Effect of Disintegrating Agents on Red Ginger (*Zingiber officinale* Roxb) Dry Extract Fast Disintegrating Tablets Using Direct Compression Method

Tias Eka Rahmawati [1)*], Ishak Lewi[2)]
[1,2] Department of Pharmaceutical Technology, Sekolah Tinggi Ilmu Farmasi Yayasan Pharmasi Semarang, Indonesia
*email: tiasekarahmawati@gmail.com

Abstract

Red ginger (*Zingiber officinale* Roxb) is one of the medicinal plants that is effective as a medicine for nausea and vomiting. One of the techniques for developing traditional medicinal products is to make fast disintegrating tablets (FDT). This research aims to compare the effect of these various disintegrating materials on the physical properties of FDT. FDT red ginger extract is made using the direct compression method. The tablets obtained were physically evaluated including weight uniformity, hardness, friability, and disintegration time. The statistical results using the one-way ANOVA test show that between tablet formulas there are significant differences in tablet disintegration time with differences in the type of disintegrating agent. The data obtained shows that all formulas meet the physical properties test requirements for tablets. The tablet formula using crospovidone produces tablets with high hardness 4,6 kg/cm^2, low friability 0,39 %, and fast disintegration time 66,33 second.

Keywords: direct compression, fast disintegrating tablet, red ginger

1. INTRODUCTION

One plant that has medicinal properties is the rhizome of red ginger (*Zingiber officinale Roxb*). This red ginger plant has many properties or benefits for humans. The red ginger plant cures a variety of diseases such as nausea, vomiting, asthma, cough, palpitation, inflammation, dyspepsia, loss of appetite, constipation, indigestion, and pain(Ginger & Pichika, 2022). Compounds such as resin, vitamin A, flandrene, gingerol, curcumin, and essential oils found in red ginger help relieve complaints such as nausea and vomiting.

One of the efforts to make traditional medicine into modern medicine is by making it into a fast disintegrating tablet dosage form(Mahran dkk., 2020). Fast disintegrating tablets (FDT) are solid dosage forms that contain medicinal ingredients or active ingredients that can disintegrate quickly, usually these preparations can disintegrate within a few seconds when placed in the mouth and without using water(Chauhan dkk., 2018). The swallowing reflex improvement action of 6-gingerol has been reported. We chose an FDTs because they can be easily taken by both pediatric patients and older people with swallowing difficulties and can be maintained at a high concentration in the oral cavity, the site of action of the main component.(Gautam & Talwan, 2023). FDT preparations are expected to immediately release the active ingredients, resulting in immediate therapeutic effects(Anil et al., n.d.,2020).

The most important component in the FDT formulation is the disintegrating

component or superdisintegrant so the tablet can disintegrate quickly(Joshi dkk., 2020). One technique for making FDT is using the direct compression method (Akdag dkk., 2020). This technique is that the production stage is very short, the equipment required is not much, it is economical, and the stability of the preparation is maintained(Juan dkk., 2024). The disintegrant materials used in FDT using the direct printing method are SSG, crospovidone, and Starch 1500(Nagaveni dkk., 2023).

Crospovidone is a superdisintegrant for the direct compression process, the particles experience deformation, when the tablet comes into contact with water or the media used, the water or media will quickly penetrate the pores of the tablet because crospovidone has a very high capillary action mechanism, so it can speed up the time crushing and dissolution of tablets(Mohamed dkk., 2012).

The disintegration mechanism of sodium starch glycolate (SSG) is water absorption (wicking), followed by a swelling process quickly and in large quantities. The ability of this disintegration material is good, namely that it has quite a large expanding power while still maintaining the integrity of the tablet. This expansion provides a boost to the surrounding area thereby helping the tablet disintegration process. Also, SSG can also absorb 200-300% water. Another advantage of the SSG superdisintegrant is that even though there are hydrophobic excipients, the efficiency of SSG is not compromised(Trisopon & Kittipongpatana, 2019).

The mechanism of starch 1500 as a disintegrating agent is by swelling, when exposed to water, the tablet will expand, making the tablet easily broken and crushed(Sabirin dkk., 2024). The concentration of Starch 1500 as a destructive agent is 2% -10%(Rowe dkk., 2009). Using too much Starch 1500 makes the tablet more fragile and the disintegration time becomes faster. Based on this description, it is necessary to research making FDTs using different types of crushers.

2. METHOD

Tool

Single punch tablet printing machine (TDT, Shanghai, China), analytical balance (Mettler tolledo, Japan), caliper (Tricle brand, China), friability tester (Erweka, Germany), hardness tester (Guoming, Shanghai China).

Material

Red ginger dry extract, PVP K30 (Brataco chemical), Starch 1500 (Brataco chemical), SSG (Brataco chemical), Crospovidone (Huangsan bonsun pharmaceutical), Avicel pH 102 (Accent), Mannitol (Brataco chemical), Mg stearate (Brataco chemical), and Talcum (Brataco chemical).

Formulation of Red Ginger Dry Extract FDT

Table 1. FDT formulation design for dry red ginger extract

Ingredients tablets	Formulas		
	F1	F2	F3
Dry ginger extract	8%	8%	8%
SSG	5%		
Crospovidone		5%	
Starch 1500			5%
PVP K30	3%	3%	3%
Mannitol	20%	20%	20%
Mg Stearate	2%	2%	2%
Talk	2%	2%	2%
Avicel PH 102	150mg	150mg	150mg
Total weight	250mg	250mg	250mg

FDT was made using the direct compression method, with the formula composition listed in Table I. Dry red ginger extract was mixed with a filler (Avicel PH 102) and a binder (PVP K30), then mixed with disintegrant agent (SSG/crospovidone/Starch 1500). The mixture of each formula was sieved with a No. 16 mesh sieve, and then magnesium stearate was added. The mixture of each formula is made into tablets with the weight of each tablet being 250 mg.

Physical Characteristics Evaluation of Red Ginger Dry Extract FDT

The uniformity of tablet weight is determined by weighing 20 tablets and then calculating the average weight of each tablet, according to the provisions in the Indonesian Pharmacopoeia 6th edition(Depkes RI, 2020).

Tablet hardness is determined by placing the tablet on a hardness tester with an initial scale of 0, the tool is run until the tablet breaks, the scale on the tool is read when the tablet breaks and the value obtained states the hardness of the tablet in Kg/cm^2(Dhakal dkk., 2022).

Tablet friability was determined by dusting twenty tablets then weighing them (Wo), placing them in a friability tester, and rotating them for four minutes at a speed of 25 revolutions per minute. The tablet was dusted again and weighed (W). The difference in weight is calculated in percent, as in the equation below:

$$F = \frac{W0 - W}{W} X\ 100\%$$

FDT disintegration time was carried out using a modified disintegration time test method. The tablet was placed in the middle of a petri dish given 20 ml of distilled water, and the time the tablet disintegrated was recorded(Desai dkk., 2016).

Data Analysis

The data analysis method in this study used the Oneway ANOVA test with IBM SPSS 23.0 software with a confidence level of 95%.

3. RESULTS AND DISCUSSION

In the tablet weight uniformity test, it was found that all formulas met the weight uniformity test requirements according to the Indonesian Pharmacopoeia 5th editions(Depkes RI, 2020). This can also ensure that the powder can flow well into the die so that tablets are produced that have good weight uniformity. The results of the FDT weight uniformity test of the dry ginger extract can be seen in Table II.

Figure 1. FDT dry red ginger extract

Table 2. FDT physical evaluation results of dry red ginger extract.

Formulas	Tablet weight (mg)	Tablet hardness (kg/cm^2)	Tablet friability (%)	Tablet disintegration time (seconds)
I	257.50 ± 0.70	3.5 ±0.17	0.68 ±0.11	100.17 ± 0.10
II	250.95 ± 0.41	4.6 ±0.15	0.39 ±0.05	66.33 ±0.25
III	250.55 ± 0.45	7.6 ±0.26	0.26 ±0.30	94.67 ± 0.21

The tablet hardness of the three formulas is in the range of 3 to 5 Kg/cm^2,

meaning that this hardness still meets the FDT tablet hardness requirements, namely 3-5 Kg/cm^2. The results are the same as the results of previous research which states that the FDT hardness is not more than 5 kg/cm(Rustiani & Andini, 2019) and in other studies FDT has a tablet hardness range between 3 - 5 kg/cm^2(Rahmawati dkk., 2023). The results of hardness tablet were tested by using one way ANOVA. Results of ANOVA between the groups had shown that P value was 0.000, which was less than 0.05 showing significant. Tablet hardness data in Table II shows that tablets using the starch 1500 have lower tablet hardness compared to another disintegrant. This is because Starch 1500 at a concentration of 5 - 10% can also be used as a binder(Rowe dkk., 2009), where the function of the binder can increase tablet hardness. Crospovidone has a porous particle structure, thereby reducing the compactibility of the tablet when compressed, which affects its ability to reduce tablet hardness(Haruna dkk., 2020). SSG has a good cohesive force. Good cohesiveness will provide good hardness when the tablet is compressed. Increasing SSG concentration can increase tablet hardness(Nugraheni dkk., 2023).

The friability test results for all formulas are listed in Table II, all formulas have friability test results of less than 1%. According to previous research the requirement for a good tablet friability test is less than 1% (Sigit Pratama, 2022). Statistic results of friability were tested by using one way ANOVA. Results of ANOVA between the groups had shown that P value was 0.011, which was less than 0.05 showing significant results. The starch 1500 component reduces the friability of the FDT. This is related to the hardness of the tablet, where tablets that have high hardness will have a low level of friability. In this regard, it is known that SSG and crospovidone have lower compactibility than starch 1500 so they tend to increase freability.

Disintegration time data shows that all formulas disintegrate in less than 3 minutes. These results are in accordance with FDA requirements. that the FDT disintegrates in less than 3 minutes. These results are in accordance with previous research, the disintegration of FDT is less than 3 minutes (Rahmawati & Nursoleha, 2022). The results of disintegration time were tested by using one way ANOVA. Results of ANOVA between the groups had shown that P value was 0.000, which was less than 0.05 showing significant results. The Starch 1500 component has the effect of increasing the tablet disintegration time because the mechanism of action of Starch 1500 is swelling. The more Starch 1500 is used, the more the particles will expand from their original size so the longer it takes for the tablet to disintegrate. Meanwhile, Crospovidone has the effect of reducing or speeding up the disintegration time because its mechanism of action is wicking which causes more water to be absorbed so that it can speed up the disintegration time of the tablet. The tablet disintegration time is also influenced by the physical and chemical characterization of the materials. Starch 1500 at a concentration of 5-10% can also be used as a binder (Rowe dkk., 2009), where the function of the binder can prolong tablet disintegration time, while Crospovidone has a porous and hollow particle structure (Haruna dkk., 2020), thus increasing the amount of water absorbed and speeding up the tablet disintegration time. The particle size of the material can also affect the disintegration speed of the FDT. Larger sizes indicate faster

disintegration than smaller particles Starch 1500 has a particle size of 30-150 μm(Sheth dkk., 1980), while Crospovidone has a particle size of 130-150 μm (Balasubramaniam dkk., 2008). The formula that uses SSG as a disintegrating agent has a longer disintegration time compared to Crospovidone because the mechanism of action is swelling. The higher concentration of SSG, the more the particles will expand from their previous size so the longer it takes for the tablet to disintegrate(Berardi dkk., 2021).

4. CONCLUSION

FDT dry red ginger extract can be made using the direct compression method by using a suitable excipient, one of which is a disintegrants agent. Differences in the type of disintegrant used will affect the physical properties of the tablets produced. The use of crospovidone as a disintegrant was found the best among other superdisintegrants. The formula FDTs using crospovidone produces tablets with high hardness 4,6 kg/cm^2, low friability 0,39 %, and fast disintegration time 66,33 second.

5. REFERENCE

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