

# MAKING OF RED GINGER CAPSULE SUPPLEMENTS FOR THE TREATMENT OF PRIMARY DYSPMENORRHEA

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## ABSTRACT

Primary dysmenorrhea is physiological menstrual pain that occurs in women at the beginning of the menstrual cycle. Primary dysmenorrhea can be overcome using herbal plants such as red ginger. In the process of making red ginger capsules, it must meet the standards in order to keep the red ginger content intact. The purpose of this study was to determine the process of making red ginger capsule supplements as a treatment for primary dysmenorrhea. Research method: Descriptive that is to describe the process of making red ginger capsule supplements. Starting with red ginger made into powder, extract and capsules. The content, characteristics of *simplicia* and extract were identified and then made into capsules according to the dosage and tested for standardization. The results: The red ginger *simplicia* content met the requirements, the characteristics of the *simplicia*, red ginger powder and extract contain phenolic compounds such as saponins, flavonoids and steroids/triterpenoids which will be converted into oleoresin which contains the chemical gingerol as an anti-inflammatory in the treatment of dysmenorrhea, red ginger capsule supplements contain red ginger extract 50 mg. Conclusion: The process of making red ginger capsule supplements has met the standard.

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## 1. Introduction

Primary dysmenorrhea is physiological menstrual pain that occurs in women at the beginning of the menstrual cycle. Primary dysmenorrhea that is not handled properly can interfere with women's comfort so that it interferes with daily activities. Treatment of primary dysmenorrhea can be pharmacological or non-pharmacological. One of the non-pharmacological methods is to use herbal plants such as red ginger.

Ginger is a medicinal plant in the form of quasi-trunked clump. Ginger comes from Asia Pacific spread from India to China. Ginger belongs to the meeting-finding tribe (*Zingeraceae*) in the same family as temu comedy, black meeting, turmeric, kencur, galangal. Ginger content can significantly prevent disease through genetic regulation and metabolic activity (Rahmani et al., 2014). The red ginger rhizome fraction consists of 2 components, namely the Non Volatile (non-volatile) fraction, namely Gingerol, shagaol, gingediol, gingediacetate, gingerdion, gingerenon (Singh, 2015) and the volatile fraction (evaporating) namely (-) zingiberene, (+)-ar-curcumene, (-)-sesquiphelandrene, Beta-bisabolene,  $\alpha$ -pinene, bornyl acetate, borneol, camphene, p-cymene, cineol, citral, cumene, beta-elemene, farnesene, betaphelandrene, geraniol, limonene, linalol, myrcene, Betapinene, sabinene. In general, ginger chemical compounds contain essential oils, oleoresin and starch. The essential oil is 1-3% ginger aroma, while the non-volatile oil is called oleoresin which gives a bitter and spicy taste as much as 3-5%. The spicy taste of fresh ginger comes from the group of gingerol compounds, which are phenol derivative compounds. The highest abundance of gingerols was 6-gingerol.

The chemical substance contained in red ginger is Gingerol located in the non-volatile fraction, namely oleoresin with a spicy taste. Oleoresin is obtained by extracting ginger that has been dried and made into powder and dissolved using organic solvents such as alcohol, hexane, ethylacetate, ethyl alcohol, isopropyl alcohol, acetone, glycerol and glyceryl.

Extraction can be used in several ways, namely: maceration, digestion, percolation, soxhletation, distillation and reflux. Maceration is the process of extracting simplicia using a solvent by immersion and several times shaking or stirring at room temperature. The filter fluid will penetrate the cell wall and enter the cell cavity containing the active substance that will dissolve, because there is a difference in the concentration of the active solution inside the cell and outside the cell, the concentrated solution is pushed out. This process is repeated so that there is a balance of concentration inside and outside the cell. The liquid filter uses water, ethanol, methanol, etc. Remaceration means addition of solvent after the first filter and so on. Percolation is extraction by moistening 10 parts of the simplicia to a fine and suitable degree using 2.5 parts of 5 parts of the filter in a closed vessel for at least 3 hours. The mass is transferred little by little into the percolator added by the liquid filter. The percolator was closed and left for 24 hours then the faucet was opened at a rate of 1 ml/minute, so that the simplicia remained submerged. The filtrate was transferred to a vessel, covered and left for 2 days in a place protected from light (Rahmadani et al., 2008).

Ginger extract can be useful as an anti-oxidant and anti-inflammatory with its contents such as 6-gingerol, 6-shogaol, zingerol and so on which can reduce inflammatory mediators such as inflammatory cytokines and chemokines which cause decreased activation of NF-Kb, COX-2 and inhibited serotonin receptors. Ginger content can prevent the biosynthesis of leukotrienes, prostaglandins by inhibiting 5-lipoxygenase and prostaglandin synthesis so that ginger content can be anti-inflammatory, anti-carcinogenic, anti-oxidative (Aryaeian & Tavakkoli, 2015). Red ginger extract can be made in capsule packaging. For the red ginger capsule supplement dosage, various studies have shown that ginger can reduce the inflammatory effect on the body associated with disease. The combination of ginger effect journal reviews states that the recommended oral dose in humans in the form of ginger powder is no more than 2 grams a day, the highest dose of red ginger consumption (*Zingiber officinale roscoe varr rubrum*) which can cause side effects is 6 grams per day because it can cause side effects. irritation of the stomach (Chrubasik et al., 2005) while the dose of toxic effects in humans is still lacking information.

In a previous study that ginger (*Zingiber officinale*) in inflammation has been shown to reduce levels of pro-inflammatory cytokines (IL-6, TNF- $\alpha$ ) and acute phase protein hs-CRP in type 2 DM patients by giving fresh ginger that has been mashed and made in tablet form containing 1 gram of ginger powder per tablet consumed 2 times a day with 1 tablet once consumed after lunch and dinner for 8 weeks (Mahluji et al., 2013). According to Shirvani, et al., 2014 in Berlin found that students taking 250 mg ginger capsules every 6 hours per day with students taking 250 mg mefenamic acid tablets on the first day of menstruation until the third day did not differ significantly during the study of 2 months/menstrual cycle (Shirvani et al., 2015). Comparison of consumption of 250 mg red ginger powder capsules with 220 mg zinc sulfate capsules both 4 times a day for 4 days from 1 day before menstruation until the first 3 days of menstruation has been shown to have the same effect on pain relief in women with primary dysmenorrhea (Kashefi et al., 2014).

Making red ginger extract from simplicia dry powder by maceration using a suitable solvent and can extract secondary metabolites contained in simplicia powder. Put one part of dry simplicia powder into the macerator, add 10 parts of solvent, soak for the first 6 hours while stirring and then let it sit for 18 hours. Separate the macerate by filtration, repeat the extraction process one more time with the same type of solvent with half the volume of solvent in the first extraction. Collect all the maserate and steam to obtain a thick extract. Calculate the yield obtained, namely the percentage of weight (w/w) between the yield and the simplicia powder used by weighing. The bath should reach a value at least as specified in the extract monograph (Rahmadani et al., 2008). Simplicia is declared qualified if it meets the standard requirements listed in the Material Medika Indonesia (MMI) for medical purposes. Identification of chemical components according to MMI for simplicia and extracts, namely the alkaloid test with Mayer LP (+) reagent if there is a white precipitate/clumping, Dragendof reagent (+) if there is a precipitate/clumping in orange colored liquid, with Bouchardat reagent (+) if there is a precipitate / lumps in brick red liquid. For the saponin test (+) if after shaking there is foam, the flavonoid test with Mg reagent added butanol (+)

if there is a more concentrated color layer than the lower liquid layer, test for tannins with FeCl<sub>3</sub> (+) reagent if there is a precipitate in the orange solution, test for tannins with FeCl<sub>3</sub> (+) reagent if there is a precipitate in the orange solution. steroid (+) if the liquid that is dry is dripped with purple N-Hexane reagent. The water content of the solid dosage form of the drug has a moisture content equal to or below 10%.

The disintegration time of the capsule is equal to or less than 30 minutes. The deviation of the contents of the weight of the capsules containing dry medicine, namely from 20 capsules no more than 2 capsules whose contents weight deviated from the average content weight > 10% and there was not a single capsule whose contents weight deviated from the average contents weight > 25% (BPOM, 2014). The extract that was put in the capsule was mixed with a binder and drying agent, namely amylum manihot and amylum magdis and lactose until it became granules. The granules were sifted with sieve no 16 and dried in an oven at 50° for 24 hours and sieved again with sieve no 16. Good granules must pass the granule quality test, namely flow time, water absorption. After inserting the granules and lactose into the capsule and after it becomes the capsule, it must pass the capsule test, namely the weight uniformity test, the disintegration time test and the hygroscopic test.

The pathophysiology of Red Ginger Capsule Supplement to overcome Primary Dysmenorrhea is that from the time of ovulation to the menstrual period there has been a stage of inflammation in the endometrium. As a result of this inflammation, the body holds a body defense in which the damaged endometrial cells will release several phospholipids including arachidonic acid. After free arachidonic acid will be activated by several enzymes including cyclooxygenase and lipoxygenase. This enzyme converts arachidonic acid into unstable forms (hydroperoxides and endoperoxides) producing prostaglandin cytokines to have a blood clotting effect by thromboxanes, widening blood vessels by prostaglandin E<sub>2</sub> (PGE<sub>2</sub>) and to narrowing blood vessels by PGF<sub>2</sub>α. At the same time, balance the three so that the menstrual process is stable. The previous theory said that the production of PGF<sub>2</sub>α will increase more during the time before menstruation and peaks on the first day of menstruation. When 5 days before menstruation, when a person takes a red ginger (*Zingiber officinale roscoe varr rubrum*) capsule supplement at a dose of 500 mg 3 times a day after eating for 3 days, after being swallowed, it enters the stomach and is absorbed by the blood vessels. The content of ginger, namely 6-gingerol, has reached the endometrial blood vessels, so the gingerol enters the endometrial cells (cytosol) and inhibits the administration of phosphate (phosphorylation) in the inactive form of NF-κB so that IκB is not degraded by ubiquitin and NF-κB does not change. in the active form and does not translocate into the nucleus to give a signal that is not activating TATA BOX for COX-2 transcription and PGF<sub>2</sub>α synthesis does not occur.

## 2. Method

The research method is descriptive research by describing the process of making red ginger capsules starting from fresh ginger so simplicia then tested for the water content of red ginger simplicia then tested for simplicia standardization then red ginger simplicia made into extract and tested again for standardization then red ginger extract packaged in capsules according to the dose specified desired and retested the standardization of the capsule

Identification of simplicia levels using the formula. The levels measured in simplicia were the percentage of water content, water soluble extract content, ethanol soluble extract content, ash content, while the percentage of acid insoluble ash content and soaking value were measured levels of simplicia and red ginger extract.

Identification of the chemical content of simplicia and red ginger extract according to MMI against simplicia and extract, namely the alkaloid test with Mayer LP (+) reagent if there is a white precipitate / clot, Dragendof reagent (+) if there is a precipitate / clot in orange liquid, with Bouchardat reagent (+) if there are deposits / lumps in the brick red liquid. For the saponin test (+) if after shaking there is foam, the flavonoid test with Mg reagent added butanol (+) if there is a more concentrated color layer than the lower liquid layer, test for tannins with FeCl<sub>3</sub> (+) reagent if there is a precipitate in the orange solution, test for tannins with FeCl<sub>3</sub> (+) reagent if there is a precipitate in the orange solution. steroid (+) if the liquid that is dry is dripped with purple N-Hexane reagent  
The process of making red ginger capsules is post-harvest fresh red ginger rhizome of 1100 grams taken at the Pancur Batu traditional market, originating from Saribu Dolok Village, Kec. Silimakuta

Kab. Simalungun Prov. North Sumatra with a harvest time of 12 months, then carried out wet sorting, namely cleaning the rhizomes. Cleaning and brushing the rhizomes using clean tap water that flows until the red ginger rhizomes are clean of dirt, then drained and aerated with a wet weight of 1000 grams. The next process is a thin transverse cut with a thickness of 3 mm, then drying at a temperature of 60° by turning every day for 6 days until it is completely dry (brittle) with a moisture content of 5% and obtained a dry weight of 200 grams of simplicia. The dried simplicia was mashed using a blender until it became a powder. Simplicia powder is extracted using the maceration method. The method of maceration is that 200 grams of powder is soaked for the first time with 2000 ml of 96% ethanol (1:1 w/v ratio) for 5 days then filtered and produces 1500 ml of filtrate and maserate. The macerate was again soaked in 1000 ml 96% ethanol (1:5 w:v ratio) for 3 days and filtered. The filtrate obtained from the second filter was 900, so the total filtrate collected from the results of the I and II baths was 2400 ml. The entire filtrate was evaporated in a water bath until all the ethanol had evaporated. The remaining liquid turns into extract as much as 20 grams

Red ginger capsule supplements will be given 3 x 1 capsule a day for 3 consecutive days, so 9 capsules are needed for each respondent. If a total of 32 respondents will need 288 capsules, as supplies, 400 red ginger capsules are made. Each capsule contains 50 mg of red ginger extract, so 400 x 50 mg results in 20000 mg (20 grams) of red ginger extract. The weight of each capsule is 500 mg, so 500 mg x 400 capsules requires 200,000 mg (200 grams) of the mass of the mixture for red ginger capsules.

How to make red ginger capsules, namely 20 grams of red ginger extract, put in a mortar and put in a binder, namely 10 grams of amylum manihot little by little so that the mass is like sticky, then mixed with 5 grams of amylum magdis drying agent and put back the mass-increasing substance, namely lactose little by little until the mass is lumpy, then the mass is put in a sieve and pressed so that the granules fall. The granules were placed under a 60 watt incandescent lamp for 1 night to dry. After drying, the granule weight is 120 grams. The weight of the granules is expected to be 200 grams, so the required lactose is 80 grams. Mix granules and 80 mg lactose little by little into a mortar while stirring without pressing until homogeneous. Test the weight of the capsules by filling 6 capsules with granules to the brim and then re-weighing the contents of the granules from the 6 capsules and taking the average weight of each capsule, which is no more or less 10% of 500 mg. Furthermore, filling all the granules into 400 capsules.

### 3. Results and Discussion

The results of the study are the identification of red ginger simplicia levels are as in table 1, identification of the chemical content of simplicia and red ginger extract in table 2

TABLE 1  
CHARACTERISTICS OF SIMPLICIA LEVELS OF RED GINGER (ZINGIBER OFFICINALE ROSC VAR RUBRUM)

Characteristics	Result	Condition	Criteria
Determination of water level	5 %	< 10%	Qualify
Determination of water soluble juice content	21%	>15,6%	Qualify
Determination of ethanol soluble extract content	8%	>4,3%	Qualify
Determination of total ash content	3,8%	< 5%	Qualify
Determination of acid insoluble ash content	1,9%	< 2%	Qualify
Simplicia soak value	20%	-	-
Extract soak value	10%	-	-

Based on the characterization of red ginger simplicia (Table 1), the water content of simplicia has met the requirements of less than 10%. Because if the water content is more than 10% it will result in the growth of fungus. The simplicia characterization of red ginger (Zingiber officinale Rosc Var rubrum) has met the requirements of the Indonesian Herbal Pharmacopoeia.

TABLE 2  
IDENTIFICATION OF THE CHEMICAL CONTENT OF SIMPLICIA AND RED GINGER EXTRACT (ZINGIBER OFFICINALE ROSC.VAR RUBRUM)

Chemical Components	Reagent/ Solvent	Result		Information
		Simplicity	Ekxtract	
Alkaloid	HCL2N+ Mayer's Reagent	+	+	White color has sediment

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	HCL2N + Dragendorff's Reagent	+	+	Brick red color has sediment
	HCL2N+ Boucharadat's Reagent	+	+	Orange color has sediment
Saponin	10 ml hot water shaken	+	+	10 seconds foam formed
Tanin	FeCL3	-	-	Orange no sediment
Flavonoid	Concentrated Mg+ HCL2N+ HCL powder	+	+	The color is clear white, there is a separate fuzzy white liquid
Steroid/ Triterpenoid	n-hexane +acetic acid anhidrat + Concentrated $H_2SO_4$	+	+	Purple red color
Glikosida	Etanol 96% + KOH 10%	+	+	red purple ring

Based on the identification of chemical constituents (Table 2) above, it is proven that simplicia and red ginger extract contain phenolic compounds such as saponins, flavonoids and steroids/triterpenoids which will be converted into oleoresin in the form of gingerol as an active substance which is useful as an anti-inflammatory in primary dysmenorrhea.

There are many types of ginger oleoresin content. The ingredients that inhibit the activity of the cyclooxygenase enzyme in cells are 10-gingerol, 8-gingerol, 6-gingerol and 6-shogaol. For 10-gingerol, 8 gingerols and 6-shogaol inhibit COX-2 ligands, the value of  $IC_{50}$  is between 1-25 M, specifically for 6-gingerol, which inhibits COX-2 with concentrations > 50 M, it is concluded that 6-gingerol is stronger. its affinity for inhibiting COX-2 . ligands.

Red Ginger Capsules Supplements are made from 1000 grams of fresh red ginger, 200 grams of red ginger powder are obtained and 20 grams of red ginger extract are packaged in 400 capsules weighing 500 mg with 50 mg red ginger extract per capsule (according to the desired dose) consumed by patients with primary dysmenorrhea 3 times a day and this dose is still within the safe range for consumption because the safe limit for consumption is 2 grams per day. Capsules containing 500 mg of ginger powder were consumed by students 3 times a day on the first day of menstruation until the third day of menstruation. Primary dysmenorrhea was proven to reduce the pain of primary dysmenorrhea (Jenabi, 2013). The content of 6-gingerol in dry ginger is 18.81 mg/gram base weight of fresh ginger. If 1 gram of fresh ginger becomes powdered ginger, it will experience about 20% shrinkage to 0.2g (200 mg), to get 500mg powder it takes 2.5 x 200 mg, which is 500mg, meaning that the 6-gingerol content in 500 mg of ginger powder is 2, 5 times 18.81mg i.e. 47 mg 6-gingerol.

In this study, capsules containing 500 mg ginger powder were consumed 3 times a day from the first day of menstruation until the second day of menstruation, which means 47 mg x 3 = 141 mg 6-gingerol. From the results of previous studies that the dose of 6-gingerol needed to inhibit Cox-2 is 26 mg/kg BW rats (Breman, et al, 2011), if converted to a human dose it takes 6-gingerol 4 mg/day. The average weight of the female students at the Akbid and Akper Harapan Mama is 60 kg, so the 6-gingerol dose needed is 4 mg x 60 kg = 240 mg 6 gingerol/day. The dose of 6 gingerols is still below the body weight requirement per day for humans, but there are other ingredients in red ginger that can inhibit COX-2, such as 10-gingerol and 8 gingerols, although the affinity is not as strong as 6 gingerols, but helps in inhibiting COX-2. There is also a chemical content of red ginger that can function as an anti-inflammatory, namely triterpenoids which can inhibit macrophage biosynthesis. Giving a dose of 50 mg ginger equivalent to 500 mg red ginger powder and equivalent to 50 mg red ginger extract has been shown to reduce pain intensity in primary dysmenorrhea (Rahnama et al, 2012). Giving 1500 mg of red ginger powder is still in the safe range (2 g). After going through all that, the capsules were consumed and tested on students of Akper and Akbid Harapan Mama Deli Serdang and the results from 32 respondents decreased primary dysmenorrhea pain (Simarmata et al, 2018).

## 4. Conclusion

The conclusion of this research is The water content of red ginger simplicia below 10% meets the standard. Simplicia and red ginger extract contain phenolic compounds which are the active substances of gingerol as anti-inflammatory. The process of making Red Ginger capsule supplements

is in accordance with procedures and in doses that are safe for human consumption.

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