharmaceutical technology with better bioavailability because the drugs are absorbed pre-gastric, namely orally dissolving film (ODF). The ODFs containing hydroxypropyl methylcellulose (HPMC) as a film-forming agent exhibit brittleness, stickiness, and a rough surface. In contrast, maltodextrin polymer-based films have a smooth transparent surface, tensile strength, and mouthfeel. Testing the effect of varying concentrations of maltodextrin as a film-forming agent on the characterization of ODF, three formulas with different ratios of HPMC and maltodextrin polymer (2:1; 2:2; 2:3) were tested for organoleptic, film thickness, pH, folding endurance, disintegration, and stability of the ODF. The test results were then analyzed statistically using the one-way analysis method. Formulas 1, 2, and 3 reduce the characteristics of ODF red ginger extract in the form of a thin yellow-brown layer with a distinctive odor and spicy taste, a film thickness of 0.06-0.10 mm, a pH of 6.82-6.92, a folding endurance of 368-418x fold, and a disintegration of 48.59-61.39 seconds. Variations in the concentration of maltodextrin as a polymer show that there is an influence on the characteristics of the ODF red ginger extract, which is indicated by a sig value of <0.05 in testing a film thickness, pH, folding endurance, and disintegration.

INTRODUCTION

Recent research revealed as many as 26% of 1,576 patients in various age groups were known to experience difficulty swallowing (dysphagia) due to factors such as large size, surface, shape, and taste (Darusman *et al.*, 2023). Orally dissolving film (ODF) preparations were developed as an alternative treatment for dysphagia, pediatric and geriatric patients as preparations that are more flexible, comfortable and can increase safety in drug administration (Ouda *et al.*, 2020; Patange and Pratapwar, 2023). ODF is a preparation with a type of drug delivery that can provide increased bioavailability, rapid onset, and avoid first-pass metabolism. The oral mucosa has 4-1000x greater permeability than the skin (Patange and Pratapwar, 2023).

An important component in ODF preparations is the film forming agent. The combination of hydroxypropyl methylcellulose (HPMC) polymer and maltodextrin is known to have good physical characteristics, good weight

uniformity, and good disintegration time (Fitriany *et al.*, 2022). ODF preparations in circulation with various types of synthetic ingredients have many side effects on the body. Accordingly, it is necessary to use natural ingredients as alternative therapies because of their low potential and side effects, one of which is red ginger rhizome. Ethanol extract of red ginger rhizomes can inhibit the growth of *Streptococcus mutans* bacteria at a concentration of 2.5% with an inhibitory zone diameter of 12.70 mm (Akib *et al.*, 2015). In this study, an ODF preparation of *Zingiber officinale* extract (ZOE) was developed with variations in the concentration of maltodextrin as a film forming agent for the assessment of the characteristics of the ZOE ODF.

METHODS

Materials

The tools used include digital analytical scales (Fujitsu FSR-A 200), blenders, macerators, rotary evaporator (Haocheng HEM-01), water

bath, desiccators, glassware, mortars and stampers, hot plates, ovens (Mettler UN30), digital thickness micrometers, pH meters (Smart sensor), disintegration testers (Biobase BK0BJ2) and other laboratory equipment. The materials used are ZOE (*Zingiber officinale* Roscoe), 70% ethanol (DPH), 2N HCl, Mayer's reagent, Wagner's reagent, Dragendorff's reagent, Mg plate, amyl alcohol, FeCl₃ 1%, 10% gelatin, chloroform, anhydrous acetic acid, Concentrated H₂SO₄, hydroxyl propyl methyl cellulose (HPMC), maltodextrin, citric acid, PEG-400, aspartame, and distilled water.

Zingiber officinale extract (ZOE)

Processing of fresh red ginger rhizomes was done in Nagrog, Linggajaya Village, Tasikmalaya City. Next, the simplicia is processed by drying it under the heat of indirect sunlight until it forms a powder through a refining process. Extraction used the maceration method by soaking red ginger rhizome simplicia powder in 70% ethanol solvent (1:10) for 3 days while stirring occasionally. The filtrate obtained was collected, evaporated using a rotary evaporator, and then concentrated using a water bath until a thick extract was obtained. The quality of the resulting extract is determined organoleptic using the five senses with parameters of shape, smell, and color (DepKes, 2017). The percentage yield of the resulting extract is calculated using the formula:

$$\% \text{Extract yield} = \frac{\text{weight of extract obtained (g)}}{\text{initial sample weight (g)}} \times 100\%$$

ODF Formulation

The ODF formulation of ZOE with variations of maltodextrin polymer uses three

formula designs which can be seen in Table 1.

The ODF is made using the solvent casting method (Fajria & Nuwarda, 2018). The HPMC polymer and maltodextrin were developed in distilled water for 10 minutes, then stirred until a thick solution was formed. Other additional ingredients are dissolved in the solvent, each solution is mixed and stirred constantly until homogeneous with a magnetic stirrer. The mixture was poured into a mold weighing as much as 12.5 g and left for a while at room temperature. Next, it was dried in an oven at 50 °C for 24 hours. The film formed is cut into pieces measuring 2x3 cm².

The quality of ODF

Organoleptic test

ODF organoleptic test include visual, shape, color, smell and taste (Fajria & Nuwarda, 2018).

Film thickness test

The ODF thickness test was conducted using a digital thickness gauge micrometer at different locations. The final evaluation results are then taken as an average of three readings. The film thickness meets the requirements if the size is in the range of 0.005–0.2 mm the by the measurement results that have been used using a digital micrometer thickness gauge with an accuracy of 0.01 mm/0.0005 inch (Putri *et al.*, 2022).

pH test

The pH test is conducted using a pH meter calibrated with a neutral buffer solution (pH 7) and an acid buffer solution (pH 4) until the instrument shows a certain pH. Starting by wetting the film with 10 mL of distilled water, the electrode is placed on the film. The average pH result is neutral close to 7 so as

Table 1. Formula design

Material	Concentration (g)			Function
	F1	F2	F3	
<i>Zingiber officinale</i> extract (ZOE)	1.875	1.875	1.875	Active substance
HPMC	1	1	1	Film forming agent
Maltodextrin	0.5	1	1.5	Film forming agent
PEG-400	2.25	2.25	2,25	Plasticizer
Citric acid	0.08	0.08	0.08	Saliva stimulating agent
Aspartame	0.75	0.75	0.75	Sweetening agent
<i>Aquadest ad.</i>	75	75	75	Solvent

not to cause irritation to the oral mucosa (Ramadhan and Lantika, 2022).

Folding endurance test

A film can be declared to meet the requirements if it has a fold value of >300 . Measurements are made by folding the film to an angle of 180° repeatedly at the same point until the film is broken (Ramadhan and Lantika, 2022).

Disintegration test

The disintegration test is done to determine the disintegration time in the medium per time at standard conditions. The ODF preparation was put into each tube from the basket, a phosphate buffer solution of pH 6.8 was used as a medium at a temperature of 37°C , and the apparatus was run. ODF preparations can be declared destroyed if there is no film remaining in the basket (Fitriany *et al.*, 2022). The ODF can disintegrate or dissolve in <1 minute (Musazzi *et al.*, 2020).

Stability test

The stability test was conducted using the cycling test method at a temperature of 4°C , then at an oven temperature of 40°C for 24 hours (one cycle). Testing was carried out in 6 cycles (Zam and Musdalifah, 2022).

Data analysis

With the Statistical Package for Social Sciences (SPSS) version 26 (IBM Corp., Chicago, USA), the analysis conducted a normality test using the Shapiro-Wilk method with data that were considered normally distributed if the p is ≥ 0.05 (Alfarez and Ramadhan, 2023). The assumption of homogeneity of variables used the Levene-test method, with homogeneous results if $p \geq 0.05$. Meanwhile, the p value ≤ 0.05 in the ANOVA test showed a significant difference in the ODF characterization results.

RESULTS AND DISCUSSION

Zingiber officinale extract (ZOE)

Extraction produced a yield of 32.345%, which met a good extract yield of at least 17.0%. Organoleptically, the extract has a thick form, a distinctive odor, and a brown color. The resulting color is different from the FHI standard due to the browner color of the simplicia powder.

ODF formulation

The constant ratio of HPMC and maltodextrin concentrations in this formula is (2:1; 2:2; 2:3). The shape of the film layer can be seen in Figure 1.

A total of 12.5 g of film material was poured into a 10 cm diameter petri dish as a mold

for several reasons, such as the ideal size and shape for making flat and uniform films. The material is made of glass, so it does not react with the material and does not change the characteristics of the film (Lee *et al.*, 2017). The preparation was dried in an oven at a temperature of 50°C for 24 hours, then stored in a desiccator to assist the cooling process under controlled conditions before being released from the mold and cut into 2x3 cm sizes to provide ease and comfort for users due to its small size.

The quality of ODF

Each test was replicated three times, and the results were expressed in the form of an average value to ensure consistency of results and reduce the effects of variability. The results of the evaluation of ODF preparations can be seen in Table 4.

HPMC has an influence on surface smoothness because it does not produce aeration and wrinkles, so the resulting surface condition is smooth (Wardani and Saryanti, 2021). The surface conditions of F2 and F3 have smooth surfaces but are still sticky, which can be influenced by the concentration of maltodextrin. Maltodextrin has hygroscopic properties and is able to bind water vapor because it contains 7% maltose (Rahman, 2022).

A constant film thickness can describe the distribution of active substances in the preparation and the uniform dose of each film (Ramadhan and Lantika, 2022). Several factors can influence the thickness of the film, including when mixing the materials, transferring the materials into the mold, the surface of the mold, the volume of the solution and the drying process.

The acidity value increases as the maltodextrin concentration increases. Maltodextrin has a pH in the range of 4–7 (Amelia *et al.*, 2023). In addition, the pH condition of the preparation is influenced by the presence of citric acid as a saliva stimulator, which has a pH of 2.2. Variations in maltodextrin concentration show that the higher the maltodextrin content, the lower the folding resistance of the ODF preparation due to humidity conditions. One aspect that can influence flexibility is the composition of the formulation with the addition of plasticizers such as PEG 400, which can reduce the glass transition temperature, resulting in increased flexibility due to interactions with polymer molecular chains, which can provide space for movement in these interactions (Takeuchi *et al.*, 2020). In addition, the type of

polymer, manufacturing method, and storage conditions (Jacob *et al.*, 2023).

The test was done on a disintegration tester using 6.8 phosphate buffer medium as a saliva simulation solution because it can simulate ion concentration, osmolarity and pH of human body fluids (Helmenstine, 2019). A temperature of 37^o C describes the normal average temperature of the human body (Bechir *et al.*, 2021). The movement process describes the movements that occur in the mouth by the tongue and other oral muscles. Increasing the concentration of maltodextrin can accelerate the disintegration time of the film (Putri *et al.*, 2022). The higher concentration of maltodextrin can increase water binding which results in an ODF preparation that moistens and expands more quickly due to its solubility in water and low viscosity (Cupone *et al.*, 2022).

Stability test

The results of organoleptic stability testing of the ODF of ZOE showed that each formula showed that ODF were unstable at extreme temperature storage (4°C and 40°C),

especially in terms of smell and taste parameters. Meanwhile, the shape and color of the preparation have good stability during storage conditions with fluctuating temperatures. Meanwhile, the stability of the preparation based on the test parameters of film thickness, pH, and folding resistance can be seen in Figure 2.

According to the results of film thickness stability testing, F2 has a thickness that tends to be stable, while F1 and F3 produce a slight decrease in thickness during conditions that fluctuate with changes in humidity and temperature. However, the thickness of the film produced after 6 cycles has a range that meets the requirements, namely 0.005–0.2 mm (Putri *et al.*, 2022). The results obtained from testing the pH stability of the ODF preparation of ZOE were in the pH range close to neutral (pH 7). In line with normal oral pH, namely 6.2–7.6 (Bechir *et al.*, 2021). According to the results of stability testing of ODF preparations of ZOE, each formula experienced a decrease in folding power during the storage cycle, which resulted in F2 and F3 not meeting the folding resistance requirements because they were <300 times folding.

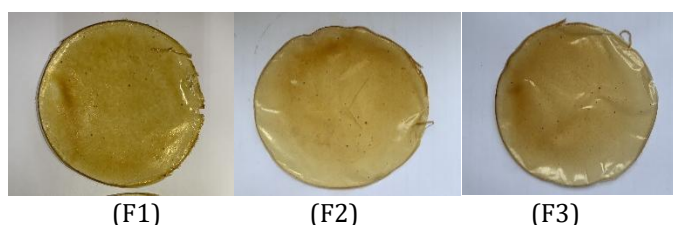


Figure 1. ODF layer of ZOE

Table 2. The quality of ODF

Parameters test	F1	F2	F3	Standard	Reference
Shape	Thin layer	Thin layer	Thin layer	Thin layer	(Fajria and Nuwarda, 2018)
Surface conditions	Smooth and not sticky	Smooth and not sticky	Smooth and not sticky	-	-
Color	Brownish yellow	Brownish yellow	Brownish yellow	-	-
Odor	Unique	Unique	Unique	A pleasant taste	(Patange and Pratapwar, 2023)
Taste	Spicy	Spicy	Spicy		
Film thickness (mm)	0.10 ± 0.02	0.08 ± 0.01	0.06 ± 0.01	0.005 – 0.2	(Putri <i>et al.</i> , 2022)
pH	6.92 ± 0.03	6.87 ± 0.04	6.82 ± 0.03	6.2 – 7.6	(Bechir <i>et al.</i> , 2021)
Folding endurance (x)	418 ± 25.58	382 ± 17.69	368 ± 10.06	≥300	(Ramadhan and Lantika, 2022)
Disintegration (second)	61.39 ± 2.52	56.01 ± 6.71	48.59 ± 4.15	≤60	(Ouda <i>et al.</i> , 2020)

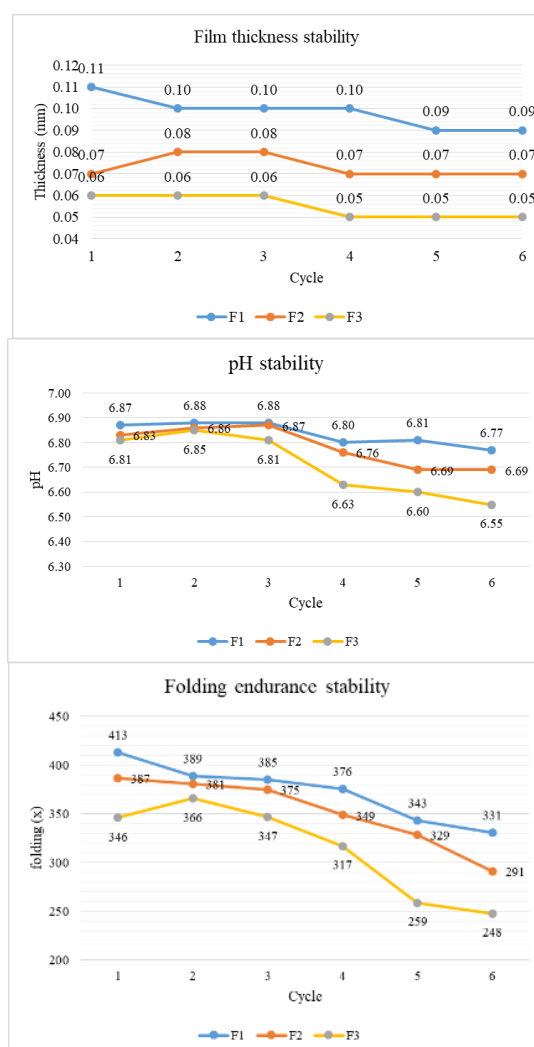


Figure 2. Stability graph of film thickness, pH, and folding resistance.

Stability testing used the cycling test method, which can mimic fluctuating environmental conditions, help identify potential stability problems that are not found under constant storage conditions, and provide information on the long-term stability of the preparation (Zam & Musdalifah, 2022). Carried out for 6 cycles, where 1 cycle involves storing the preparation at a low temperature of 4 °C for 24 hours to describe the characterization of the preparation at low storage conditions, which can prevent physical and chemical changes that occur in the preparation due to inhibited growth of microorganisms. High temperatures, namely 40 °C for 24 hours, provide an overview of the stability of the preparation in extreme storage conditions because high temperatures can accelerate chemical reactions that can occur in the preparation, such as drug degradation (Hasibuan *et al.*, 2019).

The distinctive smell and spicy taste of

ODF preparations are produced from ZOE, which comes from the compounds gingerol and shogaol (Supu *et al.*, 2019). This content during testing can decrease due to fluctuating temperature conditions. When at high temperatures, gingerol shows reverse kinetics, where gingerol undergoes a dehydration-hydration transformation with shogaol so that its content decreases (Jung *et al.*, 2018). Good stability during cycling tests indicates that the film can maintain its thickness to ensure quality during use and storage conditions (Ortiz *et al.*, 2022). Factors that can influence the decrease in pH of the preparation during the stability test are that high temperatures during the stability test can increase the rate of hydrolysis and oxidation. The film produced during stability testing has a drier surface condition, so it is easily brittle, which reduces its folding resistance. Excessive drying can cause the film to lose its flexibility and moisture. Another factor that can influence

folding power is the folding strength during the testing process, which can vary so that it can affect the amount of film folding power.

Data analysis

The characteristic evaluation data tested were analyzed statistically to test whether there were significant differences in the research results with a confidence level of 95%. Hypothesis 0 (H_0) describes that there is no significant difference in the use of maltodextrin polymer to characterize the ODF preparation of ZOE. Meanwhile, hypothesis 1 (H_1) describes a significant difference in the use of maltodextrin polymer to characterize the ODF preparation of ZOE.

The results of the film thickness, pH, folding resistance, and disintegration data that were analyzed fulfilled the assumptions of normality and homogeneity because they had a value (p -value > 0.05) so that the ANOVA test could be carried out. The ANOVA test results for film thickness, pH, folding resistance, and disintegration showed a sig value (p -value < 0.05), so H_0 was rejected and H_1 was accepted.

CONCLUSIONS

Varying the concentration of maltodextrin as a polymer produces characteristics of the ODF preparation of ZOE in the form of a thin yellow-brown layer with a characteristic odor and spicy taste, film thickness, pH, folding resistance, and disintegration that meet the requirements. Variations in the concentration of maltodextrin as a polymer show that there is an influence on the characteristics of the ODF preparation of ZOE, which is indicated by the value (p -value < 0.05) in testing film thickness, pH, folding resistance, and disintegration. Furthermore, it is necessary to test the antibacterial activity of *Streptococcus mutans* in ODF preparations that are influenced by maltodextrin as a film-forming polymer, develop other polymers that can improve the disintegration characteristics and stability of the preparation, and use more effective plasticizers that can increase flexibility without reducing drug stability.

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CONFLICT OF INTEREST

The author states that there is no conflict of interest with the parties involved in this research.

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