A Clinical Study On Fiber Enriched Milk Tablet

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Abstract

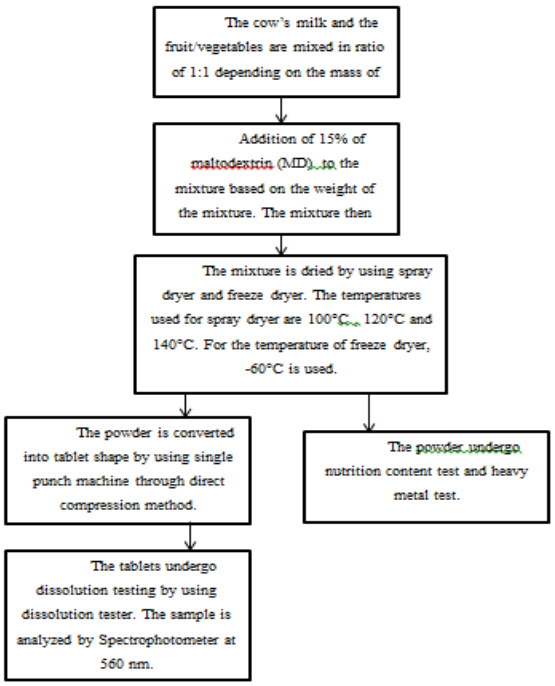
Fiber enriched milk tablet is a supplement that produced to overcome the malnutrition problem that happen to the children. It is formulated from the fiber source such as vegetables and fruit juice that mixed together with either cow's milk. The vegetables that used are spinach and carrot. The fruits that we used are mango, watermelon and also dragon fruit. The reason of why the vegetables and fruits are chosen is because they are they are rich in nutrition especially the vitamin that is vital to the health. The milk is mixed with the fruit and vegetables juice because milk is rich with nutrients such as calcium and protein that is essential for growing and building a strong bone. The addition of maltodextrin into the mixture as the carrier during spray dryer is vital because the powder will not stick to the wall of the spray dryer chamber and the wall of cyclone. The effect of addition of maltodextrin is studied along this project. Through some journal reading, it is said that the maltodextrin will produce a strong and high tensile strength tablet. The effect of different method of drying such as freeze drying and spray drying also studied in this research where the inlet temperature of spray dryer the mixture will be spray dried in three temperatures which are 100˚C,120 ˚C, and 140 ˚C while freeze dry the temperature was constant at -60 ˚C. Several tests were done towards the products which were the dissolution test, nutritional content test and heavy metal content test. For dissolution test, it is carried out in four different dissolution medium such as distilled water (at 27°C), simulated saliva, phosphate buffer pH 6.8 (mimic intestinal fluid (IF)) and also hydrochloric acid (HCl) buffer pH 1.2 (mimic gastric fluid (GF)) at 37.5°C. The dissolution rate is higher in gastric fluid which is not followed as the theory of the dissolution of weak acids material. The heavy metal test also conducted towards the product to detect any harmful potential of the product. The result of the heavy metal contained in the product is less than 0.07 mg/kg arsenic, less that 0.03 mg/kg of lead , less than 0.004 mg/kg cadmium, less than 0.01 mg/kg of mercury and less than 0.01 mg/kg of antimony. As conclusion, the fiber enriched milk tablet have own percent dissolve in every medium tested and for the heavy metal content, the value did not exceed the maximum permitted concentration of the heavy metal.

Keywords: Fiber enriched milk tablet, dissolution, freeze dry, spray dry, direct compression method.

INTRODUCTION

The fiber enriched milk tablet is a type of dietary supplements that will be useful in overcoming the malnutrition disease in children. The basic concept of producing the fiber enriched milk tablet is combining nutrients in milk and fruit or vegetables (as a source of fiber) in a tablet to reduce the malnutrition disease in children. The nutrition in the tablet can be absorbed by the children by consuming it as a chewable tablet just like the chocolate or sweets. It will attract the children to consume healthy food and get enough nutrition by consuming the tablet. In preserving the quality of the product, it must be produced in the form of tablet. This is due to the fact that tableting of the powder can overcome the problem that is associated with post-processing handling, packaging and also storing the fiber enriched milk powder. It is stated that the fruit powder in the tablet is less hygroscopic than in the powdered form due to the reduction in the surface area which can reduces the packaging cost (1). In observing the quality of the fiber enriched milk tablet must undergo several test such as the nutritional content, heavy metal and dissolution test. The dissolution test will allow the researcher to know the bioavailability of the tablet towards the consumer. It is also has been successfully implemented on the conventional dosage forms and generalized monographs described in pharmacopoeias are usually sufficient to test the new formulation (2). The dissolution of the fruit tablet would be induced by the structure of the bonding and the pore size of the powder (3).

I. METHODOLOGY



A. Production of fiber enriched milk tablet

The aim of the experiment conducted is to study the dissolution profile of the fiber enriched milk tablet in different medium. The medium used are distilled water, simulated saliva, phosphate buffer pH 6.8 (mimic simulated intestinal fluid) and hydrochloric acid (HCl) buffer pH 1.2 (mimic gastric fluid). Figure 1 below shows the experimental work.

B. Materials and Apparatus

In the production of fiber enriched milk tablet, there is five types of fiber source which are carrot, spinach, mango, dragon fruit (red flashes) and watermelon (red flashes). The fiber source

and also the cow's milk were bought from a supermarket in Section 7, Shah Alam and the maltodextrin used is produced by Merck. The fiber source is cut into small pieces, mixed well with pasteurized full cream cow's milk (Dutch Lady) and maltodextrin by using blender (Panasonic). The maltodextrin is used as the carrier agent fiber enriched milk tablet. The mixture is then filtered by using filter cloth to remove the pulp of the fiber source.

The mixture is dried by using two methods which are spray drying and freeze drying. The spray drying process is conducted by using spray dryer (Basic Lab Plant model) at temperature of 100 °C, 120°C and 140°C at the speed pump of 3. Basically, for every one liter of the sample, it might take about 90 minutes to finish the spray drying process. For the viscous sample such as mango and dragon fruit, the time will take longer time to finish spray dyer. The sample is collected and weighed by using weighing balance.

For freeze drying (FD) by using freeze dryer (SASTEC model), sample is prepared about 250 ml in the round bottom flask and freeze in the freezer at least for 24 hours. The sample is then freeze dried for 90 hours for non-viscous mixture such as watermelon, carrot and spinach. For the viscous mixture such as mango and dragon fruit, the time taken for the freeze dry is shorter which is 72 hours. The particle is coarser than spray dryer and need to be grinded by using mortar to get the fine particle.

C. Fiber enriched milk tablet formulation

The fiber enriched milk tablet is formulated by the mixing of 500 g of fiber source with 500g of full cream cow's milk (Dutch Lady) with the addition of 15% of maltodextrin from the weight of the mixture. The mixture is then spray dry at 100°C, 120°C and 140 °C while -60°C for the freeze dryer. The table about the formulation of fiber enriched milk tablet can be seen below.

Table 1.
The formulation of fiber enriched milk tablet

Source of fibre	Ratio of cow's milk to the fruit/vegetable juice	Percentage of maltodextrin (%)	Temperature of freeze dry (˚C)	Temperature Of spray dry (˚C)
Carrot	1:1	15	-60	100
				120
				140
Spinach	1:1	15	-60	100
				120
				140
Watermelon	1:1	15	-60	100
				120
				140
Mango	1:1	15	-60	100
				120
				140
Dragon fruit	1:1	15	-60	100
				120
				140

D. Fiber enriched tablets production

The fiber enriched milk tablet powder is tableted by using direct compression method. The machine that is used for tableting process is machine model MCTM-1 Globe Pharma in Faculty Pharmacy of University Malaya. The die punch used is 12 mm. About 0.7 gram of the powder is weighed by using digital balance and compacted to the ultimate stresses within the die. Once the tablet has been formed, the tablet is unload from the die by removing the bottom punch and the tablet is ejected from the die.

E. Preparation of the medium

Simulated saliva

Simulated saliva is prepared without the addition of the enzyme. For 1 L of the distilled water used, there are contains 0.720g of potassium chloride, 0.220g of calcium chloride dehydrate,0.600g of sodium chloride, 0.680g of potassium phosphate monobasic, 0.866g of sodium phosphate dibasic, 1.500g of sodium bicarbonate, 0.060g of potassium thiocyanate and 0.030g of citric acid are added into the distilled water (4). The pH of the simulated saliva is maintained at pH 6.5 and it can be stored for 8 days under storage temperature of 5°C.

HCl buffer at pH 1.2 (mimic Gastric Fluid)

The HCl buffer at pH 1.2 is actually the 0.1 N HCl solution at pH 1.2. It is prepared by the addition of 0.2 M of Potassium Chloride (KCl) and also 0.2 M of HCl. About 50 mL of 0.2 M KCl and 85 mL of 0.2 M of HCl is added together and the volume is added up to 200 mL to produce 0.2 L of HCl buffer at pH 1.2 (5). The pH meter (Metler Toledo) is used to check the pH.

Phosphate buffer at pH 6.8

The phosphate buffer is consists of the mixture of monobasic dihydrogen phosphate (KH_2PO_4) and dibasic monohydrogen phosphate (K_2HPO_4) (6) . For the preparation of 1L of 0.1 M of potassium phosphate buffer at pH of 6.8 about 49.7 mL of 1 M of K_2HPO_4 and 50.3 mL of 1 M of KH_2PO_4. Then the volume is added up to 1L in the volumetric flask.

F. Dissolution test

Dissolution test is conducted by using dissolution tester (Electrolab TDL-08L) at 50 rpm paddle speed. There are four types of medium that are used which are distilled water, simulated saliva, phosphate buffer pH 6.8 to mimic IF and HCl buffer pH 1.2 to mimic the GF. The dissolution test on distilled water is carried out at room temperature and other medium are carried out at 37.5°C. about 900 mL of dissolution medium is poured into the dissolution chamber. The timer is started right after the tablet is put into the media and the stirrer is switched on. At time 0, 5, 10, 20 and 30 minutes, about 5ml of the sample is taken out from dissolution chamber by using syringe and put into the vial bottle for further analysis. The volume of the sample that taken out must be replaced in the same amount immediately after the sample is taken out from the chamber. The procedure of taken out the sample is the same for different medium. The dissolution test is stopped after 4 hours of the test.

G. Measurement of the percent solute released/ percent dissolved

The equipment that is used to analyze the amount of the solute present in the collected sample is Ultra Violet spectrophotometer (UviLite 9400). The sample must be filtered by using syringe

filter with pore size of 0.45µm before put into the cuvette. The wavelength that is used to measure the absorbance is 540 nm (7). The percent dissolution /solute released is calculated by using the following formula :-

Percent dissolution / percent solute release at any time

$$= \frac{A_t - A_0}{A_f} \, x \, 100\%$$

Where,

A_t = Absorbance of sample at any time,

A_0= Absorbance of control sample (fresh medium)

A_f= Absorbance of the sample when complete dissolution (4 hours)

H. Dissolution profiling

The dissolution profiling the fiber enriched milk tablet is created by plotting the graph of the time versus percent dissolution / percent solute release at any time (8)

I. Heavy metals content test

The method includes the digestion of the sample by putting 10 gram of sample and 10 mL of concentrated nitric acid into 100 mL round bottom flask at heated up to 120°C. The hydrogen peroxide is added up periodically at 1 mL until the digestion step is finished (a clear solution). Then the sample is diluted up to 50 mL by using distilled water. The analysis of the sample is continued by the AAS with a graphite furnace for Cd and Pb and hydride generation-atomic fluorescence, for As and Hg and antimony (Sb). The experiment is conducted by SIRIM QAS International Sd. Bhd.

J. Nutritional content test

The nutritional content test is conducted to study the total carbohydrate, protein, fat and energy content of the fiber enriched milk tablet. The tablet is conducted in SIRIM QAS International Sd. Bhd. The energy content of the tablet can be determined by using the value of protein, fat and also total carbohydrate. The energy content is calculated by using Atwater system which using this formula.

$$Energy\ (kcal) = \left(4\frac{kcal}{g} x\ g\ protein\right) + \left(4\frac{kcal}{g} x\ g carbohydrate\right) + \left(9\frac{kcal}{g} x\ g\ fat\right)$$

The expected nutritional content of the fiber enriched milk tablet is predicted as below:-

Table 2

The expected result of nutritional content fiber enriched milk tablet

Materials	Energy (Cal)	Total Carbohydrate (g)	Fat (g)	Protein (g)
Carrot	477.47	106.48	3.75	4.43
Watermelon	467.13	104.46	3.65	4.10
Spinach	462.61	100.54	3.89	6.36
Dragon fruit	483.51	107.9	4.11	3.75
Mango	487.72	108.88	3.88	4.32

K. RESULTS AND DISCUSSION

1. Properties of the tablets and the tablet ingredients

Fiber enriched milk tablet is the combination of fiber source such as carrot, watermelon, spinach, and dragon fruit with cow's milk. The mixture was then added with maltodextrin that acts as the carrier during drying process. The maltodextrin will change the amourphous state of the mixture by increasing the glass transition temperature(Tg). Tg is the temperature at which the mechanical properties of a material is radically change due to the internal movement of the polymer chains that form the material(Corrosiopedia, 2016) . Thus, with the aid of maltodextrin it will increase the solid content and produce a bulky material. The increasing of the inlet temperature will affect the mixture due to the agglomeration problem.

The preparation of the sample for spray dry process is about 1L for every sample while only 250 ml of the sample is prepared for freeze dry. High inlet spray dry temperature will make the mixture become stickier due to the high sugar content in the fiber source. The yield of the spray dry also will become lesser when high inlet temperature is used due to the stickiness of the mixture and its difficulties in converting the mixture into powder(Y. A. Lai Pei Zea, Mohammad Gulzarul Aziz, Chin Nyuk Ling, Nor Amaiza Mohd Amin, 2012). The yield issue can be overcome by using other methods of drying which is freeze drying. However, the addition of maltodextrin to the mixture for freeze dry sample also is needed to minimize the hygroscopic and difficult to compact problem(Y. A. Lai Pei Zea, Mohammad Gulzarul Aziz, Chin Nyuk Ling, Nor Amaiza Mohd Amin, 2012). The yield of the sample can be seen in the table below. With the increasing of the inlet temperature, the yield of the powdered sample will be decreased. The freeze dry powder sample can be categorized as high yield due to the small volume of mixture is prepared earlier. Figures below show the spray dry machine and also freeze dry machine.

The particle size of spray dried powder is smaller than the particle size of freeze dried powder. This is due to the sublimation process which converts the water inside the freeze dried sample into gas. Furthermore, the freeze dried product is collected in the same container with the fresh sample earlier. The tendency of the product to clump together as a solid is higher. The tendency of the product not to dry fully is also higher. This is due to the fact that water cannot escape from the big clump produced in the freeze drying process. When it comes to spray drying product, the product is finer than the freeze drying product due to the function of atomizer which spray the liquid in the small droplet. The product of freeze dried must undergo further purification by grinding it by using mortar and pestle.

Table 3

Powder yield for each fiber source

Powder		Yield (g)
Spinach	100°C	79
	120°C	106
	140°C	102
	Freeze Dry	61
Mango	100°C	48.63
	120°C	65
	140°C	57
	Freeze Dry	63
Carrot	100°C	46
	120°C	79
	140°C	82
	Freeze Dry	62
Watermelon	100°C	93
	120°C	91
	140°C	87
	Freeze Dry	75

Dragon Fruit	100°C	60
	120°C	48
	140°C	40
	Freeze Dry	79

2. Compaction of the tablet

Fiber enriched milk powder is compacted by using direct compression method which is the simplest method rather than the granulation method. The compaction of the tablet is by using the tablet machine (MCTM-1 Globe Pharma) in Faculty of Pharmacy University Malaya. The tableting technique is followed theprocedure that is highlighted in Journal of The Drying and Tabletting of Pitaya Powder. The uniaxial direct compression of the powder is using the upper punch, lower punch and a die(F. S. M. S. Y.A Yusof, N.L Chin, R.A Talib, 2010). The die functions as a mold structure so the shape of the tablet will follow the shape of the die. The powder must be weighed first before pouring it into the die. In this study the size of the die that is used is 12 mm and the weight of the powder that poured into the die is about 0.7 gram.

The tablets undergo some mechanical test such as friability and hardness test. The result of the test is very vital to the dissolution profiling.

3. Dissolution test

3.1 Dissolution testing impact to the tablet

The fiber enriched milk tablet undergo dissolution test of the tablet on the 4 types of medium. The medium used are distilled water, simulated saliva, phosphate buffer pH 6.5 and HCl buffer pH 1.2. For distilled water, the experiment is conducted in the room temperature while for other medium; they were set at 37.5°C to create a body temperature condition. The dissolution test is an in-vitro process that played a vital role in deliberating a drug from the tablet matrix and marking whether it is available for subsequent gastrointestinal absorption as in this research, the active ingredient from the fruit is assessed(A.M. Taufiq, 2014). The USP type 2 with paddle is used in conducting the dissolution test with stirrer speed of 50 rpm(A.M. Taufiq, 2014). It is stated in journal titled Dissolution Testing of Orally Disintegrating Tablets that experience has shown that the USP 2 paddle apparatus is the most suitable and common choice for orally disintegrating tablet with a paddle speed of 50 rpm(Klancke, 2003). In 5 minutes interval until minutes 30, the sample is taken out from the dissolution chamber. The volume of the sample taken from the chamber must be replaced immediately by fresh medium(Y. A. Y. M.Saifullah, N.L Chin, M.G. Aziz, M.A.P Mohammed, N.A.Aziz, 2016) .

The experiment is limited until 4 hours (240 minutes) although the tablet is not fully dissolve in the medium. This is because it is stated that in a fed stomach, the extended release pellet formulation had gastric emptying times of 119 to 285 minutes depending on the size of the food administered(M. Zahirul, 1996). Although the tablet is not an extended release tablet, but it is a chewable tablet which takes longer time taken to be dissolve in the medium without any mechanical action.

The chewable tablet is not easily to break or dissolve due to the absence of effervescent agent as one of the ingredient. In the tablet with presence of effervescent agent, the agent itself absorbed the water and swell up when it is placed in the dissolution medium. As the by-product, the carbon dioxide bubbles produce in the dissolution chamber and rupture the outer layer of the tablet (9).

Figure 3.1 : The picture of tablet swelled up after immersed in the tablet for a long time

3.2 Dissolution profiling

The media that is used in dissolution test has different pH. For distilled water, the pH is 7 which is neutral while for simulated saliva, it was prepared at pH 5.8 . For mimic the gastric fluid, the HCl buffer is prepared at pH 1.2 and for mimic the intestinal fluid, phosphate buffer it is prepared at pH 6.5. The tablet is prepared from different fiber source and method of drying. In this research, the dissolution profiling is done to identify the relation between the fiber source, inlet drying temperature and the types of medium to the percent dissolution of the API from the fiber enriched milk tablet. There were 5 types of fiber source which were carrot, watermelon, dragon fruit, spinach and also mango while the types of media used were the distilled water (DW), simulated saliva (SS) at pH 5.8 , phosphate buffer pH 6.5 (Simulated Intestinal Fluid (IF)) and also HCl buffer pH 1.2 (Simulated Gastric Fluid (GF)).

There are so many factors that influenced the dissolution rate of tablet into the medium such as agitator speed, temperature and also the pH of the medium (10). In this test, the agitator speed was set as constant at 50 rpm while the pH of the media and the temperature of conducting the test are different. The pH of the media is in the range of 1.2 until 7 while the temperature is vary when conducting the dissolution test by using distilled water. For the effect of pH value can only being compared to the simulated saliva, phosphate buffer and also HCl buffer. It is stated that the higher the pH, the higher the dissolution rate. In journal of In-Vitro Dissolution of Compressed Tamarind and Pineapple Powder Tablets, it also highlighted that the dissolution rate of the tablet is higher in 0.1N simulated intestinal buffer pH 6.8 than in distilled water and also simulated gastric medium 0.1 N HCl.

In the Handbook of Bioequivalence Testing written by Sarfaeaz K.Niazi, it is stated that the weakly basic (acidic) compound will general dissolve in an acid fluid while the weakly acidic compound (basic) will generally dissolve faster in intestinal fluid which is basic fluid. For instance, for weak acids component such as tolbutamide, the dissolution rate increase at basic pH and for the weak bases such as tetracycline, it has high dissolution rate at acid pH medium. It is also stated that the tolbutamide dissolution in gastric fluid is 14 times lower than in simulated intestinal fluid while for dissolution of the tetracycline is decreased about 2600 times in intestinal fluid compare to the gastric fluid (11). The materials that was used to made the fiber enriched milk tablet is generally a weak acid component which have in range of pH 5.0 to 6.0. Thus, its dissolution rate should be higher in the most basic medium which is phosphate buffer pH 6.5.

During dissolution testing , it is set at room temperature while other media is set at 37 °C .In the result estimation earlier, it is said that the dissolution that conduct in high temperature has more percent dissolve than the other. It is stated in the journal paper entitled Tableting and Dissolution Characteristics of Mixed Fruit Powder stated that the dissolution was positively influenced by the temperature of the dissolution medium and has a proportional relationship between temperature and reaction rate and dissolving power of dissolution medium (9). The increasing in percent dissolve of the tablets as the temperature increase shows that the dissolution is an endothermic reaction so that the energy can be used to break the bond of the solute particle, thus will increase the dissolution rate of the tablet.

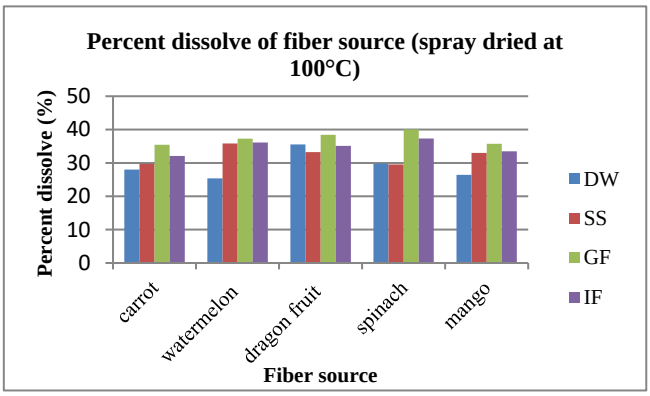


Figure 3.2 : The graph of the percent dissolve of inlet temperature at 100°C versus fiber source

DW= Distilled water

SS= Simulated Saliva (pH 5.8)

GF= Simulated gastric fluid (HCl buffer pH 1.2)

IF = simulated intestinal fluid (phosphate buffer pH 6.5)

In Figure 3.2 ,the graph shows that the percent dissolution of the tablet based on the fiber source at 100°C inlet spray drying. From the result, the dissolution rate of the tablets in distilled water is low but the dragon fruit tablet has high reading of dissolution rate. This might be due to the tensile strength of the dragon fruit and spinach that sprayed at 100°C are low. The tensile strength has the relation to the flowability of the tablet. Flowability is the ability of the powder to flow under a specific condition (12). Thus the flowability of the particle in the product must be high due to the probability of the particle size is small and in irregular shape so that the interlocking between particle is low and structure of the tablet is easily raptured during the dissolution of the tablet (13). For the simulated saliva, the percent dissolve of carrot, watermelon and mango has higher percent dissolve in simulated saliva but for dragon fruit and spinach, the value of percent dissolve is a bit lower than the distilled water. The data for percent dissolve of all types of tablet in GF is higher than the dissolution rate in IF which has the higher pH value than GF. There must be any error that happens while preparing the GF solution because it is happen in all result. The IF has more percent dissolve of the tablet for any fruit tablet then the simulated saliva due to the pH factor.

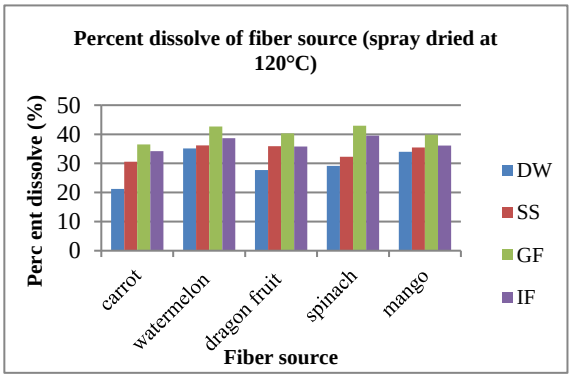


Figure 3.3 : The graph of the percent dissolve of inlet temperature at 120°C versus fiber source.

In Figure 3.3, the graph showed that the percent dissolve of the inlet temperature at 120°C versus fiber source. In this dissolution test, the dissolution rate of the tablet in DW is lower than the SS for all type of tablet. This shows the effect of temperature to the dissolution of the tablet. In real life, the carbohydrate will be digested in the mouth. Here, in simulated saliva, the percent dissolve of the carbohydrate rich content such as watermelon, dragon fruit and also mango are high For the result of dissolution in GF, the result is higher than the SS and IF. The result should be low due to fact the pH of IF is higher than the GF. For the dissolution rate of IF, most of the tablet has the second highest value after the rate of dissolution in GF.

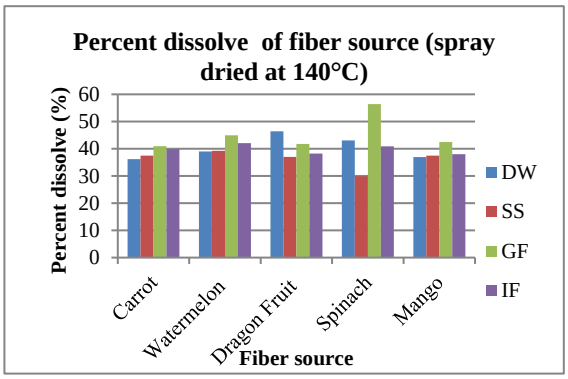


Figure 3.4 : The graph of the percent dissolve of inlet temperature at 140°C versus fiber source

In Figure 3.4 shows the result of percent dissolve of tablet with 140°C as the inlet temperature of spray dryer in different types of media. For dissolution rate in DW, several tablet samples such as dragon fruit, spinach and watermelon has higher percent dissolve than the buffered solution and did not follow the fact of the dissolution rate is affected by temperature. The dissolution rate of the tablets in GF has the highest rate for each tablet except the dragon fruit. The dissolution rate result of dragon fruit and spinach was showed that they are contradicting in the percent dissolve of tablet in DW and also GF. For the spinach, it might be due to the capping problem of the tablet. The capping problem is happen when the air is trapped in the tablet structure during the tableting process (14). So, the structure of the tablet become porous becomes porous and fragile, thus the dissolution media could be absorbed into the inner layer of the tablet that led to capping. Capping is one of the characteristics of dissolution that must be observed during the dissolution test. Due to the capping of the tablet, there is floating material inside the dissolution chamber. This will increase the percent dissolve of the tablet in the medium due to the dissolution of smaller floating particle is higher than the dissolution of a bigger size of the tablet due to the higher the surface that exposed to the dissolution medium.

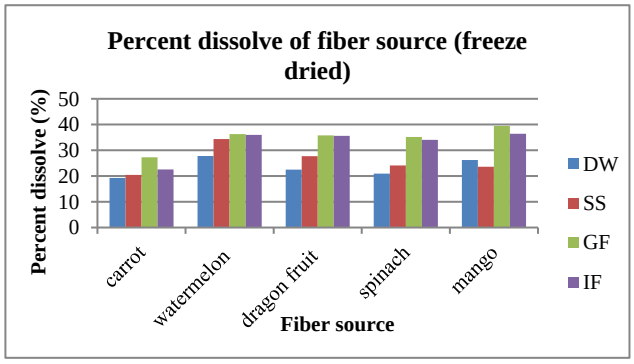


Figure 3.15 : The graph of the percent dissolve of inlet temperature at FD versus fiber source

In Figure 3.15 , it shows the graph of the percent dissolve for inlet temperature at FD versus fiber source. The value of the dissolution is the following the trend of the effect of the temperature and pH to the dissolution rate. However, for the dissolution of mango tablet in DW is much higher than in SS.

This might be happened due to the capping during the tableting process, which makes the tablet become more fragile and easy to breakdown.

The dissolution rate in distilled water is lower than in the buffered solution due to the ionic particle strength is weaker in the buffered solution media compare to the normal water media that resulting in the high release of active ingredients of the tablet (15). The effect of temperature to the dissolution rate is depend on the type of tablet whether it is a endothermic tablet or exothermic tablet. The chewable tablet is an endothermic tablet because it the dissolution rate is high at 37° C more than in room temperature.

The dissolution result of the tablet in HCl buffer pH 1.2 is due to the corrosiveness of the medium which might corrode the structure of the surface of the tablet. Thus, the tablet will easily degrade into small particle and have a high surface area to the tablet so that the dissolution rate become high. The pH of the gastric fluid inside the stomach is in the pH range of 1 to 3 which is it can be categorized as a strong acid. The measurement of the acid pH is approximately categorized as battery acid. The ability of the gastric fluid in the stomach might corrode the wood structure. However, in the prevention of the acid from corroding the stomach wall, the mucous produced by epithelial cells will form a physical barrier between the stomach and the acid produced (16). The other reason of the unexpected result is due to the contamination of the HCl buffer pH 1.2 solutions that prepared in terms of preparation and also storage.

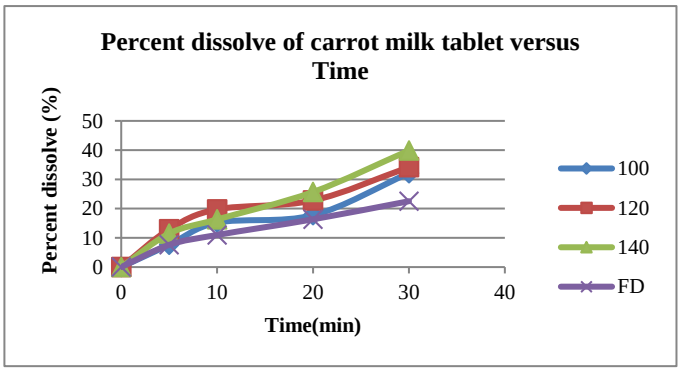


Figure 3.5 : The percent dissolution of carrot milk tablet in phosphate buffer pH 6.5

Figure 3.5 above shows that the percent dissolution of the carrot milk tablet in the phosphate buffer pH 6.5 to mimic the intestinal fluid. In this graph, it shows that the percent dissolved of freeze dried carrot milk tablet is the lowest among the tablets that spray dried at 100,120 and 140°C. The highest percent dissolve of this tablet is about 40% which is released by tablet that spay dried at 140°C and followed by the tablet that spray dried at 120°C and 100°C. The dissolution of the freeze dried tablet is low due to the tensile strength of the carrot tablet in Appendix 2 that shows the freeze dried carrot tablet has the highest tensile strength value than other tablets. With high pressure used to break the tablet, the density of the tablet become decrease and the consequently the porosity of the powder will be decreased (1) . For spray drying at 140°C, the percent dissolve of the tablet is the highest due to the lowest tensile strength of the tablet. Lower tensile strength will require less pressure to break the tablet, thus the density of the tablet is high. This will lead to the high dissolution of the tablet due to the lower porosity of the carrot tablet. The fluctuation of the percent dissolve value at minute 10 in tablet spray dried at 140°C and 100 °C is might be due to the error happened during conducting the dissolution test. This might be due to the technique of the sampling method which the sample did not withdraw in the constant place so that concentration distribution of the percent dissolve is not the same.

3.3 Heavy metal analysis

Heavy metal analysis of the fiber enriched milk powder must be conducted to find out the find out the value of heavy metals content contained in the powder. For a product that will be consumed by the human, this analysis is very vital to prevent any health effect to the consumer. It is believed that the high exposure to the heavy metals had negative effect to human health such as cancers and damage of nervous system (17).

Based on the result that released by SIRIM QAS International Sdn. Bhd, the heavy metals that contained in the product are less than 0.07 mg/kg arsenic, less that 0.03 mg/kg of lead , less than 0.004 mg/kg cadmium, less than 0.01 mg/kg of mercury and less than 0.01 mg/kg of antimony. It is stated in International/ National Standards for Heavy Metals in Food , the maximum content of arsenic is 0.04 mg/kg, for antimony, it must be below 1 mg/kg. For cadmium, the content must be less than 0.1 mg/kg while for lead, the value must be below than 1 mg/kg while for mercury, it must be lower than 0.5 mg/kg. Based on the report released, it can be said that the product is safe and does not bring any harm to the consumer. Below is the result that released by SIRIM QAS International Sdn. Bhd. On heavy metal content of dragon fruit enriched milk powder.

Table 4
The heavy metals content in dragon fruit fiber enriched milk powder

Heavy metals	Maximum value (mg/kg)	Value (mg/kg)
Arsenic	0.04	less than 0.07
Antimony	1	less than 0.01
Cadmium	0.1	less than 0.004
Mercury	0.5	less than 0.01
Lead	1	less than 0.03

The reason of why the fiber enriched milk powder is contaminated by heavy metals is from the vegetables and the fruit that used as the fiber source. The fiber sources used is readily contaminated by the irrigation water, industrial emission, harvesting process, storage and the point of sale (18). The heavy metals such as Cd and Pb are dispersed into water, soil and air so that they could accumulated by the crops (19). The heavy metal content also might be present in the product due to the way of processing the product without implementing Good Manufacturing Practice (GMP).

3.4 Nutritional content test

Based on the result that is released by SIRIM QAS Sdn. Bhd., the nutritional content of the fiber enriched milk tablet is listed in the tablet below.

Materials	Energy (Cal)	Total Carbohydrate (g)	Fat (g)	Protein (g)
Carrot	379	77.9	8.7	8.2
Watermelon	414	81.1	6.9	6.8
Spinach	462.61	76.2	7.6	9.4
Dragon fruit	406	82.9	5.3	5.3
Mango	408	82.3	6.3	5.5

Tablet above shows that the nutritional content in different type of fiber enriched milk tablet depending on the type of fiber source. It is stated that spinach tablet has the highest value of energy which is 462.61 Calories per 100 gram of the tablet

followed by watermelon, mango and also dragon fruit. The least energy content is carrot tablet which is at 379 calories per 100 gram of the carrot tablet. However, for the total carbohydrate, the spinach has the least value which is at 76.2 gram per 100 gram spinach tablet and the highest is dragon fruit at 82.9 gram per 100 gram dragon fruit tablet. In the protein and fat content, the contents are higher than the expected result. This might due to the formulation of the fiber enriched milk tablet that mixed the fiber source, milk and also maltodextrin in a tablet. The maltodextrin that act as the binder might containing the high fat and protein content. The total carbohydrates of each of the fiber enriched milk tablet are lower than the expected due to the filtration of the mixture of the sample before undergo drying process.

4 Conclusion

Fiber enriched milk tablet is the combination of fiber source and cow's milk with the addition of the maltodextrin as the carrier for spray drying process and also binder to strengthen the tablet. The compaction of the tablet from powder is by using direct compression method where the single compression machine is used. The dissolution rate of the tablets is conducted by using four types of media which are the DW, SS, GF and also the IF. The parameter that was tested on tablet is temperature and also pH impact of the medium to the dissolution rate of the fiber enriched milk tablet. The fiber enriched milk tablet is temperature and pH dependent. To make sure the tablet dissolve in the medium, the energy in the form of heat is required to break the bond inside the tablet. This can be seen in the result which stated that the dissolution rate in Gastrointestinal fluid at 37°C is higher than the dissolution rate in water at room temperature which is 25 °C. The dissolution of the fiber enriched milk tablet also is a pH dependent which can be proved from the dissolution rate of the weak acid materials is higher in the weak acid solution which is the phosphate buffer pH 6.5. The fiber enriched milk tablet is classified as the weak acid material because the origin ingredient of the tablet such as milk and fiber source juice mostly in the range of pH 5 to 6. Thus, the dissolution of the tablet is higher in the phosphate buffer pH 6.5. However, in this experiment, it is shown in the result, that the HCl buffer pH 1.2 has the highest percent dissolve in most of the fiber enriched milk tablet. This might due to the corrosiveness of the HCl buffer pH 1.2 is higher which corrode the structure and the surface of the tablet so that the tablet ruptured and dissolved into the media. For heavy metal test, it must be conducted to see the heavy metal content in the product, so that the product produced does not harm the consumer.

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